

**MEDICINAL PRODUCTS ACT
(THE DRUG LAW)
(ARZNEIMITTELGESETZ – AMG)**

of the

FEDERAL REPUBLIC OF GERMANY

Non-official translation

This version incorporates:

1. the version of the notification of the Law of 12th December 2005 (Federal Law Gazette I p. 3394),
2. Article 12 of the Law of 14th August 2006 (Federal Law Gazette I p. 1869), which entered into force on 18th August 2006.
3. Article 5 of the Law of 21st December 2006 (Federal Law Gazette I p. 3294), which entered into force on 28th December 2006,
4. Article 2 of the Law of 21st December 2006 (Federal Law Gazette I p. 3367), which entered into force on 29th December 2006,
5. Article 30 of the Law of 26th March 2007 (Federal Law Gazette I p. 378), which partially entered into force on 1st April 2007 and will partially enter into force on 1st January 2009
6. Article 2 of the Law of 14th June 2007 (Federal Law Gazette I p. 1066), which entered into force on 30th June 2007,
7. Article 2 of the Law of 20th July 2007 (Federal Law Gazette I p. 1574), which entered into force on 1st August 2007,
8. Article 2 of the Law of 24th October 2007 (Federal Law Gazette I p. 2510), which entered into force on 1st November 2007,

**Medicinal Products Act
(The DRUG LAW)
(Arzneimittelgesetz – AMG)^{*)}**

Summary of Contents

First Chapter

Purpose of the Act and definition of terms

Section 1	Purpose of the Act
Section 2	The term 'medicinal product'
Section 3	The term 'substance'
Section 4	Definitions of additional terms
Section 4a	Exceptions to the scope of the present Act

Second Chapter

Requirements on medicinal products

Section 5	Prohibition in respect of unsafe medicinal products
-----------	---

^{*)} This Act serves to incorporate:

- Directive 2001/83/EC of the European Parliament and of the Council of 6th November 2001 on the Community code relating to medicinal products for human use (OJ L 311 p. 67),
- Directive 2001/82/EC of the European Parliament and of the Council of 6th November 2001 on the Community code relating to veterinary medicinal products (OJ L 311 p. 1),
- Directive 2001/20/EC of the European Parliament and of the Council of 4th April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121 p. 34),
- Directive 2002/98/EC of the European Parliament and of the Council of 27th January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33 p. 30),
- Directive 2004/23/EC of the European Parliament and of the Council of 31st March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102 p. 48),
- Directive 2004/24/EC of the European Parliament and of the Council of 31st March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136 p. 85),
- Directive 2004/27/EC of the European Parliament and of the Council of 31st March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136 p. 34),
- Directive 2004/28/EC of the European Parliament and of the Council of 31st March 2004 amending Directive 2001/82 on the Community code relating to veterinary medicinal products (OJ L 136 p. 58).

Section 6	Empowerment in respect of health protection
Section 6a	Prohibition of medicinal products for doping purposes in sport
Section 7	Radiopharmaceuticals and medicinal products treated with ionizing radiation
Section 8	Prohibitions to prevent deception
Section 9	The party responsible for placing on the market
Section 10	Labelling
Section 11	Package leaflet
Section 11a	Expert information
Section 12	Empowerment for labelling, package leaflet and pack sizes

Third Chapter

Manufacture of medicinal products

Section 13	Manufacturing authorisation
Section 14	Decision on the manufacturing authorisation
Section 15	Expert knowledge
Section 16	Limitation of the manufacturing authorisation
Section 17	Deadlines for the granting of an authorisation
Section 18	Withdrawal, revocation, suspension
Section 19	Areas of responsibility
Section 20	Obligations to notify
Section 20a	Applicability to active substances and other substances
Section 20b	Authorisation for the procurement of tissues and the pertinent laboratory testing
Section 20c	Authorisation for the processing, preservation and storage or the placing on the market of tissues or preparations made from tissues

Fourth Chapter

Marketing authorisation for medicinal products

Section 21	Obligation to obtain a marketing authorisation
Section 21a	Authorisation of tissue preparations
Section 22	Marketing authorisation documents
Section 23	Particular documents required for medicinal products intended for administration to animals
Section 24	Expertises

Section 24a	Use of a previous applicant's documents
Section 24b	Authorisation of a generic medicinal product, document protection
Section 24c	Additional requests
Section 24d	General right of use
Section 25	Decision on marketing authorisation
Section 25a	Prior examination
Section 25b	Mutual-recognition procedure and decentralised procedure
Section 26	Guidelines for the testing of medicinal products
Section 27	Deadlines for the granting of marketing authorisations
Section 28	Power to impose conditions
Section 29	Obligation to notify, renewal of the marketing authorisation
Section 30	Withdrawal, revocation, suspension
Section 31	Expiry, prolongation
Section 32	Official batch testing
Section 33	Costs
Section 34	Informing the public
Section 35	Empowerments in respect of marketing authorisation and exemptions
Section 36	Empowerment in respect of standard marketing authorisations
Section 37	Authorisation by the Commission of the European Communities or the Council of the European Union for placing on the market, marketing authorisations for medicinal products from other states

Fifth Chapter

Registration of medicinal products

Section 38	Registration of homeopathic medicinal products
Section 39	Decision on the registration of homeopathic medicinal products
Section 39a	Registration of traditional herbal medicinal products
Section 39b	Registration documents for traditional herbal medicinal products
Section 39c	Decision on the registration of traditional herbal medicinal products
Section 39d	Other procedural provisions for traditional herbal medicinal products

Sixth Chapter

Protection of human subjects in clinical trials

Section 40	General conditions for the clinical trial
Section 41	Special conditions for the clinical trial

Section 42	Ethics Committee procedure, procedure for authorisation by the Higher federal authority
Section 42a	Withdrawal, revocation and suspension of the authorisation

Seventh Chapter
Sale of medicinal products

Section 43	Pharmacy-only requirement, placing on the market by veterinarians
Section 44	Exceptions to the pharmacy-only requirement
Section 45	Authority to allow further exceptions to pharmacy-only requirement
Section 46	Authority to extend the pharmacy-only requirement
Section 47	Distribution channel
Section 47a	Special distribution channels, obligation to keep records
Section 48	Prescription requirement
Section 49	(deleted)
Section 50	Retail trading of over-the-counter medicinal products
Section 51	Sale by itinerant traders
Section 52	Prohibition of self-service
Section 52a	Wholesale trading of medicinal products
Section 53	Expert consultation

Eighth Chapter
Safety and quality control

Section 54	Internal regulations
Section 55	Pharmacopoeia
Section 55a	Official compilation of test procedures

Ninth Chapter
Special provisions for medicinal products intended for use in animals

Section 56	Medicated feedingstuffs
Section 56a	Prescription, dispensing and use of medicinal products by veterinarians

Section 56b	Exceptions
Section 57	Acquisition and possession by keepers of animals, records
Section 58	Use in food-producing animals
Section 59	Clinical trial and residue testing in food-producing animals
Section 59a	Trade in substances and preparations from substances
Section 59b	Substances for conducting residue tests
Section 59c	Obligations to keep records of substances which can be used as veterinary medicinal products
Section 60	Pet animals
Section 61	Powers of veterinary schools

Tenth Chapter

Observation, collection and evaluation of the risks of medicinal products

Section 62	Organisation
Section 63	Graduated plan
Section 63a	Graduated plan officer for the graduated plan
Section 63b	Documentation and notification obligations
Section 63c	Special documentation and notification obligations for blood and tissue preparations

Eleventh Chapter

Supervision

Section 64	Conducting supervision
Section 65	Sampling
Section 66	Obligation to tolerate and collaborate
Section 67	General notification requirement
Section 67a	Database-supported information system
Section 68	Obligation to inform and to report
Section 69	Measures by the competent authorities
Section 69a	The supervision of substances which can be used as medicinal products for animals
Section 69b	Use of specific data

Twelfth Chapter

Special provisions for the Federal Armed Forces,

Federal Police, Public Order Police, Civil Protection

Section 70	Application and enforcement of the Act
Section 71	Exceptions

Thirteenth Chapter
Import and export

Section 72	Import authorisation
Section 72a	Certificates
Section 72b	Import authorisation and certificates for tissues and specific tissue preparations
Section 73	Prohibition of introduction
Section 73a	Export
Section 74	Participation of customs offices

Fourteenth Chapter
Information Officer, Pharmaceutical Consultant

Section 74a	Information Officer
Section 75	Expert knowledge
Section 76	Duties

Fifteenth Chapter

Designation of the competent Higher Federal Authorities and other provisions

Section 77	Competent higher federal authority
Section 77a	Independence and transparency
Section 78	Prices
Section 79	Authority to permit exceptions in times of crises
Section 80	Authority to issue procedural and compassionate use regulations
Section 81	Relation to other laws
Section 82	General administrative regulations
Section 83	Approximation to Community legislation

Sixteenth Chapter
Liability for damages caused by medicinal products

Section 84	Absolute liability
Section 84a	Right to disclosure
Section 85	Contributory negligence
Section 86	Extent of liability for damages in the case of death
Section 87	Extent of liability for damages in the case of bodily injury
Section 88	Maximum amounts
Section 89	Compensation in the form of annuities
Section 90	(deleted)
Section 91	Extended liability
Section 92	Mandatory provisions
Section 93	Several parties liable for damages
Section 94	Coverage provision
Section 94a	Local jurisdiction

Seventeenth Chapter
Penal provisions and provisions on administrative fines

Section 95	Penal provisions
Section 96	Penal provisions
Section 97	Administrative fines
Section 98	Confiscation
Section 98a	Extended forfeiture

Eighteenth Chapter
Transitional and interim provisions

First sub-chapter

Sections 99 to 124 Transitional provisions arising out of the Law on the Reform of Drug Legislation

Second sub-chapter

Sections 125 and 126 Transitional provisions arising out of the First Act Amending the Drug Law

Third sub-chapter

Sections 127 to 131 Transitional provisions arising out of the Second Act Amending the Drug Law

Fourth sub-chapter

Section 132 Transitional provisions arising out of the Fifth Act Amending the Drug Law

Fifth sub-chapter

Section 133 Transitional provisions arising of the Seventh Act Amending the Drug Law

Sixth sub-chapter

Section 134 Transitional provisions arising out of the Transfusion Act

Seventh sub-chapter

Section 135 Transitional provisions arising out of the Eighth Act Amending the Drug Law

Eighth sub-chapter

Ninth sub-chapter

Tenth sub-chapter

Section 138 Transitional provisions arising out of the Twelfth Act Amending the Drug Law

Eleventh sub-chapter

Section 139 Transitional provisions arising out of the First Act Amending the Transfusion Act and the Regulations on Medicinal Products

Twelfth sub-chapter

Thirteenth sub-chapter

Section 141 Transitional provisions arising out of the Fourteenth Act Amending the Drug Law

Fourteenth sub-chapter

Section 142 Transitional provisions arising out of the Tissues Act

Fifteenth sub-chapter

Section 143 Transitional provisions arising out of the Act on improving measures against doping in sport

Annex

FIRST CHAPTER
PURPOSE OF THE ACT AND DEFINITION OF TERMS

Section 1
Purpose of the Act

It is the purpose of the present Act to guarantee, in the interest of furnishing both human beings and animals with a proper supply of medicinal products, safety in respect of the trade in medicinal products, ensuring in particular the quality, efficacy and safety of medicinal products in accordance with the following provisions.

Section 2
The term 'medicinal product'

(1) Medicinal products are substances and preparations made from substances which, by application on or in the human or animal body, are intended

1. to cure, alleviate, prevent or diagnose diseases, suffering, bodily injury or disease symptoms,
2. to diagnose the nature, the state or the functions of the body or the mental health conditions,
3. to substitute active substances or body fluids produced in the human or animal body,
4. to ward off pathogens, parasites or substances alien to the body or to destroy them or render them harmless,
5. to influence either the nature, the state or the functions of the body or mental health conditions.

(2) The following shall be considered as medicinal products:

1. objects which contain a medicinal product as specified in sub-section 1 or to the surface of which a medicinal product specified in sub-section 1 is applied and which are intended to come into either temporary or permanent contact with the human or animal body,
- 1a. veterinary instruments in so far as they are intended for single use and the labelling of which indicates that they have been subjected to a procedure for microbe reduction,
2. objects which, without being objects as specified in no. 1 or 1a, are intended for the purposes indicated in sub-section 1 no. 2 or 5, to be introduced either temporarily or permanently into the human or animal body, with the exception of veterinary instruments,
3. wound dressings and surgical sutures in so far as they are intended for use on or in animals and are not covered by nos. 1, 1a or 2,
4. substances and preparations made from substances which, also in combination with other substances or preparations made from substances, without being applied on or in the human or animal body, are intended to diagnose the nature, state or functions of the animal body or to identify pathogens in animals.

(3) The term 'medicinal product' shall not apply to:

1. foodstuffs within the meaning of Section 2 sub-section 2 of the Food and Feed Code,
2. cosmetic products within the meaning of Section 2 sub-section 5 of the Food and Feed Code,
3. tobacco products within the meaning of Section 3 of the Provisional Tobacco Act,
4. substances or preparations made from substances which are exclusively intended for the external cleaning or hygiene or for influencing the appearance or the body odour of an animal, provided that no substances or preparations made from substances are added which are excluded from trade outside of pharmacies,
5. (deleted)
6. feedingstuffs within the meaning of Section 3 nos. 11 to 15 of the Food and Feed Code,

7. medical devices and accessories for medical devices within the meaning of § 3 of the Medical Devices Act unless they are medicinal products within the meaning of Section 2 sub-section 1 no. 2,
8. organs within the meaning of Section 1a no. 1 of the Transplantation Act if they are intended for transplanting to human beings.

(4) As long as a product is authorised or registered as a medicinal product pursuant to the present Act, or is exempted from the need for authorisation or registration by ordinance, such product shall be considered as a medicinal product. A product shall not be considered as a medicinal product if its authorisation or registration has been rejected by the competent higher federal authority, on the grounds that it is not a medicinal product.

Section 3

The term 'substance'

For the purpose of the present Act, substances are:

1. chemical elements and chemical compounds as well as their naturally occurring mixtures and solutions,
2. plants, parts of plants and plant constituents, algae, fungi or lichen whether in the processed or crude state,
3. the bodies of animals, including those of living animals, as well as parts of the body, body constituents and metabolic products of human beings or animals, whether in the processed or crude state,
4. micro-organisms, including viruses, as well as their constituents or metabolic products.

Section 4

Definitions of additional terms

(1) Finished medicinal products are medicinal products which are manufactured beforehand and placed on the market in packaging intended for distribution to the consumer or other medicinal products intended for distribution to the consumer, in the preparation of which any form of industrial process is used or medicinal products which are produced commercially, ex-

cept in pharmacies. Finished medicinal products are not intermediate products intended for further processing by a manufacturer.

(2) Blood preparations are medicinal products which are or which contain, as medically active substances, blood, plasma or serum conserves obtained from blood, blood components or preparations made from blood components.

(3) Sera are medicinal products within the meaning of Section 2 sub-section 1 derived from blood, organs, organ parts or organ secretions of healthy, sick or previously sick living organisms or organisms which have been pre-treated with immunising substances containing antibodies which form the basis for the intended use. Sera shall not be considered as blood preparations as defined in sub-section 2.

(4) Vaccines are medicinal products within the meaning of Section 2 sub-section 1, containing antigens and intended for use in human beings or animals for the production of specific antitoxins and protective agents.

(5) Allergens are medicinal products within the meaning of Section 2 sub-section 1, containing antigens or haptens and intended for use on human beings or animals for the diagnosis of specific antitoxins or protective agents (test allergens) or containing substances which are used to achieve an antigen-specific reduction in the case of a specific immunological oversensitivity (therapeutic allergens).

(6) Test sera are medicinal products within the meaning of Section 2 sub-section 2 no. 4, which are obtained from blood, organs, parts of organs or secretions from organs of the healthy or the sick, or from beings who have been sick or previously immunized, which contain specific antibodies and which are intended to be used on account of these antibodies, as well as the control sera appertaining to these medicinal products.

(7) Test antigens are medicinal products within the meaning of Section 2 sub-section 2 no. 4, which contain antigens or haptens and which are intended to be used as such.

(8) Radiopharmaceuticals are medicinal products which are or contain radioactive substances and spontaneously emit ionizing radiation and which are intended to be used on account of these properties; radionuclides (precursors) which have been manufactured for the radiolabelling of other substances prior to administration as well as systems with a fixed mother radionuclide which forms a daughter radionuclide (generators) shall also be regarded as radiopharmaceuticals.

(9) Gene transfer medicinal products are medicinal products intended for human use, within the meaning of Section 2 sub-section 1 which, for the purpose of the genetic modification of somatic cells by means of the transfer of genes or gene segments, are or contain specific naked nucleic acids, viral or non-viral vectors, genetically modified human cells or recombinant micro-organisms, without the purpose being, in the case of the latter, to prevent or treat the infectious diseases caused by them.

(10) Medicated feedingstuffs are medicinal products in the form of ready feedingstuffs, manufactured from medicated pre-mixes and mixed feed and intended to be marketed for administration to animals.

(11) Medicated pre-mixes are medicinal products intended exclusively for use in the manufacture of medicated feedingstuffs. They shall be regarded as finished medicinal products.

(12) The withdrawal period is the period necessary between the last administration of the veterinary medicinal product in keeping with its intended purpose to animals and the production of foodstuffs from such animals, in order to protect public health and ensure that such foodstuffs do not contain residues in quantities in excess of the maximum limits for pharmaco- logically active substances laid down in Council Regulation (EEC) No. 2377/90 of 26th June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products used in foodstuffs of animal origin (OJ L 224 p. 1).

(13) Side effects are those unintended, harmful reactions which occur when a medicinal product is administered in keeping with its intended purpose. Serious side effects are side effects which are fatal or life-threatening, require hospitalisation or the prolongation of existing hospitalisation, or lead to permanent or serious disability, invalidity, congenital anomalies or birth defects; in the case of medicinal products intended for administration to animals, side effects are also serious if they cause recurring or persistent symptoms. Unexpected side effects are side effects the nature, extent or outcome of which differs from the medicinal product's package leaflet. Sentences 1 to 3 also apply to such side effects as occur as a result of interactions.

(14) Manufacturing is the producing, preparing, formulating, treating or processing, filling as well as decanting, packaging, labelling and release of medicinal products.

(15) Quality is the nature of a medicinal product, determined by identity, content, purity and other chemical, physical and biological properties or by the manufacturing procedure.

(16) A batch is the quantity of a medicinal product produced from the same amount of starting material in a standard manufacturing process or, in the case of a continuous manufacturing process, within a specific period of time.

(17) Marketing is the keeping in stock for sale or for other forms of supply, the exhibiting and offering for sale and the distribution to others.

(18) In the case of medicinal products requiring a marketing authorisation or registration, the pharmaceutical entrepreneur shall be the holder of the marketing authorisation or registration. The pharmaceutical entrepreneur is also any person who places medicinal products on the market under his own name.

(19) Active substances are substances which are intended for use as medically active constituents in the manufacture of medicinal products or which, through their use in the manufacture of medicinal products, are intended to become medically active substances.

(20) Somatic cell therapy products are medicinal products intended for human use within the meaning of Section 2 sub-section 1, which are or contain human somatic cells the biological characteristics of which have or have not been modified using biotechnological procedures other than genetic modification, excluding cellular blood preparations for transfusion or for haematopoietic reconstitution.

(21) Xenogenic cell therapy products are medicinal products intended for human use within the meaning of Section 2 sub-section 1, which are or contain living animal somatic cells the biological characteristics of which have been modified genetically or using procedures other than genetic modification.

(22) Wholesale trade in medicinal products is any professional or commercial activity for the purpose of doing business which consists of the procuring, storing, dispensing or exporting of medicinal products, with the exception of the dispensing of medicinal products to consumers other than physicians, dentists, veterinarians or hospitals.

(23) A clinical trial on human beings is any investigation on human subjects intended to investigate or verify the clinical or pharmacological effects of medicinal products, or to identify side-effects or to study the absorption, distribution, metabolism or excretion, with the aim of ascertaining the safety or efficacy of the medicinal product. Sentence 1 does not apply to non-

interventional trials. A non-interventional trial is a study, in the context of which findings resulting from persons' treatment with medicinal products pursuant to the specifications for use contained in the marketing authorisation are analysed using epidemiological methods; the treatment, including the diagnosis and monitoring shall not follow a predetermined trial protocol but shall result exclusively from current medical practice.

(24) The sponsor is a natural or legal person who assumes responsibility for the commissioning, organisation and financing of a clinical trial on human beings.

(25) The investigator is generally a physician responsible for the conduct of the clinical trial on human beings at a site or, in justified exceptional cases, another person whose profession, owing to the scientific requirements and the experience in the care of patients which it calls for, qualifies him to conduct research on human beings. If a clinical trial is being conducted by several investigators at one site, the person in charge of the team shall be the principal investigator. If a clinical trial is being conducted at various trial sites, the sponsor shall name one investigator as the chief investigator.

(26) A homeopathic medicinal product is any medicinal product prepared in accordance with a homeopathic manufacturing procedure described in the European Pharmacopoeia or, in absence thereof, in the pharmacopoeias currently used officially in the EU Member States. A homeopathic medicinal product can also contain a number of active substances.

(27) A risk linked to the use of a medicinal product is:

- a) any risk to patients' health or public health linked to the quality, safety or efficacy of the medicinal product and, in the case of medicinal products intended for use in animals, any risk to human or animal health,
- b) any risk of adverse effects on the environment.

(28) The risk-benefit balance is an assessment of the positive therapeutic effects of the medicinal product in relationship to the risk referred to in sub-section 27 letter a, and in the case of medicinal products intended for use in animals, also referred to in sub-section 27 letter b.

(29) Herbal medicinal products are medicinal products which exclusively contain, as active substances, either one or more herbal substances, one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.

(30) Tissue preparations are medicinal products which are tissues within the meaning of Section 1a no. 4 of the Transplantation Act or are manufactured from such tissues. Human sperm or egg cells including impregnated egg cells (germ cells) and embryos are neither medicinal products nor tissue preparations.

Section 4a

Exceptions to the scope of the present Act

The present Act shall not apply to:

1. medicinal products which are manufactured using pathogens or biotechnology and are intended for use in the prevention, diagnosis or cure of epizootics,
2. the procurement and marketing of germ cells for the artificial insemination of animals,
3. medicinal products used by a physician, veterinarian or other person who is authorised to practise medicine, on human beings or animals in so far as the medicinal product is manufactured exclusively for this purpose under the direct professional responsibility of the administering physician, veterinarian or other person authorised to practise medicine,
4. tissues which are removed from a person in order to reinsert them into the same person in one and the same surgical procedure.

Sentence 1 no. 1 shall not apply to Section 55. Sentence 1, no. 3 shall not apply to medicinal products which have been manufactured for doping purposes in sports.

SECOND CHAPTER

REQUIREMENTS ON MEDICINAL PRODUCTS

Section 5

Prohibition in respect of unsafe medicinal products

- (1) The placing on the market of unsafe medicinal products shall be prohibited.

(2) Medicinal products shall be considered unsafe if, according to the current level of scientific knowledge, there is reason to suspect that, when used in accordance with their intended purpose, they have harmful effects which exceed the limits considered tolerable in the light of current medical knowledge.

Section 6

Empowerment in respect of health protection

(1) The Federal Ministry of Health (the Federal Ministry) is hereby empowered to specify, restrict or prohibit, by ordinance subject to the approval of the *Bundesrat*, the use of certain substances, preparations from substances or objects in the manufacture of medicinal products and to forbid the marketing and use of medicinal products which have not been manufactured in compliance with these regulations in so far as this is deemed necessary in the interest of risk prevention or in order to prevent medicinal products from posing a direct or indirect hazard to human or animal health. The ordinance pursuant to sentence 1 shall be issued by the Federal Ministry of Consumer Protection, Food and Agriculture in agreement with the Federal Ministry in so far as the medicinal products are intended for administration to animals.

(2) The ordinance referred to in sub-section 1 shall be promulgated in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety in the case of radiopharmaceuticals and medicinal products in the manufacture of which ionizing radiation is used.

Section 6a

Prohibition of medicinal products for doping purposes in sport

(1) The placing on the market, prescribing or administering of medicinal products to others for the purpose of doping in sport, is prohibited.

(2) Sub-section 1 shall apply only to medicinal products which contain substances belonging to the groups of prohibited active substances or substances contained in the Appendix to the Anti-Doping Convention (Act of 2nd March 1994 on the Anti-Doping Convention of 16th November 1989, Federal Law Gazette 1994 II p. 334) which are intended for use in the prohibited measures listed therein in so far as human beings are or are intended to be the subjects of the doping. The package leaflet and the expert information of these medicinal products shall contain the following warning: "The use of the medicinal product [insert name of the medicinal product] can lead to positive results in the event of a doping test." If the misuse of the medicinal

product for doping purposes can endanger health, this shall also be included. Sentence 2 shall not apply to medicinal products which have been manufactured using a homeopathic manufacturing procedure.

(2a) It is prohibited to be in possession of medicinal products which are or contain substances listed in the annex to the present Act in non-small quantities for the purpose of doping in sports in so far as human beings are to be the subject of doping. The Federal Ministry of Health shall specify, in agreement with the Federal Ministry of the Interior, after hearing experts, by means of ordinance with the approval of the *Bundesrat*, what constitutes the non-small quantity of the substances mentioned in sentence 1. The Federal Ministry of Health is hereby empowered, in agreement with the Federal Ministry of the Interior, after hearing experts:

1. to include in the annex to the present Act additional substances which can be used for doping purposes in sport, are used in considerable quantities for this purpose and the use of which without a therapeutic assessment is dangerous, and
2. to specify what constitutes a non-small quantity of such medicinal products by ordinance with the consent of the *Bundesrat*.

By ordinance pursuant to sentence 3, medicinal products can be deleted from the annex to the present Act if the prerequisites contained in sentence 3 no. 1 no longer exist.

(3) The Federal Ministry is hereby empowered to specify, in agreement with the Federal Ministry of the Interior, by ordinance subject to the approval of the *Bundesrat*, additional substances or preparations made from substances to which sub-section 1 shall apply, in so far as this is deemed necessary in order to prevent medicinal products from posing a direct or indirect hazard to human health through doping in sport.

Section 7

Radiopharmaceuticals and medicinal products treated with ionizing radiation

(1) It shall be forbidden for radiopharmaceuticals or medicinal products in the manufacture of which ionizing radiation has been used to be placed on the market unless the authorisation to do so has been given by ordinance according to sub-section 2.

(2) The Federal Ministry is hereby empowered to authorize, in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, by means of an ordinance subject to the approval of the *Bundesrat*, the placing of radiopharmaceuticals on the market or the use of ionizing radiation in the manufacture of medicinal products in so far as this

is deemed, according to the current level of scientific knowledge, to be justified for medical purposes and in so far as it does not compromise human or animal health. The ordinance may prescribe the channel of distribution for the medicinal products and specify that certain data concerning their radioactivity are to appear on the container, the outer wrapping and the package leaflet. The ordinance shall be issued by the Federal Ministry of Consumer Protection, Food and Agriculture in agreement with the Federal Ministry and the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, in so far as medicinal products intended for administration to animals are concerned.

Section 8

Prohibitions to prevent deception

(1) It shall be prohibited for medicinal products

1. which, by deviating from recognized pharmaceutical principles, are of considerably reduced quality,
 - 1a. which are incorrectly labelled with regard to their identity or origin (counterfeit medicinal products) or
 2. which bear otherwise misleading designations, specifications or presentations to be manufactured or placed on the market. Deception shall be said to exist, in particular, in cases where
 - a) claims are made to the effect that certain medicinal products have a therapeutic efficacy or effects which they do not possess,
 - b) the erroneous impression is given that success can be expected with certainty or that no harmful effects can be expected to occur when the medicinal product is used in accordance with its intended purpose or over a prolonged period,
 - c) designations, specifications or presentations having an influence on the assessment of the medicinal product are employed to mislead others with regard to its quality.

(2) It shall be prohibited for medicinal products whose expiry date has elapsed to be marketed.

Section 9

The party responsible for placing on the market

(1) Medicinal products which are placed on the market within the purview of the present Act shall bear the name or the company and the address of the pharmaceutical entrepreneur. This shall not apply to medicinal products intended for use in a clinical trial on human subjects.

(2) Within the purview of the present Act, medicinal products may only be placed on the market by a pharmaceutical entrepreneur whose registered place of business is situated within the purview of the present Act, in another Member State of the European Union or another State Party to the Agreement on the European Economic Area. If the pharmaceutical entrepreneur appoints a local representative, this shall not release him from his legal responsibility.

Section 10

Labelling

(1) Finished medicinal products which are medicinal products within the meaning of Section 2 sub-section 1 or sub-section 2 no. 1, and are not intended for clinical trials on human beings or exempted from the obligation to obtain a marketing authorisation, in accordance with Section 21 sub-section 2 nos. 1a or 1b, may only be marketed within the purview of the present Act provided that the following particulars are displayed on the containers and, where used, on the outer wrapping in easily legible and indelible characters, in easily comprehensible German and in accordance with the details referred to in Section 11a:

1. the name or the company and the address of the pharmaceutical entrepreneur and, if available the name of the appointed local representative,
2. the name of the medicinal product, followed by details of the strength and pharmaceutical form and, if applicable, information stating that it is intended for administration to babies, children or adults unless this information is already included in the name,
3. the marketing authorisation number with the abbreviation 'Zul.-Nr.',
4. the batch identification, if the medicinal product is placed on the market in batches, with the abbreviation 'Ch.-B.'; if it cannot be marketed in batches, the date of manufacture,
5. the pharmaceutical form,
6. the content by weight, volume or number of units,

7. the method of administration,
8. the active substances by type and quantity and other constituents by type in so far as this is imposed as a condition by the competent higher federal authorities pursuant to Section 28 sub-section 2 no. 1 or provided for by an ordinance pursuant to Section 12 sub-section 1 no. 4, also in conjunction with sub-section 2, or pursuant to Section 36 sub-section 1; in the case of medicinal products intended for parenteral or topical use, including application to the eye, all constituents by type,
- 8a. in the case of medicinal products produced using genetic engineering, the active substance and the name of the genetically modified micro-organism or cell line used in its manufacture,
9. the expiry date with the instruction '*verwendbar bis*' (to be used by),
10. in the case of medicinal products which may only be dispensed upon prescription by a physician, dentist or veterinarian, the indication '*Verschreibungspflichtig*' (prescription-only), in the case of other medicinal products which may only be sold to consumers in pharmacies, the indication '*Apothekenpflichtig*' (pharmacy-only),
11. in the case of samples, the indication '*unverkäufliches Muster*' (sample - not for sale),
12. the indication that medicinal products are to be kept out of the reach of children unless they are curative waters,
13. where necessary, special precautions for the disposal of unused medicinal products or other special precautions to avoid hazards to the environment,
14. the intended use in the case of non-prescription medicinal products.

In so far as the information pursuant to sentence 1 is also provided in another language, the data provided in that language shall be identical. Furthermore, space should be provided to state the prescribed dose; this shall not apply to the containers and ampoules referred to in sub-section 8 sentence 3 and to medicinal products intended exclusively for use by members of the medical profession. Additional information shall be permitted if it is linked to the use of the medicinal product, is important in providing health information to the patient and is not inconsistent with the information referred to in Section 11a.

(1a) In the case of medicinal products containing not more than three active substances, the World Health Organisation's international abbreviation must be stated or, if not available, the customary abbreviation; this shall not apply if the information referred to in sub-section 1 sentence 1 no. 2 includes the name of the active ingredient referred to in sub-section 1 sentence 1 number 8.

(1b) In the case of medicinal products which are intended for use in human beings, the name of the medicinal product shall also be placed on the outer wrapping in braile. The other information mentioned in sub-section 1 sentence 1 no. 2 on the pharmaceutical form and the group of persons for which the medicinal product is intended do not have to be written in braile; this shall also apply if this information is contained in the name of the medicinal product. Sentence 1 shall not apply to medicinal products which:

1. are intended for the exclusive use of members of the medical professions,
2. are placed on the market in containers with a net content of not more than 20 millilitres or not more than 20 grammes.

(2) Moreover, warnings, specific storage instructions for the consumer as well as storage instructions for experts shall be given, in so far as this is deemed necessary according to the current level of scientific knowledge or has been imposed as a condition by the competent higher federal authority pursuant to Section 28 sub-section 2 no. 1 or provided for by an ordinance.

(3) In respect of sera, particulars on the type of living organism from which the sera were obtained, in respect of virus vaccines, particulars of the host system which was used for the multiplication of the virus shall be indicated.

(4) In the case of medicinal products included in the Register of Homeopathic Medicinal Products, instead of the particulars referred to in sub-section 1 sentence 1 nos. 1 to 14 and in addition to the clearly recognisable information: 'Homeopathic Medicinal Product', the following particulars should be included:

1. the nature and quantity of the stocks and the degree of dilution; in this regard, symbols from the pharmacopoeias currently used officially, should be utilised; the scientific name of the stock can be supplemented by an invented name,

2. name and address of the pharmaceutical entrepreneur and, if available, of his local representative,
3. method of administration,
4. expiry date; sub-section 1 sentence 1 no. 9 and sub-section 7 shall apply,
5. pharmaceutical form,
6. content by weight, volume or number of items,
7. information stating that medicinal products should be kept out of the reach of children, other special precautionary measures for storage and warnings, including additional information for safe use if required or if stipulated in sub-section 2,
8. batch number,
9. registration number abbreviated to 'Reg.-Nr.' and the phrase 'Registered homeopathic medicinal product therefore no therapeutic indication stated',
10. information advising the user to seek medical advice if medical symptoms persist during the use of the medicinal product,
11. for medicinal products to be sold only in pharmacies, the information '*Apothekenpflichtig*' (pharmacy-only),
12. for samples, the information '*Unverkäufliches Muster*' (sample - not for sale).

Sentence 1 shall apply accordingly to medicinal products exempted from registration in accordance with Section 38 sub-section 1 sentence 3; sub-section 1b shall not apply. The labelling of medicinal products manufactured using homeopathic manufacturing procedures and authorised for marketing pursuant to Section 25, should include a reference to the homeopathic nature of the product. In the case of medicinal products intended for administration to animals, the target species shall also be stated.

(4a) In the case of traditional herbal medicinal products pursuant to Section 39a, the following information shall also be included in addition to the particulars in sub-section 1:

1. the medicinal product is a traditional medicinal product registered for the field of application exclusively based on long-standing use, and
2. if medical symptoms persist, or in the event of side effects other than those referred to in the package leaflet, the user should consult a doctor or other medically qualified person.

The information in sub-section sentence 1 no. 3 is replaced by the registration number abbreviated to 'Reg.-Nr.'

(5) In respect of medicinal products which are intended for administration to animals, the following additional particulars shall be given:

1. the indication '*Für Tiere*' (for animals) or the animal species for which the medicinal product is intended,
2. the withdrawal period, if the medicinal products are intended for administration to food-producing animals; should a withdrawal period not be necessary, this shall be indicated,
3. (deleted)
4. in the case of premix medicinal products, the indication '*Arzneimittel-Vormischung*' (premix medicinal product).

In the information pursuant to sub-section 1 sentence 1 no. 2, the animal species shall be indicated instead of the group of persons. Sub-section 1 sentence 1 no. 8 second half of the sentence shall not apply. Sub-section 1a shall apply only to those medicinal products containing not more than one active substance.

(6) For the designation of the ingredients, the following shall apply:

1. for the designation of the type, the international non-proprietary names fixed by the World Health Organization or, if such names do not exist, other common scientific names shall be given. The Federal Ministry is hereby empowered to stipulate the individual designations by ordinance, without the approval of the *Bundesrat*. The Federal Ministry may transfer this empowerment by ordinance, without the approval of the *Bundesrat* to the Federal Institute for Drugs and Medical Devices. The ordinance pursuant to sentences 2 and 3 shall be issued by the Federal Ministry of Agriculture, Food and Consumer Protec-

tion in agreement with the Federal Ministry, in so far as medicinal products intended for administration to animals are concerned,

2. for the indication of quantity, units of measure shall be used; if biological units or other specifications regarding valence are customarily in scientific use, then these shall be used.

(7) The month and the year shall be given as the expiry date.

(8) Blister packaging is to be affixed with the name or the firm of the pharmaceutical entrepreneur, the name of the medicinal product, the batch number and the expiry date. It shall not be necessary to state the name and firm of a parallel importer. In the case of containers with a volume of not more than ten millilitres and single-dose ampoules, the particulars specified in sub-sections 1, 1a, 2 to 5 need only be displayed on the outer packaging; the containers and the ampoules must, however, at least bear the particulars specified in sub-section 1 nos. 2, 4, 6, 7, 9 as well as sub-section 3 and sub-section 5 no. 1; adequate abbreviations may be used. In the case of fresh plasma preparations and preparations of blood cells, at least the particulars specified in sub-section 1 nos. 1 and 2 must be included, without stating the strength, pharmaceutical form and target group, nos. 3, 4, 6, 7 and 9 and the name and volume of the anticoagulant and, if available, the additive solution, storage temperature, blood group and, in the case of preparations derived from red blood cells, the rhesus formula as well and, in the case of thrombocyte concentrates, also the rhesus factor. In the case of tissue preparations, at least the information pursuant to sub-section 1 sentence 1 nos. 1 and 2 without the information regarding the strength, pharmaceutical form and relevant persons, nos. 3, 4, 6 and 9 as well as the information 'Biological Danger' in the event that infectiosity has been detected must be given. In the case of autologous tissue preparations, the information 'Only for Autologous Use' must also be provided and, in the case of autologous and targeted tissue preparations, an additional indication as to the recipient.

(9) Abbreviations customary in the medicinal product trade may be used in the indications given in compliance with sub-sections 1 to 5. The company to be indicated under sub-section 1 no. 1 may be abbreviated, provided that the firm is generally recognizable from the abbreviation.

(10) For medicinal products which are intended for administration to animals and for use in a clinical trial or for residue testing, sub-section 1 nos. 1, 2 and 4 to 7 as well as sub-sections 8 and 9 shall be applicable, in so far as they are relevant. Where relevant, these medicinal products shall be labelled '*Zur klinischen Prüfung bestimmt*' (for clinical trial) or '*Zur Rückstand-*

sprüfung bestimmt (for residue testing). Blister packaging shall bear the name, the batch identification number and the information pursuant to sentence 2.

(11) Partial amounts removed from finished medicinal products, intended for use in humans, may only be dispensed with labelling which corresponds at least to the requirements stipulated in sub-section 8 sentence 1. Sub-section 1b shall not apply.

Section 11

Package leaflet

(1) Finished medicinal products which are medicinal products within the meaning of Section 2 sub-section 1 or sub-section 2 no. 1 and are intended neither for clinical trial nor residue testing, or are exempted from the obligation to obtain a marketing authorisation in accordance with Section 21 sub-section 2 nos. 1a and 1b, may only be placed on the market within the purview of the present Act with a package leaflet bearing the heading '*Gebrauchsinformation*' (Instructions for Use) and containing, in the same order as below, in easily legible, readily comprehensible German and in conformity with the particulars referred to in Section 11a:

1. for the purpose of identifying the medicinal product:
 - a) the name of the medicinal product, Section 10 sub-section 1 sentence 1 no. 2 and sub-section 1a shall apply *mutatis mutandis*,
 - b) the substance or indication group or the mode of action,
2. the fields of application,
3. a list of information that must be read before taking the medicinal product:
 - a) contra-indications,
 - b) corresponding precautions for use,
 - c) interactions with other medicinal products or other products, if they are able to influence the effect of the medicinal product,
 - d) warnings, especially if imposed by the competent higher federal authority pursuant to Section 28 sub-section 2 no. 2 or stipulated by ordinance pursuant to Section 12 sub-section 1 no. 3,
4. the instructions under normal conditions of use, relating to
 - a) posology,

- b) method of administration,
- c) frequency of administration, if necessary stating the exact time when the medicinal product can or must be taken

and, if required, depending on the nature of the medicinal product:

- d) duration of treatment if a specific duration is required,
- e) warnings in the event of an overdose, forgotten doses or warnings on the risk of adverse consequences if the treatment is stopped,
- f) the specific recommendation that a doctor or pharmacist should be consulted in the event of queries relating to the use,

5. side effects; if required according to the current state of scientific knowledge, the necessary countermeasures should be stated; the instruction to the patient that he should inform the physician or pharmacist of any side effect that is not referred to in the package leaflet,

6. mention of the expiry date stated on the packaging and also:

- a) a warning that the medicinal product may not be used after expiry of this date,
- b) if required, special precautions for storage and information on shelf life after opening of the container or after preparation of the ready-to-use preparation by the user,
- c) if required, a warning about specific visible signs indicating that the medicinal product may no longer be used,
- d) complete qualitative composition in terms of active substances and other constituents and quantitative composition in terms of the active substances, using the usual common names for each of the medicinal product's pharmaceutical forms; Section 10 sub-section 6 shall apply,
- e) pharmaceutical form and content by weight, volume or number of items for each of the medicinal product's pharmaceutical forms,
- f) name and address of the pharmaceutical entrepreneur and, where applicable, of his local representative,
- g) name and address of the manufacturer or importer who released the finished medicinal product for placing on the market,

7. in the case of a medicinal product known by other names in other Member States of the European Union and approved for placing on the market in accordance with Articles 28 to 39 of Directive 2001/83/EC of the European Parliament and of the Council of 6th November 2001 on the Community code relating to medicinal products for human use (OJ L 276, 30.10.2001, p. 1 to 23).

ber 2001 on the Community code relating to medicinal products for human use (OJ L 311 p. 67), amended by Directives 2004/27/EC (OJ L 136 p. 34) and 2004/24/EC of 31st March 2004 (OJ L 136 p. 85), a list of the names approved in the individual Member States,

8. the date of the last revision of the package leaflet.

Explanatory information on the terms listed in sentence 1 is admissible. In so far as information referred to in sentence 1 is also rendered on the package leaflet in another language, the information provided in this language shall be identical. Sentence 1 shall not apply to medicinal products which do not require a marketing authorisation pursuant to Section 21 sub-section 2 no. 1. Additional information is permitted provided it relates to the use of the medicinal product, is important for the health education of patients and does not contradict the information referred to in Section 11a. With regard to the information referred to in sentence 1 no. 3 letters a to c, account is to be taken of the special situation of specific groups of persons such as children, pregnant women or nursing mothers, the elderly or persons with specific diseases, in so far as this is deemed necessary in the light of the current level of scientific knowledge; furthermore, where necessary, the effects which the use of the medicinal product could have on a person's ability to drive or to operate specific machines should also be indicated.

(1a) A sample of the package leaflet and modified versions shall be sent to the competent higher federal authority unless the medicinal product is exempted from the obligation to obtain a marketing authorisation or registration.

(2) Furthermore, the package leaflet shall contain references to ingredients, the knowledge of which is necessary for the safe and effective use of the medicinal product, as well as specific storage instructions for the consumer in so far as this is deemed necessary according to the current level of scientific knowledge or if imposed as a condition by the competent higher federal authority pursuant to Section 28 sub-section 2 no. 2, or provided for by ordinance.

(2a) In the case of radiopharmaceuticals, sub-section 1 shall apply *mutatis mutandis* with the proviso that the precautions which are to be taken by the user and the patient in the preparation and administration of the medicinal product, as well as special precautionary measures for the disposal of the containers used for transport and for the disposal of medicinal products which are not used, are taken.

(3) In the case of medicinal products included in the register of homeopathic medicinal products, sub-section 1 shall apply *mutatis mutandis* with the proviso that the particulars stipu-

lated in Section 10 sub-section 4, with exception of the batch number and expiry date, are included, as well as the name and address of the manufacturer who released the finished medicinal product for placing on the market, where this person is not the pharmaceutical entrepreneur. Sentence 1 shall apply *mutatis mutandis* to medicinal products which are exempted from registration pursuant to Section 38 sub-section 1 sentence 3.

(3a) In the case of sera, sub-section 1 shall apply *mutatis mutandis* with the proviso that the type of living organism from which they are derived, in the case of virus vaccines, the host system used for virus multiplication and, in the case of medicinal products derived from human blood plasma for fractionation, the country of origin of the blood plasma should be stated.

(3b) In the case of traditional herbal medicinal products pursuant to Section 39a, sub-section 1 shall apply *mutatis mutandis* with the proviso that the information referred to in sub-section 1 sentence 1 no. 2, shall state that the medicinal product is a traditional medicinal product, registered for the specific field of application, exclusively on the basis of long-standing use. In addition, the package leaflet should include the advice referred to in Section 10 sub-section 4a sentence 1 no. 2.

(3c) The marketing authorisation holder shall ensure that at the request of patients' organisations, the package leaflet is made available in formats appropriate for the blind and partially-sighted persons in the case of medicinal products intended for administration to humans.

(3d) In the case of spa-waters, notwithstanding the requirements referred to in sub-section 2, the particulars referred to in sub-section 1 sentence 1 no. 3 letter b, no. 4 letters e and f, no. 5, provided that the information stated therein is stipulated, and no. 6 letter c, can be omitted. Furthermore, in the case of spa-waters, the order stipulated in sub-section 1 is not compulsory.

(4) In the case of medicinal products which are intended for administration to animals, sub-section 1 shall apply accordingly provided that, instead of the particulars referred to in sub-section 1 sentence 1, the following particulars specified in sub-section 1 sentences 2 and 3 are given in the same order as below, in clearly legible, readily comprehensible German and in conformity with the particulars referred to in Section 11a:

1. the name and address of the pharmaceutical entrepreneur and, where applicable, of his local representative, and the manufacturer who released the finished medicinal product for placing on the market,

2. name of the medicinal product, followed by details of the strength and pharmaceutical form; the common name of the active substance shall be included if the medicinal product contains only one active substance and its name is an invented name; in the case of a medicinal product that has been granted marketing authorisation under Articles 31 to 43 of Directive 2001/82 EC of the European Parliament and of the Council of 6th November 2001 on the Community code relating to veterinary medicinal products (OJ L 311 p.1), amended by Directive 2004/28/EC (OJ L 136 p. 58), under different names in Member States of the European Union, a list of the names authorised in each Member State,
3. fields of application,
4. contra-indications and side-effects provided that these particulars are relevant for use; should it not be possible to provide information in this respect, the indication '*keine bekannt*' (none known) shall be given; the instruction that the user or animal keeper is to inform the veterinarian or pharmacist of any side-effect that is not listed in the package leaflet,
5. the animal species for which the medicinal product is intended, dosage instructions for each species, method and route of administration, if necessary, instructions for use in keeping with its intended purpose,
6. the withdrawal period, if the medicinal products are intended for administration to food-producing animals; should a withdrawal period not be necessary, this shall be indicated,
7. special precautions relating to storage,
8. special warnings in so far as this is imposed as a condition by the competent higher federal authority or provided for by an ordinance,
9. if necessary due to the current state of scientific knowledge, special precautions for the disposal of unused medicinal products or other special precautions to avoid risks to the environment.

The date of the last revision of the package leaflet shall be stated. In respect of medicated pre-mixes, indications for the correct manufacture of medicated feedingstuffs, the types of mixed feed and manufacturing procedures suitable for this purpose, interactions with additives authorised by legislation governing feedingstuffs as well as information on the shelf life of the medicated feedingstuffs shall be included. Additional particulars are permitted in so far as

they relate to the use of the medicinal product, are important for the user or animal keeper and do not contradict the particulars referred to in Section 11a.

(5) Should it not be possible to provide the information stipulated in sub-section 1 sentence 1 no. 3 letters a and c as well as no. 5, the indication "*keine bekannt*" (none known) shall be given. Should additional particulars be given on the package leaflet, they shall be clearly set out and well separated from those particulars specified in sub-sections 1 to 4.

(6) The package leaflet may be omitted provided that the information specified in sub-sections 1 to 4 is to be found either on the container or on the outer packaging. Sub-section 5 shall apply *mutatis mutandis*.

(7) Partial amounts removed from finished medicinal products, intended for use in humans, may only be dispensed together with a copy of the package leaflet prescribed for the finished medicinal product. Sub-section 6 sentence 1 shall apply *mutatis mutandis*. By way of derogation from sentence 1, in the case of the regular dispensing of partial amounts removed from finished medicinal products and dispensed in new, customised patient blisters in the context of long-term medication, copies of the package leaflet prescribed for the specific finished medicinal product must only be inserted if they have been modified compared with those previously inserted.

Section 11a

Expert information

(1) The pharmaceutical entrepreneur shall be obliged to make available upon request to physicians, dentists, veterinarians, pharmacists and, if the medicinal products concerned are not subject to prescription, to other persons practising medicine or dentistry professionally, instructions for use by experts (expert information) for finished medicinal products which are subject to or exempted from the obligation to obtain a marketing authorisation, are medicinal products within the meaning of Section 2 sub-section 1 or sub-section 2 no. 1 and are not released for trade outside of pharmacies. These instructions for expert use shall bear the heading "*Fachinformation*" (expert information) and include the following particulars written in clearly legible type in conformity with the Summary of Product Characteristics approved within the framework of the marketing authorisation, and in the following order:

1. the name of the medicinal product followed by the strength and the pharmaceutical form;
Section 10 sub-section 1a shall apply *mutatis mutandis*,

2. information on the qualitative and quantitative composition in terms of active substance and other constituents, knowledge of which is required for proper administration of the product, with the usual common or chemical name indicated; Section 10 sub-section 6 shall apply,
3. pharmaceutical form,
4. clinical particulars:
 - a) fields of application,
 - b) posology and method of administration for adults and, in so far the medicinal product is indicated for administration to children, for children,
 - c) contra-indications,
 - d) special warnings and precautions for use, and in the case of immunological medicinal products, any special precautions to be taken by persons coming into contact with and administering these medicinal products to patients, together with any precautions to be taken by the patient, if required as a result of conditions imposed by the competent higher federal authority in accordance with Section 28 sub-section 2 no. 1 letter a or if stipulated by an ordinance,
 - e) interaction with other medicinal products or other products if this is likely to influence the effect of the medicinal product,
 - f) use during pregnancy and lactation,
 - g) effects on ability to drive or operate machinery,
 - h) side-effects,
 - i) overdosage: symptoms, emergency procedures, antidotes;
5. pharmacological properties:
 - a) pharmacodynamic properties,
 - b) pharmacokinetic properties,
 - c) preclinical safety data;
6. pharmaceutical particulars:
 - a) list of other ingredients,
 - b) main incompatibilities,
 - c) shelf life and where necessary, the shelf life after reconstitution of the medicinal product or after first opening the container,

- d) special precautions for storage,
- e) nature and contents of the container,
- f) special precautions for disposal of an opened medicinal product, or waste materials derived from it, in order to avoid any risk to the environment,

7. marketing authorisation holder,
8. marketing authorisation number;
9. the date of first authorisation or prolongation of the authorisation,
10. date of revision of the expert information.

Additional particulars are admissible if they are related to the use of the medicinal product and do not contradict the information referred to sentence 2; they must be clearly separate and distinct from the particulars referred to sentence 2. Sentence 1 shall not apply to medicinal products, which do not require a marketing authorisation pursuant to Section 21 sub-section 2 or are manufactured according homeopathic procedures.

(1a) In the case of sera, the type of living organism from which they are derived, in the case of virus vaccines, the host system used for virus multiplication and, in the case of medicinal products derived from human blood plasma for fractionation, the country of origin of the blood plasma shall be indicated.

(1b) In respect of radiopharmaceuticals, details of the internal radiation dosimetry, additional detailed instructions for the extemporaneous preparation and the quality control of this preparation shall also be given and, where necessary, the maximum storage time shall also be indicated during which an intermediate preparation, such as an eluate or the medicinal product when ready for use, corresponds to its specifications.

(1c) In the case of medicinal products intended for use in animals, the expert information specified under number 4 'clinical particulars' must include the following particulars:

- a) particulars on each target animal species to which the medicinal product is to be administered,
- b) instructions for use, specifying the target animal species,
- c) contra-indications,
- d) special warnings for each target animal species,

- e) special precautions for use, including special precautions to be taken by the person administering the medicinal product,
- f) side-effects (frequency and seriousness),
- g) use during pregnancy, lactation or lay,
- h) interactions with other medicinal products and other forms of interaction,
- i) dosage and method of administration,
- j) overdosage, emergency procedures, symptoms, antidotes, if necessary,
- k) withdrawal periods for all foodstuffs, including those for which there is no withdrawal period.

The particulars referred to in sub-section 1 sentence 2 no. 5 letter c are not necessary.

(1d) In the case of medicinal products available only on prescription by a doctor, dentist or veterinarian, the information "*Verschreibungspflichtig*" (prescription only) should also be added, for narcotics the information "*Betäubungsmittel*" (narcotics), in the case of other medicinal products available to consumers only in pharmacies, the information "*Apotheken-pflichtig*" (pharmacy only), in the case of medicinal products containing a substance or a preparation referred to in Section 48 sub-section 2 no. 1, the information that these medicinal products contain a substance the effect of which is not generally known in medical science.

(1e) For marketing authorisations of medicinal products in accordance with Section 24b, the particulars referred to in sub-section 1 relating to fields of application, dosages or other objects of a patent can be omitted if they are still covered by patent law at the time of placing on the market.

(2) The pharmaceutical entrepreneur shall be obliged to make all modifications to the expert information, which are relevant for therapy, accessible to the experts in an appropriate form. In so far as necessary, the competent higher federal authority may, by imposition of a condition, stipulate the form in which the changes are to be made accessible to all or to certain groups of experts.

(3) A sample of the expert information and revised versions thereof shall be sent immediately to the competent higher federal authority unless the medicinal product is exempted from the obligation to obtain a marketing authorisation.

(4) The obligations referred to in sub-section 1 sentence 1 can also be fulfilled in the case of medicinal products which are administered exclusively by members of the health professions by including the information referred to in sub-section 1 sentence 2 in the package

leaflet. The package leaflet must be headed with the title "*Gebrauchsinformation und Fachinformation*" (instructions for use and expert information).

Section 12

Empowerment in respect of labelling, package leaflet and package sizes

(1) The Federal Ministry is hereby empowered, in agreement with the Federal Ministry of Economics and Technology by ordinance subject to the approval of the *Bundesrat*:

1. to extend the provisions of Sections 10 and 11a to cover other medicinal products and to extend the expert information to include further details,
2. to stipulate that the particulars indicated in Sections 10 and 11 are to be made known to the consumer in another way,
3. to stipulate that, for certain medicinal products or certain groups of medicinal products, warnings, warning symbols or recognition marks shall be contained in or affixed to
 - a) the containers, the outer packaging or the package leaflet or
 - b) the expert information,
4. to stipulate that specific constituents are to be listed by nature on the containers and outer packaging or that attention should be drawn to them in the package leaflet,

if this is deemed necessary in order to ensure the proper handling and proper administration of medicinal products within the purview of the present Act and in order to prevent any direct or indirect risk to human or animal health, which could occur as a result of inadequate information.

(1a) Furthermore, the Federal Ministry is hereby empowered to allow, by ordinance subject to the approval of the *Bundesrat*, the use of summarizing names for substances or preparations from substances in the information provided on containers and outer packaging or in package leaflets or in expert information, as long as active constituents are not involved and no direct or indirect hazard to human or animal health arising from a lack of information is to be feared.

(1b) Furthermore, the Federal Ministry is hereby empowered, in agreement with the Federal Ministry of Economics and Technology, by means of an ordinance subject to the approval of the *Bundesrat* to regulate

1. the labelling of starting materials intended for the manufacture of medicinal products, and
2. the labelling of medicinal products intended for clinical trials,

where it is deemed necessary to prevent a direct or indirect hazard to human or animal health owing to inadequate labelling.

(2) In the case of medicinal products intended for administration to animals, the Federal Ministry of Agriculture, Food and Consumer Protection shall take the place of the Federal Ministry in the cases provided for in sub-section 1, 1a, 1b or 3, and shall in each case issue the ordinance in agreement with the Federal Ministry. The ordinance pursuant to sub-section 1, 1a or 1b shall be issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety in the case of radiopharmaceuticals and medicinal products in the manufacture of which ionizing radiation is used or where, in the cases provided for in sub-section 1 no. 3, warnings, warning symbols or recognition marks with regard to the particulars stipulated in Section 10 sub-section 1 sentence 1 no. 13, Section 11 sub-section 4 sentence 1 no. 9 or Section 11a sub-section 1 sentence 2 no. 6 letter f are required.

(3) Furthermore, the Federal Ministry is hereby empowered to stipulate, by ordinance not subject to the approval of the *Bundesrat*, that medicinal products may only be placed on the market in specific package sizes and that they shall be labelled accordingly by the pharmaceutical entrepreneur on the container or, if used, on the outer packaging. The fixing of these package sizes shall be done for specific active substances and shall take into account the fields of application, the duration of application and the pharmaceutical form. In fixing the package size, the following sub-division shall, in principle, be used as a basis:

1. packages for a short duration of application or tolerance tests,
2. packages for an intermediate duration of application,
3. packages for a relatively prolonged duration of application.

THIRD CHAPTER
MANUFACTURE OF MEDICINAL PRODUCTS

Section 13
Manufacturing authorisation

(1) Any person wishing to manufacture medicinal products within the meaning of Section 2 sub-section 1 or sub-section 2 no. 1, test sera, test antigens or active substances, which are of human, animal or microbial origin or are manufactured using genetic engineering, as well as other substances of human origin intended for the manufacture of medicinal products on a commercial or professional basis for the purpose of dispensing to others, shall require an authorisation by the competent authority. The same shall also apply to legal persons, non-incorporated associations and companies established under civil law which manufacture medicinal products for distribution to their members. Distribution to others, in the meaning of the first sentence, shall exist if the person manufacturing the medicinal product is not the same as the person using it. Sentence 1 shall not apply to tissues within the meaning of Section 1a no. 4 of the Transplantation Act nor to tissue preparations for which an authorisation pursuant to Section 20c is to be granted.

(2) The following shall not require an authorisation as defined in sub-section 1:

1. the owner of a pharmacy manufacturing medicinal products within the scope of the normal operation of a pharmacy,
2. the body responsible for a hospital, in so far as it is authorised to distribute medicinal products pursuant to the Law on Pharmacies,
3. the veterinarian operating a veterinary practice dispensary for:
 - a) the decanting, packaging or labelling of medicinal products, without altering them,
 - b) the manufacture of medicinal products which contain substances or preparations from substances released exclusively for trade outside of pharmacies,
 - c) the manufacture of homeopathic medicinal products which, in so far as they are intended for administration to food-producing animals, contain only active substances listed in Annex II of Regulation (EEC) No. 2377/90,
 - d) the preparation of medicinal products from a finished medicinal product and medically non-active constituents,
 - e) the mixing of finished medicinal products for the immobilisation of zoo, wild and reserve animals,

in so far as these activities are undertaken for the animals in his care,

4. the wholesaler decanting, packaging or labelling medicinal products without altering them, provided the packages concerned are not intended for direct distribution to the consumer,
5. the retailer who, in possession of the expert knowledge defined in Section 50, decants, packages or labels medicinal products without altering them for direct distribution to the consumer,
6. the manufacturer of active substances which are intended for use in the manufacture of medicinal products which are manufactured using a procedure described in the homeopathic section of the Pharmacopoeia.

The exceptions specified in sentence 1 shall not apply to the manufacture of blood preparations, sera, vaccines, allergens, test sera, test antigens and radiopharmaceuticals.

(2a) The owner of a hospital pharmacy or a pharmacy which supplies hospitals shall also not require an authorisation pursuant to sub-section 1 for the manufacture of medicinal products for clinical trials in humans, if the decanting, packaging or labelling of medicinal products which are authorised in a Member State of the European Union is concerned, and such medicinal products are intended for use in facilities supplied by these pharmacies.

(3) An authorisation issued pursuant to sub-section 1 concerning the decanting of liquefied medical gases into the delivery receptacle of a tanker truck also covers the decanting of liquefied medical gases, without altering them, from a delivery receptacle of a tanker truck into containers installed at a hospital or on the premises of other consumers.

(4) The decision on the granting of the authorisation shall be reached by the competent authority of the federal Land where the factory site is situated or is to be situated. As far as blood products, tissue preparations, sera, vaccines, allergens, gene transfer medicinal products, somatic cell therapy products, xenogenic cell therapy products, medicinal products manufactured using genetic engineering as well as active substances and other substances intended for the manufacture of medicinal products and which are of human, animal or microbial origin or are manufactured using genetic engineering are concerned, the decision on the authorisation shall be reached in consultation with the competent higher federal authority.

Section 14

Decision on the manufacturing authorisation

(1) An authorisation may only be refused if

1. there is not at least one person available with the expertise required in accordance with Section 15 (qualified person pursuant to Section 14) who is responsible for the activities referred to in Section 19; this qualified person can be identical to one of the persons referred to in number 2,
2. a Production Manager and a Quality Control Manager with sufficient specialist qualifications and practical experience are not available,
3. the qualified person pursuant to number 1 and the managers pursuant to number 2 are not sufficiently reliable in the performance of their job,
4. the qualified person referred to in number 1 cannot consistently perform the duties incumbent upon him,
5. (deleted)
- 5a. in enterprises which manufacture medicated feedingstuffs from medicated pre-mixes, the person responsible for supervising the technical side of the manufacturing procedure does not possess sufficient knowledge and experience in the field of mixing technology, or
- 5b. the physician under whose responsibility pre-treatment of the donor is carried out for the purpose of separating blood stem cells or other blood components, does not possess the expert knowledge required,
- 5c. contrary to Section 4 sentence 1 no. 2 of the Transfusion Act, no physician in charge has been appointed or said person does not possess the necessary professional knowledge according to the state of the medical art or, contrary to Section 4 sentence 1 no. 3 of the Transfusion Act, no physician is present when the withdrawal procedure is carried out on a human donor,
6. suitable premises and equipment for the intended manufacture, testing and storage of the medicinal products are not available, or
- 6a. the manufacturer is not in a position to ensure that the manufacture or the testing of the medicinal products is carried out according to the latest standards prevailing in science

and technology, and in the procurement of blood and blood components, additionally, according to the provisions contained in Part Two of the Transfusion Act.

(2) In the case of enterprises which apply exclusively for an authorisation to manufacture medicated feedingstuffs from medicated pre-mixes, the Production Manager can also be the Quality Control Manager.

(2a) The physician in charge pursuant to Section 4 sentence 1 no. 2 of the Transfusion Act can also be the qualified person in accordance with sub-section 1 no.1.

(2b) In enterprises or establishments which prepare tissue preparations exclusively for use within said enterprises and facilities, the Production Manager can also be the Quality Control Manager.

(3) (deleted)

(4) By way of derogation from sub-section 1 no. 6, it shall be possible to conduct partly outside of the manufacturer's factory site:

1. the manufacture of medicinal products for clinical trials on human beings at a commissioned pharmacy,
2. the changing of the expiry date of medicinal products for clinical trials on human beings at a trial site by a person commissioned by the manufacturer, in so far as these medicinal products are exclusively intended for use at this trial site,
3. the testing of medicinal products at commissioned enterprises,
4. the procurement or testing, including laboratory testing of the donor samples of substances of human origin intended for the manufacture of medicinal products, with the exception of tissues, in other enterprises or facilities,

which require no authorisation of their own, can be carried out on condition that they have the premises and equipment suitable for this purpose and it is guaranteed that the manufacture and testing are carried out in accordance with the obtaining state of scientific and technical knowledge and the Production Manager and Quality Control Manager are able to assume their responsibilities.

(5) Should the documentation presented be deemed flawed, the applicant shall be given the opportunity to correct the flaws within an appropriate period of time. If the flaws are not corrected, the manufacturing authorisation shall be refused.

Section 15

Expert knowledge

(1) Proof of the required expert knowledge on the part of the qualified person referred to in Section 14 shall be furnished by

1. the licence to practise as a pharmacist, or
2. the diploma in pharmacy, chemistry, biology, human or veterinary medicine attained upon completion of university studies

as well as a period of at least two years' practical experience in the testing of medicinal products.

(2) In the cases specified in sub-section 1 no. 2, proof shall be furnished to the competent authority that the university studies comprised theoretical and practical instruction at least in the following basic subjects and that an adequate knowledge exists thereof:

experimental physics,
general and inorganic chemistry,
organic chemistry,
analytical chemistry,
pharmaceutical chemistry,
biochemistry,
physiology,
microbiology,
pharmacology,
pharmaceutical technology,
toxicology,
pharmaceutical biology.

The theoretical and practical instruction and sufficient knowledge may also be acquired at a university upon completion of university studies within the meaning of sub-section 1 no. 2 and may be proved by examination.

(3) Sub-section 2 shall not apply to the manufacture and testing of blood preparations, sera, vaccines, allergens, test sera and test antigens. In place of the evidence of practical experience required in sub-section 1, proof shall be furnished of at least three years' experience in the field of medical serology or medical microbiology. By way of derogation from sentence 2, in place of the practical experience required in sub-section 1, proof shall be furnished of

1. at least three years' experience in manufacture or testing in plasma processing enterprises with a manufacturing authorisation, in addition to at least six months' experience in the field of transfusion medicine or medical microbiology, virology, hygiene or analytic procedure, in the case of blood preparations produced from blood plasma for the purpose of fractionation,
2. at least two years' experience in the field of transfusion medicine covering all the areas of manufacture and testing in the case of blood preparations made from blood cells and preparations made from fresh plasma as well as in the case of substances and blood components for the manufacture of blood preparations,
3. at least six months' experience in transfusion medicine or one year's experience in the manufacture of autologous blood preparations in the case of autologous blood preparations,
4. in the case of preparations made from blood stem cells, in addition to sufficient knowledge, at least two year's experience in this field of activity especially in the technology on which it is based.

With regard to the pre-treatment of patients for the purpose of separating blood stem cells or other blood components, the responsible physician shall provide evidence of sufficient knowledge in addition to at least two years' experience in this field of activity. The prerequisites contained in sub-section 1 remain valid for packaging and labelling.

(3a) Sub-section 2 shall not apply to the manufacturing and testing of gene-transfer medicinal products, medicinal products for use in in-vivo diagnosis by means of marker genes, tissue preparations, radiopharmaceuticals and active substances. In place of the practical experience required in sub-section 1, proof must be furnished of at least 2 years' experience in a medically relevant field of genetic engineering, in particular microbiology, cell biology, virology or molecular biology in the case of medicinal products for use in in-vivo diagnosis by means of marker genes and gene-transfer medicinal products; at least two years' experience in the

manufacture and testing of such medicinal products in enterprises or facilities which require a manufacturing authorisation pursuant to the present Act or possess a manufacturing authorisation under community legislation, in the case of tissue preparations; at least three years' experience in the field of nuclear medicine or that of radiopharmaceutical chemistry in the case of radiopharmaceuticals and at least two years' experience in the manufacture and testing of active substances in the case of active substances other than those listed under sub-section 3 sentence 3 no. 2.

(4) The period of practical experience specified in sub-section 1 shall be spent at a firm which has been granted a manufacturing authorisation by a Member State of the European Union, by another State Party to the Agreement on the European Economic Area or by a state with which an agreement exists as to the mutual recognition of certificates pursuant to Section 72a sentence 1 no. 1.

(5) The period of practical experience shall not be required for the manufacturing of medicated feedingstuffs from medicated pre-mixes; sub-section 2 shall not apply.

Section 16

Limitation of the manufacturing authorisation

The authorisation shall be issued to the manufacturer for a specific factory site and for particular medicinal products and pharmaceutical forms of medicinal products and, in cases as defined in Section 14 sub-section 4, also for a specific factory site of the commissioned company or the other company.

Section 17

Deadlines for the granting of an authorisation

(1) The competent authority shall reach a decision on the application for an authorisation within three months. The competent authorities shall enter the data on the authorisation into a database in accordance with Section 67a. Sentence 2 shall not apply if only medicated feedingstuffs are to be manufactured.

(2) If the holder of the authorisation makes an application for the authorisation to be modified in respect of the medicinal products to be manufactured or the premises and equipment as defined in Section 14 sub-section 1 no. 6, the authority shall reach a decision within one month. In exceptional cases, the deadline shall be extended by a further two months. The

applicant shall be notified thereof prior to the expiry of the deadline and shall be informed of the grounds.

(3) If the authority gives the applicant the opportunity to correct the flaws in accordance with Section 14 sub-section 5, the deadlines shall be interrupted until such flaws have been corrected or until the expiry of the deadline set in accordance with Section 14 sub-section 5. The interruption of the deadline shall begin on the day the applicant receives the request to correct the flaws.

Section 18

Withdrawal, revocation, suspension

(1) The authorisation shall be withdrawn if it becomes known subsequently that one of the grounds for refusal, as specified in Section 14 sub-section 1, existed at the time the authorisation was granted. The authorisation shall be revoked if one of the grounds for refusal subsequently developed; the suspension of the authorisation may be ordered instead of its revocation. Section 13 sub-section 4 shall apply *mutatis mutandis*.

(2) The competent authority may issue a provisional order mandating that the manufacture of a medicinal product be discontinued if the manufacturer fails to furnish the evidence required for manufacture and testing. The provisional order may be restricted to one batch.

Section 19

Areas of responsibility

(1) The qualified person pursuant to Section 14 shall be responsible for ensuring that each batch of the medicinal product is manufactured and tested in accordance with the regulations applicable to the trade in medicinal products. He must certify the fulfilment of these provisions for each batch of medicinal products in a serially numbered register or comparable document before it is placed on the market.

Section 20

Obligations to notify

The marketing authorisation holder shall notify the competent authority in advance of any change in the information referred to in Section 14 sub-section 1 and submit evidence. Any

unforeseen change in the qualified person referred to in Section 14, must be notified immediately.

Section 20a

Applicability to active substances and other substances

Section 13 sub-sections 2 and 4 and Sections 14 to 20 shall apply *mutatis mutandis* to active substances and to other substances of human origin intended for use in the manufacture of medicinal products, in so far as their manufacture pursuant to Section 13 sub-section 1 requires an authorisation.

Section 20b

Authorisation for the procurement of tissues and the pertinent laboratory testing

(1) Any establishment seeking to procure tissues intended for human applications within the meaning of Section 1a no. 4 of the Transplantation Act (removal establishments) or seeking to conduct the laboratory testing necessary for such procurement, shall require an authorisation from the competent authority. Procurement within the meaning of sentence 1 is the direct or extracorporeal removal of tissues including all measures which are intended to maintain the tissues in a processable state, clearly identifiable and transportable. The authorisation may only be refused if:

1. an appropriately qualified person with the necessary professional experience who, in the case of a removal establishment, can also be the medical person within the meaning of Section 8d sub-section 1 sentence 1 of the Transplantation Act is not present,
2. the additional personnel involved is insufficiently qualified,
3. appropriate rooms for the specific tissue procurement or for the laboratory testing are not available, or
4. it is not guaranteed that the procurement of tissues or the laboratory testing are conducted according to the state of medical science and technology and according to the provisions contained in Parts 2, 3 and 3a of the Transplantation Act.

The competent authority may dispense with an inspection within the meaning of Section 64 sub-section 3 sentence 2 prior to the granting of an authorisation pursuant to this provision.

The authorisation will be granted to the removal establishment by the competent authority for a specific facility and for a specific tissue and, to the laboratory, for a specific site and for specific activities. In the process, the competent authority may involve the competent higher federal authority.

(2) An individual authorisation pursuant to sub-section 1 shall not be required by a person conducting such activities on a contractual basis for a manufacturer or a processor who is in possession of an authorisation pursuant to Section 13 or Section 20c for the processing of tissue or tissue preparations. In this case, the manufacturer or processor shall notify the locally competent authority responsible for the removal establishment or the laboratory of the latter and shall include, with the notification, the information and documents pursuant to sub-section 1 sentence 3. One month subsequent to the notification pursuant to sentence 2, the manufacturer or processor shall notify the competent authority responsible for him/her of the removal establishment or the laboratory unless the competent authority responsible for the removal establishment or the laboratory has objected. In exceptional cases, the deadline pursuant to sentence 3 can be extended for an additional two months. The manufacturer or processor shall be informed thereof before expiry of the deadline and shall be informed of the grounds. If the competent authority has objected, the deadlines pursuant to sentences 3 and 4 shall be suspended until the grounds for the objection have been rectified. Sub-section 1 sentences 3 to 6 shall apply *mutatis mutandis* provided that the authorisation pursuant to sub-section 1 sentence 5 is granted to the manufacturer or processor.

(3) The authorisation shall be withdrawn if it subsequently becomes known that one of the grounds for the rejection pursuant to sub-section 1 sentence 3 existed at the time of the granting of the authorisation. If one of these grounds arises subsequently, the authorisation shall be revoked; instead of the revocation, the suspension of the authorisation can also be ordered. The competent authority is entitled to prohibit the procurement of tissue or the laboratory testing temporarily if the removal establishment, the laboratory, the manufacturer or the processor fail to submit the necessary supporting documents for the procurement of tissue or the laboratory testing..

Section 20c

Authorisation for the processing, preservation and storage or the placing on the market of tissues or preparations made from tissues

(1) Any establishment which wishes to process, preserve, store or place on the market tissues or tissue preparations which are not processed using industrial procedures and the essential processing procedures of which are sufficiently well known in the European Union, requires, by way of derogation from Section 13 sub-section 1, an authorisation from the competent authority pursuant to the following provisions. This shall also apply to tissues or tissue preparations the processing procedures for which are new but comparable with a known procedure. The decision about whether to grant the authorisation shall be taken by the competent authority of the Land in which the facility is located or is to be located, in consultation with the competent higher federal authority.

(2) The authorisation may only be refused if:

1. a person with the necessary expert knowledge and experience pursuant to sub-section 3 (responsible person pursuant to Section 20c) responsible for ensuring that the tissue preparations and tissues are processed, preserved, stored or placed on the market in keeping with the statutory provisions in force, is not available,
2. additional participating personnel is insufficiently qualified,
3. suitable premises and establishments are not available for the envisaged activities,
4. it is not guaranteed that the processing including the labelling, preservation and storage is conducted according to state-of-the-art scientific and technical procedures, or
5. a quality management system pursuant to the principles of Good Practice has not been installed or has not been kept up to date.

(3) Proof that the responsible person pursuant to Section 20c possesses the necessary expert knowledge, shall be provided by a certificate testifying to the successful completion of university studies in human medicine, biology, biochemistry or a course of studies considered equivalent as well as at least two years' practical experience in the processing of tissues or tissue preparations.

(4) Should there be any objections against the submitted documents, the applicant shall be given an opportunity to correct the flaws within an appropriate period of time. If the flaws are not corrected, the authorisation shall be refused. The authorisation shall be granted for a specific facility and for specific tissues or tissue preparations.

(5) The competent authority shall take the decision on the application for an authorisation within three months. Should the holder of an authorisation apply for a modification to the authorisation, the authority shall take the decision within one month. In exceptional cases, the deadline shall be extended by an additional two months. The applicant shall be notified thereof prior to the expiry of the deadline and informed of the grounds. If the authority gives the applicant pursuant to sub-section 4 sentence 1, the opportunity to correct the flaws, the deadlines shall be interrupted until such flaws have been corrected or until the expiry of the deadline set in accordance with sub-section 4 sentence 1. The interruption of the deadline shall begin on the day the applicant receives the request to correct the flaws.

(6) The holder of an authorisation shall notify the competent authority in advance of any change in the information referred to in sub-section 2 and shall submit evidence thereof; the changes may be made only after receipt of a written authorisation from the competent authority. Any unforeseen change in the responsible person pursuant to Section 20c shall be notified immediately.

(7) The authorisation shall be withdrawn if it becomes known subsequently that one of the grounds for refusal, as specified in sub-section 2 existed at the time the authorisation was granted. The authorisation shall be revoked if one of the grounds for refusal developed subsequently, the suspension of the authorisation may be ordered instead of its revocation. Sub-section 1 sentence 3 shall apply *mutatis mutandis*. The competent authority may issue a provisional order mandating that the processing of tissues or tissue preparations be discontinued if the processor fails to furnish the evidence required for processing. If the processing of tissues or tissue preparations is terminated, the processor shall ensure that stored tissue preparations and tissues continue to be stored in a quality-assured manner and are transferred to other manufacturers, processors or distributors in possession of an authorisation pursuant to sub-section 1 or Section 13 sub-section 1. This shall also apply to the information and data about the processing which is necessary for the tracing of these tissue preparations and tissues.

FOURTH CHAPTER

MARKETING AUTHORISATION FOR MEDICINAL PRODUCTS

Section 21

Obligation to obtain a marketing authorisation

(1) Finished medicinal products which are medicinal products as defined in Section 2 sub-section 1 or sub-section 2 no. 1, may only be placed on the market within the purview of the present Act, if they have been authorised by the competent higher federal authority or if the Commission of the European Communities or the Council of the European Union has granted an authorisation for them to be placed on the market pursuant to Article 3 paragraph 1 or 2 of Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31st March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ EC No. L 136, p. 1). The same shall apply to medicinal products which are not finished medicinal products and which are intended for administration to animals, provided they are not intended for distribution to pharmaceutical entrepreneurs holding an authorisation for the manufacture of medicinal products.

(2) A marketing authorisation (*Zulassung*) shall not be required for medicinal products which

1. are intended for administration to human beings and the essential manufacturing stages of which, owing to the documented frequency with which they are the subject of medical and dental prescriptions, are carried out in a pharmacy in an amount of up to one hundred packages ready for dispensing in the space of one day within the framework of the existing pharmacy operating licence,
- 1a. are medicinal products manufactured from substances of human origin, which are intended for autologous use or for targeted administration to a specific person, or are prepared on prescription for individual persons, unless medicinal products pursuant to Section 4 sub-sections 4, 9 or 20 are concerned, with the exception of the processing or reproduction of autologous somatic cells in the context of tissue engineering for tissue regeneration,
- 1b. are medicinal products other than those referred to in number 1a, which are manufactured for individual persons on prescription as therapy allergens or are manufactured from medicinal products authorised within the purview of the present Act for pharmacies, or in enterprises authorised in accordance with Section 50 to conduct retail trade in medicinal products outside of pharmacies,
- 1c. are intended for use in human beings, show antibacterial or antiviral efficacy and are intended for the treatment of a dangerous communicable disease – the spread of which renders necessary an immediate supply of specific medicinal products in excess of nor-

mal requirements – and are manufactured from active substances, which have been stored for this purpose by Federal and Land health authorities, or agencies designated by them, provided that they are manufactured in a pharmacy for dispensing within the framework of the existing pharmacy operating licence or for dispensing to other pharmacies,

- 1d. are tissue preparations which are subject to the obligation to obtain a marketing authorisation pursuant to the provisions contained in Section 21a sub-section 1.
2. are intended for use in clinical trials on human beings,
3. are medicated feedingstuffs, manufactured in keeping with their designated purpose from medicated pre-mixes for which a marketing authorisation has been issued in accordance with Section 25,
4. are manufactured for individual animals or animals belonging to a specific stock, in pharmacies or in veterinary practice dispensaries under the prerequisites specified in sub-section 2a,
5. are intended for use in clinical trials on animals or in residue tests, or
6. are made available under the conditions specified to in Article 83 of Regulation (EC) No. 726/2004 for administration to patients with a seriously debilitating disease or whose disease is life-threatening, and who can not be treated satisfactorily with an authorised medicinal product; rules of procedure shall be specified in an ordinance pursuant to Section 80.

(2a) Medicinal Products which contain substances and preparations from substances which have not been released for trade outside of pharmacies, may only be manufactured pursuant to sub-section 2 no. 4 if a medicinal product authorised for the treatment of the animal species in question or for the specific field of application is not available, if the necessary medicinal treatment of the animals would otherwise be seriously jeopardized and if no direct or indirect danger to the health of human beings and animals is to be feared. The manufacture of medicinal products pursuant to sentence 1 is only admissible in pharmacies. Sentence 2 does not apply to the preparation of medicinal product from a finished medicinal product and medically non-active constituents nor to the mixing of finished medicinal products intended for the immobilisation of zoo, wild and reserve animals. For the purposes of sentence 1, the decanting,

packaging or labelling of medicinal products in unchanged form shall not be considered as manufacturing, in so far as

1. no finished medicinal products are available commercially in package sizes suitable for the individual case, or
2. in other cases, the container or any other form of pharmaceutical packaging coming into direct contact with the medicinal product is not damaged.

Sentences 1 to 4 shall not apply to homeopathic medicinal products which are either registered or exempt from registration and, should they be intended for use in food-producing animals, if they contain only the active substances included in the list in Annex II of Regulation (EEC) No. 2377/90.

(3) Application for a marketing authorisation shall be made by the pharmaceutical entrepreneur. For a finished medicinal product manufactured in pharmacies or at other retail dealers using standardized procedures, and distributed to the consumer under a standardized name, the application for a marketing authorisation shall be made by the party responsible for the issue of the master formula. If a finished medicinal product is manufactured for several pharmacies or other retail dealers and is to be distributed to the consumer under their name and under a standardized name, then the manufacturer shall apply for the marketing authorisation.

(4) Furthermore, upon request by the competent authority of the *Land*, the competent higher federal authority shall decide on the obligation to obtain a marketing authorisation for a specific medicinal product, irrespective of an application for a marketing authorisation pursuant to sub-Section 3.

Section 21a

Authorisation of tissue preparations

(1) Tissue preparations which are not manufactured involving an industrial process and the essential processing procedures of which are sufficiently well known in the European Union, and the effects and side effects of which are known and evident from scientific data may only be placed on the market within the purview of the present Act, if they have been authorised by the competent higher federal authority, by way of derogation from the marketing authorisation obligations pursuant to Section 21 sub-section 1. This shall also apply to tissue preparations the processing procedures for which are new but comparable with a known procedure. Sentence 1 shall apply *mutatis mutandis* to blood stem cell preparations intended for

autologous use or for targeted administration to a specific person. The authorisation shall cover the procedures for the procurement, processing and testing, the choice of donors and the documentation for each operational step as well as the quantitative and qualitative criteria for tissue preparations. Especially the critical processing procedure must be evaluated to ascertain that the procedures do not render the tissues clinically ineffective or harmful to patients.

(2) The application for an authorisation shall be accompanied by the following information and documents to be supplied by the applicant:

1. the name or the company and the address of the processor,
2. the name of the tissue preparation,
3. the therapeutic indications as well as the method of administration and, in the case of tissue preparations which are intended to be used for a limited period of time, the duration of the application,
4. information about the processing of the tissue preparation as well as the harvesting, donor testing, preservation and storage of the tissue preparation,
5. the type of preservation, the shelf life, and the conditions for storage,
6. a description of the functionality and the risks of the tissue preparation,
7. documents containing the results of microbiological, chemical and physical examinations and the methods used in their determination, in so far as these documents are necessary, as well as
8. all of the information and documents which is relevant to the purpose of evaluation of the medicinal product.

(3) In respect of the information pursuant to sub-section 2 no. 3, scientific findings which are also able to compare with empirical medical findings prepared according to scientific methods can be submitted. These could include studies conducted by the manufacturer of the tissue preparation, data from publications or subsequent assessments of the clinical findings on the manufactured tissue preparations.

(4) The competent higher federal authority shall reach a decision on the application for an authorisation within five months. If the applicant is given the opportunity to correct flaws, the deadlines shall be interrupted until such flaws have been corrected or until the expiry of the deadline set for the correction of the flaws. The interruption of the deadline shall begin on the day the applicant receives the request to correct the flaws.

(5) The competent authority may combine the authorisation with the imposition of conditions. Section 28 shall apply *mutatis mutandis*.

(6) The competent authority may only refuse an authorisation if:

1. the documents submitted are incomplete,
2. the tissue preparation does not correspond to the current state of scientific knowledge, or
3. the tissue preparation does not fulfil the envisaged function or the benefit-risk ratio is unfavourable.

(7) The applicant, or subsequent to the authorisation, the holder of the authorisation shall immediately notify the competent higher federal authority of any changes in the information pursuant to sub-sections 2 and 3 and include the corresponding documents with the notification. In the event of a change in the documents pursuant to sub-section 3, the change may only be carried out if the competent higher federal authority has consented.

(8) The authorisation shall be withdrawn if it subsequently becomes known that one of the grounds for refusal, pursuant to sub-section 6 nos. 2 and 3 existed at the time the authorisation was granted. The authorisation shall be revoked if one of the grounds for refusal subsequently developed. In both cases, the temporary suspension of the authorisation may also be ordered. Before a decision is reached pursuant to sentences 1 to 3, the holder of the authorisation shall be heard unless danger is imminent. If the authorisation has been withdrawn, revoked or suspended, the tissue preparation may not be placed on the market, nor shall it be introduced into the purview of the present Act.

(9) By way of derogation from sub-section 1, tissue preparations which are allowed to be placed on the market in a Member State of the European Union or in another State Party to the Agreement on the European Economic Area, shall require a certificate from the competent higher federal authority before the first placing on the market within the purview of the present Act. Before issuing the certificate, the competent higher federal authority shall examine whether the processing of the tissue preparations meet the requirements with respect to the removal

and processing procedures including the donor selection procedures and the laboratory examinations, and whether the quantitative and qualitative criteria for the tissue preparations meet the requirements of the present Act and its ordinances. The competent higher federal authority must issue the certificate if the authorisation certificate or another certificate from the competent authority of the country of origin demonstrates the equivalence of the requirements pursuant to sentence 2 and the proof of authorisation in the Member State of the European Union or in another State Party to the Agreement on the European Economic Area is submitted. The competent higher federal authority shall be informed on time of any change in the requirements pursuant to sentence 2 prior to any further introduction of the tissue preparation into the purview of the present Act. The certificate is to be withdrawn if one of the prerequisites pursuant to sentence 2 had not been met; it shall be revoked if one of the prerequisites pursuant to sentence 2 is, subsequently, no longer met.

Section 22

Marketing authorisation documents

(1) The applicant shall attach the following particulars, written in German, to his application for a marketing authorisation:

1. the name or the company and the address of the applicant and the manufacturer,
2. the name of the medicinal product,
3. the constituents of the medicinal product by type and quantity; Section 10 sub-section 6 shall apply,
4. the pharmaceutical form,
5. the effects,
6. the fields of application,
7. the contra-indications,
8. the side effects,
9. the interactions with other products,

10. the dosage,
11. information on the medicinal product's manufacture,
12. the method of administration and, in the case of medicinal products which should only be administered for a limited period of time, the duration of the administration,
13. the package sizes,
14. the method of preservation, shelf-life, storage conditions, results of stability tests,
15. the methods of quality control (test methods).

(2) Furthermore, the following information shall be submitted:

1. the results of physical, chemical, biological or microbiological examinations and the methods used in their determination (analytical test),
2. the results of the pharmacological and toxicological tests,
3. the results of clinical trials or other medical, dental or veterinary tests,
4. a statement to the effect that clinical trials conducted outside the European Union meet requirements which are equivalent to the ethical requirements of Directive 2001/20/EC of the European Parliament and of the Council of 4th April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121 p. 34),
5. a detailed description of the pharmacovigilance and, if applicable, the risk management system which the applicant will introduce,
6. evidence that the applicant has access to a qualified person in accordance with Section 63a who is equipped with the necessary resources to perform the duties referred to in Section 63b,

7. a copy of each orphan medicinal product designation pursuant to Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16th December 1999 on orphan medicinal products (OJ L 18 p. 1).

The results pursuant to sentence 1 nos. 1 to 3 shall be substantiated by documentary evidence in such a way that the type, scope and exact time of the tests are clearly evident. The application for a marketing authorisation shall be accompanied by all of the relevant particulars and documents necessary for the assessment of the medicinal product, whether favourable or unfavourable. This shall also apply to incomplete or discontinued toxicological or pharmacological experiments or clinical trials carried out using the medicinal product in question.

(3) Instead of the results specified in sub-section 2 nos. 2 and 3, other scientific documents may be presented:

1. in the case of a medicinal product which contains active substances that have been used for at least ten years in the European Union for general medical or veterinary purposes, the effects and side effects of which are known and evident from scientific data,
2. in the case of a medicinal product which, in its composition, is comparable to a medicinal product as specified in no. 1,
3. for the constituents of the medicinal product, in the case of a medicinal product which is a new combination of constituents which are already known; however, other documents containing scientific findings may also be presented for the combination as such, if the efficacy and safety of the medicinal product according to its composition, dosage, pharmaceutical form and fields of application can be determined by these documents.

Furthermore, the medical experience gained by the specific schools of therapy must also be taken into consideration.

(3a) If the medicinal product contains more than one active substance, evidence shall be provided to prove that every active substance contributes to the positive assessment of the medicinal product.

(3b) In the case of radiopharmaceuticals which are generators, a general description of the system, including a detailed description of those components of the system which are able to influence the composition or quality of the secondary radioactive nuclide preparation, as well as the particular qualitative and quantitative characteristics of the eluate or the sublimate, are to be provided.

(3c) Documents should also be submitted for the evaluation of possible environmental risks and if the storage of the medicinal product or its administration or the disposal of its waste require special safety precautions, measures to avoid endangering the environment or impairing the health of human beings, animals or plants, this shall also be stated. Information on how to reduce these dangers shall also be submitted and substantiated.

(4) If an application is made for a marketing authorisation in respect of a medicinal product manufactured within the purview of the present Act, proof shall be furnished that the manufacturer is entitled to manufacture the medicinal product. This shall not apply in the case of an application as specified in Section 21 sub-section 3 sentence 2.

(5) If an application is made for a marketing authorisation in respect of a medicinal product manufactured outside the purview of the present Act, proof shall be furnished that the manufacturer is entitled to manufacture medicinal products in accordance with the legal regulations laid down by the country of manufacture and, in the event that the medicinal product is imported from a country which is not a Member State of the European Union or a State Party to the Agreement on the European Economic Area, that the importer is in possession of an authorisation to import the medicinal product into the territory governed by the present Act.

(6) If the medicinal product has already been granted a marketing authorisation in another state or in several other states, a copy of such authorisation shall be included. Where an application for a marketing authorisation has been denied in whole or in part, the details of that decision shall be furnished and the grounds for it explained. Where an application for a marketing authorisation is currently being examined in one or several Member States of the European Union, this shall be stated. Copies of the summaries of the product characteristics and package leaflets authorized by the competent authorities of the Member States or, where these documents are not available, the versions of these documents proposed by the applicant in the course of a procedure pursuant to sentence 3, shall also be included. Furthermore, where an application for the recognition of the marketing authorisation of another Member State is submitted, the declarations required under Article 28 of Directive 2001/83/EC or in Article 32 of Directive 2001/82/EC shall be submitted along with the other particulars stipulated therein. Sentence 5 shall not apply to medicinal products which have been manufactured according to homeopathic manufacturing procedures.

(7) The application for a marketing authorisation shall be accompanied by the wording of the particulars which are meant to appear on the container, the outer packaging and the package leaflet as well as by the draft of the expert information pursuant to Section 11a sub-section 1 sentence 2 which corresponds with the Summary of Product Characteristics. In the

case of medicinal products intended for administration to human beings, the results of evaluations of the package leaflet conducted in collaboration with patient target groups shall also be submitted to the competent higher federal authority. The competent higher federal authority may require the submission of one or more samples or mock-ups of the sales presentation of the medicinal product, including the package leaflets, as well as starting materials, intermediate products and substances which are used in the manufacture or testing of the medicinal products, in a quantity sufficient to conduct the test and in a state suitable to the conduct of said test.

Section 23

Particular documents required for medicinal products intended for administration to animals

(1) In respect of medicinal products intended for administration to food-producing animals, the following particulars shall be given in addition to those specified in Section 22:

1. particulars of the withdrawal period shall be given and shall be substantiated by documents on the results of the residue tests and particularly on the fate of the pharmacologically active constituents and their metabolic products in the animal body and on the influence on foodstuffs of animal origin, in so far as these results are necessary for the assessment of withdrawal periods taking stipulated maximum levels into account, and
2. in the case of a medicinal product with a pharmacologically active constituent not listed in Annex I, II or III of Regulation (EEC) No. 2377/90, a certificate confirming that an application pursuant to Annex V for the establishment of maximum residues pursuant to the aforementioned Regulation had been submitted to the European Medicines Agency at least 6 months previously, and
3. the results of tests evaluating possible environmental risks; Section 22 sub-section 2 sentences 2 to 4 shall apply *mutatis mutandis*,

Sentence 1 no. 2 shall not apply if Section 25 sub-section 2 sentence 5 applies.

(2) In the case of medicated pre-mixes, the particulars of the mixed feed intended as carrier shall be given with the designation of the type of feedingstuff. Furthermore, it shall be justified and proved by documents that the medicated pre-mixes are suited for the intended manufacture of the medicated feedingstuff, and particularly that they allow a homogeneous and stable distribution of the active substances in the medicated feedingstuffs taking into considera-

tion the manufacturing methods applied in the production of mixed feed; furthermore, the shelf-life of medicated feedingstuffs shall be indicated, grounds provided and proved by documents. Moreover, a routine test method suitable for the quantitative and qualitative analysis of the active substances in the medicated feedingstuffs, shall be described and documents on test results submitted as proof.

(3) The nature and scope of as well as the date on which the tests were carried out shall be inferable from the documents containing the results of the residue tests and the residue test procedures pursuant to sub-section 1, as well as from the evidence regarding the suitability of the medicated pre-mixes for the intended manufacture of the medicated feedingstuff and the test results of the test methods pursuant to sub-section 2. Instead of the documents, the evidence and test results referred to in sentence 1, other scientific findings may be submitted.

Section 24

Expertises

(1) Expertises in which the test methods, test results and residue test procedures are summarized and assessed, shall be included with the required documents as specified in Section 22 sub-section 1 no. 15, sub-sections 2 and 3 and Section 23. In particular, the following information shall be included in detail in the expertises presented:

1. the analytical expert opinion shall state whether the medicinal product is of appropriate quality in accordance with recognized pharmaceutical practice, whether the proposed test methods comply with the prevailing standard of scientific knowledge and are suitable for quality assessment,
2. the pharmacological-toxicological expert opinion shall state the medicinal product's toxic effects and pharmacological properties,
3. the clinical expert opinion shall state whether the medicinal product has the required effect in the specified fields of application, whether it is tolerated, whether the prescribed dosage is appropriate and which contra-indications and side effects exist,
4. the expert opinion on the residue test shall state whether, and if so, how long after the administration of the medicinal product, residues occur in the foodstuffs obtained from the animals which have undergone treatment, how these residues are to be assessed and whether the prescribed withdrawal period is sufficient.

Moreover, the expert opinion shall state whether the type and quantity of residue present after the prescribed withdrawal period has elapsed are below the maximum levels stipulated by Regulation (EEC) No. 2377/90.

(2) In so far as scientific documentation is presented pursuant to Section 22 sub-section 3 and Section 23 sub-section 3 sentence 2, it must be evident from the expert opinion, that the documents on scientific findings were elaborated under analogous application of the Guidelines for the Testing of Medicinal Products.

(3) The expert opinion shall be accompanied by particulars regarding the name, training and professional practice of the expert as well as his professional relationship with the applicant. The experts shall sign their statements personally, stating the place and the date of issue of the expert opinion.

Section 24a

Use of a previous applicant's documents

The applicant can refer to the documents referred to in Section 22 sub-sections 2, 3, 3c and Section 23 sub-section 1, including the expertise report referred to in Section 24 sub-section 1 sentence 2 submitted by an earlier applicant (previous applicant), if he submits the previous applicant's written agreement, including confirmation that the documents referred to meet the requirements of the Guidelines for the Testing of Medicinal Products pursuant to Section 26. The previous applicant shall respond to a request for agreement, within a period of three months.

Section 24b

Authorisation of a generic medicinal product, document protection

(1) In the case of a generic medicinal product within the meaning of sub-section 2, reference can be made, without the previous applicant's agreement, to the documents referred to in sentence 1 of Section 22 sub-section 2 sentence 1 nos. 2 and 3, sub-section 3c and Section 23 sub-section 1, including the expert report referred to in Section 24 sub-section 1 sentences 2 to 4 for the previous applicant's medicinal product (reference medicinal product), provided that the reference medicinal product has been authorised for at least eight years or was authorised at least eight years previously; this shall also apply to authorisation in another Member State of the European Union. A generic medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed following the first authorisation of the reference medicinal product. The period referred to in sentence 2 shall be ex-

tended to a maximum of eleven years if, during the first eight years of authorisation, the marketing authorisation holder obtains authorisation for one or more new fields of application which during the scientific evaluation conducted prior to their authorisation by the competent higher federal authority are held to bring significant clinical benefit in comparison with existing therapies.

(2) Authorisation as a generic medicinal product in accordance with sub-section 1 shall require that the medicinal product in question has the same qualitative and quantitative composition of active substances and the same pharmaceutical form as the reference medicinal product and that the bioequivalence has been demonstrated in bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be one and the same active substance unless their properties differ significantly with regard to safety or efficacy. In such cases, the applicant must submit additional proof of the safety or efficacy of the different salts, esters, ethers, isomers, mixture of isomers, complexes or derivatives of the active substance. The various immediate release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. The applicant shall not be required to submit bioavailability studies if he can otherwise demonstrate that the generic medicinal product meets the relevant bioequivalence criteria in accordance with current scientific knowledge. In cases where the medicinal product does not meet the requirements of a generic medicinal product or where the bioequivalence cannot be demonstrated through bioequivalence studies or in the case of a change in the active substance, field of application, strength, pharmaceutical form or route of administration vis-à-vis the reference medicinal product, the results of appropriate preclinical tests or clinical trials shall be provided. In the case of medicinal products intended for use in animals, the corresponding safety studies and in the case of medicinal products intended for use in food-producing animals, the results of corresponding residue tests shall also be submitted.

(3) If the reference medicinal product was not authorised by the competent higher federal authority but by the competent authority of another Member State, the applicant shall indicate in the application form, where the reference medicinal product is or has been authorised. In this case, the competent higher federal authority shall ask the competent authority of the other Member State to transmit within one month a confirmation that the reference medicinal product is or has been authorised, together with the full composition of the reference medicinal product and other documents relevant to the authorisation of the generic medicinal product. In the case where the reference medicinal product has been authorised by the European Medicines Agency, the competent higher federal authority shall ask the latter for the information and documents referred to in sentence 2.

(4) If the competent authority of another Member State where an application is submitted requests particulars or documents referred to in sub-section 3 sentence 2 of the competent higher federal authority, the latter shall respond to this request within one month, provided that at least eight years have elapsed since the reference medicinal product was first authorised.

(5) Where a biological medicinal product which is similar to a biological reference medicinal product does not meet the conditions for generic medicinal products, referred to in sub-section 2 owing to, in particular, differences relating to raw materials or differences between the manufacturing processes of the biological medicinal product and the reference biological medicinal product, the results of appropriate preclinical tests or clinical trials relating to these deviations must be provided. The type and quantity of the supplementary data to be provided must comply with the relevant criteria according to current scientific knowledge. The results of other tests from the documents submitted for the reference medicinal product's authorisation shall not be provided.

(6) In addition to the provisions laid down in sub-section 1, where an application is made for a new field of application for a known active substance that has been in general medical use for at least ten years in the European Union, a non-cumulative period of one year of data exclusivity shall be granted for the data gained from significant preclinical or clinical studies carried out in connection with the new field of application.

(7) Sub-section 1 sentence 3 and sub-section 6 shall not apply to generic medicinal products intended for use in animals. The period referred to in sub-section 1 sentence 2 shall be extended

1. to thirteen years in the case of veterinary medicinal products intended for use in fish or bees,
2. in the case of veterinary medicinal products intended for one or more food-producing species, containing a new active substance that had not been authorised in the Community by 30th April 2004, by one year for each extension of the marketing authorisation to another food-producing species which takes place within the five years following the granting of the initial marketing authorisation. This period shall not, however, exceed a total of thirteen years for a marketing authorisation for four or more food-producing species.

The prolongation of the ten-year period to eleven, twelve or thirteen years for a veterinary medicinal product intended for a food-producing species shall be granted only if the mar-

keting authorisation holder also originally applied for the setting of maximum residues limits for the species covered by the authorisation.

(8) If the extension of a marketing authorisation is for a veterinary medicinal product registered in accordance with Section 22 sub-section 3 and relates to a food-producing species and was obtained on submission of new residue tests in accordance with Regulation (EEC) No. 2377/90 and new clinical trials, the data obtained in the aforementioned tests shall be covered by an exclusivity period of three years after the granting of the authorisation.

Section 24c

Additional requests

If several holders of a marketing authorisation have to be requested to submit additional documents, the competent higher federal authority shall notify every holder of a marketing authorisation of the documents necessary for the further assessment as well as of the names and addresses of the other holders of a marketing authorisation who are involved. The competent higher federal authority shall give those holders of the marketing authorisation who are involved the opportunity to decide among themselves as to who will submit the documents within a period of time to be determined by the authority. If an agreement is not reached, the competent higher federal authority shall decide and immediately notify all persons concerned. Unless the other holders of a marketing authorisation choose to forgo the marketing authorisation granted for their own pharmaceutical product, they shall be obliged to contribute proportionally to the expenditure incurred in the preparation of the documents, calculated according to the number of marketing authorisation holders involved; they are jointly and severally liable. Sentences 1 to 4 shall apply *mutatis mutandis* to persons using standard marketing authorisations, as well as in cases where documents with the same contents are requested from several applicants in ongoing marketing authorisation procedures.

Section 24d

General right of use

The competent higher federal authority is empowered to utilize the documents submitted to it, with the exception of those referred to under Section 22 sub-section 1 nos. 11, 14 and 15 as well as sub-section 2 no. 1, and the expert opinion pursuant to Section 24 sub-section 1 sentence 2 no. 1, in fulfilling its tasks under the present Act, provided that at least eight years have elapsed since the medicinal product first received a marketing authorisation in one of the Member States of the European Union or a procedure pursuant to Section 24c has not yet been terminated.

Section 25

Decision on marketing authorisation

(1) The marketing authorisation, together with a marketing authorisation number, shall be issued in writing by the competent higher federal authority. The marketing authorisation shall only be applicable to the medicinal product specified in the marketing authorisation notice and, in the case of medicinal products manufactured according to homeopathic manufacturing procedures, it shall also apply to the degree of dilution mentioned in results published in accordance with Section 25 sub-section 7 sentence 1 of the version in force prior to 17th August 1994 and specified in the marketing authorisation notice.

(2) The competent higher federal authority may only refuse to grant the marketing authorisation if:

1. the documents submitted are incomplete,
2. the medicinal product has not been sufficiently tested in accordance with the confirmed state of scientific knowledge or the other scientific information material referred to in Section 22 sub-section 3 does not correspond to the confirmed state of scientific knowledge,
3. the medicinal product does not show appropriate quality in accordance with recognised pharmaceutical rules,
4. the therapeutic efficacy attributed to the medicinal product by the applicant is lacking or is insufficiently substantiated by the applicant in accordance with the confirmed state of scientific knowledge,
5. the benefit/risk profile is unfavourable,
- 5a. in the case of a medicinal product containing more than one active substance, insufficient grounds are provided to demonstrate that each active substance contributes towards a positive assessment of the medicinal product, whereby the special features of the particular medicinal product should be considered in a risk evaluation,
6. the stated withdrawal period is not long enough,

- 6a. in the case of medicated pre-mixes, the test methods used for the qualitative and quantitative detection of the active substances in the medicated feedstuffs cannot be routinely conducted,
- 6b. the medicinal product is intended for use in food-producing animals and contains a pharmacologically active ingredient not listed in Annex I, II or III of Regulation (EEC) No. 2377/90,
7. the marketing of the medicinal product or its administration to animals would violate legal regulations or a regulation or directive issued or a decision adopted by the Council or the Commission of the European Communities,
8. the medicinal product has been exempted from the obligation to obtain a marketing authorisation by virtue of an ordinance pursuant to Section 36 sub-section 1, or is identical with such a medicinal product in terms of the type and quantity of its active substances, in so far as no legitimate interest in a marketing authorisation pursuant to sub-section 1 for export purposes can be demonstrated.

The marketing authorisation may not be refused pursuant to sentence 1 no. 4, because therapeutic results have been achieved in only a limited number of cases. Therapeutic efficacy is lacking if the applicant fails to prove, according to the confirmed state of scientific knowledge at the time, that a therapeutic effect can be produced with the medicinal product. Medical experience in the particular therapeutic field shall be considered. In accordance with sentence 1 no. 6b, the marketing authorisation may be refused if the medicinal product is intended for the treatment of individual equidae to which the conditions referred to in Article 6 paragraph 3 of Directive 2001/82/EC apply and if it fulfils the other conditions in Article 6 paragraph 3 of Directive 2001/82/EC.

(3) The marketing authorisation shall be refused for a medicinal product which differs, in the nature or the quantity of its active substances, from a medicinal product bearing the same name which has been authorised for marketing or is already on the market. Deviating from sentence 1, a difference in the quantity of active substances shall be harmless if the medicinal products differ in their pharmaceutical form.

(4) If the competent higher federal authority is of the opinion that a marketing authorisation cannot be granted on the basis of the documents submitted, it shall inform the applicant, stating reasons. The applicant shall then have the opportunity to correct the flaw within an appropriate deadline which may not exceed six months. Should these flaws not be corrected

within the prescribed deadline, the marketing authorisation shall be refused. After the decision has been taken to refuse the marketing authorisation, the submission of documents in order to correct flaws shall not be allowed.

(5) The marketing authorisation shall be granted on the basis of the examination of the documents submitted as well as on the basis of the expert opinions. In the assessment of the documents, the competent higher federal authority may utilize its own scientific results, call in experts or request expert opinions. The competent higher federal authority may examine authorisation-related data and documents also in connection with a marketing authorisation pursuant to Article 3 paragraph 1 or 2 of Regulation (EC) No. 726/2004 in enterprises and facilities which develop, manufacture, test or clinically investigate medicinal products. For this purpose, persons commissioned by the competent higher federal authority, in consultation with the respective competent authorities, may enter the operating and business premises during usual business hours to inspect documents and request information. Moreover, in making a decision in respect of the marketing authorisation, the competent higher federal authority is also entitled to have the documents assessed by independent counter-experts and shall apply the results of their evaluation in deciding on the marketing authorisation and, in so far as medicinal products which are subject to mandatory prescription under Section 48 sub-section 2 no. 1 are concerned, as a basis for the draft of the marketing authorisation decision which is to be submitted to the marketing authorisation commission pursuant to sub-section 6 sentence 1. The competent higher federal authority may commission, as a counter-expert pursuant to sentence 5, any person who possesses the requisite expert knowledge and the reliability required to do the work of a counter-expert. Upon request, the applicant shall be permitted to peruse the expert opinions. If the applicant requires that experts be called in whom he himself selects, these persons shall also be heard. Sub-Section 6 sentences 5 and 6 shall apply *mutatis mutandis* for the appointment of experts and counter-experts.

(5a) The competent higher federal authority shall also prepare an assessment report on the quality, safety and efficacy documents submitted; in the case of medicinal products intended for use in food-producing animals, the assessment report shall also relate to the results of residue tests. The assessment report should be updated if any new information becomes available.

(5b) Sub-section 5a shall not apply to medicinal products which have been manufactured according to homeopathic manufacturing procedures in so far as these medicinal products are subject to Article 16 paragraph 2 of Directive 2001/83/EC or Article 19 paragraph 2 of Directive 2001/82/EC.

(6) Prior to the decision on the marketing authorisation of a medicinal product subject to prescription pursuant to Section 48 sub-section 2 no. 1, a marketing authorisation commission shall be consulted. The hearing shall cover the contents of the documents presented, the expert opinions, the expertises requested, the comments of the experts summoned, the result of the tests and the reasons which played an essential role in the decision taken on the marketing authorisation or the assessment of the counter-experts. Should the Higher Federal Authority diverge from the result of the hearing in deciding on the application, it shall set forth its reasons for doing so. The Federal Ministry shall appoint the members of the marketing authorisation commission in agreement with the Federal Ministry of Agriculture, Food and Consumer Protection, in so far as medicinal products intended for administration to animals are concerned, taking into account the proposals of the chambers of the medical professions, the professional societies of medical practitioners, dentists, veterinarians, pharmacists, alternative medical practitioners as well as the main central associations of the pharmaceutical entrepreneurs, patients and consumers responsible for representing their interests. In appointing the commission's members, consideration shall be given to the individual peculiarities of the medicinal products. The experts to be appointed to the marketing authorisation commission shall be persons who possess scientific knowledge and have gained practical experience in the specific fields of application as well as in the school of therapy in question (phytotherapy, homeopathy, anthroposophy).

(7) For medicinal products not subject to prescription pursuant to Section 48 sub-section 2 no. 1, commissions shall be set up for specific fields of application or schools of therapy at the competent higher federal authority. Sub-section 6 sentences 4 to 6 shall apply *mutatis mutandis*. In preparing the decision regarding the prolongation of marketing authorisations pursuant to Section 105 sub-section 3 sentence 1, the competent higher federal authority may involve the competent commission. If the decision pursuant to sentence 3 affects medicinal products from a specific school of therapy (phytotherapy, homeopathy, anthroposophy), the competent commission shall be involved if the intention is to refuse the prolongation pursuant to Section 105 sub-section 3 sentence 1 totally, or if the decision is of fundamental importance; the competent commission shall be afforded a period of two months in which to respond. In cases where the competent higher federal authority does not take the opinion of the commission into account in making its decision under sentence 4, it shall set forth its reasons for not doing so.

(7a) In order to improve the safety of medicinal products for children and young people, a Commission on Medicinal Products intended for Children and Young People shall be set up at the Federal Institute for Drugs and Medical Devices. Sub-section 6 sentences 4 to 6 shall apply *mutatis mutandis*. In preparing the decision regarding an application for a marketing au-

thorisation for a medicinal product which is also intended for use in children and young people, the competent higher federal authority shall involve said commission. Furthermore, the competent higher federal authority is entitled to involve the commission when preparing a decision regarding an application for a marketing authorisation of a medicinal product, other than that specified in sentence 3, for which the administration to children or young people is envisaged. The commission has the opportunity to issue an opinion. In cases where the competent higher federal authority does not take the commission's opinion into account in making its decision, it shall set forth its reasons. Furthermore, in the case of medicinal products which have not been authorised for administration to children and young people, the commission may establish the prerequisites for their administration to children and young people in accordance with recognised scientific principles. In the case of medicinal products from the phytotherapeutic, homeopathic and anthroposophic schools of medicine, the tasks and authority conferred by sentences 3 to 7 shall be assumed by the commissions pursuant to sub-section 7 sentence 4.

(8) In the case of sera, vaccines, blood preparations, tissue preparations, allergens, gene transfer medicinal products, somatic cell therapy products and xenogenic cell therapy products, the competent higher federal authority shall grant the marketing authorisation either on the basis of an examination of the documents submitted, its own tests or based on observation of the tests carried out by the manufacturer. For this purpose, persons commissioned by the competent higher federal authority, in consultation with the respective competent authorities, may enter the operating and business premises during usual business hours and carry out an inspection, both of said premises and of the company's transport facilities. At the request of the competent higher federal authority, the applicant shall give particulars of the manufacturing process. Sub-sections 6, 7 and 7a shall not apply to these medicinal products.

(8a) Sub-section 8 sentences 1 to 3 shall apply *mutatis mutandis* to test methods pursuant to Section 23 sub-section 2 sentence 3.

(9) If an application is submitted for different strengths, pharmaceutical forms, administration routes or presentations of a medicinal product, at the applicant's request, these can be the subject of a uniform comprehensive marketing authorisation; this shall also apply to subsequent amendments and extensions. This shall require a uniform authorisation number to which further codes must be added to allow differentiation between the different pharmaceutical forms or concentrations. For authorisations pursuant to Section 24b sub-section 1, individual authorisations of a reference medicinal product shall be regarded as a uniform comprehensive authorisation.

(10) The marketing authorisation shall be without prejudice to the pharmaceutical entrepreneur's penal or civil liability.

Section 25a

Prior examination

(1) The competent higher federal authority shall have the application for a marketing authorisation examined by independent experts to determine whether it is complete and whether the medicinal product has been sufficiently tested according to the current, recognized state of scientific knowledge. Section 25 sub-section 6 sentence 5 shall apply *mutatis mutandis*.

(2) Should flaws within the meaning of sub-section 1 be identified, the expert shall grant the applicant an opportunity to correct such flaws within a period of three months.

(3) If, on the basis of the final opinion delivered by the expert, the application for a marketing authorisation continues to be incomplete or flawed within the meaning of Section 25 sub-section 2 no. 2 after the deadline has passed, the marketing authorisation shall not be granted. Section 25 sub-sections 4 and 6 shall not apply to the prior examination.

(4) If the competent higher federal authority establishes that an identically worded marketing authorisation application is being checked in another EU Member State, it shall reject the application and inform the applicant that a procedure in accordance with Section 25b shall apply.

(5) If the competent higher federal authority referred to in Section 22 is informed that an application relates to a medicinal product already authorised in another EU Member State, it shall reject the application unless it was submitted in accordance with Section 25b.

Section 25b

Mutual-recognition procedure and decentralised procedure

(1) If the applicant is applying for a marketing authorisation or approval in more than one EU Member State, the applicant shall submit an application based on identical documents in these Member States; this can be worded in English.

(2) If the medicinal product has already been approved or given a marketing authorisation in another EU Member State when the application is submitted, this marketing authorisation shall be recognised on the basis of the assessment report sent by this State, unless there

is reason to believe that the authorisation of the medicinal product represents a serious risk to public health or, in the case of medicinal products for use in animals, a serious risk to human or animal health or the environment. In this case, the competent higher federal authority shall proceed in accordance with Article 29 of Directive 2001/83/EC or Article 33 of Directive 2001/82/EC.

(3) If the medicinal product does not have a marketing authorisation at the time of the application, the competent higher federal authority, provided that it is a reference Member State within the meaning of Article 28 of Directive 2001/83/EC or Article 32 of Directive 2001/82/EC, shall prepare drafts of the assessment report, the summary of the product characteristics of the medicinal product, the labelling and package leaflet and transmit them to the competent Member States and to the applicant.

(4) With regard to recognition of the marketing authorisation granted by another Member State, Section 4 of Directive 2001/83/EC and Section 4 of Directive 2001/82/EC shall apply.

(5) In the case of a divergent decision with regard to the marketing authorisation, its suspension or revocation, Articles 30, 32, 33 and 34 of Directive 2001/83/EC and Articles 34, 36, 37 and 38 of Directive 2001/82/EC shall apply. In the case of a decision in accordance with Article 34 of Directive 2001/83/EC or Article 38 of Directive 2001/82/EC, a decision about the marketing authorisation shall be reached based on the decision taken in accordance with these Articles by the Commission of the European Communities or the Council of the European Union. Preliminary proceedings in accordance with Section 68 of the Rules of the Administrative Courts shall not take place in the case of remedies against decisions of the competent higher federal authority referred to in sentence 2. In addition, Section 25 sub-section 6 shall not apply.

(6) Sub-sections 1 to 5 shall not apply to medicinal products manufactured using a homeopathic manufacturing procedure, in so far as these medicinal products are subject to Article 16 paragraph 2 of Directive 2001/83/EC or Article 19 paragraph 2 of Directive 2001/82/EC.

Section 26

Guidelines for the testing of medicinal products

(1) After consultation with experts from the fields of medical and pharmaceutical science and practice and with the approval of the *Bundesrat*, the Federal Ministry be empowered to regulate by ordinance the requirements for the particulars, documents and expert opinions specified in Sections 22 to 24, also in conjunction with Section 38 sub-section 2, as well as for their examination by the competent higher federal authority. The regulations must comply with the prevailing state of scientific knowledge and are to be continually adjusted to it; animal ex-

periments, in particular, shall be replaced by other test methods if this is reasonable in the light of the state of scientific knowledge and considering the purpose of the test. The ordinance shall be issued, in so far as radiopharmaceuticals and medicinal products in the manufacture of which ionizing radiation is used are concerned, and in so far as tests for ecotoxicity are concerned, in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and, in so far as medicinal products intended for administration to animals are concerned, in agreement with the Federal Ministry of Agriculture, Food and Consumer Protection. Section 25 sub-section 6 sentences 4 and 5 shall apply accordingly in respect of the appointment of the experts.

(2) The competent higher federal authority and the commissions specified in Section 25 sub-section 7 shall apply the Guidelines for the Testing of Medicinal Products analogously to the documents on scientific findings specified in Section 22 sub-section 3 and Section 23 sub-section 3 sentence 2, whereby consideration shall be given to the peculiarities of the individual medicinal product. Documents on empirical medical findings prepared in accordance with scientific methods shall also be deemed to be documents on scientific findings.

(3) (deleted)

Section 27

Deadlines for the granting of marketing authorisations

(1) The competent higher federal authority shall reach its decision on the application for a marketing authorisation within a period of seven months. The decision on the recognition of a marketing authorisation shall be taken within a period of three months following receipt of the assessment report. An assessment report is to be drawn up within a period of three months.

(2) If the competent higher federal authority gives the applicant the opportunity to correct the flaws pursuant to Section 25 sub-section 4, then the deadline shall be interrupted until the flaws are corrected or until the deadline set pursuant to Section 25 sub-section 4 has expired. The interruption shall commence on the day on which the applicant is served with the request to correct the flaws. The same shall apply to the deadline granted to the applicant, at his request, for the purpose of giving his opinion, including the calling in of experts.

(3) In the case of procedures in accordance with Section 25b sub-section 3, the period for completion of the procedure shall be extended by three months, in accordance with the provisions contained in Article 28 of Directive 2001/83/EC and Article 32 of Directive 2001/82/EC.

Section 28

Power to impose conditions

(1) The competent higher federal authority may combine the marketing authorisation with the imposition of conditions. In the case of conditions imposed pursuant to sub-sections 2 to 3c for the protection of the environment, the competent higher federal authority shall decide, in agreement with the Federal Environmental Agency, when the impact on the environment needs to be evaluated. For this purpose, the competent higher federal authority shall transmit the data and documents, necessary for its evaluation of the environmental impact, to the Federal Environmental Agency. Conditions may also be imposed subsequently.

(2) The conditions specified in sub-section 1 may be imposed in order to ensure that:

1. the labelling of the containers and outer wrappings complies with the regulations laid down in Section 10; in this connection, it may be prescribed that the following details shall be given:
 - a) instructions or warnings, in so far as they are necessary to prevent a direct or indirect health hazard to human beings or animals by administration of the medicinal product,
 - b) keeping instructions for the consumer and storage instructions for experts, in so far as they are deemed necessary in order to maintain the required medicinal product quality,
2. the package leaflet complies with the regulations laid down in Section 11; in this connection it may be prescribed that the following details shall be given:
 - a) the instructions or warnings mentioned in no. 1 letter a and
 - b) keeping instructions for the consumer, in so far as they are deemed necessary in order to maintain the required medicinal product quality,
- 2a. the expert information complies with the provisions of Section 11a; in this connection it may be stipulated that the following details shall be given
 - a) the instructions or warnings mentioned in no. 1 letter a,

- b) particular storage and keeping instructions, in so far as they are deemed necessary to maintain the required medicinal product quality,
- c) references to conditions pursuant to sub-section 3,

3. the details given pursuant to Sections 10, 11 and 11a comply with the documents submitted for the marketing authorisation and that, in this connection, standardized and generally comprehensible terms as well as a standardized wording are used, whereby the provision of information regarding additional contra-indications, side-effects and interactions remains admissible; the competent Higher Federal Authorities may generally make use of this authority for reasons of medicinal product safety, transparency or to ensure a rational method of working; in this connection, provisions may be imposed prescribing that certain fields of application be omitted in respect of prescription-only medicinal products, if there is reason to fear that by giving such details, the therapeutic aim will be jeopardized,
4. the medicinal product is marketed in package sizes appropriate to the fields of application and the envisaged duration of administration,
5. the medicinal product is marketed in a container of a particular form with a specific seal or some other kind of safety measure, in so far as it is deemed necessary to guarantee compliance with the dosage instructions or to prevent the danger of misuse by children.

(2a) Warnings pursuant to sub-section 2 can also be stipulated so as to ensure that the medicinal product is only prescribed by physicians with a certain speciality and administered only under their supervision or in clinics or special clinics, or in collaboration with such institutions, where necessary, so as to avoid any direct or indirect danger to the health of human beings in its administration, especially when the administration of the medicinal product appears to be completely safe only in the presence of special knowledge or in special therapeutic facilities.

(3) Furthermore, the competent higher federal authority may impose conditions prescribing that additional analytical and pharmaceutical-toxicological tests or clinical trials are to be carried out and a report be submitted on the results, if there is sufficient indication that the medicinal product can have a high therapeutic value and that, therefore, it is in the public interest to have the medicinal product introduced onto the market forthwith, even though further important details are still required to facilitate a comprehensive assessment of the same. Sentence 1 shall apply *mutatis mutandis* to documents on the residue test procedure pursuant to Section 23 sub-section 1 no. 2.

(3a) The competent higher federal authority may, if it is deemed to be necessary in the interest of medicinal product safety, impose conditions prescribing, in addition, that findings resulting from the administration of the medicinal product be systematically collected, documented and evaluated subsequent to the granting of the marketing authorisation and that a report be submitted to it on the results of this investigation within a specific period of time.

(3b) In the case of conditions pursuant to sub-sections 3 and 3a, the competent higher federal authority may specify the nature and scope of the investigation or tests to be conducted. The results are to be proven by means of documents in such a way that the latter clearly show the nature, scope and date of the investigation or tests.

(3c) Furthermore, the competent higher federal authority may impose conditions prescribing that, in the manufacture and control of such medicinal products and their starting materials which are of biological origin or are manufactured using biotechnology,

1. specific requirements have to be fulfilled and specific measures and procedures implemented,
2. documents have to be submitted substantiating the suitability of specific measures and procedures, including documents bearing on validation,
3. the introduction or modification of specific requirements, measures or procedures requires the prior approval of the competent higher federal authority,

in so far as this is deemed necessary to ensure adequate quality or to prevent risks. The conditions imposed shall be immediately enforceable. The lodging of an objection or action to rescind shall have no suspensive effect.

(3d) (deleted)

(4) Should the marketing authorisation be subject to a condition, the deadline envisaged in Section 27 sub-section 1 shall be interrupted until the deadline granted to the applicant for comment has expired. Section 27 sub-section 2 shall apply *mutatis mutandis*.

Section 29

Obligation to notify, renewal of the marketing authorisation

(1) The applicant shall notify the competent higher federal authority forthwith, enclosing the corresponding documents, in the event of any changes to the particulars or documents referred to in Sections 22 to 24a and 25b. The marketing authorisation holder shall comply with the requirement referred to in sentence 1 once the marketing authorisation has been granted.

(1a) In addition to the obligations contained in sub-section 1 and Section 63b, the marketing authorisation holder shall notify the competent higher federal authority immediately of all prohibitions or restrictions by the competent authorities of each country where the medicinal product in question is marketed and of all other new information that could affect the assessment of the benefit and risks of the medicinal product in question. The marketing authorisation holder shall also submit all particulars and documents demonstrating that the risk-benefit balance is still favourable to the competent higher federal authority on request. Sentences 1 and 2 shall not apply to a parallel importer.

(1b) The marketing authorisation holder shall notify the competent higher federal authority immediately of the date on which the medicinal product is to be placed on the market, taking into consideration the different pharmaceutical forms and strengths authorised.

(1c) The marketing authorisation holder shall notify the competent higher federal authority in compliance with sentence 2 in the event of temporary or permanent cessation of the marketing of the medicinal product. Notification shall be submitted at least two months before the suspension of marketing. This shall not apply in the event of circumstances over which the marketing authorisation holder has no control.

(1d) The marketing authorisation holder shall submit all sales data for the medicinal product as well as all data available on prescription levels if the competent higher federal authority requests them for reasons of medicinal product safety.

(2) In the case of a change in the name of the medicinal product, the marketing authorisation notice shall be amended accordingly. A pharmaceutical entrepreneur may place the medicinal product on the market under its current name for a further period of one year, wholesalers and retailers for a further period of two years, beginning on the following 1st January or 1st July after the promulgation of the change in the Federal Journal of Official Publications.

(2a) A change

1. in the information pursuant to Sections 10, 11 and 11a bearing on the dosage, nature and duration of the administration, the fields of application, if it does not concern an addition

or modification of an indication which is to be classified under another area of therapy, a limitation of the contra-indications, side-effects or interactions with other substances, in so far as medicinal products which are excluded from trade outside of pharmacies are concerned,

2. in the active substances, excluding the medically active constituents,
3. in a pharmaceutical form which is comparable with the one authorised for marketing,
- 3a. in treatment with ionizing radiation,
4. in the manufacturing and test procedures or the indication of longer shelf-life for sera, vaccines, preparations derived from blood, allergens, test sera and test antigens as well as any change in manufacturing procedures using genetic engineering technology,
5. in the package size, and
6. in the withdrawal period of a medicinal product intended for administration to animals, when this is based on the stipulation or change in a maximum residue limit pursuant to Regulation (EEC) No. 2377/90, or if the withdrawal period-determining component of a fixed combination is no longer contained in the medicinal product,

may only be made if the competent higher federal authority has granted its approval. Sentence 1 no. 1 shall also apply to the extension of the target species in the case of medicinal products not intended for use in food-producing animals. The approval shall be deemed to be granted if no objection to the change has been filed within a period of three months.

(3) In the following cases an application shall be made for renewal of the marketing authorisation for a medicinal product:

1. in the case of a change in the composition of the active substances either in type or quantity,
2. in the case of a change in the pharmaceutical form unless a change pursuant to sub-section 2a no. 3 is concerned,
3. in the case of an extension of the fields of application, as long as this does not constitute a change pursuant to sub-section 2a no. 1,

- 3a. in the case of the introduction of manufacturing procedures using genetic engineering, and
4. (deleted)
5. in the case of a reduction of the withdrawal period, in so far as a change according to sub-section 2a sentence 1 no. 6 is not concerned.

The competent higher federal authority shall decide on the obligation to obtain a marketing authorisation pursuant to sentence 1.

(4) Sub-sections 1, 2, 2a and 3 shall not be applicable to medicinal products which have been granted a marketing authorisation by the Commission of the European Communities or the Council of the European Union. For such medicinal products, the obligations of the pharmaceutical entrepreneur shall be those stipulated in Regulation (EC) No. 726/2004 on condition that, within the purview of the present Act, an obligation on the part of the relevant competent higher federal authority to notify or to inform the Member States exists.

(5) Sub-sections 2a and 3 shall not apply as long as Commission Regulation (EC) No. 1084/2003 of 3rd June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State (OJ1 EU No. L 159 p. 1) is applicable to medicinal products.

Section 30

Withdrawal, revocation, suspension

(1) A marketing authorisation shall be withdrawn if it becomes subsequently known that one of the grounds for refusal of marketing authorisations, as defined in Section 25 sub-section 2 nos. 2, 3, 5, 5a, 6 or 7, existed at the time of issuance; the marketing authorisation shall be revoked if one of the grounds for refusal as specified in Section 25 sub-section 2 nos. 3, 5, 5a, 6 or 7 has subsequently developed. The marketing authorisation shall furthermore be withdrawn or revoked, if:

1. it comes to light that the medicinal product is lacking in therapeutic efficacy,

2. in the cases referred to in Section 28 sub-section 3, the therapeutic efficacy has not been sufficiently proved according to the prevailing standard of scientific knowledge.

Therapeutic efficacy is lacking if it is clear that no therapeutic results can be achieved with the medicinal product. In the cases referred to in sentence 1, the suspension of the marketing authorisation may also be ordered for a limited period of time.

(1a) Furthermore, the authorisation may be partially or completely withdrawn or revoked if necessary to comply with a decision adopted by the Commission of the European Communities or the Council of the European Union pursuant to Article 34 of Directive 2001/83/EC or pursuant to Article 38 of Directive 2001/82/EC. No preliminary procedure pursuant to Section 68 of the Rules of the Administrative Courts shall be held in the event of an appeal against decisions by the competent higher federal authority pursuant to sentence 1. In the cases covered by sentence 1, the suspension of the authorisation may also be ordered on a temporary basis.

(2) The competent higher federal authority may

1. withdraw the marketing authorisation if incorrect or incomplete information is given in the documents specified in Sections 22, 23 or 24 or if one of the grounds for the refusal of a marketing authorisation, as defined in Section 25 sub-section 2 no. 6a or 6b existed at the time when it was granted,
2. revoke the marketing authorisation, if one of the grounds for refusal as defined in Section 25 sub-section 2 nos. 2, 6a or 6b subsequently developed or if one of the conditions imposed pursuant to Section 28 has not been met and the flaw has not been corrected within a reasonable period of time which is to be specified by the competent higher federal authority; in this regard, the conditions referred to in Section 28 sub-sections 3 and 3a should be reviewed annually,
3. revoke the marketing authorisation in consultation with the competent authority, if the quality tests specified for the medicinal product are either not carried out at all or are not carried out adequately.

In these cases, the suspension of the marketing authorisation may also be ordered for a limited period of time.

(2a) In the cases referred to in sub-sections 1 and 1a, the marketing authorisation shall be amended by imposing a condition if, as a result, the reason for rejection referred to in sub-

section 1 becomes inapplicable, or in order to comply with the decision referred to in sub-section 1a. In the cases referred to in sub-section 2, the marketing authorisation can be amended by imposing a condition if this is sufficient to comply with the requirements of medicinal product safety.

(3) Before a decision is reached pursuant to sub-sections 1 to 2a, the holder of the marketing authorisation shall be heard, unless danger is imminent. In the cases set forth in Section 25 sub-section 2 no. 5, the decision can be implemented immediately. The lodging of an objection or action to rescind shall have no suspensive effect.

(4) If the marketing authorisation of a medicinal product has been withdrawn or revoked or if the marketing authorisation has been suspended, the medicinal product

1. shall neither be placed on the market,
2. nor shall it be introduced into the purview of the present Act.

It shall be permitted to return the medicinal product, appropriately marked, to the pharmaceutical entrepreneur. The competent authority may order the return of a medicinal product.

Section 31

Expiry, prolongation

(1) The marketing authorisation shall expire:

1. if the authorised medicinal product is not placed on the market within three years of the granting of the marketing authorisation, or if the authorised medicinal product that was placed on the market in accordance with the marketing authorisation is not marketed for three successive years,
2. by written renouncement,
3. five years after it was granted, unless an application for prolongation is filed at the latest six months prior to the expiry date.

3a. in the case of a medicinal product intended for administration to food-producing animals, and which contains a pharmacologically active constituent listed in Annex IV of Regulation (EEC) No. 2377/90, at the end of a period of 60 days following its publication in the Official Journal of the European Union unless, within this deadline, the areas of applica-

tion with respect to food-producing animals have been waived pursuant to Section 29 sub-section 1; in the case of a notification of changes pursuant to Section 29 sub-section 2a, the aim of which is to remove the relevant pharmacologically active constituent, the 60-day deadline shall be interrupted until the decision by the competent higher federal authority or until the expiry of the deadline pursuant to Section 29 sub-section 2a sentence 2 and the authorisation shall be suspended during this period after the 60-day deadline has expired; the half-sentences 1 and 2 shall apply *mutatis mutandis* in so far as Regulation (EC) No. 1084/2003 is applicable as regards the alteration of the medicinal product,

4. if the prolongation of the marketing authorisation is refused.

In the cases referred to in the sentence 1 no. 1, the competent higher federal authority can allow exceptions if required to protect human or animal health.

(1a) A marketing authorisation which is prolonged shall be valid for an unspecified period unless, in the case of prolongation pursuant to sub-section 1 sentence 1 no. 3, the competent higher federal authority considers it necessary to grant a prolongation of a further five year period pursuant to the provisions of sub-section 1 sentence 1 no. 3 in conjunction with sub-section 2 in order to ensure the continued safe placing of the medicinal product on the market.

(2) The application for prolongation shall be supplemented by a report giving details of whether, and to what extent, the criteria by which the medicinal product is assessed have altered over the previous five years. To this end, the marketing authorisation holder shall submit to the competent higher federal authority a revised version of the quality, safety and efficacy documents including all amendments made since the marketing authorisation was granted; in the case of medicinal products intended for use in animals, a consolidated list of amendments shall be submitted instead of the revised version. In respect of medicinal products intended for administration to food-producing animals, the competent higher federal authority may furthermore demand that the report comprise details of experience gained in the residue test procedure.

(3) The marketing authorisation in the cases referred to in sub-section 1 sentence 1 no. 3 or sub-section 1a, shall be prolonged for a further five years within the six months prior to its expiry on condition that none of the grounds for refusal as specified in Section 25 sub-section 2 nos. 3, 5, 5a, 6, 6a or 6b, 7 or 8 exist, that the marketing authorisation is not to be withdrawn or revoked pursuant to Section 30 sub-section 1 sentence 2 and that no use is to be made of the possibility of withdrawal pursuant to Section 30 sub-section 2 no. 1 or of revocation pursuant to

Section 30 sub-section 2 no. 2. Section 25 sub-section 5 sentence 5 and sub-section 5a shall apply *mutatis mutandis*. In respect of the decision regarding prolongation, it shall be verified whether findings exist which could influence the subordination of the medicinal product to the prescription requirement.

(4) If the marketing authorisation expires pursuant to sub-section 1 no. 2 or 3, the medicinal product may be marketed for a further two years, commencing on the 1st January or 1st July following the promulgation of the expiry pursuant to Section 34. This shall not apply if the competent higher federal authority ascertains that a condition for the withdrawal or the revocation of the marketing authorisation as defined in Section 30 existed; Section 30 sub-section 4 shall apply.

Section 32

Official batch testing

(1) A batch of a serum, a vaccine or an allergen may only be marketed, without prejudice to the marketing authorisation, if it has been released by the competent higher federal authority. The batch shall be released if a test (official batch test) has shown that the batch has been manufactured and tested by methods of manufacture and control which comply with the prevailing standard of scientific knowledge and that it possesses the required quality, efficacy and safety. The batch shall also be released if the competent authority of another Member State of the European Union has decided, on the basis of an experimental investigation, that the prerequisites stated in sentence 2 are met.

(1a) The competent higher federal authority shall reach a decision pursuant to sub-section 1 within two months of receipt of the batch sample to be tested. Section 27 sub-section 2 shall apply *mutatis mutandis*.

(2) The Federal Ministry shall issue general administrative regulations on the requirements to be set by the federal higher authority for methods of manufacture and control, as defined in sub-section 1, following consultation with experts from the fields of medical and pharmaceutical science and practice and shall promulgate them as Guidelines for the Testing of Medicinal Products in the Federal Journal of Official Publications. The regulations must comply with the prevailing standard of scientific knowledge and are to be continually adjusted to it.

(3) Section 25 sub-section 8 and Section 22 sub-section 7 sentence 2 shall apply *mutatis mutandis* to the execution of the official batch testing.

(4) Release, pursuant to sub-section 1 sentence 1, shall not be necessary if the medicinal products specified therein are exempted by ordinance according to Section 35 sub-section 1 no. 4 or by the competent higher federal authority; the competent higher federal authority shall grant an exemption if the manufacturing and test methods of the manufacturer have reached a level of development which guarantees the quality, efficacy and safety required.

(5) The release as defined in sub-section 1 or the exemption by the competent higher federal authority as defined in sub-section 4 shall be withdrawn if one of their conditions has not been fulfilled; it shall be revoked if one of the conditions is subsequently no longer fulfilled.

Section 33

Costs

(1) The competent higher federal authority shall levy charges (fees and expenses) for the decisions reached on marketing authorisations, on the authorisation of tissue preparations, batch releases, the processing of applications, activities in the context of the compilation and evaluation of risks of medicinal products, for the protest procedure against an administrative act promulgated on the basis of this Act or the determination of costs on the basis of an ordinance in accordance with subsection 2 sentence 1 or Section 39 sub-section 3 sentence 1 no. 2 or Section 39d sub-section 6 no. 2 as well as for other official acts, including independent consulting and information services, in so far as these do not consist of oral information and simple written information within the meaning of Section 7 no. 1 of the Administrative Costs Act, in compliance with the present Act and pursuant to Regulation (EC) No. 1084/2003.

(2) The Federal Ministry is hereby empowered to determine, in agreement with the Federal Ministry for Economics and Technology, and, in so far as medicinal products intended for administration to animals is concerned, also with the Federal Ministry of Agriculture, Food and Consumer Protection, by ordinance not subject to the approval of the *Bundesrat*, which elements are liable to a fee, and to establish fixed rates or rate schedules in the process. The amount of fees payable for the decisions on the marketing authorisations, on the authorisation of tissue preparations, batch releases, as well as other official acts shall be determined in each case according to the expenditure for personnel and material, including in particular the costs for the marketing authorisation procedure in the case of sera, vaccines and allergens and also the expenditure for the tests and for the development of appropriate testing procedures. The amount of fee payable for the decision in respect of a batch release shall be determined by the average costs for personnel and material, whereby the expenditure for tests made previously shall not be taken into account; in addition, appropriate consideration shall be given to the sig-

nificance, the economic value or other benefit derived from the release by the party liable to pay the fee.

(3) The Law on Administration Costs shall apply.

(4) If a protest pursuant to sub-section 1 is successful, necessary expenses shall be reimbursed according to Section 80 sub-section 1 of the Administrative Procedures Act, up to the level of the fees envisaged in an ordinance pursuant to sub-section 2 sentence 1 or Section 39 sub-section 3 sentence 1 no. 2 or Section 39d sub-section 6 no. 2, for the rejection of a corresponding protest procedure and, in the case of framework fees, up to the level of their mean value.

Section 34

Informing the public

(1) The competent higher federal authority shall promulgate the following in the Federal Journal of Official Publications:

1. the granting and prolongation of a marketing authorisation,
2. the withdrawal of a marketing authorisation,
3. the revocation of a marketing authorisation,
4. the suspension of a marketing authorisation,
5. the expiry of a marketing authorisation,
6. the ascertainment pursuant to Section 31 sub-section 4 sentence 2,
7. the change in the name pursuant to Section 29 sub-section 2,
8. the withdrawal or revocation of the release of a batch pursuant to Section 32 sub-section 5,
9. a decision to prolong a protection period in accordance with Section 24b sub-section 1 sentence 3 or sub-section 7 or to grant a data protection period in accordance with Section 24b sub-sections 6 or 8.

Sentence 1 nos. 1 to 5 and no. 7 shall apply *mutatis mutandis* to decisions adopted by the Commission of the European Communities or by the Council of the European Union.

(1a) The competent higher federal authority shall make information on:

1. the granting of a marketing authorisation and the Summary of Product Characteristics,
2. the assessment report with an opinion on the results of pharmaceutical, pharmacological-toxicological and clinical trials for each field of application applied for and, in the case of medicinal products intended for food-producing animals, also on residue tests after removal of all confidential data of a commercial nature,
3. in the case of a marketing authorisation with conditions for a medicinal product intended for use in humans, the conditions with time limits and deadlines for fulfilment,

immediately available to the public. The same shall also apply to changes in the aforementioned information.

(1b) The public shall also be informed of decisions relating to the withdrawal, revocation or suspension of a marketing authorisation.

(1c) Sub-sections 1a and 1b shall not apply to medicinal products approved in accordance with Regulation (EC) No 726/2004.

(1d) The competent higher federal authority shall make the information referred to in sub-sections 1a and 1b available in electronic format.

(2) The competent higher federal authority may promulgate an administrative act executed on the basis of the present Act in the Federal Journal of Official Publications if more than 50 addressees are affected. Two weeks after publication of the administrative act in the Federal Journal of Official Publications, the act shall be considered to be promulgated. Other notifications by the competent higher federal authority, including the letters giving the parties affected the opportunity to submit comments pursuant to Section 28 sub-section 1 of the Law on Administrative Procedures, may also be promulgated in the Federal Journal of Official Publications if more than 50 addressees are affected. Sentence 2 shall apply *mutatis mutandis*.

Section 35

Empowerments in respect of marketing authorisation and exemptions

(1) The Federal Ministry is hereby empowered to:

1. (deleted)
2. extend the provisions on the marketing authorisation to other medicinal products, in so far as it is deemed necessary to prevent direct or indirect hazards to human or animal health,
3. extend the provisions on the release of a batch and on official batch testing to other medicinal products which are subject to variation in their composition or in their content of active substances, in so far as it is deemed necessary to prevent direct or indirect hazards to human or animal health,
4. exempt certain medicinal products from the official batch testing, if the manufacturing and testing procedures of the manufacturer have attained a level of development which guarantees quality, efficacy and safety,

by ordinance, subject to the approval of the *Bundesrat*.

(2) The ordinances, as specified in sub-section 1 nos. 2 to 4, shall be issued in agreement with the Federal Ministry for Economics and Technology and, in the case of radiopharmaceuticals and medicinal products in the manufacture of which ionizing radiation is used, in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and, in the case of medicinal products intended for administration to animals, in consultation with the Federal Ministry of Agriculture, Food and Consumer Protection.

Section 36

Empowerment in respect of standard marketing authorisations

(1) The Federal Ministry is hereby empowered to exempt, by ordinance subject to the approval of the *Bundesrat* and subsequent to consultation with experts, certain medicinal products or groups of medicinal products or medicinal products presented in particular pharmaceutical forms from the obligation to obtain a marketing authorisation, in so far as no direct or indirect danger to human or animal health is to be feared, since it is evident that the requirements with regard to the necessary quality, efficacy and safety have been met. For the sake of the protection of human or animal health, the exemption may be made dependent on a particular manufacturing procedure, composition, labelling, package leaflet, expert information or pharmaceutical form and be limited to certain methods, fields or ranges of application. It is admissi-

ble for the pharmaceutical entrepreneur to provide information regarding additional contra-indications, side-effects and interactions.

(2) In selecting the medicinal products to be exempted from the obligation to apply for a marketing authorisation, account must be taken of the legitimate interests of the consumer of the medicinal product, the health professions and the pharmaceutical industry. The pharmaceutical entrepreneur is free to choose the name of the medicinal product.

(3) The ordinance as specified in sub-section 1 shall be promulgated in agreement with the Federal Ministry for Economics and Technology and, in the case of radiopharmaceuticals and medicinal products in the manufacture of which ionizing radiation is used, in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and, in the case of medicinal products intended for administration to animals, in agreement with the Federal Ministry of Agriculture, Food and Consumer Protection.

(4) In cases where it is necessary to make immediate changes to information regarding contra-indications, side-effects and interactions and, on condition that the validity of the ordinance having the force of law does not exceed a maximum period of one year, the hearing of experts and the approval of the *Bundesrat* shall not be necessary prior to the promulgation of an ordinance pursuant to sub-section 1. The deadline may be prolonged once for a further year if the procedure pursuant to sub-section 1 cannot be completed within the one-year period.

Section 37

Authorisation by the Commission of the European Communities or the Council of the European Union for placing on the market, marketing authorisations for medicinal products from other states

(1) The marketing authorisation issued by the Commission of the European Communities or the Council of the European Union pursuant to Regulation (EC) 726/2004 shall rank equally with a marketing authorisation issued pursuant to Section 25 in so far as the provisions of Sections 11a, 13 sub-section 2a, Section 21 sub-sections 2 and 2a, Sections 40, 56, 56a, 58, 59, 67, 69, 73, 84 or 94 are geared to a marketing authorisation. The marketing authorisation issued for a medicinal product by another state shall be considered a valid marketing authorisation as defined in Section 21, in so far as this is stipulated in an ordinance issued by the Federal Ministry.

(2) The Federal Ministry is hereby empowered to issue an ordinance pursuant to sub-section 1, which shall not be subject to the approval of the *Bundesrat*, in order to implement a

directive of the Council of the European Communities or where the marketing authorisation of medicinal products is mutually recognized in international treaties as being of equivalent value. The ordinance shall be issued in agreement with the Federal Ministry of Agriculture, Food and Consumer Protection, in so far as medicinal products intended for administration to animals is concerned.

FIFTH CHAPTER

REGISTRATION OF MEDICINAL PRODUCTS

Section 38

Registration of homeopathic medicinal products

(1) Finished medicinal products which are medicinal products as defined in Section 2 sub-section 1 or sub-section 2 no. 1 may only be placed on the market as homeopathic medicinal products within the purview of the present Act, if they have been entered into the Register for Homeopathic Medicinal Products kept by the competent higher federal authority (registration). A marketing authorisation shall not be necessary; Section 21 sub-section 1 sentence 2 and sub-section 3 shall apply accordingly. A registration is not required for medicinal products which are marketed by a pharmaceutical entrepreneur in amounts of up to 1,000 packages per year, unless these are medicinal products:

1. which contain preparations made from substances pursuant to Section 3 no. 3 or 4,
2. which contain more than the one-hundredth part of the smallest dose used in non-homeopathic medicinal products which are subject to prescription pursuant to Section 48 or,
3. in which the conditions contained in Section 39 sub-section 2 nos. 3, 4, 5, 6, 7 or 9 are present.

(2) The particulars, documents and expert opinions specified in Sections 22 to 24 shall be enclosed with the application for registration except for the particulars referred to in the Section 22 sub-section 7 sentence 2. This shall not apply to the particulars on the effects and fields of application nor to the documents and expert opinions on the clinical trials. The documents on the pharmaceutical-toxicological test are to be submitted if the safety of the product, especially as results from an adequately high degree of dilution, is not otherwise evident.

Section 39

Decision on the registration of homeopathic medicinal products

(1) The competent higher federal authority shall register the homeopathic medicinal product and inform the applicant in writing as to the registration number. Section 25 sub-section 4 and 5 sentence 5 shall apply *mutatis mutandis*. The registration shall only be valid for the homeopathic medicinal product and its degrees of dilution as specified in the notice of registration. The competent higher federal authority may connect the registration notice with the imposition of conditions. Conditions may also be imposed subsequently. Section 28 sub-sections 2 and 4 shall apply.

(2) The competent higher federal authority shall refuse registration if

1. the documents submitted are incomplete,
2. the medicinal product has not been sufficiently tested analytically in compliance with the prevailing standard of scientific knowledge,
3. the medicinal product does not possess the appropriate quality according to acknowledged pharmaceutical principles,
4. there is good reason to suspect that, if used in keeping with its designated purpose, the medicinal product has harmful effects which exceed the bounds considered justifiable in the light of the knowledge available to medical science,
- 4a. the medicinal product is intended for administration to food-producing animals and contains a pharmacologically active constituent not listed in Annex II of Regulation (EEC) No. 2377/90,
5. the withdrawal period given is insufficient,
- 5a. the medicinal product, in so far as it is intended for administration to human beings, is intended neither for oral administration nor for external use,
- 5b. the medicinal product contains more than one part per 10,000 of the stock, or in the case of medicinal products intended for use in humans, more than 1/100th part of the smallest dose used in allopathic medicinal products that are subject to prescription in accordance with Section 48,

6. the medicinal product is subject to a prescription, unless it exclusively contains substances listed in Annex II of Regulation (EEC) No. 2377/90,
7. the medicinal product is not manufactured according to a procedure described in the homeopathic section of the Pharmacopoeia,
- 7a. the use of the individual active substances as homeopathic or anthroposophic medicinal products is not generally known,
8. a marketing authorisation has been granted for the medicinal product,
9. the marketing of the medicinal product or its use on animals would violate legal regulations.

(2a) If the medicinal product has already been registered in a Member State of the European Union or in another State Party to the Agreement on the European Economic Area, the registration is to be carried out on the basis of this decision unless a reason to refuse pursuant to sub-section 2 is present. For recognition of the registration by another Member State, Chapter 4 of Directive 2001/83/EC and, for medicinal products intended for use in animals, Chapter 4 of Directive 2001/82/EC shall apply *mutatis mutandis*; Article 29 paragraphs 4, 5 and 6, Articles 30 to 34 of Directive 2001/83/EC, Article 33 paragraphs 4, 5 and 6 and Articles 34 to 38 of Directive 2001/82/EC shall not apply.

(2b) The registration shall expire five years after it has been issued unless an application for prolongation is submitted at the latest six months before the deadline expires. For the expiry and prolongation of the registration, Section 31 shall apply *mutatis mutandis* provided that the grounds for refusal pursuant to sub-section 2 nos. 3 to 9 apply.

(3) For homeopathic medicinal products, the Federal Ministry is hereby empowered to issue, in compliance with the provisions on marketing authorisation:

1. by ordinance, subject to the approval of the *Bundesrat*, provisions on the obligation to notify, on renewal of the registration, cancellation, promulgation and
2. by ordinance, not subject to the approval of the *Bundesrat*, provisions on costs and the exemption from registration.

The ordinance shall be issued in agreement with the Federal Ministry of Agriculture, Food and Consumer Protection, in so far as medicinal products intended for administration to animals are concerned. Section 36 sub-section 4 shall apply *mutatis mutandis* to the amendment of an ordinance on the exemption from registration.

Section 39a

Registration of traditional herbal medicinal products

Finished medicinal products which are herbal medicinal products and medicinal products within the meaning of Section 2 sub-section 1, may be placed on the market as traditional herbal medicinal products only if they are registered by the competent higher federal authority. This shall also apply to herbal medicinal products containing vitamins or minerals provided that the action of the vitamins or minerals is ancillary to that of the traditional herbal medicinal product regarding the field or fields of application.

Section 39b

Registration documents for traditional herbal medicinal products

(1) The applicant must enclose the following particulars and documents, in German, with the registration application:

1. the particulars and documents referred to in Section 22 sub-sections 1, 3c, 4, 5 and 7 and Section 24 sub-section 1 no. 1,
2. the results of analytical tests referred to in Section 22 sub-section 2 sentence 1 no. 1,
3. the summary of the product characteristics of the medicinal product with the particulars referred to in Section 11a sub-section 1, taking into consideration the fact that it is a traditional herbal medicinal product,
4. bibliographic evidence of the traditional use or expert reports showing that the medicinal product in question, or a corresponding product has been in medicinal use by humans or in animals for at least 30 years preceding the date of the application, including at least 15 years within the European Union and that under the stated conditions of use, the medicinal product is safe and the pharmacological effects or efficacy of the medicinal product are plausible based on use and experience over many years,.

5. a bibliographic review of safety data together with an expert report pursuant to Section 24 and, where required, additional particulars and documents necessary for assessing the safety of the medicinal product,
6. any registrations or marketing authorisations obtained by the applicant in another Member State, or in a third country, to place the medicinal product on the market, and details of any decision to refuse to grant a registration or marketing authorisation and the reasons for any such decision.

Pursuant to sentence 1 no. 4, evidence of use over a period of 30 years can also be provided if no special approval has been granted for placing a medicinal product on the market. It can also be provided if the number or quantity of active substances of the medicinal product has been reduced over this period. A corresponding medicinal product as referred to in sentence 1 no. 4, is characterised by having the same or comparable active substances, irrespective of the excipients used, the same or similar intended use, equivalent strength and posology and the same or similar route of administration as the medicinal product for which registration is applied.

(2) Instead of submitting the particulars and documents referred to in sub-section 1 sentence 1 nos. 4 and 5, in the case of medicinal products for use in humans, reference can also be made to a Community herbal monograph in accordance with Article 16h paragraph 3 of Directive 2001/83/EC or its presence on the list pursuant to Article 16f of Directive 2001/83/EC.

(3) If the medicinal product contains more than one herbal active substance or substance pursuant to Section 39a sentence 2, the particulars referred to in sub-section 1 sentence 1 no. 4 shall be submitted for the combination. If the individual active substances are not sufficiently well known, particulars shall be provided about the individual active substances.

Section 39c

Decision on the registration of traditional herbal medicinal products

(1) The competent higher federal authority shall register traditional herbal medicinal products and inform the applicant of the registration number in writing. Section 25 sub-section 4 and 5 sentence 5 shall apply *mutatis mutandis*. The registration shall apply only for the herbal medicinal product listed in the notification. The competent higher federal authority can make the registration notification subject to conditions. Conditions can also be imposed at a later date. Section 28 sub-sections 2 and 4 shall apply *mutatis mutandis*.

(2) The registration shall be refused by the competent higher federal authority if the application does not contain the particulars and documents stipulated in Section 39b, if

1. the qualitative or quantitative composition does not correspond to the particulars referred to in Section 39b sub-section 1 or the pharmaceutical quality is otherwise inadequate,
2. the fields of application do not comply exclusively with those of traditional herbal medicinal products which, according to their composition and intended use, are intended for use in humans without the need for medical supervision with respect to making a diagnosis, prescription or supervising the treatment,
3. the medicinal product can be harmful under normal conditions of use,
4. the safety of vitamins or minerals contained in the medicinal product has not been proved,
5. the particulars on traditional use are insufficient, especially if pharmacological effects or efficacy are not plausible on the basis of long-standing use and experience,
6. the medicinal product is not exclusively intended for administration in a specific strength or posology,
7. the medicinal product is not exclusively intended for oral or external use or for inhalation,
8. the time requirement stipulated in Section 39b sub-section 1 sentence 1 no. 4 has not been fulfilled, or
9. a marketing authorisation pursuant to Section 25 or a registration in accordance with Section 39 has been granted for the traditional herbal medicinal product or a corresponding medicinal product.

For medicinal products intended for use in animals, the first sentence shall apply accordingly.

(3) The registration shall terminate after a period of five years has elapsed unless an application for prolongation is submitted not less than six months before expiry of the term. For the expiry and prolongation of the registration, Section 31 shall apply accordingly provided that the reasons for rejection referred to in sub-section 2 apply.

Section 39d

Other procedural provisions for traditional herbal medicinal products

(1) On request, the competent higher federal authority shall notify the applicant and in the case of medicinal products intended for use in humans, the Commission of the European Communities and the competent authority of a EU Member State, of any decision it takes to refuse traditional-use registration and the reasons for the refusal.

(2) For medicinal products corresponding to Article 16d paragraph 1 of Directive 2001/83/EC, Section 25b shall apply accordingly. For medicinal products referred to in Article 16d paragraph 2 of Directive 2001/83/EC, a registration by another Member State shall be duly considered.

(3) On application, the competent higher federal authority can request the Committee on Herbal Medicinal Products, set up in accordance with Article 16h of Directive 2001/83/EC, for an opinion on the evidence of traditional use if there are doubts as to the fulfilment of the conditions referred to in Section 39b sub-section 1 sentence 1 no. 4.

(4) Where a medicinal product has been used in the Community, in humans, for less than 15 years, but is otherwise eligible for registration in accordance with Sections 39a to Section 39c, the competent higher federal authority shall initiate the procedure envisaged under Article 16c paragraph 4 of Directive 2001/83/EC with the participation of the Committee for Herbal Medicinal Products.

(5) If a herbal substance, a herbal preparation or a combination thereof is removed from the list referred to in Article 16f of Directive 2001/83/EC, registrations pursuant to Section 39b sub-section 2 granted for traditional herbal medicinal products containing this substance intended for use in humans shall be revoked unless the particulars and documents referred to in Section 39b are submitted within three months.

(6) The Federal Ministry shall be authorised, in the case of traditional herbal medicinal products in accordance with provisions of the marketing authorisation,

1. to enact provisions on the notification requirement, registration, cancellation, promulgation, by ordinance with the agreement of the *Bundesrat*, and
2. to enact provisions on the costs of registrations, by ordinance without the agreement of the *Bundesrat*.

SIXTH CHAPTER

PROTECTION OF HUMAN SUBJECTS IN CLINICAL TRIALS

Section 40

General conditions for the clinical trial

(1) The sponsor, the investigator and all of the other persons involved in the clinical trial shall, in the conduct of the clinical trial of a medicinal product on human beings, fulfil the requirements of good clinical practice laid down in Article 1 paragraph 3 of Directive 2001/20/EG. The clinical trial of a medicinal product on human beings may only be commenced by the sponsor if the competent Ethics Committee has issued a favourable opinion on it pursuant to Section 42 sub-section 1 and the competent higher federal authority has given its approval pursuant to Section 42 sub-section 2. The clinical trial of a medicinal product may only be conducted on human beings if and as long as:

1. a sponsor or a representative of the sponsor whose registered place of business is situated in a Member State of the European Union or in another State Party to the Agreement on the European Economic Area, is available,
2. the foreseeable risks and inconveniences are medically justifiable, compared with the benefit for the person on whom the clinical trial is to be conducted (person concerned), and the anticipated significance of the medicinal product for medical science,
- 2a. according to the state of scientific knowledge in relation to the purpose of the clinical trial of a medicinal product consisting of a genetically modified organism or a combination of genetically modified organisms or containing such organisms, unjustifiable harmful effects on
 - a) the health of third persons and
 - b) the environmentare not to be expected,
3. the person concerned:

- a) is of age and is capable of understanding the nature, significance and implications of the clinical trial and to form a rational intention in the light of the facts,
- b) has been informed pursuant to sub-section 2 sentence 1 and has given written consent, in so far as no deviating provisions are specified in sub-section 4 or Section 41, and
- c) has been informed pursuant to sub-section 2a sentences 1 and 2 and has given written consent; consent must refer specifically to the collection and processing of health-related data,

4. the person concerned has not been committed to an institution by virtue of an order issued either by the judicial or the administrative authorities,

5. it is conducted in an appropriate facility by a suitably qualified investigator in a responsible manner and its management is assumed by an investigator, principal investigator or chief investigator who can provide evidence of at least two years' experience in the clinical trial of medicinal products,

6. a pharmacological-toxicological test of the medicinal product in accordance with the prevailing state of scientific knowledge has been carried out,

7. each investigator has been informed, by a scientist responsible for the pharmacological-toxicological test, about the findings of the test and the foreseeable risks involved in the clinical trial,

8. in the event that a person is killed or a person's body or health is injured during the course of the clinical trial, an insurance policy which provides benefits, even when no one else is liable for the damage, exists in accordance with the provisions contained in sub-section 3, and

9. a physician is responsible for the medical care of the person concerned or in the case of dental treatment, a dentist.

(2) The person concerned shall be informed by an investigator who is a physician, or in the case of a dental trial, a dentist, about the nature, significance, risks and implications of the clinical trial as well as about his right to withdraw from the clinical trial at any time; a generally comprehensible information sheet is to be handed out to him. Furthermore, the person con-

cerned is to be given the opportunity to have a counselling session with an investigator about the other conditions surrounding the conduct of the clinical trial. A declaration of consent pursuant to sub-section 1 sentence 3 no. 3 letter b to participate in a clinical trial, can be revoked at any time before the investigator, orally or in writing, without disadvantage to the person concerned.

(2a) The person concerned shall be informed of the purpose and scope of the recording and use of personal data, especially medical data. The person concerned shall be informed especially of the fact that:

1. where necessary, the recorded data:

- a) will be kept available for inspection by the supervisory authority or the sponsor's representative in order to verify the proper conduct of the clinical trial,
- b) will be passed on in a pseudonymised version to the sponsor or to an agency commissioned by the latter for the purpose of scientific evaluation,
- c) will be passed on, in a pseudonymised version, to the applicant and the competent authority for the marketing authorisation if an application for a marketing authorisation is filed,
- d) will be passed on, in a pseudonymised version, to the sponsor and the competent authority and subsequently by the latter to the European database in the event of undesirable events in connection with the investigational medicinal product,

2. the consent pursuant to sub-section 1 sentence 3 no. 3 letter c is irrevocable,

3. in the case of a revocation of a declaration of consent pursuant to sub-section 1 sentence 3 no. 3 letter b, the stored data may continue to be used where necessary, in order to:

- a) determine the effects of the investigational medicinal product,
- b) to ensure that those interests of the person concerned which are worthy of special protection are not prejudiced,
- c) satisfy the obligation to provide complete marketing authorisation documents,

4. the data will be stored with the specified bodies for the specified period pursuant to Section 42 sub-section 3.

In the case of a revocation of a declaration of consent made pursuant to sub-section 1 sentence 3 no. 3 letter b, the competent bodies shall determine immediately whether the data stored for the purposes provided for in sentence 2 no. 3 might still be needed. Data which are no longer needed are to be deleted immediately. Furthermore, the collected personal data shall be deleted after the period specified on the basis of Section 42 sub-section 3 has elapsed as long as no legal statutory or contractual retention periods exist to the contrary.

(3) The insurance pursuant to sub-section 1 sentence 3 no. 8 must be taken out in favour of the person concerned in a clinical trial with an insurance carrier authorised to conduct business in a Member State of the European Union or another State Party to the Agreement on the European Economic Area. Its scope must be reasonably commensurate with the risks involved in the clinical trial and determined on the basis of the risk assessment in such a way as to ensure that for every case of the death or permanent occupational disability of a person concerned by clinical trial, at least 500,000 € will be available. In so far as benefits are paid by the insurance, all claims to damages shall be extinguished.

(4) In respect of a clinical trial on minors, sub-sections 1 to 3 shall apply with the following proviso:

1. the medicinal product must be intended to diagnose or prevent diseases in minors and the use of the medicinal product must be indicated in accordance with medical knowledge for the purpose of diagnosing or preventing diseases in the minor. The medicinal product is indicated if its administration to minors is medically indicated,
2. clinical trials performed on adults cannot be expected to produce satisfactory test results according to medical knowledge,
3. the consent is granted by the legal representative after being informed in accordance with sub-section 2. It must correspond to the minor's presumed will where such a will can be ascertained. Before the start of the clinical trial, the minor shall be informed, by an investigator who is experienced in dealing with minors, about the trial, the risks and benefits, in so far as this is possible taking into account the minor's age and mental maturity; should the minor declare or express in any other way that he does not wish to take part in the clinical trial, this must be respected. If the minor is in a position to comprehend the nature, significance and implications of the clinical trial and to form a rational intention in

the light of these facts, then his consent shall also be required. An opportunity for a counselling session pursuant to sub-section 2 sentence 2 shall be offered, not only to the legal representative but also to the minor,

4. the clinical trial may only be conducted if it subjects the person concerned to as little burden and other foreseeable risks as possible; both the degree of burden and the risk threshold must be defined specifically in the trial protocol and monitored constantly by the investigator,
5. with the exception of adequate compensation, no advantages may be granted.

(5) The person concerned, his legal representative or authorised representative, shall have access to a competent contact point from which information about all of the facts which are likely to be of significance for the conduct of a clinical trial can be obtained. The contact point shall be set up at the Higher Federal Authority competent in the specific case.

Section 41

Special conditions for the clinical trial

(1) In the case of a clinical trial on a person of legal age who is suffering from a disease which is to be treated by the investigational medicinal product, Section 40 sub-sections 1 to 3 shall apply with the following provisos:

1. the use of the investigational medicinal product is indicated according to the findings of medical science in order to save the person's life, to restore his health, alleviate his suffering, or
2. it must be of direct benefit to the group of patients who are suffering from the same disease as this person.

If, in an emergency situation, consent cannot be obtained, treatment which is necessary without delay to save the life of the person concerned, restore good health or alleviate suffering, can be dispensed immediately. Consent for continued participation must be obtained as soon as it is possible and reasonable.

(2) Section 40 sub-sections 1 to 4 shall apply, with the following provisos, to the conduct of a clinical trial on a minor suffering from a disease in the treatment of which the investigational medicinal product is to be used:

1. the use of the investigational medicinal product must be indicated according to the findings of medical science in order to save the life of the person concerned, to restore him or her to health, to alleviate his or her suffering, or
2.
 - a) the clinical trial must be of direct benefit to the group of patients suffering from the same disease as the person concerned,
 - b) the research must be absolutely necessary in order to confirm data obtained in clinical trials on other persons or by means of other research methods,
 - c) research must relate to a clinical condition from which the minor concerned is suffering, and
 - d) the research may cause only minimal risk and minimal burden to the person concerned; research bears a minimal risk only when it is to be expected, owing to the nature and scope of the intervention, that it will result, at the most, in a very slight and temporary impairment of the health of the person concerned; it causes a minimal burden only when it is to be expected that the discomfort will be, at the most, temporary and very slight for the person concerned.

Sentence 1 no. 2 shall not apply to minors to whom sub-section 3 would apply when they are of legal age.

(3) Section 40 sub-sections 1 to 3 shall apply under the following provisos to the conduct of a clinical trial on a person of legal age who is incapable of comprehending the nature, significance and implications of the clinical trial and of determining his/her will in the light of these facts and who is suffering from a disease in the treatment of which the investigational medicinal product is to be used:

1. the use of the investigational medicinal product must be indicated, according to the findings of medical science, in order to save the life of the person concerned, to restore him to health or to alleviate his suffering; furthermore, such research must relate directly to a life-threatening or highly debilitating clinical condition suffered by the person concerned and the clinical trial may involve as little burden and other foreseeable risks as possible for the person concerned; both the degree of burden and the risk threshold must be defined specifically in the trial protocol and monitored constantly by the investigator. The clinical trial may only be conducted if there is a justified expectation that the benefits of

using the investigational medicinal product for the person concerned outweigh the risks or that the use does not entail any risks,

2. consent shall be given by the legal representative or authorised representative after he has been duly informed pursuant to Section 40 sub-section 2. Section 40 sub-section 4 no. 3 sentences 2, 3 and 5 shall apply correspondingly,
3. the research must be absolutely necessary for the confirmation of data obtained from clinical trials conducted on persons capable of granting informed consent or by means of other research methods. Section 40 sub-section 4 no. 2 shall apply correspondingly,
4. with the exception of adequate compensation, no advantages may be granted.

Section 42

Ethics Committee procedure, procedure for authorisation by the Higher Federal Authority

(1) An application for the favourable opinion from the ethics committee required pursuant to Section 40 sub-section 1 sentence 2 shall be submitted by the sponsor to the independent, interdisciplinary Ethics Committee responsible under *Land* law for the investigator. If the clinical trial is to be conducted by several investigators, the application shall be submitted to the independent Ethics Committee responsible for the principal investigator or the chief investigator. Details regarding the setting up, composition and financing of the Ethics Committee shall be stipulated by *Land* law. The sponsor shall submit to the Ethics Committee all of the information and documents required by the Ethics Committee for its opinion. In assessing the documents, the Ethics Committee can use its own scientific findings, consult experts or request expert opinions. It shall call in experts or ask for expert reports in the case of clinical trials conducted on minors if it is not in possession of expert knowledge of its own in the field of paediatrics, including the ethical and psychosocial aspects of paediatrics, or in the case of xenogenic cell therapy products or gene transfer medicinal products. A favourable opinion may only be refused if:

1. the documents submitted are incomplete even after expiry of an appropriate deadline given to the sponsor for their supplementation,
2. the documents submitted, including the trial protocol, the investigators brochure, and the modalities for selecting trial subjects, do not correspond to the current state of scientific knowledge, and especially, the clinical trial is unsuitable for providing proof of the safety

or efficacy of a medicinal product, including a difference in the mode of action in women and men, or

3. the requirements specified in Section 40 sub-section 1 sentence 3 nos. 2 to 9 sub-section 4 and Section 41 are not fulfilled.

Details shall be specified in the ordinance pursuant to sub-section 3. The Ethics Committee shall have at the latest 60 days from the date of receipt of the required documents to give its opinion on the application referred to in sentence 1, which period can be extended or shortened in compliance with the ordinance pursuant to sub-section 3; no time limit with respect to the authorisation period shall apply in the testing of xenogenic cell therapy products.

(2) An application for the authorisation by the competent higher federal authority required pursuant to Section 40 sub-section 1 sentence 2 shall be made by the sponsor to the competent higher federal authority. In this regard, the sponsor shall submit all the information and documents necessary for the assessment especially the results of the analytical and pharmacological-toxicological tests as well as the trial protocol and the clinical data on the medicinal product including the investigators brochure. The authorisation may only be refused if

1. the documents submitted are incomplete even after expiry of the adequate deadline given to the sponsor for their completion,
2. the documents submitted, especially the data on the medicinal product and the trial protocol including the investigators brochure, do not comply with the current state of scientific knowledge, and especially, the clinical trial is unsuitable for providing proof of the safety or efficacy of a medicinal product, including a difference in the mode of action in women and men, or
3. the requirements stipulated in Section 40 sub-section 1 sentence 3 nos. 1, 2, 2a and 6, in the case of xenogenic cell therapy products also in Number 8, in particular regarding the insurance of third-party risks, are not fulfilled.

The authorisation shall be considered granted if the competent higher federal authority does not inform the sponsor of any reasoned objections within a maximum of 30 days after receipt of the application documents. If the sponsor fails to modify the application correspondingly, within a maximum of 90 days following the reasoned objections, the application shall be deemed to be rejected. Details shall be specified in the ordinance pursuant to sub-section 3. By way of derogation from sentence 4, the clinical trial of medicinal products:

1. which fall under Number 1 of the Annex to Regulation (EC) No. 726/2004,
2. which are somatic cell therapy products, xenogenic cell therapy products, gene transfer medicinal products,
3. which contain genetically modified organisms, or
4. the active substance of which is a biological product of human or animal origin, contains biological components of human or animal origin or requires such components in its manufacture,

can only be commenced if the competent higher federal authority has issued the sponsor with a written authorisation. The competent higher federal authority shall take a decision on the application for the authorisation of a medicinal product pursuant to sentence 7 nos. 2 to 4, within a maximum of 60 days, after receipt of the required documents stipulated in sentence 2, which period can be extended or shortened in compliance with an ordinance pursuant to sub-section 3; no time limit with respect to the authorisation period shall apply in the testing of xenogenic cell therapy products.

(2a) The competent higher federal authority responsible for authorising a clinical trial pursuant to sub-section 2 shall inform the competent Ethics Committee pursuant to sub-section 1 if it is in possession of information bearing on other clinical trials which is of significance to the Ethics Committee's assessment of the clinical trial on which it is to issue an expert opinion; this applies especially to information on aborted or otherwise prematurely discontinued investigations. In such instances, no transmission of personal data shall take place; furthermore, business and company secrets shall remain confidential.

(3) The Federal Ministry is hereby empowered to issue, by ordinance subject to the approval of the *Bundesrat*, regulations to ensure the proper conduct of the clinical trial and the obtention of documents which correspond to the state of scientific knowledge. The ordinance may contain in particular regulations concerning:

1. the tasks and responsibilities of the sponsor, the investigator or other persons conducting or monitoring the clinical trial including notification, documentation and reporting obligations, especially with respect to side effects or other adverse events occurring in the course of the study and which could endanger the safety of the trial subjects or the conduct of the study,

2. the tasks of the ethics committee and the procedure it follows including the documents to be submitted, also with details concerning the adequate participation of women and men as trial subjects, the interruption, extension or curtailment of the processing period and the special requirements placed on the ethics committee in the case of clinical trials pursuant to Section 40 sub-section 4 and Section 41 sub-sections 2 and 3,
3. the tasks of the competent authorities and the official authorisation procedure including the documents to be submitted, also with details concerning the adequate participation of women and men as trial subjects, the interruption, extension or shortening of the processing period, the procedure for inspecting documents in enterprises and facilities as well as the prerequisites and the procedure for the withdrawal, revocation and suspension of the authorisation or prohibition of a clinical trial,
4. the requirements regarding the furnishing and preservation of evidence,
5. the transmission of the name and the registered place of business of the sponsor and of the investigator responsible and non-personal data pertaining to the clinical trial by the competent authority to a European database,
6. the powers to collect and utilise personal data, if so required for the conduct and supervision of the clinical trial or in the case of clinical trials of medicinal products consisting of a genetically modified organism or a combination of genetically modified organisms or containing such organisms, for protection against risks to the health of third persons or the environment as an interactive structure; this also applies to the processing of data which are not processed or used in files,
7. the tasks and powers of the authorities to protect against risks to the health of third persons and the environment as an interactive structure in clinical trials of medicinal products consisting of a genetically modified organism or a combination of genetically modified organisms or containing such organisms;

furthermore, the transmission of documents and copies of the decisions to the competent authorities and to the Ethics Committees responsible for the investigators can be regulated and it can be stipulated that documents be submitted in multiple copies as well as in electronic form or on optical storage media. The ordinance shall provide for exceptions for authorised medicinal products pursuant to Directive 2001/20/EC.

Section 42a

Withdrawal, revocation and suspension of the authorisation

(1) The authorisation shall be withdrawn if it becomes known that one of the grounds for refusal as referred to in Section 42 sub-section 2 sentence 3 nos. 1, 2 or 3 existed at the time of issuance; it shall be revoked, if facts subsequently arise which would justify refusal as specified in Section 42 sub-section 2 sentence 3 no. 2 or no. 3. In the cases referred to in sentence 1, the suspension of the authorisation may also be ordered for a limited period of time.

(2) The competent higher federal authority may withdraw the authorisation if the conditions surrounding the clinical trial do not correspond to the information contained in the authorisation application or if facts give reason to doubt the safety or the scientific basis of the clinical trial. In such a case, the suspension of the authorisation can also be ordered for a limited period of time. The competent authority shall immediately inform the other competent supervision authorities and ethics committees, as well as the Commission of the European Communities and the European Medicines Agency, stating the grounds for its action.

(3) Before a decision pursuant to sub-sections 1 and 2 is taken, the sponsor shall be allowed a deadline of one week to submit a statement. Section 28 sub-section 2 no. 1 of the Administrative Procedures Act shall apply *mutatis mutandis*. In the event that the competent higher federal authority orders the immediate interruption of the clinical trial, it shall inform the sponsor immediately of this order. The lodging of an objection and action to rescind the revocation, the withdrawal or the order to suspend the authorisation as well as against orders pursuant to sub-section 5, shall have no suspensive effect.

(4) If the authorisation to conduct a clinical trial is withdrawn, revoked or suspended, the clinical trial may not be continued.

(5) If the competent higher federal authority, in the context of its activities, becomes aware of facts which justify the assumption that the sponsor, one of the investigators or another participant no longer fulfils his obligations with regard to the proper conduct of the clinical trial, the competent higher federal authority shall immediately inform said person thereof and shall order remedial measures to be taken by this person; should the measures not relate to the sponsor, he shall be informed of the order. This shall be without prejudice to measures taken by the competent supervision authority pursuant to Section 69.

SEVENTH CHAPTER

SALE OF MEDICINAL PRODUCTS

Section 43

Pharmacy-only requirement, placing on the market by veterinarians

(1) Medicinal products as defined in Section 2 sub-section 1 or sub-section 2 no. 1, which are not released for trade outside of pharmacies by the provisions either of Section 44 or of the ordinance issued in compliance with Section 45 sub-section 1 may, except for the cases provided for in Section 47, be placed on the market professionally or commercially to the consumer exclusively in pharmacies and not by mail-order without official authorisation; further details are regulated by the Act on Pharmaceutical Services (*Apothekengesetz*). With the exception of the cases provided for in sub-section 4 and Section 47 sub-section 1, no trade may be conducted outside of pharmacies with those medicinal products reserved exclusively for sale in pharmacies pursuant to sentence 1.

(2) Medicinal products reserved, in compliance with sub-section 1 sentence 1, for trade in pharmacies, may not be dispensed by legal persons, non-incorporated associations and companies established under civil law and under commercial law to their members, unless these members are either pharmacies themselves or are persons and establishments as defined in Section 47 sub-section 1 and the dispensing of medicinal products is carried out under the conditions specified therein.

(3) Medicinal products as defined in Section 2 sub-section 1 or sub-section 2 no. 1 may only be dispensed by pharmacies upon prescription. This shall be without prejudice to Section 56 sub-section 1.

(4) Medicinal products within the meaning of Section 2 sub-section 1 or sub-section 2 no. 1 may furthermore be dispensed by veterinarians, within the framework of the operation of a veterinary practice dispensary, to the owners of animals undergoing treatment and may be held in stock for this purpose. This shall also apply to the dispensing of medicinal products, deemed advisable by veterinarians and supervised by them, for the purpose of implementing measures to prevent illness in animals whereby the amount dispensed may not exceed the amount needed according to veterinarian indication. Furthermore, medicinal products within the meaning of Section 2 sub-section 1 or sub-section 2 no. 1, which are intended for the conduct of animal health measures and are not subject to prescription, may continue to be dispensed to animal keepers by the veterinary authorities, in the amounts necessary in each case. At the time of dispensing, the animal keeper shall be given written instructions about the manner, timing and duration of use.

(5) Medicinal products intended for administration to animals and which are not released for trade outside of pharmacies, may only be dispensed to the animal keeper or to other

persons not mentioned in Section 47 sub-section 1 in pharmacies or in the veterinarian's house dispensary or by the veterinarian. This shall apply neither to medicated feedingstuffs nor to medicinal products within the meaning of sub-section 4 sentence 3.

(6) In the context of the transfer of a veterinary praxis to the successor operating the veterinarian's house dispensary, medicinal products may be handed over.

Section 44

Exceptions to the pharmacy-only requirement

(1) Medicinal products which are intended by the pharmaceutical entrepreneur solely to serve purposes other than the curing or alleviation of disease, suffering, bodily injuries or symptoms of illness shall be released for trade outside of pharmacies.

(2) Furthermore, the following shall be released for trade outside of pharmacies:

1.
 - a) natural curative waters as well as their salts, also in the form of tablets or pastilles,
 - b) synthetic curative waters as well as their salts, also in the form of tablets or pastilles, but only if they are equivalent in their composition to natural curative waters,
2. therapeutic clays, mud for mud baths and other peloids, preparations for the manufacturing of baths, soaps for external use,
3. designated by their customary German names,
 - a) plants and parts of plants, also chopped,
 - b) mixtures of whole or cut plants or parts of plants as finished medicinal products,
 - c) distillates made from plants and parts of plants,
 - d) juices pressed from fresh plants and parts of plants in so far as they are prepared without the use of any solvents other than water,
4. plasters,

5. disinfectants intended exclusively or mainly for external use as well as disinfectants for the mouth and the throat.

(3) Sub-sections 1 and 2 shall not apply to medicinal products which

1. may only be dispensed upon a medical, dental or veterinarian prescription or
2. are excluded by ordinance pursuant to Section 46 from trade outside of pharmacies.

Section 45

Authority to allow further exceptions to the pharmacy-only requirement

(1) The Federal Ministry is hereby empowered to release, in agreement with the Federal Ministry of Economics and Technology and upon consultation with experts, by ordinance, subject to the approval of the *Bundesrat*, substances, preparations made from substances or objects which are intended to be used either in part or exclusively in curing or alleviating diseases, suffering, bodily injuries or symptoms of diseases, for trade outside of pharmacies:

1. in so far as they may not only be dispensed upon a medical, dental or veterinarian prescription,
2. in so far as they do not require testing, storage and dispensing to be carried out in a pharmacy, as a result of their composition or effect,
3. in so far as a direct or indirect hazard to human or animal health need not be feared as a result of their release or in particular as a result of inappropriate handling or
4. in so far as the proper supply of medicinal products is not jeopardized by their release.

The ordinance shall be promulgated by the Federal Ministry of Agriculture, Food and Consumer Protection in agreement with the Federal Ministry and the Federal Ministry of Economics and Technology, in so far as medicinal products intended for administration to animals are concerned.

(2) The release may be limited to finished medicinal products, certain dosages, fields of application or pharmaceutical forms.

(3) The ordinance shall be issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, in so far as radiopharmaceuticals and medicinal products in the manufacture of which ionizing radiation is used are concerned.

Section 46

Authority to extend the pharmacy-only requirement

(1) The Federal Ministry is hereby empowered to exclude, in agreement with the Federal Ministry for Economics and Technology and upon consultation with experts, by ordinance subject to the approval of the *Bundesrat*, medicinal products as defined in Section 44 from trade outside of pharmacies, if a direct or indirect hazard to human or animal health is to be feared even when such medicinal products are used in keeping with their designated purpose or in the customary manner. The ordinance shall be promulgated by the Federal Ministry of Agriculture, Food and Consumer Protection in agreement with the Federal Ministry and the Federal Ministry of Economics and Technology, in so far as medicinal products intended for administration to animals are concerned.

(2) The ordinance in compliance with sub-section 1 may be limited to certain dosages, fields of application or pharmaceutical forms.

(3) The ordinance shall be issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, in so far as radiopharmaceuticals and medicinal products in the manufacture of which ionizing radiation is used are concerned.

Section 47

Distribution channel

(1) Pharmaceutical entrepreneurs and wholesalers may only supply medicinal products reserved for pharmacies to the following parties other than pharmacies:

1. other pharmaceutical entrepreneurs and wholesalers,
2. hospitals and physicians as far as the following items are concerned:
 - a) blood preparations obtained from human blood or blood components manufactured using genetic engineering which, in so far as clotting factor preparations are concerned, are authorised for dispensing by the haemostaseologically qualified physi-

cian to his or her patients within the framework of the medically supervised self-treatment of haemophiliacs,

- b) human or animal tissue,
- c) infusion solutions in containers of at least 500 ml intended for the replacement or the correction of body fluid, as well as solutions for haemodialysis and transperitoneal dialysis,
- d) preparations which are exclusively intended for the diagnosis of the nature, state or functions of the body or mental health conditions,
- e) medical gases which are licensed also for distribution to alternative medical practitioners,
- f) radiopharmaceuticals

or

- g) medicinal products which are labelled '*Zur klinischen Prüfung bestimmt*' (for clinical trial), in so far as they are furnished free of charge,

- 3. hospitals, public health offices and physicians, in the case of vaccines intended for use in a vaccination programme conducted free of charge, on the basis of Section 20 sub-sections 5, 6 or 7 of the Federal Protection against Infection Act of 20th July 2000 (Federal Law Gazette I, p.1045), or supplies of vaccines required to avoid the risk of an epidemic or threat to life,
 - 3a. recognized vaccination centres as far as yellow fever vaccines are concerned,
 - 3b. hospitals and public health offices, in the case of medicinal products with an antibacterial or antiviral action intended for use on the basis of Section 20 sub-sections 5, 6 or 7 of the Protection against Infection Act of 20th July 2000 (Federal Law Gazette I, p.1045) for specific prophylaxis against communicable diseases,
 - 3c. federal health authorities or health authorities of the *Laender* or agencies designated by them in individual cases, in the case of medicinal products which are being stockpiled in case of a dangerous, communicable disease, the spread of which renders necessary an immediate supply of specific medicinal products in excess of normal requirements,

4. veterinary authorities, as far as medicinal products intended for use in the execution of public health measures are concerned,
5. central medicinal product purchasing agencies, established on a statutory basis or approved by the competent authority in consultation with the Federal Ministry,
6. veterinarians, within the framework of the operation of a veterinary practice dispensary, in so far as finished medicinal products are concerned, for administration to animals undergoing treatment by them and for dispensing to the owners of those animals,
7. persons entitled to practise dentistry, as far as finished products are concerned, which are used exclusively in the field of dentistry and in the treatment of a patient,
8. research and scientific institutions which have been granted an authorisation pursuant to Section 3 of the German Law on Narcotic Drugs (*Betäubungsmittelgesetz*) entitling them to purchase the medicinal product in question,
9. universities, as far as medicinal products needed for the education of students of pharmacy and veterinary medicine are concerned.

The recognition of the central purchasing agency pursuant to sentence 1 no. 5 shall be granted, in so far as medicinal products intended for administration to animals are concerned, in consultation with the Federal Ministry of Agriculture, Food and Consumer Protection.

(1a) Pharmaceutical entrepreneurs and wholesalers may only supply medicinal products intended for administration to animals to the recipients specified in sub-section 1 no. 1 or 6 if the latter have submitted a certificate from the competent authority stating that they have fulfilled their obligation to notify according to Section 67.

(1b) Pharmaceutical entrepreneurs and wholesalers shall keep records on the purchase and distribution of prescription-only medicinal products intended for administration to animals and which are not exclusively intended for administration to animals other than those whose products and meat are intended for human consumption, from which the amount of the purchase with indication of the supplier(s) and the amounts supplied with indication of the recipient(s) can be proven for each of these medicinal products separately and in chronological order, and shall submit these records to the competent authority upon request.

(1c) Pharmaceutical entrepreneurs and wholesalers shall notify the central medicinal product information system, pursuant to Section 67a sub-section 1, as prescribed in the ordinance pursuant to Section 67a sub-section 3, about the supply to veterinarians of the substances with an antimicrobial effect specified in Annexes 1 and III of Regulation (EEC) No. 2377/90, substances prohibited pursuant to Annex IV of Regulation (EEC) No. 2377/90, finished medicinal products containing such substances as well as medicinal products subject to the Ordinance on Substances with Pharmacological Effects.

(2) The recipients specified in sub-section 1 nos. 5 to 9 may only obtain medicinal products for their own use within the framework of the fulfilment of their duties. The central purchasing agencies specified in sub-section 1 no. 5 shall only be officially recognized if evidence is produced that they are run under the professional supervision of a pharmacist or, in so far as medicinal products intended for administration to animals are concerned, under the professional supervision of a veterinarian, and provided that suitable premises and equipment are available for the testing, control and storing of the medicinal products.

(3) Pharmaceutical entrepreneurs may supply samples of finished medicinal products or have samples of finished medicinal products supplied to

1. physicians, dentists or veterinarians or
2. other persons practising medicine or dentistry as a profession, provided no prescription-only medicinal products are involved,
3. training centres for health professions.

Pharmaceutical entrepreneurs may supply samples of a finished medicinal product or have samples of a finished medicinal product supplied to training centres for health professions only in the amounts required for the purpose of training. Samples may not contain any of the substances or preparations referred to in Section 2 of the German Law on Narcotic Drugs or listed as such in Annexes II or III of the German Law on Narcotic Drugs.

(4) Pharmaceutical entrepreneurs may supply samples of a finished medicinal product or have samples of a finished medicinal product supplied to persons pursuant to sub-section 3 sentence 1 only upon written request in the smallest package size and, in the course of one year, not more than two samples of one finished medicinal product. Samples shall be accompanied by the relevant expert information in so far as such information is provided for in Section 11a. The sample shall particularly serve the purpose of informing the physician about the me-

dicinal product itself. Records shall be kept on the recipients of samples, the kind and extent as well as the date on which the samples were supplied, under separate cover for each recipient, and they shall be submitted to the competent authority upon request.

Section 47a

Special distribution channels, obligation to keep records

(1) Pharmaceutical entrepreneurs may supply medicinal products which are authorised for the conduct of abortions only to facilities within the meaning of Section 13 of the Act on the Assistance to Cope with Conflicts in Pregnancy of 27th July 1992 (Federal Law Gazette I, p. 1398) amended by Article 1 of the Act of 21st August 1995 (Federal Law Gazette I, p. 1050) and only on the prescription of one of the doctors administering treatment in said facility. Other persons are not authorised to place the medicinal products mentioned in sentence 1 on the market.

(2) Pharmaceutical entrepreneurs shall give serial numbers to the packages of the medicinal products mentioned in sub-section 1 sentence 1 which are intended for delivery; the medicinal products may not be delivered without this labelling. The pharmaceutical entrepreneur shall keep records of the delivery and both the facility and the attending physician shall keep records of the receipt and use of said medicinal products and shall submit them for inspection to the competent authority upon request.

(2a) Both the pharmaceutical entrepreneur and the facility shall store the medicinal products mentioned in sub-section 1 sentence 1 which are in their possession in a separate place and secure them against unauthorised removal.

(3) Sections 43 and 47 shall not apply to the medicinal products mentioned in sub-section 1 sentence 1.

Section 48

Prescription requirement

(1) Medicinal products

1. which by ordinance issued in sub-section 2, also in conjunction with sub-sections 4 and 5, are certain substances, preparations from substances or objects or which have such substances or preparations from substances added to them, or

2. which are not included under number 1 and are intended for use in food-producing animals,

shall be dispensed to consumers only on prescription by a doctor, dentist or veterinarian. Sentence 1 no. 1 shall not apply to dispensing by pharmacies for the equipping of merchant vessels in accordance with the applicable legal provisions.

(2) The Federal Ministry is hereby empowered, in agreement with the Federal Ministry of the Economy and Technology by ordinance subject to the approval of the *Bundesrat*.

1. to specify substances, preparations thereof or objects with effects that are not generally known in medical science which are contained in medicinal products within the meaning of Section 2 sub-section 1 and sub-section 2 no. 1. This shall also apply to preparations from substances with generally known effects, if the effects of these preparations are not generally known in medical science, unless the effects can be determined from the preparation's composition, dosage, pharmaceutical form or field of application. This shall not apply to medicinal products that are preparations from substances with known effects if these are available outside of pharmacies,

or after consulting experts,

2. to specify substances, preparations thereof or objects
 - a) that can either directly or indirectly endanger human health or, if they are intended for use in animals, the health of the animal, the user or the environment, even under normal conditions of use, if used without medical, dental or veterinary supervision,
 - b) that are frequently used in considerable quantity, in a manner which is not in keeping with their designated purpose, if this might represent a direct or indirect risk to human or animal health; or
 - c) if they are intended for use in animals, if their use requires a prior veterinary diagnosis or can have effects that render subsequent diagnostic or therapeutic procedures more difficult or interfere with them,
3. to repeal the prescription-only status of medicinal products if experience gained from using them shows that the conditions referred to in number 2 do not or no longer exist; in

the case of medicinal products referred to in number 1, the prescription-only status cannot be repealed until at least three years have elapsed since entry into force of the ordinance on which it is based,

4. for substances or preparations thereof, to stipulate that they may be supplied only if certain maximum quantities for single and daily use are not exceeded in the prescription or if, when they are exceeded, the prescriber has expressly made this clear,
5. to specify that a medicinal product cannot be repeatedly dispensed on the same prescription,
6. to stipulate that a medicinal product can be supplied only on prescription by a doctor with a specific specialty or for use in facilities authorised to carry out treatment with the medicinal product or that records must be kept of the prescription, dispensing and use of the medicinal product,
7. to issue provisions on the form and content of the prescription, including prescriptions in electronic form.

(3) The ordinance referred to in sub-section 2, also in conjunction with sub-sections 4 and 5, can be restricted to specific dosages, strengths, pharmaceutical forms, finished medicinal products or fields of application. Similarly, an exception to the prescription-only requirement may be envisaged for dispensing to midwives and obstetric nurses where this is deemed necessary for the proper exercise of their profession. The restriction to specific finished medicinal products for use in humans in accordance with sentence one shall apply if, pursuant to Article 74a of Directive 2001/83/EC, the prescription-only requirement is repealed on the basis of significant preclinical tests or clinical trials; in this regard, the period of one year referred to in Article 74a shall be observed.

(4) The ordinance shall be promulgated by the Federal Ministry of Agriculture, Food and Consumer Protection in agreement with the Federal Ministry and the Federal Ministry of the Economy and Technology in the case of medicinal products intended for use in animals.

(5) The ordinance shall be issued in agreement with the Ministry of the Environment, Nature Conservation and Nuclear Safety in the case of radiopharmaceuticals or medicinal products the manufacturing process of which uses ionising radiation.

(6) In the case referred to in sub-section 1 sentence 1 no. 2, the Federal Ministry of Agriculture, Food and Consumer Protection shall be empowered, in agreement with the Federal Ministry, by ordinance subject to the approval of the *Bundesrat*, to grant exemptions from the prescription requirement subject to compliance with the requirements laid down in Articles 67 (aa) of Directive 2001/82/EC.

Section 49

(deleted)

Section 50

Retail trading of over-the-counter medicinal products

(1) The retailing, outside of pharmacies, of medicinal products as defined in Section 2 sub-section 1 or sub-section 2 no. 1 which are released for trade outside of pharmacies, may only be carried out if the entrepreneur, the legally appointed representative of the enterprise or a person commissioned by the entrepreneur either to head the enterprise or to head its sales section, is in possession of the necessary expert knowledge. Enterprises with several branch premises shall require a person having the necessary expert knowledge for each of the branch premises.

(2) To be considered as possessing the necessary expert knowledge, the person in question shall furnish proof of experience and skill in respect of the proper filling, packaging, labelling, storing and marketing of medicinal products which are released for trade outside of pharmacies as well as knowledge of the existing regulations applicable to these medicinal products. The Federal Ministry is hereby empowered to issue, in agreement with the Federal Ministry of Economics and Technology and the Federal Ministry for Education and Research, by ordinance subject to the approval of the *Bundesrat*, regulations as to how proof of the necessary expert knowledge is to be furnished in order to guarantee a proper trade in medicinal products. It may hereby recognize certificates of professional training or of attendance at further education courses. Furthermore, it may stipulate that proof of the expert knowledge shall be furnished by means of an examination set by the competent authority or by an office accordingly designated by that same authority and may regulate the particulars of the examination requirements and procedure. The ordinance shall be issued by the Federal Ministry of Agriculture, Food and Consumer Protection in agreement with the Federal Ministry, the Federal Ministry of Economics and Technology and the Federal Ministry for Education and Research in so far as medicinal products intended for administration to animals are concerned.

(3) Expert knowledge as specified in sub-section 1 shall not be required by a person retailing finished medicinal products which

1. may be distributed in itinerant trading,
2. are intended for use as a contraceptive or for the prevention of venereal diseases in human beings,
3. (deleted)
4. are disinfectants intended exclusively for external use, or
5. are oxygen.

Section 51

Sale by itinerant traders

(1) Itinerant traders shall be prohibited from offering medicinal products for sale or seeking to procure orders for medicinal products; exempted from the prohibition shall be finished medicinal products released for trade outside of pharmacies which

1. are plants, parts of plants or juices pressed from fresh plants or parts of plants, the effects of which are generally known and which are designated by their customary German names, provided they are manufactured without the use of any solvent other than water, or
2. are curative waters and their salts in their natural mixing proportions or imitations thereof.

(2) The prohibition contained in the first half-sentence of sub-section 1 shall not apply if the trader visits other persons within the framework of their business activities, unless the trader offers for sale medicinal products which are intended for administration to animals in agricultural and forestry undertakings, commercial livestock enterprises as well as for use in vegetable, fruit growing and horticultural enterprises, or in wine-growing, bee-keeping and fishery, or seeks to procure, in such undertakings, orders for medicinal products, the dispensing of which is reserved solely for pharmacies. The same shall also apply to commercial travellers and other persons active on behalf of and in the name of a trader.

Section 52

Prohibition of self-service

(1) Medicinal products as defined in Section 2 sub-section 1 or sub-section 2 no. 1 may

1. not be placed on the market by means of vending machines,
2. nor be placed on the market using other forms of self-service.

(2) Sub-section 1 shall not apply to finished medicinal products which

1. may be supplied in itinerant trading,
2. are intended for use as contraceptives or for the prevention of venereal disease in human beings and which have been released for trade outside of pharmacies,
3. (deleted)
4. are disinfectants intended exclusively for external use, or
5. are oxygen.

(3) Furthermore, sub-section 1 no. 2 shall not be applicable to medicinal products released for marketing outside of pharmacies in cases where a person in possession of the expert knowledge required under Section 50 is available.

Section 52a

Wholesale trading of medicinal products

(1) Any person who engages in the wholesale trading of medicinal products within the meaning of Section 2 sub-section 1 or sub-section 2 no. 1, test sera or test antigens, requires an authorisation to do so. Excepted from this obligation to obtain an authorisation are the finished medicinal products released for trade outside of pharmacies, specified in Section 51 sub-section 1 second-half sentence, as well as gases for medical purposes.

(2) In submitting the application, the applicant shall:

1. name the specific sites for which the authorisation is to be issued,

2. submit evidence that he is in possession of suitable and adequate premises, installations and facilities in order to ensure the proper storage and distribution and, where envisaged, proper decanting, packaging and labelling of medicinal products,
3. appoint a responsible person who possesses the required expert knowledge to perform the activity and
4. enclose a statement in which he commits himself in writing to observe the regulations governing the proper operation of a wholesale enterprise.

(3) The decision on granting the authorisation shall be taken by the competent authority of the *Land* in which the site is or will be located. The competent authority shall take the decision on the application for authorisation within three months. Should the competent authority require additional information from the applicant on the prerequisites pursuant to sub-section 2, the deadline specified in sentence 2 shall be interrupted until such time as the competent authority has received the necessary additional information.

(4) The authorisation may only be refused if:

1. the prerequisites pursuant to sub-section 2 are not fulfilled or
2. facts justify the assumption that the applicant or the person responsible pursuant to sub-section 2 no. 3 does not possess the necessary reliability to perform the activity.

(5) The authorisation shall be withdrawn if it subsequently becomes known that one of the grounds for refusal pursuant to sub-section 4 existed at the time of issuance. The authorisation is to be revoked if the prerequisites for the granting of an authorisation no longer exist; instead of the revocation, the suspension of the authorisation may also be ordered.

(6) An authorisation pursuant to Section 13 or Section 72 shall also include authorisation for the wholesale trading of the medicinal products covered by the authorisation referred to in Section 13 or Section 72.

(7) Sub-sections 1 to 5 shall not apply to the activities conducted by pharmacies within the framework of normal pharmacy operations.

(8) The authorisation holder shall notify the competent authority in advance of any changes in the particulars mentioned in sub-section 2 as well as any fundamental change in

the wholesale trading activity, submitting evidence to that effect. In the case of an unforeseen change with respect to the person responsible pursuant to sub-section 2 no. 3, the notification shall be immediate.

Section 53

Expert consultation

(1) In so far as expert opinions need to be heard in accordance with Section 36 sub-section 1, Section 45 sub-section 1 and Section 46 sub-section 1 prior to the issue of ordinances, the Federal Ministry shall establish an expert committee by ordinance not subject to the approval of the *Bundesrat*. The committee shall comprise experts from the field of medical and pharmaceutical science, from hospitals, from the health professions, from the business circles involved and from the social security institutions. In the ordinance, the exact details of the composition, appointment of the members and the procedure of the committee may be determined. The ordinance shall be issued by the Federal Ministry of Agriculture, Food and Consumer Protection in agreement with the Federal Ministry, in so far as medicinal products intended for administration to animals are concerned.

(2) In so far as the opinion of experts needs to be heard in accordance with Section 48 sub-section 2 prior to the issue of an ordinance, sub-section 1 shall apply *mutatis mutandis*, subject to the provision that the committee shall comprise experts from the fields of medical and pharmaceutical science and practice as well as from the pharmaceutical industry.

EIGHTH CHAPTER

SAFETY AND QUALITY CONTROL

Section 54

Internal regulations

(1) The Federal Ministry is hereby empowered to issue in agreement with the Federal Ministry for Economics and Technology, by ordinance subject to the approval of the *Bundesrat*, internal regulations for enterprises or facilities which bring medicinal products into the purview of the present Act or in which medicinal products are developed, manufactured, tested, stored, packaged or marketed, in so far as it is deemed necessary in order to ensure the proper operation of the enterprise or facility and the quality required of the medicinal products; this shall apply *mutatis mutandis* to active substances and other substances as well as tissues intended for the manufacture of medicinal products. The ordinance shall be issued by the Federal Ministry of Agriculture, Food and Consumer Protection in agreement with the Federal Ministry and the

Federal Ministry for Economics and Technology, in so far as medicinal products intended for administration to animals are concerned. The ordinance shall be issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety if radiopharmaceuticals or medicinal products in the manufacture of which ionizing radiation is used are concerned.

(2) In the ordinance pursuant to sub-section 1, regulations may be laid down in particular concerning:

1. the development, manufacture, testing, storage, packaging, quality assurance, acquisition and marketing,
2. the maintaining and keeping of records on the operational processes mentioned in no. 1,
3. the keeping and monitoring of the animals used in the manufacture and testing of medicinal products and the records kept on them,
4. staffing requirements,
5. the nature, size and equipment of the premises,
6. sanitation requirements,
7. the nature of the containers,
8. the labelling of the containers in which medicinal products and their starting materials are stored,
9. the stand-by obligation for medicinal product wholesalers,
10. the retention of batch samples including quantities and duration of storage,
11. the labelling, separation or destruction of medicinal products which are unfit for marketing,
12. the prerequisites and requirements regarding the veterinarian's activities as specified in Number 1 (operation of a veterinary practice dispensary), as well as the requirements re-

garding the administration of medicinal products by the veterinarian to the animals he treats.

(2a) (deleted)

(3) The regulations under sub-sections 1 and 2 shall also apply to persons practising the activities indicated in sub-section 1 professionally.

(4) Sub-sections 1 and 2 shall apply to pharmacies as defined in the Law on Pharmacies, in so far as these require an authorisation pursuant to Section 13, Section 52a or Section 72.

Section 55

Pharmacopoeia

(1) The Pharmacopoeia is a collection of recognized pharmaceutical practice regarding the quality, testing, storage, dispensing and designation of medicinal products and the substances used in their manufacture, published by the Federal Ministry. The Pharmacopoeia also contains requirements regarding the nature of containers and outer packaging.

(2) The rules contained in the Pharmacopoeia are laid down by the German Pharmacopoeia Commission or by the European Pharmacopoeia Commission. Publication of the rules can be refused or annulled for legal or technical reasons.

(3) It is incumbent upon the German Pharmacopoeia Commission to stipulate the rules contained in the Pharmacopoeia and to assist the Federal Ministry with its work within the framework of the Convention on the Elaboration of a European Pharmacopoeia.

(4) The German Pharmacopoeia Commission shall be set up at the Federal Institute for Drugs and Medical Devices. In consultation with the Federal Ministry of Agriculture, Food and Consumer Protection, the Federal Ministry shall appoint the members of the German Pharmacopoeia Commission, proportionally, from among experts in the fields of medical and pharmaceutical science, the health professions, the affected business circles and the field of pharmacovigilance. In consultation with the Federal Ministry of Agriculture, Food and Consumer Protection, the Federal Ministry shall appoint the chairperson of the Commission and his or her deputies and shall issue rules of procedure after hearing the Commission.

(5) In principle, the German Pharmacopoeia Commission shall take decisions regarding the rules contained in the Pharmacopoeia unanimously. Decisions taken by three-quarters of the members of the Commission or less shall not be valid. Further details are settled in the rules of procedure.

(6) Sub-sections 2 to 5 shall apply *mutatis mutandis* to the work of the German Homeopathic Pharmacopoeia Commission.

(7) Publication shall take place in the Federal Journal of Official Publications. It can be limited to indicating the source of the version of the Pharmacopoeia in question and the date on which the revised version becomes valid.

(8) Medicinal products may only be manufactured and placed on the market for distribution to consumers within the purview of the present Act if the substances they contain and their pharmaceutical forms comply with recognized pharmaceutical rules. Furthermore, medicinal products may be placed on the market for distribution to consumers within the purview of the present Act if the containers and outer packaging comply with recognized pharmaceutical rules in cases where they come into contact with the medicinal products. Sentences 1 and 2 shall not apply to medicinal products within the meaning of Section 2 sub-section 2 no. 4.

(9) In so far as medicinal products intended for administration to animals are concerned, the Federal Ministry of Agriculture, Food and Consumer Protection shall supersede the Federal Ministry in the cases provided for in sub-section 1 sentence 1 and sub-section 3; publication pursuant to sub-section 1 sentence 1 shall take place in agreement with the Federal Ministry.

Section 55a

Official compilation of test procedures

The competent higher federal authority shall publish an official compilation of test procedures for the sampling and testing of medicinal products and their starting materials. The procedures shall be established in consultation with experts from the field of pharmacovigilance, scientists and pharmaceutical entrepreneurs. The compilation of procedures shall be kept up to date.

NINTH CHAPTER

SPECIAL PROVISIONS FOR MEDICINAL PRODUCTS INTENDED FOR USE IN ANIMALS

Section 56

Medicated feedingstuffs

(1) By way of derogation from Section 47 sub-section 1, medicated feedingstuffs may only be supplied by the manufacturer directly to the animal keeper, and only upon prescription issued by a veterinarian; this shall also apply in cases where the medicated feedingstuffs are manufactured in another Member State of the European Union or another State Party to the Agreement on the European Economic Area using medicated pre-mixes authorised for marketing within the purview of the present Act or such medicated pre-mixes as possess the same qualitative and a comparable quantitative composition as medicated pre-mixes authorised for marketing within the purview of the present Act, where the other medicinal product provisions valid within the purview of the present Act are observed and the medicated feedingstuffs carry an accompanying certificate based on the sample certificate published by the Federal Ministry of Agriculture, Food and Consumer Protection. In the case of sentence 1 second half-sentence, the prescribing veterinarian shall immediately transmit a copy of the prescription to the authority responsible pursuant to Section 64 sub-section 1 for supervising compliance by the animal keeper with the regulations on medicinal products. Repeated dispensing on one prescription shall not be admissible. The Federal Ministry of Agriculture, Food and Consumer Protection is hereby empowered to issue ordinances containing regulations governing the form and content of the prescriptions, in consultation with the Federal Ministry and the Federal Ministry for Economics and Technology.

(2) For the manufacture of a medicated feedingstuff, only medicated pre-mixes may be used which are authorised for marketing pursuant to Section 25 sub-section 1 or are exempted from the need for a marketing authorisation pursuant to Section 36 sub-section 1. On the basis of a prescription, by way of derogation from sentence 1, a medicated feedingstuff may be manufactured from a maximum of three medicated pre-mixes, each of which is authorised for administration to the animal species in question, if:

1. an authorised medicated pre-mix is not available for the specific field of application,
2. in the individual case, the medicated feedingstuff does not comprise more than two medicated pre-mixes containing an antimicrobially effective substance or at most one medicated pre-mix with several such substances and
3. a homogenous and stable distribution of the active substances in the medicated feedingstuff is ensured.

(3) If medicated feedingstuffs are manufactured, the mixed feed used for this purpose shall have to comply with the provisions of the legislation on feedingstuffs before and after the mixing procedure and it may not contain any antibiotic or coccidiostatic agent as a feedingstuff additive.

(4) Only mixed feed complying with an ordinance pursuant to Section 4 sub-section 1 of the Feedingstuffs Act may be used for medicated feedingstuffs. The daily dose of the medicinal product shall be contained in a quantity of mixed feed which covers at least half of the daily feed ration of the animals under treatment and, in the case of ruminants, at least half of the daily supplementary feed requirement with the exception of mineral feed. The mixtures ready for feeding shall be clearly and visibly labelled '*Fütterungssarzneimittel*' (medicated feedingstuff), and shall carry particulars about the percentage of the feed requirement they are intended to cover, as defined in sentence 2.

(5) The veterinarian may only prescribe medicated feedingstuffs:

1. if they are intended for the animals treated by him,
2. if they are intended for the animal species and fields of application specified in the package leaflets of the medicated pre-mixes,
3. if their use according to the field of application and quantity is justified in the light of the latest standard of veterinary medicinal science in order to achieve the treatment objective, and
4. if the amount of the medicated feedingstuffs prescribed for food-producing animals, which
 - a) subject to letter b, contain medicated pre-mixes available only on prescription, is intended for use within 31 days of dispensing, or
 - b) contain antimicrobially effective substances, is intended for use within seven days of dispensing,

save where the authorisation conditions of the medicated pre-mix provide for a longer period of use.

Section 56a sub-section 2 shall apply *mutatis mutandis* to the prescription of medicated feedingstuffs. If medicated feedingstuffs are prescribed in accordance with sentence 1 no. 4, Section 56a sub-section 1 sentence 2 shall also apply *mutatis mutandis*.

Section 56a

Prescription, dispensing and use of medicinal products by veterinarians

(1) The veterinarian may only prescribe or dispense medicinal products, which are not released for trade outside of pharmacies, to the animal keeper if:

1. they are intended for animals treated by him,
2. they have been authorised for marketing or may be placed on the market on the basis of Section 21 sub-section 2 no. 4 in conjunction with sub-section 1 or fall within the scope of application of an ordinance pursuant to Section 36 or Section 39 sub-section 3 sentence 1 no. 2 or may be marketed pursuant to Section 38 sub-section 1,
3. according to the marketing authorisation, they are intended for administration to the animal species under treatment in that specific field of application,
4. their use, according to the field of application and quantity, is justified in the light of the latest standard of veterinary medicinal science in order to achieve the treatment objective, and
5. in the case of administration to food-producing animals,
 - a) subject to letter b, the prescribed or dispensed quantity of prescription-only medicinal products, is intended for use within 31 days of dispensing, or
 - b) the quantity of medicinal products, prescribed or dispensed, containing antimicrobially effective substances and not exclusively intended for local use according to the marketing authorisation conditions, is intended for use within seven days of dispensing,

save where the marketing authorisation conditions provide for a longer period of use.

In a particular treatment case, the veterinarian may only re-dispense or re-prescribe prescription-only medicinal products for administration to food-producing animals if he has

examined the treated animals or the treated livestock within a period of 31 days prior to the day which, according to his treatment instructions, the last administration of the dispensed or prescribed medicinal product is intended to take place. Sentence 1 nos. 2 to 4 shall apply *mutatis mutandis* to the administration by the veterinarian. By way of derogation from sentence 1, the veterinarian may neither prescribe nor dispense, to the animal keeper, any medicated pre-mixes which are not at the same time authorised for marketing as finished medicinal products.

(2) If the medicinal care required by the animals would otherwise be seriously jeopardized, and if there are no grounds to fear direct or indirect risk to human or animal health, the veterinarian may, in the case of individual animals or animals from a particular stock, by way of derogation from sub-section 1 sentence 1 no. 3, also in conjunction with sub-section 1 sentence 3, prescribe, administer or dispense the medicinal products designated below which are authorised or exempted from authorisation:

1. a medicinal product which is authorised for the particular animal species and another field of application, if an authorised medicinal product is not available for the treatment of the particular animal species and the specific field of application;
2. a medicinal product which is authorised for a different species, if a suitable medicinal product pursuant to Number 1 is not available for the species in question;
3. an authorised medicinal product for administration to humans or, also by way of derogation from sub-section 1 sentence 1 No 2, also in conjunction with sub-section 1 sentence 3, a medicinal product which is authorised for use on animals in a Member State of the European Union or another State Party to the Agreement on the European Economic Area, if a suitable medicinal product, pursuant to Number 2, is not available, in the case of food-producing animals, however, only such medicinal products from other Member States of the European Union or other State Party to the Agreement on the European Economic Area as are authorised for use in food-producing animals;
4. a medicinal product manufactured in a pharmacy or by the veterinarian in accordance with Section 13 sub-section 2 sentence 1 no. 3 letter d, if a suitable medicinal product pursuant to Number 3 is not available.

In the case of food-producing animals, however, the medicinal product may only be used by the veterinarian or administered under his supervision and may only contain pharmacologically active substances listed in Annex I, II or III of Regulation (EEC) No. 2377/90. The

veterinarian shall specify the length of the withdrawal period; all further details are regulated in the Veterinary Practice Dispensary Ordinance. Sentences 1 to 3 shall apply *mutatis mutandis* to medicinal products which are manufactured according to Section 21 sub-section 2 no. 4 in conjunction with sub-section 2a. Registered homeopathic medicinal products or such homeopathic medicinal products as are exempted from registration, may be prescribed, dispensed and administered by way of derogation from sub-section 1 sentence 1 no. 3; this shall apply to medicinal products which are intended for administration to food-producing animals if they contain only active substances listed in Annex II of Regulation (EEC) no 2377/90.

(2a) By way of derogation from sub-section 2 sentence 2, medicinal products for equidae intended for food production and for which this property is included in Part III - A of Section IX of the equidae passport referred to in Commission Decision 93/623/EEC of 20th October 1993 on the identification document (passport) accompanying registered equidae (OJ L 298 p. 45), amended by Decision 2000/68/EC of the Commission of 22nd December 1999 (OJ L 23 p. 72), can also be used, prescribed or dispensed if they contain substances that are included in the list referred to in Article 10 paragraph 3 of Directive 2001/82/EC. The list shall be published in the Federal Gazette by the Federal Ministry of Agriculture, Food and Consumer Protection provided that it does not form part of an immediately applicable legal instrument of the Commission of the European Communities or of the Council of the European Union.

(3) The Federal Ministry of Agriculture, Food and Consumer Protection is hereby empowered to stipulate, in agreement with the Federal Ministry, by ordinance subject to the approval of the *Bundesrat*, requirements for the dispensing of medicinal products for administration to animals and to prescribe that:

1. veterinarians must keep records on the prescription and administration of medicinal products not released for trade outside of pharmacies,
2. specific medicinal products may be used only by the veterinarian himself if such medicinal products
 - a) are capable of posing a danger to human and animal health, directly or indirectly, even when used in keeping with the intended purpose, if they are used in an unprofessional manner, or
 - b) are frequently used in considerable quantities in a manner which is not in keeping with the intended purpose and can therefore constitute a direct or indirect danger to human or animal health.

The ordinance may contain provisions regulating the type, form and content of these records as well as the period for which they must be kept. The obligation to keep records may be restricted to certain medicinal products, fields of application or forms of administration.

(4) The veterinarian shall not prescribe or dispense to animal keepers medicinal products determined by ordinance pursuant to sub-section 3 sentence 1 no. 2.

(5) The Federal Ministry of Agriculture, Food and Consumer Protection is hereby empowered, in agreement with the Federal Ministry by ordinance subject to the approval of the *Bundesrat* to set up a Commission on Veterinary Medicinal Product Use. The Commission on Veterinary Medicinal Product Use shall describe, in guidelines, the standard of veterinary medicinal science, particularly for the use of medicinal products containing antimicrobially effective substances. Further details on the composition and appointment of members and the procedure of the Commission on Veterinary Medicinal Product Use shall be determined in the ordinance. Further duties may also be transferred to the Commission on Veterinary Medicinal Product Use by ordinance.

(6) It shall be assumed that justification, according to the latest standards of veterinary medicinal science within the meaning of sub-section 1 sentence 1 no. 4 or Section 56 sub-section 5 sentence 1 no. 3 is given, as long as the guidelines of the Commission on Veterinary Medicinal Product Use in accordance with sub-section 5 sentence 2 have been observed.

Section 56b

Exceptions

The Federal Ministry of Agriculture, Food and Consumer Protection is hereby empowered, in agreement with the Federal Ministry, by ordinance subject to the approval of the *Bundesrat*, to allow exceptions to Section 56a in so far as the necessary provision of medicinal care for the animals is otherwise seriously jeopardised.

Section 57

Acquisition and possession by keepers of animals, records

(1) The animal keeper may only acquire medicinal products which are not released for trade outside of pharmacies, for administration to animals, either in pharmacies or from the veterinarian treating the animals or, in those cases defined in Section 56 sub-section 1, from manufacturers. Other persons not defined in Section 47 sub-section 1 may acquire such me-

dicinal products in pharmacies only. Sentence 1 does not apply for medicinal products within the meaning of Section 43 sub-section 4 sentence 3. By way of derogation from sentence 1, the animal keeper may not purchase medicated pre-mixes which are not, at the same time authorised for marketing as finished medicinal products.

(1a) Animal keepers may not have in their possession any medicinal products which are reserved by ordinance for administration exclusively by the veterinarian himself. This shall not apply if the medicinal product is intended for a purpose other than the administration to animals or if possession is allowed pursuant to Council Directive 96/22/EC of 29th April 1996 concerning the prohibition on the use in stock-farming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ EC, No. L 125 p. 3).

(2) The Federal Ministry of Agriculture, Food and Consumer Protection is hereby empowered to stipulate, in agreement with the Federal Ministry, by ordinance subject to the approval of the *Bundesrat*, that

1. enterprises which keep food-producing animals and market these animals or products manufactured from them, and
2. other persons who are allowed to acquire medicinal products, pursuant to sub-section 1, in pharmacies only

shall be required to keep records on the acquisition, the storage and the whereabouts of the medicinal products as well as a register or records of the administration of the medicinal products in so far as this is deemed necessary in order to guarantee the proper utilization of medicinal products and in so far as enterprises pursuant to no. 1 are concerned, this is necessary for the implementation of legal acts of the European Communities in this field. The ordinance may contain provisions regulating the type, form and content of these registers and records as well as the period for which they must be kept.

Section 58

Use in food-producing animals

(1) Animal keepers and other persons who are not veterinarians may only administer prescription-only medicinal products or other medicinal products prescribed by or purchased from a veterinarian to food-producing animals according to treatment instructions from a veterinarian for the specific case. Medicinal products not subject to a prescription which are not re-

leased for trade outside of pharmacies and which are not administered on the basis of treatment instructions from a veterinarian, may only be administered:

1. if they are authorised for marketing or fall within the scope of an ordinance pursuant to Section 36 or Section 39 sub-section 3 sentence 1 no. 2 or are placed on the market pursuant to Section 38 sub-section 1,
2. to the animal species and in the fields of application specified in the labelling or package leaflet and
3. in a quantity corresponding to the labelling of the medicinal product as to dosage and duration of administration.

By way of derogation from sentence 2, medicinal products within the meaning of Section 43 sub-section 4 sentence 3 may only be used in accordance with the instruction of the veterinary authorities under Section 43 sub-section 4 sentence 4.

(2) The Federal Ministry of Agriculture, Food and Consumer Protection is hereby empowered, in agreement with the Federal Ministry, to prohibit by ordinance subject to the approval of the *Bundesrat*, medicinal products intended for administration to food-producing animals from being marketed for particular fields or areas of application or from being used for these purposes, as long as this is deemed necessary in order to prevent an indirect hazard to human health.

Section 59

Clinical trial and residue testing in food-producing animals

(1) A medicinal product within the meaning of Section 2 sub-section 1 or sub-section 2 no. 1 may be administered by the manufacturer or on his behalf, by way of derogation from Section 56a sub-section 1, for the purposes of clinical trials and residue tests, if the application is limited to a test which, in accordance with the currently prevailing level of scientific knowledge, is necessary in both type and extent.

(2) The animals on which these tests are conducted may not be used for food production. Sentence 1 shall not apply if the competent higher federal authority has stipulated an appropriate withdrawal period. The withdrawal period must

1. at least correspond to the withdrawal period pursuant to the Ordinance on Veterinary Practice Dispensaries and, where applicable, include a safety factor which takes into account the type of medicinal product, or
2. if maximum residue levels have been set by the Community pursuant to Regulation (EEC) No. 2377/90, ensure that these maximum levels are not exceeded in foods derived from these animals.

The manufacturer shall submit to the competent higher federal authority the test results concerning residues of the medicinal products used and their conversion products in foods, stating the detection method used.

(3) Where a clinical trial or residue test is conducted on food-producing animals, the notification required under Section 67 sub-section 1 sentence 1 must contain, in addition, the following particulars:

1. name and address of the manufacturer and of the persons conducting the tests on his behalf,
2. the type and purpose of the test,
3. the species and number of animals envisaged for the tests,
4. the location, date of commencement and envisaged duration of the tests, and
5. particulars on the envisaged use of the animal products which are obtained either during or upon completion of the tests.

(4) Records shall be kept on the tests carried out and shall be presented to the competent authority upon request.

Section 59a

Trade in substances and preparations from substances

(1) Persons, enterprises and establishments mentioned in Section 47 sub-section 1 shall not acquire substances or preparations from substances, the use of which in the manufacture of medicinal products for animals is prohibited by ordinance pursuant to Section 6, for the purpose of manufacturing such medicinal products or of administration to animals, nor shall they offer for sale, store, package, carry with them or place them on the market for the purpose

of such a manufacturing activity or administration. Animal keepers as well as other persons, enterprises and establishments not mentioned in Section 47 sub-section 1 shall not acquire, store, package or carry with them such substances or preparations, unless they are intended for a manufacturing activity or use not prohibited by ordinance pursuant to Section 6.

(2) Veterinarians may only obtain substances or preparations from substances which are not released for trade outside of pharmacies for administration to animals, and such substances and preparations may only be distributed to veterinarians, if they have been authorised for marketing as medicinal products or if they may be traded without a marketing authorisation on the basis of Section 21 sub-section 2 no. 3 or 5 or on the basis of an ordinance pursuant to Section 36. Animal keepers may only acquire or store them for administration to animals if they have been prescribed as medicinal products or dispensed by a veterinarian. Other persons, enterprises and establishments not specified in Section 47 sub-section 1, shall not acquire, store, package, carry with them or place on the market substances or preparations from substances determined by an ordinance pursuant to Section 48, unless the substances or preparations are intended for a purpose other than the administration to animals.

(3) The foregoing shall be without prejudice to the provisions of the Feedingstuffs Act.

Section 59b

Substances for conducting residue tests

The pharmaceutical entrepreneur shall place at the disposal of the competent authority, on request, in exchange for an appropriate compensation, sufficient quantities of the substances needed to conduct the residue tests in the case of medicinal products intended for food-producing animals. In the case of medicinal products which are no longer being marketed by the pharmaceutical entrepreneur, the provisions contained in sentence 1 shall be valid for a period of three years starting from the last date on which the pharmaceutical entrepreneur markets the medicinal product, but ending at the latest on the expiry date, indicated pursuant to Section 10 sub-section 7, of the last batch marketed.

Section 59c

Obligations to keep records of substances which can be used as veterinary medicinal products

Enterprises and facilities which manufacture, store, import or market substances or preparations from substances which can be used as veterinary medicinal products or in the manufacture of veterinary medicinal products and which display anabolic, infection-inhibiting,

parasite-repelling, anti-inflammatory, hormonal or psychotropic characteristics, shall keep records on the acquisition or sale of these substances or preparations from substances which indicate the name of the previous supplier or the recipient as well as the amounts received or delivered in each case, shall preserve these records for at least three years and shall submit them, upon request, to the competent authority. Sentence 1 shall also apply to persons who carry out these activities on a professional basis. In the case of substances or preparations from substances with a thyreostatic, oestrogenic, androgenic or gestagenic effect or β -agonists with an anabolic effect, these records shall take the form of a register in which the amounts manufactured or purchased, as well as the amounts sold for the purpose of or used in the manufacture of medicinal products, are documented in chronological order along with the name of the previous supplier and the recipient.

Section 60

Pet animals

(1) The provisions in Section 21 to Section 39d and Section 50 shall not apply to medicinal products intended exclusively for administration to aquarium fish, cage or singing birds, carrier-pigeons, terrarium animals, small rodents, ferrets or rabbits not used for food production and which are authorised for marketing outside of pharmacies.

(2) The provisions on the manufacture of medicinal products shall apply on condition that the evidence pertaining to two years' practical experience according to Section 15 sub-section 1 is not required.

(3) The Federal Ministry of Agriculture, Food and Consumer Protection is hereby empowered to extend, in agreement with the Federal Ministry for Economics and Technology and the Federal Ministry, by ordinance subject to the approval of the *Bundesrat*, the regulations governing marketing authorisations to medicinal products used for the animals specified in sub-section 1, in so far as it is deemed advisable in order to prevent either a direct or indirect hazard to human or animal health.

(4) The competent authority may authorise exceptions to Section 43 sub-section 5 sentence 1, in so far as the supply of medicinal products for the animals mentioned in sub-section 1 is concerned.

Section 61

Powers of veterinary schools

Facilities belonging to veterinary schools at university level, which are directed by a veterinarian or pharmacist and are involved in dispensing medicinal products for animals under treatment there, shall have the same rights and obligations as a veterinarian under the regulations of the present Act.

TENTH CHAPTER

OBSERVATION, COLLECTION AND EVALUATION OF RISKS OF MEDICINAL PRODUCTS

Section 62

Organisation

In the interests of preventing direct or indirect hazards to human or animal health, it shall be the responsibility of the competent higher federal authority to centrally record and evaluate those risks occurring during the administration of medicinal products, in particular side effects, interactions with other products, adulterations as well as potential risks to the environment owing to the use of a veterinary medicinal product and to co-ordinate the measures to be adopted in accordance with the present Act. For this purpose, the Higher Federal Authority shall act in co-operation with the agencies of the World Health Organization, the European Medicines Agency, the medicinal product authorities of other countries, the health and veterinary authorities of the federal *Laender*, the medicinal product commissions of the chambers of the health professions and national pharmacovigilance centres as well as with others who, in the execution of their work, keep records on medicinal product risks. The competent higher federal authority may inform the public about medicinal product-related risks and envisaged measures.

Section 63

Graduated plan

By means of general administrative regulations subject to the approval of the *Bundesrat*, the Federal Government shall draw up a graduated plan detailing the execution of the tasks indicated in Section 62. This plan shall specify the details of the co-operation to take place between the authorities and the services involved at the various danger levels, the intervention of the pharmaceutical entrepreneurs as well as the participation of the Federal Government Commissioner for Patient Affairs and shall stipulate the various measures to be taken in compliance with the provisions of the present Act. In the graduated plan, information means and channels may also be specified.

Section 63a

Graduated plan officer for the graduated plan

(1) Anyone who, in his capacity as a pharmaceutical entrepreneur, places finished medicinal products which are medicinal products under the terms of Section 2 sub-section 1 or sub-section 2 no. 1 on the market, shall appoint a qualified person who is resident in a Member State of the European Union having the required expert knowledge and the reliability necessary for exercising his/her function (graduated plan officer), to collect and evaluate notifications on medicinal product risks that have become known and co-ordinate the necessary measures. Sentence 1 shall not apply to persons who do not require a manufacturing authorisation pursuant to Section 13 sub-section 2 sentence 1 nos. 1, 2, 3 or 5. The graduated plan officer shall be responsible for meeting the obligations to notify in so far as they concern medicinal product risks. He shall also ensure that additional information for the evaluation of the risk-benefit profile of a medicinal product, including his own evaluations, are sent immediately and in full, if requested by the competent higher federal authority. Further particulars shall be settled by the Ordinance on Internal Regulations for Pharmaceutical Entrepreneurs. Persons other than those specified in sentence 1 shall not be authorised to perform the duties of the commissioner for the graduated plan.

(2) Proof of the required expert knowledge on the part of the commissioner for the graduated plan shall be furnished, either by a certificate proving the successful completion of an examination taken at the end of university studies in human medicine, human biology, veterinary medicine or pharmacy in addition to professional experience of at least two years, or by the proof provided for in Section 15. The graduated plan officer may be a qualified person in accordance with Section 14 at the same time.

(3) The pharmaceutical entrepreneur shall have to inform the competent authority about the identity of the commissioner for the graduated plan and present the proof that the requirements pursuant to sub-section 2 have been met and shall give notice of any change beforehand. In the case of an unforeseen change in the person of the commissioner for the graduated plan, notice shall be given immediately.

Section 63b

Documentation and notification obligations

(1) The holder of a marketing authorisation shall keep detailed records of all cases of suspected side-effects occurring in the Community or in a third country, as well as data about the quantities dispensed and, in the case of blood and tissue preparations, with the exception of blood preparations within the meaning of sub-section 2 sentence 3 and tissue preparations within the meaning of Section 21a, also about the number of recalls.

(2) The holder of a marketing authorisation shall, moreover:

1. record every case of serious suspected side-effects which has occurred within the purview of the present Act, and shall report to the competent higher federal authority immediately or at the latest within 15 days of it coming to his knowledge,
- 2.a) report every case of serious suspected, unexpected side-effects which has occurred in a country which is not a member of the European Union and of which he has been informed by a member of the health professions,
- b) in the case of medicinal products which contain constituents from starting materials of human or animal origin, every suspected case of infection which comes to his knowledge which constitutes a serious side-effect, has been caused by a contamination of this medicinal product by pathogens and has not occurred in a Member State of the European Union,

to the competent higher federal authority as well as the European Medicines Agency immediately, or at the latest within 15 days of it coming to his knowledge, and

3. notify the competent higher federal authority immediately of frequent abuse or individual cases of substantial abuse if this can directly jeopardise human or animal health.

The obligation to notify pursuant to sentence 1 nos. 1 and 2 letter a shall apply *mutatis mutandis* to side-effects in human beings arising from the administration of a medicinal product intended for administration to animals. The notification requirement referred to in sentence 1 no. 2 letter a and letter b, as regards the European Medicines Agency, shall not apply in the case of medicinal products derived from blood and tissues referred to in Directive 2002/98/EC of the European Parliament and of the Council of 27th January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33 p. 30) and Directive 2004/23/EC of the European Parliament and of the Council of 31st March 2004 on setting stan-

dards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102 p. 48).

(3) The marketing authorisation holder who obtained the marketing authorisation through the mutual-recognition procedure or the decentralised procedure, shall also ensure that each suspected case of

1. a serious side-effect or
2. a side-effect in humans due to the use of a medicinal product intended for use in animals,

occurring within the scope of this Act, shall also be made known to the competent authority of the Member State whose marketing authorisation was the basis of the recognition or who acted as rapporteur within the framework of an arbitration procedure in accordance with Article 32 of Directive 2001/83/EC or Article 36 of Directive 2001/82/EC.

(4) The competent higher federal authority shall be provided with all of the existing documentation for the assessment of suspected or observed cases of abuse as well as a scientific evaluation.

(5) The holder of the marketing authorisation shall, unless specified otherwise in a condition or in sentence 5 and 6, submit to the competent higher federal authority on the basis of the obligations specified in sub-section 1 and in Section 63a sub-section 1 a regularly updated report on the safety of the medicinal product immediately upon request or at least every six months after obtaining the authorisation until placing on the market. He shall also submit such reports immediately on request or at least every six months during the first two years after first placing on the market and annually in the following two years. He shall then submit such reports in three-year intervals or immediately on request. The regularly updated medicinal product safety reports shall also include a scientific assessment of the benefits and risks of the medicinal product in question. The competent higher federal authority can prolong the interval between reports upon request. In the case of medicinal products which are exempt from a manufacturing authorisation under Section 36 sub-section 1, the competent higher federal authority shall specify when the regularly updated medicinal product safety report is to be submitted in a notice published in the Federal Gazette. In the case of blood and tissue preparations, with the exception of blood preparations within the meaning of sub-section 2 sentence 3 and tissue preparations within the meaning of Section 21a, the holder of the manufacturing authorisation shall submit to the competent higher federal authority, on the basis of the obligations stipulated in sentence 1, an updated report about the safety of the medicinal product immediately upon

request or, where recalls, cases or suspected cases of serious side-effects are concerned, at least once per year. Sentences 1 to 7 do not apply to a parallel importer.

(5a) At enterprises and facilities which manufacture medicinal products, place them on the market or test them clinically, the competent higher federal authority shall be entitled to inspect the recording and evaluation of medicinal product risks and the coordination of necessary measures. For this purpose, officials of the competent higher federal authority, in consultation with the competent authority, can enter manufacturing and business premises during normal working hours, inspect documents and request information.

(5b) In connection with the authorised medicinal product, the marketing authorisation holder may not make any pharmacovigilance information public without notifying the competent Higher Federal Authority beforehand or simultaneously. He shall ensure that such information is presented objectively and is not misleading.

(6) The competent higher federal authority shall inform the European Medicines Agency and, where necessary, the holder of the manufacturing authorisation of every suspected serious side-effect, which has occurred within the purview of the present Act, immediately or at the latest within 15 days of it coming to its knowledge. This shall not apply to medicinal products referred to in sub-section 2 sentence 3.

(7) The obligations referred to in sub-sections 1 to 4 shall apply *mutatis mutandis* to the registration holder, to the applicant before authorisation is granted and to the marketing authorisation holder, regardless of whether the medicinal product is still on the market or the marketing authorisation still exists. Sub-sections 1 to 5a shall apply *mutatis mutandis* to a pharmaceutical entrepreneur who is not the holder of the marketing authorisation. Fulfilment of the obligations pursuant to sub-sections 1 to 5 can be totally or partly transferred to the holder of the marketing authorisation, by means of a written agreement between the holder of the marketing authorisation and the pharmaceutical entrepreneur who is not the holder of a the marketing authorisation.

(8) Sub-sections 1 to 7 shall not apply to medicinal products which have been granted a marketing authorisation by the Commission of the European Communities or the Council of the European Union. For such medicinal products, the obligations of the pharmaceutical entrepreneur shall be those stipulated in Regulation (EC) No. 726/2004 as well as his obligations pursuant to Regulation (EC) No. 540/95 of the Commission laying down the arrangements for reporting suspected unexpected adverse reactions which are not serious, whether arising in the Community or in a third country, to medicinal products for human or veterinary use authorised

in accordance with the provisions of Council Regulation (EEC) No. 2309/93 (OJ EC No. L 55 p. 5) in the current version on condition that, within the purview of the present Act, an obligation on the part of the relevant competent higher federal authority to notify or to inform the Member States exists. In the case of medicinal products for which a marketing authorisation granted by the competent higher federal authority is the basis of mutual recognition or for which a Higher Federal Authority is rapporteur in an arbitration process in accordance with Article 32 of Directive 2001/83/EC or Article 36 of Directive 2001/82/EC, the competent Higher Federal Authority shall take responsibility for analysing and monitoring all suspected cases of serious side-effects occurring in the European Community; this shall also apply to medicinal products that have been authorised in the decentralised procedure.

Section 63c

Special documentation and notification obligations in respect of blood and tissue preparations

(1) The holder of a marketing authorisation for blood preparations pursuant to Section 63b sub-section 2 sentence 3 or for tissue preparations pursuant to Section 21a, shall keep documents on all suspected cases of serious incidents or serious adverse reactions in the Member States of the European Union or in the States Parties to the Agreement on the European Economic Area or in a third country, and which affect the quality and safety of blood or tissue preparations or can be traced back to them, as well as on the number of recalls.

(2) The holder of a marketing authorisation for blood or tissue preparations pursuant to sub-section 1, shall, furthermore, document every suspected case of a serious incident which can affect the quality and safety of the blood or tissue preparations and shall document every suspected case of serious adverse reactions which can affect the quality or safety of the blood or tissue preparation or can be traced to it and shall report them to the competent higher federal authority immediately, or at the latest within 15 days of coming to this knowledge. The report shall contain all of the necessary information, especially the name or firm and address of the pharmaceutical entrepreneur, name and number or code of the blood or tissue preparation, date and documentation of the emergence of the suspicion of the serious incident or the serious adverse reaction, date and place where the removal of the blood components or tissue took place, enterprises or facilities supplied as well as information on the donor. The incidents or reactions reported pursuant to sentence 1 are to be examined with respect to their causes and effects and subsequently evaluated and the results together with the measures to trace and protect both the donor and the recipient reported immediately to the competent higher federal authority.

(3) In the case of blood and tissue preparations as well as blood and blood components, and tissues which are not subject to marketing authorisation, the blood and plasma donation facilities or the tissue facilities shall notify the competent authority, immediately, of every suspected case of a serious incident which could affect the quality or safety of the blood or tissue preparation and every suspected case of a serious adverse reaction which could affect or be traced to the quality or the safety of the blood or tissue preparation. The notification shall contain all the necessary information such as the name or firm and address of the donation or tissue facility, name and number or code of the blood or tissue preparation, date and documentation of the emergence of the suspected serious incident or the serious adverse reaction, date on which the blood or tissue preparation was manufactured as well as information on the donor. Sub-section 2 sentence 3 shall apply *mutatis mutandis*. The competent authority shall transmit the notifications pursuant to sentences 1 and 2 as well as the Mitteilungen pursuant to sentence 3 to the competent higher federal authority.

(4) The holder of a marketing authorisation for blood or tissue preparations within the meaning of sub-section 1 shall submit, to the competent higher federal authority, on the basis of the obligations contained in sub-section 1, an updated report on the safety of the medicinal product immediately upon request or, where recalls, cases or suspected cases of serious incidents or serious adverse reactions are involved, at least once a year.

(5) The provisions contained in Section 63b sub-section 5a shall apply to blood and plasma donation facilities or to tissue facilities; the provisions contained in Section 63b sub-section 5b shall apply *mutatis mutandis* to the holder of an authorisation for blood or tissue preparations.

(6) A serious incident within the meaning of the foregoing provisions is any undesired event in connection with the harvesting, testing, processing, preserving, storage or sale of tissues or blood preparations which could lead to the transmission of an infectious disease, the death of a patient, a life-threatening state, disability or invalidity of patients, the need for or prolongation of hospitalisation or disease.

(7) A serious adverse reaction within the meaning of the foregoing provisions is an unintended reaction, including an infectious disease in the donor or recipient in connection with the harvesting of tissues or blood or the transplanting of tissue or blood preparations, which is fatal or life-threatening or leads to disability or invalidity or requires hospitalisation or the prolongation of existing hospitalisation or causes or prolongs a disease.

SUPERVISION

Section 64

Conducting supervision

(1) Enterprises and facilities in which medicinal products are manufactured, tested, stored, packaged or marketed, or in which any other form of trade with them takes place, shall be subject in this regard to supervision by the competent authority; the same shall apply to enterprises and facilities which develop medicinal products, subject them to clinical trials, residue tests or acquire or administer medicinal products pursuant to Section 47a sub-section 1 sentence 1 or medicinal products intended for administration to animals. The development, manufacture, testing, storage, packaging and the marketing of active substances and other substances and tissues intended for the manufacture of medicinal products or any other form of trade in such active substances and substances shall be subject to supervision in so far as they are regulated by an ordinance pursuant to Section 54, pursuant to Section 12 of the Transfusion Act or pursuant to Section 16a of the Transplantation Act. In the case of Section 20b sub-section 2, the removal facilities and the laboratories are subject to supervision by the competent authority responsible for them locally. Sentence 1 shall also apply to persons carrying out these activities professionally, to persons carrying with them medicinal products not exclusively intended for personal use, to the sponsor of a clinical trial or his representative pursuant to Section 40 sub-section 1 sentence 3 no. 1, as well as to persons or associations collecting medicinal products for others.

(2) Persons in charge of supervision shall carry out this activity as their main profession. The competent authority may call in experts. In so far as blood preparations, tissues and tissue preparations, radiopharmaceuticals, medicinal products produced using genetic engineering, sera, vaccines, allergens, gene transfer medicinal products, somatic cell therapies, xenogenic cell therapy products or active substances or other substances of human, animal or microbial origin or which have been manufactured using genetic engineering are concerned, the competent authority shall summon members of the competent higher federal authority to participate as experts. With regard to pharmacies which are not hospital pharmacies or which do not require an authorisation in compliance with Section 13, the competent authority may commission experts to carry out the supervision.

(3) The competent authority shall satisfy itself that the provisions on the trade in medicinal products, on advertising in the field of medicine, of Part Two of the Transfusion Act, of Parts 2, 3 and 3a of the Transplantation Act and on pharmacies are observed. The competent authority shall carry out inspections regularly to an appropriate extent, paying special attention to

possible risks, and have medicinal product samples tested officially; enterprises and facilities requiring an authorisation pursuant to Section 13 or Section 72, as well as veterinary practice dispensaries are to be inspected every two years, as a rule. An authorisation pursuant to Section 13, Section 52a or Section 72 shall be granted by the competent authority only after the latter has satisfied itself by means of an inspection that the requirements for granting an authorisation are fulfilled. The competent authority shall issue a certificate of Good Manufacturing Practice to the manufacturer, within 90 days of the inspection, if the latter shows that this manufacturer observes the principles and guidelines of good manufacturing practice laid down in Community legislation. Certification shall be withdrawn if it subsequently becomes known that the conditions were not fulfilled; it shall be revoked if the conditions cease to apply. The data on the issue, refusal, withdrawal or revocation shall be entered into a data base in accordance with Section 67a. Sentences 4 to 6 shall not apply if the enterprises and facilities exclusively manufacture medicated feedingstuffs.

(4) The persons in charge of the supervision shall be authorised

1. to enter and inspect during normal business hours properties, office premises, operating rooms, transport facilities and also, for the prevention of imminent danger to public order and security, residential housing in which the activities referred to in sub-section 1 are carried out; the fundamental right to the inviolability of the home (Article 13 of the Basic Law) shall be limited in this regard,
2. to review documentation on the development, manufacture, testing, clinical trial or residue testing, acquisition, storing, packaging, marketing and other whereabouts of the medicinal products as well as on the advertising material currently in circulation and on the liability coverage required in accordance with Section 94,
- 2a. to prepare or request transcripts or photocopies of documents pursuant to number 2 or printouts or copies of data storage media on which documents pursuant to number 2 are stored in so far as personal data from patients are not concerned,
3. to demand from natural and legal persons and associations without legal capacity all the necessary information, in particular on the company operations mentioned in no. 2,
4. to issue provisional orders also on the closing of the company or facility, in so far as this is deemed necessary for the prevention of imminent danger to public order and safety.

(4a) If it is required for the implementation of the present Act or of ordinances issued on the basis of the present Act or Regulation (EC) No. 726/2004, experts from the Member States of the European Union may exercise the powers contained in sub-section 4 no. 1, if they are in the company of the persons responsible for the supervision.

(5) The person under obligation to give information may refuse to answer certain questions if he/she has reason to fear that answering them could expose him/her or one of the relatives specified in Section 383 sub-section 1 nos. 1 to 3 of the German Code of Civil Procedure (*Zivilprozeßordnung*) to the danger of prosecution under criminal law or to a lawsuit under the Act on Administrative Offences (*Gesetz über Ordnungswidrigkeiten*).

(6) The Federal Ministry is hereby empowered, to issue, by ordinance subject to the approval of the *Bundesrat*, regulations governing the fulfilment of supervisory tasks in cases where medicinal products are imported into the territory governed by the present Act, by a pharmaceutical entrepreneur who has no registered place of business in the territory governed by the present Act, in so far as necessary for the implementation of the provisions governing the trade in medicinal products as well as advertising in the field of medicine. In the process, the main responsibility for supervisory tasks, which arise out of the import of a medicinal product from a specific Member State of the European Union *Laender*, can be assigned in each case to a specific *Land* or to a facility supported by one of the. The ordinance shall be issued by the Federal Ministry of Agriculture, Food and Consumer Protection in agreement with the Federal Ministry, in so far as medicinal products intended for administration to animals are concerned.

Section 65

Sampling

(1) To the extent necessary for the implementation of the provisions on the trade in medicinal products, on advertising in the field of medicine of Part Two of the Transfusion Act, of Parts 2, 3 and 3a of the Transplantation Act and on pharmacies, those persons in charge of supervision shall be authorised to demand or to take samples of their own selection, against receipt, for the purposes of testing them. This authorisation shall extend to the taking of samples of feedingstuffs, trough water and samples from living animals including the necessary interventions on these animals for this purpose. In so far as the pharmaceutical entrepreneur does not explicitly waive his right thereto, a part of the sample or, if the sample is not divisible in parts of equal quality without endangering the purpose of the test, a second sample of the same type as the sample taken shall be left behind.

(2) The samples left behind shall be officially closed or sealed. They shall be marked with the date on which the sample was taken and the date after which the closing or sealing of the sample may be considered as cancelled.

(3) For samples which are not drawn from the pharmaceutical enterprise, an appropriate compensation shall be paid by the pharmaceutical entrepreneur if this right is not explicitly waived.

(4) Eligible for appointment as a private expert for the testing of samples left behind pursuant to sub-section 1 sentence 2 shall only be a person who

1. has the expert knowledge pursuant to Section 15. The practical experience pursuant to Section 15 sub-sections 1 and 4 can be replaced by practical experience in the control and assessment of medicinal products in medicinal product control laboratories or in other similar medicinal product institutes,
2. is reliable enough to perform his/her duties as an expert for the testing of official samples and
3. has adequate premises and facilities at his/her disposal for the intended testing and assessment of medicinal products.

Section 66

Obligation to tolerate and collaborate

The party subject to supervision in compliance with Section 64 sub-section 1 shall be obliged to tolerate the measures defined in Sections 64 and 65 and to give full support to the persons in charge of supervision in the fulfilment of their duties, in particular, indicating to them, upon request, the premises and transport facilities, opening rooms, containers and receptacles, giving information and enabling the taking of samples. The same requirement shall apply to the qualified person referred to in Section 14, the Production Manager, Quality Control Manager, Graduated Plan Officer, Information Officer and the clinical trial investigator, and their representatives, also with regard to queries by the competent higher federal authority.

Section 67

General notification requirement

(1) Enterprises or facilities which develop or manufacture medicinal products, subject medicinal products to clinical trials or to residue tests, test, store, package, market them or are otherwise engaged in the trade in medicinal products shall accordingly notify the competent authorities and, in the case of a clinical trial on human beings the competent higher federal authority as well, before taking up these activities. The development of medicinal products shall be notified in so far as it is governed by an ordinance pursuant to Section 54. The same shall apply to persons practising these activities on a self-employed and professional basis as well as to persons or associations who collect medicinal products for others. The notification shall state the type of activity and the factory site; if medicinal products are collected, details shall be given regarding the type of collection made and the place of storage. If, according to sentence 1, notification is to be given of a clinical trial on human beings, its sponsor, his representative pursuant to Section 40 sub-section 1 sentence 3 no. 1 if any, as well as all investigators, where necessary also indicating their status as principal investigator (*Hauptprüfer*) or chief investigator (*Leiter der klinischen Prüfung*), shall also be designated by name. Sentences 1 to 4 shall apply *mutatis mutandis* to enterprises and facilities which manufacture, test, store, package, market or otherwise trade in active substances or other substances intended for use in the manufacture of medicinal products, in so far as these activities are regulated by an ordinance pursuant to Section 54.

(2) If medicinal product manufacture is envisaged, for which an authorisation as defined in Section 13 is not necessary, the medicinal products shall be notified indicating their name and composition.

(3) Notification shall likewise be given of subsequent changes. If the start of a clinical trial on human beings is to be notified pursuant to sub-section 1, the competent higher federal authority shall also be notified of the progression, termination and results of the clinical trial; further details shall be specified in the ordinance pursuant to Section 42.

(4) Except for the obligation to notify clinical trials, sub-sections 1 to 3 shall not apply to those persons holding an authorisation under Section 13, Section 52a or Section 72 nor to pharmacies in accordance with the Law on Pharmacies. Sub-section 2 shall not apply to veterinarians' house dispensaries.

(5) A person who, in his/her capacity as a pharmaceutical entrepreneur, markets a medicinal product which, pursuant to Section 36 sub-section 1, is exempted from the obligation to obtain a marketing authorisation and not authorised for trade outside pharmacies, shall notify the competent higher federal authority of this immediately. The notification shall include the

name used for the medicinal product and the non-active substances used in so far as they are not specified in the ordinance pursuant to Section 36 sub-section 1.

(6) The pharmaceutical entrepreneur shall immediately give notice to the Federal Panel Doctors' Association, the Central Federal Association of the statutory health insurance funds, as well as the competent higher federal authority of tests which serve the purpose of gathering knowledge on the application of authorised or registered medicinal products. In this regard, the location, time and purpose of the non-interventional study shall be stated together with the names of the participating doctors. Remuneration paid to doctors for their participation in tests pursuant to sentence 1 shall be calculated, as to type and amount, in such a way as to provide no incentive for the preferential prescription or recommendation of specific medicinal products. In so far as participating doctors provide benefits which are reimbursable by the statutory health insurance, the type and amount of the remuneration paid to them as well as a copy of the contract signed with them shall accompany the notices pursuant to sentence 1; notices to the competent higher federal authority shall be excluded herefrom.

Section 67a

Database-supported information system

(1) The federal and Land authorities responsible for the implementation of the present Act shall collaborate with the German Institute for Medical Documentation and Information (DIMDI) to set up a central information system for medicinal products, and their manufacturer or importer, which can be used jointly. This information system shall collate all of the important data necessary for the fulfilment of the specific tasks affecting more than one authority. The German Institute for Medical Documentation and Information shall set up this information system on the basis of the data supplied to it by the competent authorities or higher federal authorities pursuant to the ordinance issued in accordance with sub-section 3 and shall be responsible for its operation. Data from the information system shall be transmitted to the competent authorities and Higher Federal Authorities for fulfilment of their legally stipulated duties and to the European Medicines Agency. The competent authority and Higher Federal Authorities shall have access, in addition, to current data from the information system for the fulfilment of their legally stipulated duties. Transmission to other agencies shall be permissible in so far as this is provided for in the ordinance issued pursuant to sub-section 3. The German Institute for Medical Documentation and Information shall be entitled to charge fees for its services. Such fees shall be listed in a catalogue of fees which is subject to the consent of the Federal Ministry.

(2) The German Institute for Medical Documentation and Information may also provide access to generally available databases which have some connection with medicinal products.

(3) The Federal Ministry is hereby empowered to grant, in agreement with the Federal Ministry of the Interior and the Federal Ministry of Economics and Technology, by ordinance subject to the approval of the *Bundesrat*, the power to process and utilize data for the purposes defined in sub-sections 1 and 2 and to collect data for the purposes contained in sub-section 2, and to issue regulations governing the transmission of data by federal and Land authorities to the German Institute for Medical Documentation and Information, including personal data, for the purposes regulated by the present Act, as well as the type and scope of such data and the requirements to be placed thereon. The ordinance in question may also contain provisions stipulating that notifications may or must be made on electronic or optical storage media, in so far as required for the proper implementation of the regulations governing the trade in medicinal products. The ordinance shall be issued by the Federal Ministry of Agriculture, Food and Consumer Protection in agreement with the Federal Ministry, the Federal Ministry of the Interior and the Federal Ministry of Economics and Technology, where medicinal products intended for administration to animals are concerned.

(4) The ordinance pursuant to sub-section 3 shall be promulgated in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety in the case of radiopharmaceuticals or medicinal products in the manufacture of which ionizing radiation is used.

(5) The German Institute for Medical Documentation and Information shall take the necessary measures to ensure that the data are transmitted only to authorised persons and that only such persons receive access to them.

Section 68

Obligation to inform and to report

(1) The federal and *Land* authorities and agencies responsible for the implementation of the present Act shall

1. inform each other of the authorities, agencies and experts responsible for the enforcement of the Act and,

2. in instances of contravention and suspected contravention of the provisions contained in the medicinal product legislation or legislation on health products advertising for the individual sphere of responsibility, report to each other immediately and support each other's investigative activities.

(2) The authorities specified in sub-section 1

1. shall furnish the competent authority of another Member State of the European Union with information, upon reasonable request, and shall transmit to it the necessary certificates and documents in so far as necessary to monitor compliance with the medicinal product-related regulations or the legislation on health products advertising currently in force,
2. shall investigate all of the facts of which it is informed by the requesting authority of another Member State and shall inform said authority of the results of the investigation.

(3) The authorities specified in sub-section 1 shall provide the competent authorities of another Member State with all of the information which is necessary to monitor compliance with the medicinal product-related regulations or the legislation on health products advertising in force in that Member State. In cases of infringement or suspected infringement, the competent authorities of other Member States, the Federal Ministry, the Federal Ministry of Agriculture, Food and Consumer Protection, as well as the European Medicines Agency, in so far as medicinal products intended for administration to animals are concerned, and the Commission of the European Communities may also be informed.

(4) The authorities specified in sub-section 1 may, if necessary for the implementation of requirements stipulated in medicinal product-related legislation or the legislation on health products advertising, also inform the competent authorities of other states and the competent offices at the Council of Europe. States Parties to the Agreement on the European Economic Area which are not Member States of the European Union shall be informed through the Commission of the European Communities.

(5) Communication with the competent authorities of other states, Council of Europe offices, the European Medicines Agency, and with the Commission of the European Communities shall be the prerogative of the Federal Ministry. The Federal Ministry may transfer this power to the competent higher federal authority or, by means of an ordinance with the approval of the *Bundesrat*, to the competent higher authorities of the *Laender*. Furthermore, in individual cases, the Federal Ministry can transfer the above-mentioned power to the competent higher

authority of the *Land* if the latter gives its consent. The higher authorities of the *Laender* are authorised to transfer the powers specified in sentences 2 and 3 to other authorities. In so far as medicinal products intended for administration to animals are concerned, the Federal Ministry of Agriculture, Food and Consumer Protection shall supersede the Federal Ministry. In such a case, the ordinance shall be promulgated pursuant to sentence 2 in agreement with the Federal Ministry.

(5a) Where the supervision of the advertising of medicinal products intended for use in humans is concerned, the Federal Office of Consumer Protection and Food Safety shall be responsible for the correspondence with the competent authorities of other Member States of the European Union and the Commission of the European Communities with respect to the implementation of Regulation (EC) No. 2006/2004 of the European Parliament and of the Council of 27th October 2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws (Regulation on consumer protection cooperation) (OJ No. L 364, p. 1) amended by Article 16 no. 2 of Directive 2005/29/EC of the European Parliament and of the Council of 11th May 2005, (OJ No. L 149, p.22).

(6) In the cases provided for in sub-section 3 sentence 2 and sub-section 4, personal data shall not be transmitted if so doing will have an adverse effect on interests of the affected person which are worthy of protection especially if, on the side of the recipient, an adequate standard of data protection is not guaranteed. Personal data may be transmitted, even if the recipient cannot guarantee an adequate standard of data protection, if necessary for reasons of health protection.

Section 69

Measures by the competent authorities

(1) The competent authorities shall issue the necessary directives to rectify any offences which have been identified and to prevent offences in the future. They may, in particular, prohibit the marketing of medicinal products or active substances and order their withdrawal from the market and seize them if:

1. the required marketing authorisation or registration of the medicinal product has not been submitted or if their suspension has been ordered,
2. the medicinal product or the active substances does not possess the appropriate quality in keeping with acknowledged pharmaceutical principles,

3. the medicinal product is lacking in therapeutic efficacy,
4. there is reason to suspect that, when used in keeping with its designated purpose, the medicinal product has harmful effects which exceed the bounds considered justifiable according to the prevailing standard of scientific knowledge,
5. the prescribed quality controls have not been carried out, or
6. the authorisation required for the manufacture of the medicinal product or the active substances or the introduction into the purview of the present Act has not been granted or a reason for the withdrawal or the revocation of the permit in accordance with Section 18 sub-section 1 exists.
7. the authorisation required to engage in wholesale trading under Section 52a has not been granted or a reason for the withdrawal or the revocation of the authorisation in accordance with Section 52a sub-section 5 exists.

In the case described in sentence 2 no. 4, the competent higher federal authority may order a medicinal product to be recalled from the market if its actions are in connection with measures pursuant to Section 28, Section 30, Section 31 sub-section 4 sentence 2 or Section 32 sub-section 5 to prevent risks posed by medicinal products to human and animal health.

(1a) In the case of medicinal products for which a marketing authorisation or an authorisation

1. pursuant to Regulation (EC) No. 726/2004, or
2. within the framework of the recognition procedure pursuant to Chapter 4 of Directive 2001/83/EC or Chapter 4 of Directive 2001/82/EC, or
3. on the basis of an expert opinion of the Committee provided for in Article 4 of Directive 87/22/EEC of 22nd December 1986 prior to 1st January 1995,

has been issued, the competent higher federal authority shall inform the Committee on Proprietary Medicinal Products or the Committee on Veterinary Medicinal products about any observed violation of the medicinal product regulations, in accordance with the procedures envisaged by the above-mentioned legal acts, submitting at the same time detailed grounds and details of the proposed procedure. In the case of these medicinal products, the competent authorities

may take the measures necessary to eliminate observed violations and to prevent future violations before informing the Committee, in so far as these are urgently needed to guarantee the protection of human or animal health or the protection of the environment. In the cases described in sentence 1 nos. 2 and 3, the competent authorities shall inform the Commission of the European Communities and the other Member States, in the cases described in sentence 1 no. 1, the Commission of the European Communities and the Medicines Agency, of the reasons for these measures by the following working day, at the latest, through the channel of the competent higher federal authority. In the case of sub-section 1 sentence 2 no. 4, the competent higher federal authority can also order the suspension of the marketing authorisation or the recall of a medicinal product if such action is urgently needed to ensure the protection of the legal rights mentioned in sentence 2; in such a case sentence 3 shall apply *mutatis mutandis*.

(2) The competent authorities may prohibit the collection of medicinal products if suitable storage of the medicinal products is not guaranteed or if there is reason to suspect that the medicinal products collected will be used improperly. Collected medicinal products may be seized if, as a result of inappropriate storage or through their distribution, human and animal health will be endangered.

(2a) The competent authorities may furthermore seize medicinal products intended for administration to animals as well as substances and preparations from substances within the meaning of Section 59a if facts justify the assumption that provisions on the trade in medicinal products have not been observed.

(3) The competent authorities may seize advertising material which fails to comply with the regulations governing the trade in medicinal products and advertising in the field of medicine.

(4) In the case of sub-section 1 sentence 3, the competent higher federal authority may also issue a public warning.

Section 69a

The supervision of substances which can be used as medicinal products for animals

Sections 64 to 69 shall apply *mutatis mutandis* to the enterprises, facilities and persons specified in Section 59c as well as to the enterprises, facilities and persons who manufacture, store, import or place on the market substances listed in Annex IV of Regulation (EEC) No. 2377/90.

Section 69b

Use of specific data

(1) The authorities responsible for the collection of data for the notification and registration of animal-keeping enterprises, pursuant to the Ordinance on the Movement of Livestock, shall transmit the data necessary for the fulfilment of its duties, on request, to the competent authority responsible for the supervision pursuant to Section 64 sub-section 1 sentence 1 second half sentence.

(2) The data may be kept for three years. The three-year deadline shall begin at the end of the year in which the data is transmitted. When the deadline has expired, the data shall be erased unless they may be kept for a longer period on the basis of other provisions.

TWELFTH CHAPTER

SPECIAL PROVISIONS FOR THE FEDERAL ARMED FORCES, FEDERAL POLICE, PUBLIC ORDER POLICE AND CIVIL PROTECTION

Section 70

Application and enforcement of the Act

(1) The provisions of the present Act shall apply *mutatis mutandis* to the establishments which supply the Federal Armed Forces, the Federal Police and the Public Order Police of the *Laender* with medicinal products as well as to the stockpiling of medicinal products for civil protection purposes.

(2) In the sphere of the Federal Armed Forces, the execution of the present Act in respect of the supervision of the trade in medicinal products shall be incumbent upon the competent agencies and experts of the Federal Armed Forces. In the sphere of the Federal Police, it shall be incumbent upon the competent agencies and experts of the Federal Police. With regard to the stockpiling of medicinal products for civil protection, it shall be incumbent on the agencies designated by the Federal Ministry of the Interior; in so far as offices of the individual *Laender* are designated, the approval of the *Bundesrat* shall be required.

Section 71

Exceptions

(1) The indication of the expiry date stipulated in Section 10 sub-section 1 no. 9 is not necessary in the case of medicinal products which are supplied to the Federal Armed Forces, the Federal Police, as well as to the Federal Government and the *Laender* for the purpose of civil protection and disaster control. The competent Federal Ministries or, in cases where medicinal products are supplied to the *Laender*, the competent *Land* authorities shall ensure that quality, efficacy and safety are also guaranteed with respect to these medicinal products.

(2) The Federal Ministry is hereby empowered to permit, by means of ordinance, exceptions to the regulations contained in the present Act and the ordinances issued by virtue of the present Act for the sphere of the Federal Armed Forces, the Federal Police, the Public Order Police of the *Laender* and the Civil Protection and Disaster Control Service, in so far as this is justified in the execution of the specific duties in these areas and in so far as the protection of human or animal health continues to be guaranteed. The ordinance shall be issued by the Federal Ministry of Agriculture, Food and Consumer Protection in agreement with the Federal Ministry, in so far as medicinal products intended for administration to animals are concerned.

(3) The ordinance shall be issued, in so far as it concerns the Federal Armed Forces, in agreement with the Federal Ministry of Defence and, in so far as it concerns the Federal Police and Civil Protection, in agreement with the Federal Ministry of the Interior without, in either instance, the approval of the *Bundesrat*; in so far as the ordinance concerns the Public Order Police of the individual federal *Laender* or the Disaster Control Service, it shall be issued in agreement with the Federal Ministry of the Interior and subject to the approval of the *Bundesrat*.

THIRTEENTH CHAPTER

IMPORT AND EXPORT

Section 72

Import authorisation

(1) A party wishing to bring medicinal products within the meaning of Section 2 sub-section 1 or sub-section 2 no. 1, test sera, test antigens or active substances which are of human, animal or microbial origin and not intended for the manufacture of a medicinal product according to a procedure described in the homeopathic section of the Pharmacopoeia, or active substances manufactured using genetic engineering, as well as other substances of human origin intended for the manufacture of medicinal products, on a commercial or professional basis into the purview of the present Act from countries which are not Member States of the European Communities or other States Parties to the Agreement on the European Economic Area for the purpose of supplying others or for further processing, shall require an authorisation by

the competent authority. Section 13 sub-section 1 sentence 2 and sub-section 4 and Sections 14 to 20a shall apply *mutatis mutandis*.

(2) A party wishing to bring medicinal products of human origin for direct use in humans into the purview of the present Act from the countries specified in sub-section 1, on a commercial or professional basis, shall also require an authorisation by the competent authority. The authorisation shall be refused if the applicant is unable to show evidence that qualified and experienced personnel are available to assess the quality and safety of the medicinal products according to the state of scientific and technical knowledge.

(3) Sub-section 1 shall not apply to tissue within the meaning of Section 1a no. 4 of the Transplantation Act and to tissue preparations within the meaning of Section 20c.

Section 72a Certificates

(1) The importer may only introduce medicinal products within the meaning of Section 2 sub-sections 1 and 2 nos. 1, 1a, 2 and 4 which are not intended for clinical trials on human beings, or active substances, from countries which are not Member States of the European Union or other States Parties to the Agreement on the European Economic Area into the purview of the present Act, if:

1. the competent authority of the manufacturing country has confirmed by certificate that the medicinal products or active substances are being manufactured in compliance with the requirements of the recognized Good Practices in the Manufacture and Quality Control of Drugs especially those adopted by the European Communities, the World Health Organization or the Pharmaceutical Inspection Convention, and on condition that such certificates as refer to medicinal products within the meaning of Section 2 sub-sections 1 and 2 no. 1, which are intended for administration to human beings, and active substances which are of human, animal or microbial origin, and are not intended for the manufacture of a medicinal product according to a procedure described in the homeopathic section of the Pharmacopoeia or are active substances manufactured using genetic engineering are mutually recognised,
2. the competent authority has certified that the afore-mentioned requirements have been adhered to in manufacturing the medicinal products and the active substances used in their manufacture in so far as they are of human or animal origin or are manufactured using genetic engineering, or in the manufacture of the active substances, or

3. the competent authority has certified that the import is in the interests of the general public.

The competent authority may only issue a document of certification

- a) as specified in number 2, if no certificate pursuant to number 1 exists and it or a competent authority of a Member State of the European Union or of another State Party to the Agreement on the European Economic Area has satisfied itself regularly in the country of manufacture that the above-mentioned requirements are being observed in manufacturing the medicinal products or the active substances,
- b) as specified in number 3, if no certificate pursuant to number 1 exists and the granting of a certification as specified in number 2 is not envisaged or not possible.

(1a) Sub-section 1 sentence 1 does not apply to:

1. medicinal products intended for a clinical trial on human subjects,
2. medicinal products of human origin for immediate use,
3. active substances which are of human, animal or microbial origin and are intended for the manufacture of a medicinal product according to a procedure described in the homeopathic section of the Pharmacopoeia,
4. active substances which are or contain substances pursuant to Section 3 no. 2 in unprocessed or processed form, in so far as the processing does not go beyond drying, chopping and initial extraction.

(1b) The provisions laid down in subsection 1 sentence 1 nos. 1 and 2 for active substances of human, animal or microbial origin or for active substances manufactured using genetic engineering shall apply *mutatis mutandis* to other substances of human origin intended for the manufacture of medicinal products.

(1c) Medicinal products and active substances of human, animal or microbial origin or active substances manufactured using genetic engineering as well as other substances of human origin intended for the manufacture of medicinal products with the exception of those me-

dicinal products specified in sub-section 1a nos. 1 and 2, may not be imported on the basis of a certificate pursuant to sub-section 1 sentence 1 no. 3.

(1d) Sub-section 1 sentence 1 shall be applicable to the import of active substances as well as other substances of human origin intended for the manufacture of medicinal products, in so far their supervision is regulated by an ordinance pursuant to Section 54.

(2) The Federal Ministry is hereby empowered to mandate, by ordinance subject to the approval of the *Bundesrat*, that substances and preparations from substances which can be used as medicinal products or in the manufacture of medicinal products may not be imported from certain countries which are not Member States of the European Union or other States Parties to the Agreement on the European Economic Area, in so far as this is necessary to prevent hazards to human health or for the purpose of taking precautions against risks.

(3) The Federal Ministry is hereby also empowered to specify, by means of ordinance with the approval of the *Bundesrat*, the additional requirements for the import of the medicinal products specified under sub-section 1a nos. 1 and 2 from countries which are not Member States of the European Union or other States Parties to the Agreement on the European Economic Area, in so far as necessary to ensure that the medicinal products are of proper quality. In this context, the Ministry can lay down regulations, in particular, which govern the tests to be carried out by the competent person pursuant to Section 14 and the possibility of supervision by the competent authority of the manufacturing country.

(4) Sub-section 1 shall not apply to tissues within the meaning of Section 1a no. 4 of the Transplantation Act and to tissue preparations within the meaning of Section 20c.

Section 72b

Import authorisations and certificates for tissues and specific tissue preparations

(1) Any person who intends to import, from a country which is not a Member State of the European Union or a State Party to the Agreement on the European Economic Area, tissues within the meaning of Section 1a no. 4 of the Transplantation Act or tissue preparations within the meaning of Section 20c, on a commercial or professional basis, for the purpose of distribution to others or for processing into the territory governed by the present Act, shall require an authorisation to do so from the competent authority. Section 20c sub-section 1 sentence 3 and sub-sections 2 to 7 shall apply mutatis mutandis.

(2) The importer pursuant to sub-section 1 may only import tissues or tissue preparations into the territory governed by the present Act if:

1. the authorities of the country of origin have confirmed in a certificate that the removal or processing and the laboratory tests were conducted according to standards which are at least equivalent to the Standards of Good Practice laid down by the Community, and such certificates are mutually recognised, or
2. the authority responsible for the importer certifies that the basic rules specified for the removal and processing of tissues as well as for laboratory tests are being observed after that authority or a competent authority of another Member State of the European Union, or a State Party to the Agreement on the European Economic Area has satisfied itself, in the country of origin, that the Standards of Good Practice are being observed in the removal or processing of tissues, or
3. the authority responsible for the importer has certified that importing is in the public interest, if a certificate pursuant to number 1 is not available and an attestation pursuant to number 2 is not possible.

By way of derogation from sentence 1 no. 2, the competent authority can dispense with an inspection of the removal facility in the country of origin if the documents submitted by the importer give no reason for complaint or if his/her facilities or factory sites, as well as the quality assurance system of the party procuring the tissue in the country of origin, is already known to them.

(3) The Federal Ministry is hereby empowered to stipulate the additional requirements for the import of tissues or tissue preparations pursuant to sub-section 2, by ordinance subject to the approval of the *Bundesrat*, so as to guarantee that tissues and tissue preparations are of proper quality. It can lay down, in particular, regulations concerning the tests to be conducted by the responsible person pursuant to Section 20c and the conduct of surveillance in the country of origin by the competent authority.

(4) Sub-section 2 sentence 1 shall apply to the import of tissues and tissue preparations within the meaning of sub-section 1, in so far as its surveillance is regulated by an ordinance pursuant to Section 54, Section 12 of the Transfusion Act or pursuant to Section 16a of the Transplantation Act.

Prohibition of introduction

(1) Medicinal products which are subject to compulsory marketing authorisation or registration may only be introduced into the purview of the present Act, with the exception of a free zone of control type I or a bonded warehouse, if they are authorised for marketing or registered within the purview of the present Act or if they have been exempted from the obligation to obtain the marketing authorisation or registration and if:

1. in the case of introduction from a Member State of the European Union or another State Party to the Agreement on the European Economic Area, the recipient is a pharmaceutical entrepreneur, a wholesaler or veterinarian or runs a pharmacy,
 - 1a. in the case of dispatch to the final consumer, the medicinal product is intended for use on or in the human body and is shipped, according to the German regulations governing distance selling or electronic commerce, by a pharmacy of a Member State of the European Union or another State Party to the Agreement on the European Economic Area, which is authorised to conduct distance selling under its national laws, in so far as they correspond to German pharmacy law as regards the provisions governing distance selling, or according to the German Act on Pharmaceutical Services, or
2. in the case of introduction from a country which is not a Member State of the European Union or another State Party to the Agreement on the European Economic Area, the recipient is the holder of an authorisation as specified in Section 72.

The medicinal products specified in Section 47a sub-section 1 sentence 1 shall only be introduced into the purview of the present Act if the recipient is one of the facilities mentioned there. The Federal Ministry shall publish at regular intervals an updated overview of the Member States of the European Union and the other States Party to the Agreement on the European Economic Area, in which safety standards exist with respect to distance selling and electronic commerce in medicinal products which are comparable with those laid down in German law.

(1a) Medicated feedingstuffs may only be introduced into the purview of the present Act if:

1. they comply with the medicinal product-related provisions in force within the purview of the present Act, and

2. the recipient belongs to the group of persons mentioned in sub-section 1, or is an animal keeper in the case of Section 56 sub-section 1 sentence 1.

(2) Sub-section 1 sentence 1 shall not apply to medicinal products which:

1. are intended, in individual cases and in small amounts, for supplying particular animals with medicinal products at animal shows, tournaments or similar events,
2. are intended for scientific and research establishments' own requirements and needed for scientific purposes with the exception of medicinal products intended for use in clinical trials on human beings,
- 2a. are needed in small quantities by a pharmaceutical entrepreneur as samples for inspection or for analysis purposes,
3. are conveyed under customs supervision through the territory governed by the present Act or are transferred to a bonded warehouse procedure or a free zone of control type II,
- 3a. are authorised in a Member State of the European Union or another State Party to the Agreement on the European Economic Area and after transit storage with a pharmaceutical entrepreneur or wholesaler, are to be re-exported, shipped onwards or shipped back,
4. are introduced for the head of state of a foreign country or for his escort and are intended for use during his stay within the purview of the present Act,
5. are intended for the personal use or consumption of members of diplomatic missions or consular representations within the purview of the present Act or of officials of international organizations located there or of their family members, in so far as these persons are neither German nor have their permanent residence within the purview of the present Act,
6. are introduced when entering into the purview of the present Act in an amount corresponding to the normal personal requirement,
- 6a. may be marketed in the country of origin and are purchased, without a commercial or professional intermediary, in a quantity which corresponds to the amount needed for normal personal use in a Member State of the European Union or another State Party to the Agreement on the European Economic Area,

7. are carried on board any means of transport and are intended exclusively for the use of or consumption by persons conveyed by these means of transport,
8. are intended for use or consumption on sea-going vessels and are consumed on board ships,
9. are sent as samples to the competent higher federal authority for the purpose of obtaining a marketing authorisation or for official batch testing,
10. are procured by federal or *Land* authorities in interstate commerce.

(3) By way of derogation from sub-section 1 sentence 1, finished medicinal products which are not authorised for marketing or registered for trade within the purview of the present Act or which are not exempted from the obligation to obtain a marketing authorisation or registration, may be introduced into the purview of the present Act if they are authorised for marketing in the State from which they are being introduced into the purview of the present Act and have been ordered by pharmacies or as part of the operation of a veterinary practice dispensary by the veterinarian for the animals treated by him. Pharmacies may obtain such medicinal products, except in cases in which they are ordered on behalf of a veterinarian and dispensed to same,

1. only in small quantities and upon the specific order of individual persons and dispense them only within the framework of the existing pharmacy operating license and,
 - a) if they are not medicinal products from Member States of the European Union or other States Parties to the Agreement on the European Economic Area, may obtain them only on prescription from a doctor or dentist if, with respect to the active substance, no identical medicinal product, and with respect to the strength, no comparable medicinal product are available, within the purview of the present Act, for the field of application in question,
 - b) if they are medicinal products from Member States of the European Union or other States Parties to the Agreement on the European Economic Area and intended for use on food-producing animals, may obtain them only on prescription by a veterinarian,

or

2. in so far as they are being held in stock for emergencies according to the provisions of the law on pharmacies or the requirements of occupational accident insurance, or must be procurable at short notice, may only obtain and distribute them within the framework of the normal operation of the pharmacy, if medicinal products for the specific field of application are not available within the purview of the present Act,

more detailed particulars shall be settled by the Pharmacies Operation Regulations.

Veterinarians and, where medicinal products within the meaning of sentence 1 are ordered on behalf of a veterinarian and dispensed to same, pharmacies may only purchase such medicinal products,

1. if these are medical products intended for administration to animals from Member States of the European Union or other States Parties to the Agreement on the European Economic Area, and
2. if within the purview of this Act no suitable authorised medicinal product intended for administration to animals is available to achieve the treatment objective.

Immediately after his order, his instruction and any prescription of a medicinal product according to sentence 3, the veterinary surgeon must notify same to the competent authority pursuant to sentence 5. The notification must state the species and field of application for which the medicinal product is intended, the State from which the medicinal product is brought into the purview of the present Act, the name and quantity of the medicinal product ordered as well as its active substances by type and quantity.

(4) The provisions of the present Act shall not be applicable to medicinal products pursuant to sub-section 2 nos. 4 and 5. The provisions of the present Act shall not be applicable to medicinal products pursuant to sub-section 2 nos. 1 to 3 and 6 to 10 and sub-section 3 sentences 1 and 2 with the exception of Sections 5, 6a, 8, 64 to 69a and 78, and furthermore in the cases referred to in sub-section 2 no. 2 and sub-section 3 sentences 1 and 2 and also with the exception of Sections 48, 95 sub-section 1 nos. 1 and 3a, sub-sections 2 to 4, Section 96 nos. 3, 10 and 11 and Section 97 sub-sections 1, 2 nos. 1 and 9 and sub-section 3 and furthermore in the cases referred to in sub-section 3 sentence 1, also in conjunction with sentence 3, and sentence 2, also with the exception of Sections 56a, 57, 58 sub-section 1 sentence 1, Sections 59, 95 sub-section 1 nos. 6, 8, 9 and 10, Section 96 nos. 15 to 17 and Section 97 sub-section 2 nos. 21 to 24 and 31 and of the ordinance on veterinarian practice dispensaries issued on the basis of Section 12 sub-section 1 nos. 1 and 2 and sub-section 2, of Section 48 sub-section 2

no. 4 and sub-section 4 of Section 54 sub-sections 1, 2 and 3 as well of Section 56a sub-section 3 and of the ordinance on the obligation to produce supporting documents for medicinal products intended for use on animals issued on the basis of Sections 12, 54 and 57.

(5) When exercising their profession in local border traffic, physicians and veterinarians may only carry medicinal products with them which have been authorised for marketing or registered within the purview of the present Act or which are exempted from the obligation to obtain a marketing authorisation or registration. By way of derogation from sentence 1, veterinarians who render services as nationals of a Member State of the European Union or of another State Party to the Agreement on the European Economic Area, may carry with them small amounts of medicinal products which are authorised for marketing in the place where they are established, in a quantity which is necessary for the performance of the services, and in their original packaging, if and in so far as medicinal products with the same composition and intended for the same fields of application are also authorised for marketing within the purview of the present Act; the veterinarian may only administer these medicinal products himself and shall inform the animal keeper of the withdrawal period specified for the corresponding medicinal product authorised for marketing within the purview of the present Act.

(6) In the case of sub-section 1 no. 2, as well as sub-section 1a no. 2, in conjunction with sub-section 1 no. 2, the presentation of a certificate issued by the authorities competent in the recipient's case, containing information on the type and quantity of the medicinal product and confirming that the requirements specified in sub-section 1 or sub-section 1a have been met, shall be necessary for customs clearance for free circulation. The customs office shall forward the certificate to the authorities which issued it, at the expense of the party paying the customs duties.

(7) In the case of sub-section 1 no. 1, a recipient who is a wholesaler or who runs a pharmacy shall prove the existence of the provision for coverage pursuant to Section 94.

Section 73a

Export

(1) By way of derogation from Sections 5 and 8 sub-section 1, the medicinal products referred to there may be exported if the competent authority of the country of destination has authorised the import of such medicinal products. The import authorisation must state that the competent authority of the country of destination is cognisant of the grounds for refusal which prevent the marketing of said medicinal products within the purview of the present Act.

(2) The competent authority shall issue a certificate corresponding to the World Health Organization's Certification Scheme. At the request of the pharmaceutical entrepreneur, the manufacturer, the importer or the competent authority of the country of destination. If the request is submitted by the competent authority of the country of destination, the consent of the manufacturer is to be obtained prior to issuing the certificate.

Section 74

Participation of customs offices

(1) The Federal Ministry of Finance and the customs offices specified by it shall participate in the supervision of the introduction of medicinal products and active substances into the purview of the present Act and of the export of the same. The authorities named may

1. retain for inspection consignments of the type named in sentence 1, as well as their means of conveyance, containers, loading and packing material,
2. inform the competent administrative authorities of suspected violations of prohibitions and restrictions of the present Act or of the ordinances issued in accordance with the present Act, if this suspicion becomes evident during customs clearance,
3. issue instructions to the effect that, in instances defined in no. 2, consignments of the type named in sentence 1 shall be presented to a competent medicinal product supervision authority at the cost and at the risk of the person holding the right of disposal of the consignment.

(2) The Federal Ministry for Finance shall settle the details of the procedure indicated in sub-section 1, in agreement with the Federal Ministry, by ordinance not subject to the approval of the *Bundesrat*. In particular, it may thereby envisage obligations to notify, register, submit information and provide assistance, as well as to tolerate the inspection of business papers and other documents and of premises and the taking of samples free of charge. The ordinance shall be issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, as far as radiopharmaceuticals and active substances or medicinal products and active substances in the manufacture of which ionizing radiation is used are concerned and in agreement with the Federal Ministry of Agriculture, Food and Consumer Protection where medicinal products intended for administration to animals are involved.

Section 74a

Information Officer

(1) Any person who, as a pharmaceutical entrepreneur, places medicinal products within the meaning of Section 2 sub-section 1 or sub-section 2 no. 1 on the market, shall commission a person with the necessary expert knowledge and the reliability required to perform his or her activities, to responsibly fulfil the tasks of providing scientific information on the medicinal products (information officer). The information officer shall, in particular, be responsible for ensuring compliance with the prohibition contained in Section 8 sub-section 1 no. 2 and ensuring that the labelling, the package leaflets, the professional information and advertisements correspond with the content of the marketing authorisation or registration or, in so far as the medicinal product is exempted from the need for a marketing authorisation or registration, with the content of the ordinances governing the exemption from marketing authorisations or registrations pursuant to Section 36 or Section 39 sub-section 3. Sentence 1 shall not apply to persons who, pursuant to Section 13 sub-section 2 sentence 1 nos. 1, 2, 3 or 5, do not require a manufacturing authorisation. Persons other than those specified in sentence 1 shall not be allowed to exercise the functions of an information officer.

(2) Proof of the necessary expert knowledge for the post of information officer shall be furnished in the form of a certificate proving the successful completion of an examination taken at the end of university studies in the field of human medicine, human biology, veterinary medicine, pharmacy, biology or chemistry, in addition to professional experience of at least two years, or by the proof provided for in Section 15. The information officer can be the Graduated Plan Officer at the same time.

(3) The pharmaceutical entrepreneur shall inform the competent authority about the identity of the information officer and present the proof that the requirements pursuant to sub-section 2 have been met and shall give notice of any change beforehand. In the case of an unforeseen change in the person of the information officer, notice shall be given immediately.

Section 75

Expert knowledge

(1) Pharmaceutical entrepreneurs may only appoint persons in possession of expert knowledge, as defined in sub-section 2, to visit members of the medical professions on a full-time basis, in order to give technical information on medicinal products within the meaning of Section 2 sub-section 1 or sub-section 2 no. 1 (pharmaceutical consultant). Sentence 1 shall

also apply to information given by telephone. The activities of a pharmaceutical consultant may not be carried out by persons other than those indicated in sentence 1.

(2) The following persons shall be deemed to possess the necessary expert knowledge:

1. pharmacists or persons holding a certificate testifying to a successfully completed course of university studies in pharmacy, chemistry, biology, human or veterinary medicine,
2. assistants of pharmacists, as well as persons who have completed training as technical assistants in the fields of pharmacy, chemistry, biology, human or veterinary medicine,
3. pharmaceutical sales representatives.

(3) The competent authority is hereby empowered to recognize a passed examination or a successfully completed course of training as being sufficient if it is at least equivalent to the level of training of any of the persons specified in sub-section 2.

Section 76

Duties

(1) The pharmaceutical consultant shall have to make the expert information pursuant to section 11a available, in so far as he provides expert information on individual medicinal products to members of the medical professions. He shall record in writing any information given to him by members of the medical professions on side effects and contraindications or other risks associated with the medicinal products and notify his contract-giver thereof in writing.

(2) In so far as the pharmaceutical consultant is commissioned by the pharmaceutical entrepreneur to distribute samples of finished medicinal products to those persons entitled to receive them in accordance with Section 47 sub-section 3, he shall keep a record of the recipients of the samples, as well as the type and quantity thereof and the time and date of their distribution and must present these records, on request, to the competent authorities.

FIFTEENTH CHAPTER

DESIGNATION OF THE COMPETENT HIGHER FEDERAL AUTHORITIES AND OTHER PROVISIONS

Section 77

Competent higher federal authority

(1) The competent higher federal authority shall be the Federal Institute for Drugs and Medical Devices unless either the Paul Ehrlich Institute (the Federal Agency for Sera and Vaccines) or the Federal Office of Consumer Protection and Food Safety is competent.

(2) The Paul Ehrlich Institute shall be competent for sera, vaccines, blood preparations, bone marrow preparations, tissue preparations, allergens, gene transfer medicinal products, somatic cell therapy products, xenogenic cell therapy products and blood components manufactured using genetic engineering.

(3) The Federal Office of Consumer Protection and Food Safety shall be responsible for medicinal products which are intended for administration to animals.

(4) The Federal Ministry is hereby empowered, by means of ordinance not subject to the approval of the *Bundesrat*, to modify the competences of the Federal Institute for Drugs and Medical Devices and the Paul Ehrlich Institute, in so far as this is necessary to take account of new scientific developments or if such a change is required for reasons of a more uniform distribution of the workload.

Section 77a

Independence and transparency

(1) As regards the guarantee of independence and transparency, the competent Higher Federal Authorities and the competent authorities shall ensure that staff employed by the authorising authorities or other competent authorities, who are involved with marketing authorisations and supervision, or experts appointed by them, have no financial or other interests in the pharmaceutical industry that could influence their neutrality. These persons shall make an annual declaration in this regard.

(2) Within the framework of performing the tasks referred to in this Act, the competent Higher Federal Authorities and the competent authorities shall make the procedural rules of their committees, the agendas and minutes of their meetings accessible to the public; manufacturing and business secrets shall be protected in the process.

Section 78

Prices

(1) The Federal Ministry of Economics and Technology is hereby empowered to fix, in agreement with the Federal Ministry and, as far as medicinal products intended for administration to animals are concerned, in agreement with the Federal Ministry of Agriculture, Food and Consumer Protection, by ordinance subject to the approval of the *Bundesrat*:

1. price margins for medicinal products which are distributed in wholesale commerce or in pharmacies or which are re-sold by veterinarians,
2. prices for medicinal products which are manufactured and distributed in pharmacies or by veterinarians, as well as for the containers in which they are sold,
3. prices for particular services rendered by pharmacies in connection with the dispensing of medicinal products.

By way of derogation from sentence 1, the Federal Ministry of Economics and Technology is hereby empowered to adjust the fixed mark-up according to how pharmacy costs develop given cost-effective management, in agreement with the Federal Ministry, by ordinance not subject to the approval of the *Bundesrat*.

(2) The prices and price margins shall take into account the legitimate interests of the medicinal product consumers, the veterinarians, the pharmacies and the wholesale trade. A uniform pharmacy retail price shall be guaranteed for medicinal products which are to be sold exclusively in pharmacies. Sentence 2 shall not apply to prescription-only medicinal products which are not subject to reimbursement by the statutory health insurance.

(3) In the case of medicinal products pursuant to sub-section 2 sentence 2 for which prices and price ranges have been specified by an ordinance pursuant to sub-section 1, the pharmaceutical entrepreneurs shall guarantee a uniform sales price; in the case of non-prescription medicinal products which are to be reimbursed by the statutory health insurance, the pharmaceutical entrepreneurs shall specify their uniform sales price from which exceptions may be made in individual cases, for the purpose of the settlement of accounts between the pharmacy and the statutory health insurance. Social insurance carriers, private health insurances, as well as their individual associations, can come to an agreement with the pharmaceutical entrepreneur on discounts off the uniform sales price for the prescription of medicinal products which they have to reimburse.

(4) In the case of medicinal products which, in the case of a threatening infectious disease, the spread of which requires an immediate supply of specific medicinal products which

goes beyond the normal amount, are dispensed by pharmacies and which have been stored for this purpose, the prices and price ranges to be specified pursuant to sub-section 2 shall be based on the sales price for the specific Land. The same shall apply to medicinal products manufactured in pharmacies from active substances stored for this purpose and dispensed in such cases. In these cases, sub-section 2 sentence 2 shall apply at Land level.

Section 79

Authority to permit exceptions in times of crisis

(1) The Federal Ministry is hereby empowered to permit exceptions to the regulations laid down by the present Act and by the ordinances issued by virtue of the present Act, in agreement with the Federal Ministry of Economics and Technology, by ordinance not subject to the approval of the *Bundesrat*, if the necessary supply of medicinal products to the population would otherwise be seriously jeopardized and if a direct or indirect hazard by medicinal products to human health is not to be feared; in particular, regulations can be adopted to counter the spread of risks that might occur in reaction to the presumed or confirmed spread of pathogenic substances, toxins, chemicals or exposure to ionising radiation.

(2) The Federal Ministry of Agriculture, Food and Consumer Protection is hereby empowered to permit exceptions to the provisions contained in the present Act and the ordinances issued on the basis of the present Act, in agreement with the Federal Ministry and the Federal Ministry of Economics and Technology, by ordinance not subject to the approval of the *Bundesrat*, if the necessary supply of medicinal products to livestock would otherwise be seriously jeopardised and if a direct or indirect hazard by medicinal products to human or animal health is not to be feared.

(3) The ordinances pursuant to sub-section 1 or 2 shall be issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, in so far as radiopharmaceuticals and medicinal products in the manufacture of which ionising radiation is used or regulations to protect against the risks of ionising radiation are concerned.

(4) The term of validity of the ordinance pursuant to sub-section 1 or 2 shall be limited to six months.

Section 80

Authority to issue procedural and compassionate use regulations

The Federal Ministry is hereby empowered to regulate, by ordinance not subject to the approval of the *Bundesrat*, further details regarding the procedure in respect of:

1. the marketing authorisation including the prolongation of the manufacturing authorisation,
2. the official batch testing and batch release,
3. the notifications in respect of changes in the marketing authorisation documents,
- 3a. the competent higher federal authority and the persons involved in the placing on the market in cases of compassionate use pursuant to Section 21 sub-section 2 sentence 1 no. 6 in conjunction with Article 83 of Regulation (EC) No. 726/2004,
4. the registration and
5. the reporting of medicinal product risks;

in the process, it may require the forwarding of duplicates to the competent authorities and stipulate that the documents are to be submitted in multiple copies as well as on electronic or optical storage media. The Federal Ministry can transfer this authority to the competent higher federal authority without the approval of the *Bundesrat*. In the ordinance pursuant to sentence 1 no. 3a, in particular, the tasks of the competent higher federal authority with regard to the participation of the European Medicines Agency and the Committee for Medicinal Products for Human Use, in accordance with Article 83 of Regulation (EC) No 726/2004, and the areas of responsibility of the treating doctors and pharmaceutical entrepreneurs or sponsors can be regulated, including notification, documentation and reporting requirements for adverse reactions in particular, in accordance with Article 24(1) and Article 25 of Regulation (EC) No. 726/2004. In this regard, regulations can also be laid down for medicinal products which, under the conditions laid down in Article 83 of Regulation (EC) No. 726/2004, relate to medicinal products which are not among those referred to in Article 3 (1 or 2) of this Regulation. The ordinance pursuant to sentences 1 and 2 shall be issued in agreement with the Federal Ministry of Agriculture, Food and Consumer Protection, in so far as medicinal products intended for administration to animals is concerned.

Section 81

Relation to other laws

The regulations contained in the legislation on narcotic medicinal products and on nuclear energy and those contained in the Law on the Protection of Animals shall not be affected.

Section 82

General administrative regulations

The Federal Government shall issue, with the approval of the *Bundesrat*, the general administrative regulations required for the implementation of the present Act. In so far as these apply to the competent higher federal authority, the general administrative regulations shall be issued by the Federal Ministry. The general administrative regulations pursuant to sentence 2 shall be issued in agreement with the Federal Ministry of Agriculture, Food and Consumer Protection, in so far as medicinal products intended for administration to animals are concerned.

Section 83

Approximation to community legislation

(1) Ordinances or general administrative regulations issued in compliance with the present Act may also be issued for the purpose of approximation to the legal and administrative regulations of the Member States of the European Economic Community, in so far as this is necessary for the implementation of regulations, directives or decisions, adopted by the Council or the Commission of the European Communities, which affect fields covered by the present Act.

(2) Ordinances covering exclusively the incorporation of directives or decisions adopted by the Council or the Commission of the European Communities into national law shall not be subject to the approval of the *Bundesrat*.

SIXTEENTH CHAPTER

LIABILITY FOR DAMAGES CAUSED BY MEDICINAL PRODUCTS

Section 84

Absolute liability

(1) If, as a result of the administration of a medicinal product intended for human use, which was distributed to the consumer within the purview of the present Act and which is subject to compulsory marketing authorisation or is exempted by ordinance from the need for a

marketing authorisation, a person is killed, or the body or the health of a person is substantially damaged, the pharmaceutical entrepreneur who placed the medicinal product on the market within the purview of the present Act shall be obliged to compensate the injured party for the damage caused. The liability to compensate shall only exist if

1. when used in accordance with its intended purpose, the medicinal product has harmful effects which exceed the limits considered tolerable in the light of current medical knowledge, or
2. the damage has occurred as a result of labelling, expert information or instructions for use which do not comply with current medical knowledge.

(2) If the medicinal product administered is capable of causing the damage, in the circumstances pertaining to the individual case, the damage will be presumed to have been caused by the medicinal product in question. The capability in the individual case will be determined according to the composition and the dosage of the administered medicinal product, the manner and duration of its administration when used as intended, the temporal relationship to the occurrence of the damage, the damage symptoms and the person's state of health at the time of the administration as well as all other circumstances which, in the individual case, speak for or against the causation of damage. The presumption shall not apply if, in the light of the circumstances pertaining to the individual case, another fact is capable of causing the damage. However, the administration of additional medicinal products which, in the circumstances pertaining to the individual case, are capable of causing the damage shall not be considered as another fact unless, owing to the administration of these medicinal products, claims for reasons other than the lack of causality for the damage, do not exist under this provision.

(3) The pharmaceutical entrepreneur shall be exempted from liability to pay damages pursuant to sub-section 1 sentence 2 no. 1, if the facts indicate that the damaging effect of the medicinal product is not attributable to its development and manufacturing process.

Section 84a

Right to disclosure

(1) Where facts exist to justify the assumption that a medicinal product has caused the damage, the injured party can request information from the pharmaceutical entrepreneur unless such information is not necessary to verify a right to compensation pursuant to Section 84. The right refers to effects, side-effects and interactions known to the pharmaceutical entrepreneur as well as suspected cases of side-effects and interactions brought to his attention and all fur-

ther knowledge which could be of significance in assessing the justifiability of harmful effects. Sections 259 to 261 of the Civil Code shall be applied *mutatis mutandis*. A right to disclosure shall not exist where statutory provisions require that the data remain secret or when non-disclosure is justified by an overriding interest of the pharmaceutical entrepreneur or a third party.

(2) A right to disclosure also exists, under the conditions laid down in sub-section 1 vis-à-vis the authorities responsible for the authorisation and supervision of medicinal products. The authority is not obliged to disclose the information where provisions require that the data remain secret or when non-disclosure is justified by an overriding interest of the pharmaceutical entrepreneur or a third party.

Section 85 **Contributory negligence**

If negligence on the part of the injured party has helped to cause the injury, Section 254 of the Civil Code shall apply.

Section 86 **Extent of liability for damages in the case of death**

(1) In the case of death, compensation shall be made by reimbursing the costs of an attempted cure as well as the costs incurred by the pecuniary prejudice sustained by the deceased party as a result of the suspension or reduction of his earning capacity or the resultant increase in his needs during his disease. The party liable for damages shall furthermore reimburse the funeral costs to the party who is responsible for defraying these expenses.

(2) If at the time of injury, the deceased party maintained a relationship with a third party by virtue of which he was or was liable to come under the legal obligation to support this third party and if the third party was deprived of the right to maintenance as a result of the death, the party liable for damages shall indemnify the third party, guaranteeing maintenance to the extent to which the deceased party would have been liable for the length of lifespan he would probably have had. Liability for damages shall also be enforced if, at the time of injury, the third party had been conceived but not yet born.

Section 87 **Extent of liability for damages in the case of bodily injury**

In the case of injury to a person's body or damage to his health, compensation shall be given by reimbursing the costs of the treatment as well as the costs incurred by the pecuniary prejudice sustained by the injured party as a result of the temporary or permanent suspension or reduction of his earning capacity or the resultant increase in his needs. In this case, reasonable financial compensation can also be claimed when the damage is not of a pecuniary nature.

Section 88

Maximum amounts

The party liable for damages shall be liable

1. in the case of the death of or injury to a person, only up to a capital amount of 600,000 euros or an annuity of up to 36,000 euros per year,
2. in the case of the death of or injury to several persons by the same medicinal product, notwithstanding the limits stipulated in no. 1, up to a capital amount of 120 million euros or an annuity of up to 7.2 million euros per year.

Should, in the case of sentence 1 no. 2, the combined indemnification to be paid to several injured parties exceed the maximum amounts specified therein, then the individual compensation shall be reduced pro-rata to the maximum total given.

Section 89

Compensation in the form of annuities

(1) Compensation on account of the suspension or reduction of earning capacity and on account of increased need on the part of the injured party, as well as the compensation to be afforded a third party in accordance with Section 86 sub-section 2, shall be paid in the future by means of an annuity.

(2) The provisions of Section 843 sub-sections 2 to 4 of the Civil Code and of section 708 no. 8 of the Code of Civil Procedure shall apply *mutatis mutandis*.

(3) If a security bond was not awarded when the party liable was sentenced to pay the annuity, the entitled party may, nevertheless, demand a security bond if the pecuniary circumstances of the liable party have deteriorated considerably; under the same circumstances, he/she may demand an increase in the security bond specified in the verdict.

Section 90
(deleted)

Section 91
Extended liability

This shall be without prejudice to legal provisions according to which the party liable for damages under section 84 shall be liable to a greater extent than stipulated by the provisions in this chapter, or according to which another party is responsible for the damage incurred.

Section 92
Mandatory provision

The liability for damages pursuant to this chapter may neither be excluded nor restricted beforehand. All agreements to the contrary shall be void.

Section 93
Several parties liable for damages

If several parties are liable for damages, they shall be jointly and severally liable. With regard to the relationship of the liable parties to each other, the obligation to pay compensation as well as the extent of the compensation to be paid shall depend on the extent to which the damage has been predominantly caused by one or the other party.

Section 94
Coverage provision

(1) The pharmaceutical entrepreneur shall ensure that he is able to meet his legal commitments in respect of compensation for the damage incurred as a result of the administration of a medicinal product intended for human use, placed by him on the market, and subject to a compulsory marketing authorisation or exempted by ordinance from a marketing authorisation (provision for coverage). The provision for coverage must be made available in the amounts specified in section 88 sentence 1. It can only be made available by means of:

1. a third party insurance taken out with an insurance company authorised to conduct business within the purview of the present Act,

2. an exemption or warranty obligation issued by a domestic credit institution, or a credit institution of one of the other Member States of the European Union or another State Party to the Agreement on the European Economic Area.

(2) If the provision for coverage is afforded by a third party insurance, Sections 158 c to 158 k of the Law on Insurance Contracts of 30th May 1908 (Reich Law Gazette p. 263), last amended by the Law of 30th June 1967 (Federal Law Gazette (*Bundesgesetzblatt*) I p. 609), shall apply *mutatis mutandis*.

(3) Provision for coverage may only be made available using exemption or warranty obligations issued by a credit institution if it is guaranteed that the credit institution will be in a position to meet its commitments within the framework of the provision for coverage for such time as it can be expected to be called upon to do so. Sections 158 c to 158 k of the Law on Insurance Contracts shall apply *mutatis mutandis* with respect to exemption or warranty obligations.

(4) The competent office within the meaning of Section 158 c sub-section 2 of the Law on Insurance Contracts shall be the authority competent for carrying out supervision pursuant to section 64.

(5) The Federal Republic of Germany and the federal *Laender* are not obliged to provide coverage in compliance with sub-section 1.

Section 94a Local jurisdiction

(1) In the case of legal actions initiated on the basis of section 84, the court in whose district the plaintiff has his domicile or, failing this, has his usual place of abode at the time of filing the action shall have jurisdiction.

(2) No account shall be taken of sub-section 1 when determining the international jurisdiction of the courts of a foreign nation pursuant to Section 328 sub-section 1 no. 1 of the Code of Civil Procedure.

SEVENTEENTH CHAPTER PENAL PROVISIONS AND PROVISIONS ON ADMINISTRATIVE FINES

Section 95
Penal provisions

(1) Any person who

1. contrary to Section 5, also in conjunction with Section 73a, markets medicinal products for which there is reasonable suspicion that it can cause harmful effects,
2. contravenes an ordinance issued in compliance with Section 6, which forbids the marketing of medicinal products, in so far as it refers to the present penal provision for specific cases,
- 2a. contrary to Section 6a sub-section 1, markets or prescribes medicinal products for doping purposes in the field of sport, or administers such medicinal products to others,
- 2b. contrary to Section 6a sub-section 2a, is in possession of non-small quantities of medicinal products for doping purposes in the field of sport,
3. markets radiopharmaceuticals and medicinal products in the manufacture of which ionizing radiation is used in breach of Section 7 sub-section 1,
- 3a. contrary to Section 8 sub-section 1 no. 1 or 1a, also in conjunction with Section 73 sub-section 4 or Section 73a, manufactures or markets medicinal products,
4. contrary to Section 43 sub-section 1 sentence 2, sub-section 2 or 3 sentence 1, trades in or dispenses medicinal products which may be dispensed to the consumer on prescription only,
5. dispenses medicinal products which may be dispensed to the consumer on prescription only, in breach of Section 47 sub-section 1, to persons or bodies other than those specified therein, or dispenses them in breach of Section 47 sub-section 1a or obtains them in breach of Section 47 sub-section 2 sentence 1,
- 5a. in breach of Section 47a sub-section 1, dispenses one of the medicinal products specified therein to any facility other than those specified therein or places such a medicinal product on the market,

6. in breach of Section 48 sub-section 1 sentence 1 in conjunction with an ordinance pursuant to Section 48 sub-section 2 no. 1 or 2, dispenses medicinal products intended for use in food-producing animals,
7. in breach of Section 56 sub-section 1, dispenses medicated feedingstuffs to animal keepers without the required prescription,
8. in breach of Section 56a sub-section 1 sentence 1, also in conjunction with sentence 3, or sentence 2, prescribes, dispenses or administers medicinal products that are intended for use on food-producing animals and may be dispensed to consumers on prescription only, or
9. in breach of Section 57 sub-section 1, acquires medicinal products which may be dispensed to consumers on prescription only,
10. in breach of Section 58 sub-section 1 sentence 1, administers medicinal products which may only be dispensed to consumers on prescription, to food-producing animals, or
11. in breach of Article 5 paragraph 2 of Regulation (EEC) No. 2377/90, administers a substance to one of the animals specified therein,

shall be liable to imprisonment for a term not exceeding three years or to a fine.

(2) The attempt to commit such acts shall be punishable.

(3) In particularly serious instances, the penalty shall be imprisonment from one to ten years. As a rule, a particularly serious instance shall be said to exist if the perpetrator

1. by means of one of the actions indicated in sub-section 1:
 - a) endangers the health of a large number of persons,
 - b) exposes another person to the risk of death or the risk of serious injury to that person's body or health,
 - c) acquires a considerable pecuniary gain for himself/herself or another person out of gross self-interest, or

2. in the cases referred to in sub-section 1 no. 2a,
 - a) dispenses medicinal products for doping purposes in the field of sport to persons under the age of 18 years or administers such medicinal products to these persons, or
 - b) acts commercially or as a member of a gang which has come together for the recurrent commission of such acts, or
3. in the cases mentioned in sub-section 1 no. 3a, manufactures or markets counterfeit medicinal products acting, in the process, commercially or as a member of a gang which has come together for the recurrent commission of such acts.

(4) If the perpetrator has acted negligently in the instances cited in sub-section 1, the penalty shall be imprisonment for a period of not more than one year or a fine.

Section 96 **Penal provisions**

Any person who

1. contravenes an ordinance pursuant to Section 6, which prescribes, restricts or prohibits the use of certain substances, preparations made from substances or materials in the manufacture of medicinal products, in so far as it refers to the present penal provision for specific cases,
2. (deleted)
3. manufactures or markets medicinal products in breach of Section 8 sub-section 1 no. 2, also in conjunction with Section 73a,
4. in breach of Section 13 sub-section 1, manufactures medicinal products within the meaning of Section 2 sub-section 1 or sub-section 2 no. 1, test sera, test antigens or active substances which are of human or animal origin or are manufactured using genetic engineering, as well as other substances of human origin intended for the manufacture of medicinal products without an authorisation, or introduces them into the purview of the present Act from countries other than Member States of the European Union or States Parties to the Agreement on the European Economic Area, without either the authorisa-

tion required by Section 72 or the necessary confirmation or certification as specified in Section 72a,

- 4a. without an authorisation pursuant to Section 20b sub-section 1 sentence 1 or sub-section 2 sentence 7, procures tissues or carries out laboratory testing or, without an authorisation pursuant to Section 20c sub-section 1 sentence 1, processes, preserves, stores or places tissues or tissue preparations on the market,
5. in breach of Section 21 sub-section 1, markets finished medicinal products or medicinal products intended for administration to animals or medicinal products specified in an ordinance pursuant to Section 35 sub-section 1 no. 2 or Section 60 sub-section 3 without a marketing authorisation or without an authorisation from the Commission of the European Communities or the Council of the European Union,
- 5a. without an authorisation pursuant to Section 21a sub-section 1 sentence 1, places tissue preparations on the market,
6. fails to submit completely or correctly the data required in accordance with Section 22 sub-section 1 nos. 3, 5 to 9, 11, 12, 14 or 15, sub-section 3b or 3c sentence 1 or Section 23 sub-section 2 sentence 2 or 3 or fails to submit a document required according to Section 22 sub-section 2 or 3, Section 23 sub-section 1, sub-section 2 sentence 2 or 3, sub-section 3, also in conjunction with Section 38 sub-section 2, or a document required according to an enforceable order pursuant to Section 28 sub-section 3, 3a or 3c sentence 1 no. 2 completely or with the correct contents,
7. markets a medicinal product in breach of Section 30 sub-section 4 sentence 1 no. 1, also in conjunction with an ordinance pursuant to Section 35 sub-section 1 no. 2,
8. markets a batch which has not been released for marketing, in breach of Section 32 sub-section 1 sentence 1, also in conjunction with an ordinance pursuant to Section 35 sub-section 1 no. 3,
9. markets finished medicinal products as homeopathic or as traditional herbal medicinal products without registration, in breach of Section 38 sub-section 1 sentence 1 or Section 39a sentence 1,
10. conducts the clinical trial of a medicinal product in breach of Section 40 sub-section 1 sentence 3 nos. 2, 2a letter a, no. 3, 4, 5, 6 or 8, in each case also in conjunction with sub-section 4 or Section 41,

11. in breach of Section 40 sub-section 1 sentence 2, begins the clinical trial of a medicinal product,
12. in breach of Section 47a sub-section 1 sentence 1, dispenses without a prescription one of the medicinal products specified therein if the act is not punishable pursuant to Section 95 sub-section 1 no. 5a,
13. in breach of Section 48 sub-section 1 sentence 1 no. 1, in conjunction with an ordinance pursuant to Section 48 sub-section 2 no. 1 or 2, dispenses medicinal products if such action is not subject to penalty under Section 95 sub-section 1 no. 6,
14. engages in wholesale trade without permission pursuant to Section 52a sub-section 1 sentence 1,
15. prescribes or dispenses a medicinal product in breach of Section 56a sub-section 4,
16. in breach of Section 57 sub-section 1a sentence 1, in conjunction with an ordinance pursuant to Section 56a sub-section 3 sentence 1 no. 2, is in possession of a medicinal product specified therein,
17. in breach of Section 59 sub-section 2 sentence 1, produces foodstuffs,
18. in breach of Section 59a sub-section 1 or 2 acquires, offers, stores, packages, carries on his/her person or markets substances or preparations from substances,
- 18a. without an authorisation pursuant to Section 72b sub-section 1 sentence 1, imports tissues or tissue preparations,
- 18b. in breach of Section 72b sub-section 2 sentence 1, imports tissues or tissue preparations,
19. markets a medicinal product intended for administration to human beings although the third party insurance or the exemption or warranty obligation required in compliance with Section 94 does not or no longer exists or
20. infringes Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31st March 2004 laying down Community procedures for the authorisation and supervision of me-

dicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136 p.1), by

- a) failing to attach information or a document correctly or completely, in breach of sentence 1 of Article 6 paragraph 1 of the Regulation in conjunction with the first indent of Article 8 paragraph 3 (c-e, h-ia or ib) of Directive 2001/83/EC of the European Parliament and of the Council of 6th November 2001 on the Community code relating to medicinal products for human use (OJ L 311 p. 67), amended by Directive 2004/27/EC of the European Parliament and of the Council of 31st March 2004 (OJ L 136 p. 34) or
- b) failing to attach information or a document correctly or completely, in breach of sentence 1 of Article 31 paragraph 1 of the Regulation in conjunction with sentence 2 of the first indent of Article 12 paragraph 3 (c-e, h-j or k) of Directive 2001/82/EC of the European Parliament and of the Council of 6th November 2001 on the Community Code relating to veterinary medicinal products (OJ L 311 p.1), amended by Directive 2004/28/EC of the European Parliament and of the Council of 31st March 2004 (OJ number 136 p. 58).

21. (deleted)

shall be liable to imprisonment for a term not exceeding three years or to a fine.

Section 97

Administrative fines

(1) Any person who commits one of the acts indicated in Section 96 by negligence shall be deemed to have committed an administrative offence.

(2) An administrative offence shall also be deemed to have been committed by any person who wilfully or negligently

1. places medicinal products whose expiry date has elapsed on the market, in breach of Section 8 sub-section 2,
2. places medicinal products which do not bear the name or the company name of the pharmaceutical entrepreneur on the market, in breach of Section 9 sub-section 1,
3. places medicinal products on the market, in breach of Section 9 sub-section 2 sentence 1 without having his place of business within the purview of the present Act or in another

Member State of the European Union or another State Party to the Agreement on the European Economic Area,

4. places medicinal products without the prescribed labelling on the market, in breach of Section 10, also in conjunction with Section 109 sub-section 1 sentence 1 or an ordinance pursuant to Section 12 sub-section 1 no. 1,
5. places medicinal products on the market without the required package leaflet, in breach of Section 11 sub-section 1 sentence 1, also in conjunction with sub-sections 2a to 3b or 4, each also in conjunction with an ordinance pursuant to Section 12 sub-section 1 no. 1,
- 5a. by way of derogation from Section 11 sub-section 7 sentence 1, dispenses a partial amount,
6. contravenes an enforceable order pursuant to Section 18 sub-section 2,
7. in breach of Section 20, Section 20c, sub-section 6, also in conjunction with Section 72b sub-section 1 sentence 2, Section 21a sub-sections 7 and 9 sentence 4, Section 29 sub-section 1 or 1c sentence 1, Section 52a sub-section 8, Section 63b sub-section 2, 3 or 4 in each case, also in conjunction with Section 63a sub-section 1 sentence 3 or in breach of Section 63b sub-section 7 sentence 1 or sentence 2, Section 63c sub-section 2 sentence 1, Section 67 sub-section 1, also in conjunction with Section 69a or Section 67 sub-section 2, 3, 5 or 6, fails to notify or fails to do so correctly, completely or in due time,
- 7a. in breach of Section 29 sub-section 1a sentence 1, sub-section 1b or 1d, fails to notify or fails to do so correctly, completely or in due time,
8. introduces medicinal products into the purview of the present Act in breach of Section 30 sub-section 4 sentence 1 no. 2 or Section 73 sub-section 1 or 1a,
9. conducts the clinical trial of a medicinal product in breach of Section 40 sub-section 1 sentence 3 no. 7,
10. in breach of Section 43 sub-sections 1, 2 or 3 sentence 1, places medicinal products on the market professionally or commercially or trades in or dispenses any medicinal products which may be dispensed to consumers without prescription,

11. in breach of Section 43 sub-section 5 sentence 1, dispenses medicinal products intended for administration to animals and not released for trade outside of pharmacies in a manner which is in breach of the relevant provisions,
12. in breach of Section 47 sub-section 1, dispenses medicinal products which may be dispensed to consumers without prescription to persons or bodies other than those specified therein or dispenses them in breach of Section 47 sub-section 1a or obtains the same in breach of section 47 sub-section 2 sentence 1,
- 12a. in breach of Section 47 sub-section 4 sentence 1, dispenses samples or has samples dispensed without a written request, in a package size other than the smallest one or in quantities exceeding the admissible limit,
13. fails to keep the records specified in Section 47 sub-section 1b or Section 47 sub-section 4 sentence 3 or in Section 47a sub-section 2 sentence 2, fails to do so correctly or fails to submit them to the competent authority upon request,
- 13a. in breach of Section 47a sub-section 2 sentence 1, dispenses any medicinal product specified therein without the prescribed labelling,
14. retails medicinal products in breach of Section 50 sub-section 1,
15. in breach of Section 51 sub-section 1, offers medicinal products for sale within the framework of itinerant trading or seeks to procure orders for medicinal products,
16. in breach of Section 52 sub-section 1, places medicinal products on the market on a self-service basis,
17. in breach of Section 55 sub-section 8 sentence 1 or 2, places medicinal products intended for dispensing to the consumer on the market within the purview of the present Act,
- 17a. in breach of Section 56 sub-section 1 sentence 2, fails to send a copy of the prescription or fails to do so in due time,
18. in breach of Section 56 sub-section 2 sentence 1, sub-section 3 or 4 sentence 1 or 2, manufactures medicated feedingstuffs,

19. fails to label medicated feedingstuffs in compliance with Section 56 sub-section 4 sentence 3,
20. in breach of Section 56 sub-section 5 sentence 1, prescribes a medicated feedingstuff or has it manufactured,
21. in breach of Section 56a sub-section 1 sentence 1 no. 1, 2, 3 or 4, in each case also in conjunction with sentence 3, prescribes, dispenses or administers medicinal products which:
 - a) are intended for use on animals not used in food production and may be dispensed to consumers on prescription only,
 - b) may be dispensed to consumers without a prescription,
- 21a. in breach of Section 56a sub-section 1 sentence 4, prescribes or dispenses medicated pre-mixes,
22. in breach of Section 57 sub-section 1, acquires medicinal products which may be dispensed to consumers without a prescription,
23. in breach of Section 58 sub-section 1 sentence 2 or 3, administers medicinal products to food-producing animals,
24. contravenes an obligation to keep records or to submit them in compliance with Section 59 sub-section 4,
 - 24a. in breach of Section 59b sentence 1, fails to place substances at the disposal of the competent authority or fails to do so correctly and in due time,
 - 24b. in breach of Section 59c sentence 1, also in conjunction with sentence 2, fails to keep any of the records mentioned therein, fails to do so correctly or completely, fails to preserve them or fails to do so for a minimum of three years or fails to submit them to the competent authority or to do so in due time,
 - 24c. in breach of Section 63a sub-section 1 sentence 1, fails to appoint a Graduated Plan Officer or, in breach of Section 63a sub-section 3, fails to give notice or fails to do so completely or in due time,
 - 24d. in breach of Section 63a sub-section 1 sentence 5, works as a Graduated Plan Officer,

- 24e. in breach of Section 63c sub-section 3 sentence 1, fails to notify or fails to do so on time,
- 24f. in breach of Section 63c sub-section 4, fails to make a report or fails to do so on time,
- 25. contravenes an enforceable order pursuant to Section 64 sub-section 4 no. 4, also in conjunction with Section 69a,
- 26. contravenes the obligation to tolerate or to collaborate as defined in Section 66, also in conjunction with Section 69a,
- 27. in breach of an enforceable order pursuant to Section 74 sub-section 1 sentence 2 no. 3, fails to present a consignment for clearance,
- 27a. in breach of Section 74a sub-section 1 sentence 1, fails to appoint an information officer or, in breach of Section 74a sub-section 3, fails to inform the competent authority or fails to do so completely or in due time,
- 27b. in breach of Section 74a sub-section 1 sentence 4, works as an information officer,
- 28. in breach of Section 75 sub-section 1 sentence 1, appoints a person as pharmaceutical consultant,
- 29. in breach of Section 75 sub-section 1 sentence 3, works as a pharmaceutical consultant,
- 30. contravenes an obligation to record, to inform or to present records in compliance with Section 76 sub-section 1 sentence 2 or sub-section 2,
- 30a. in breach of Section 109 sub-section 1 sentence 2, places a finished medicinal product on the market,
- 31. contravenes an ordinance pursuant to Section 7 sub-section 2 sentence 2, Section 12 sub-section 1 no. 3 letter a, Section 12 sub-section 1b, Section 42 sub-section 3, Section 54 sub-section 1, Section 56a sub-section 3, Section 57 sub-section 2, Section 58 sub-section 2 or Section 74 sub-section 2, in so far as it relates to this regulation on administrative fines for specific cases,

32. in breach of sentence 1 or 2 of Article 16 paragraph 2 of Regulation (EC) No. 726/2004 in conjunction with the first indent of Article 8 paragraph 3 (c-e, h-ia or ib) of Directive 2001/83/EC or sentence 1 or 2 of Article 41 paragraph 4 of Regulation (EC) No. 726/2004 in conjunction with sentence 2 of the first indent of Article 12 paragraph 3 (c-e, h-j or k) of Directive 2001/82/EC, each in conjunction with Section 29 sub-section 4 sentence 2, fails to inform the European Medicines Agency or the competent higher federal authority of information referred to therein, or to pass on the information correctly, completely or in due time,
33. in breach of Article 24 paragraph 1 sub-paragraph 1 or paragraph 2 sentence 1 or Article 49 paragraph 1 sub-paragraph 1 or paragraph 2 sentence 1 of Regulation (EC) No. 726/2004 in each case in conjunction with Section 29 sub-section 4 sentence 2, fails to ensure that the competent higher federal authority or the European Medicines Agency is notified of any of the side-effects mentioned therein,
34. in breach of Article 24 paragraph 3 sub-paragraph 1 or Article 49 paragraph 3 sub-paragraph 1 of Regulation (EC) No 726/2004 fails to keep a document described therein or keeps it incorrectly or incompletely or
35. in breach of Article 1 of Regulation (EC) No. 540/95 of the Commission of 10 March 1995 laying down the arrangements for reporting non-serious suspected unexpected adverse reactions which are not serious, whether arising in the Community or in a third country, to medicinal products for human or veterinary use authorised in accordance with the provisions of Regulation (EEC) No 2309/93 (OJ L 55 p. 5), in conjunction with Section 63b sub-section 8 sentence 2, fails to ensure that the European Medicines Agency and the competent higher federal authority are notified of a side-effect mentioned therein.

(3) The committing of an administrative offence may be liable to a fine not exceeding 25,000 euros.

(4) The administrative authority within the meaning of Section 36 sub-section 1 no. 1 of the Act on Administrative Offences shall be the competent higher federal authority pursuant to Section 77 in the cases provided for in sub-section 1 in conjunction with Section 96 nos. 6, 20 and 21, sub-section 2 no. 7 in conjunction with Section 29 sub-section 1 and Section 63b sub-sections 2, 3 and 4 and sub-section 2 nos. 32 to 35.

Section 98

Confiscation

Materials connected with an offence as defined in Section 95 or Section 96 or an administrative offence as defined in Section 97 may be confiscated. Section 74a of the Penal Code and Section 23 of the Law on Administrative Offences shall apply.

Section 98a
Extended forfeiture

In the cases mentioned in Section 95 sub-section 1 no. 2a, as well as the manufacture and placing on the market of counterfeit medicinal products pursuant to Section 95 sub-section 1 no. 3a in conjunction with Section 8 sub-section 1 no. 1a, Section 73d of the Penal Code shall apply if the perpetrator acts commercially or as a member of a gang which has come together for the recurrent commission of such acts.

EIGHTEENTH CHAPTER
TRANSITIONAL AND INTERIM PROVISIONS

First sub-chapter

Transitional provisions arising out of the Law on the Reform of Drug Legislation

Section 99
1961 Drug Law

The 1961 Drug Law within the meaning of the present Act is the Law on the Trade in Drugs of 16th May 1961 (Federal Law Gazette I p. 533) last amended by the law of 2nd July 1975 (Federal Law Gazette I p. 1745).

Section 100

(1) Any authorisation which had been granted pursuant to Section 12 sub-section 1 or Section 19 sub-section 1 of the 1961 Drug Law and was still valid on 1st January 1978, shall continue to be valid to the previous extent as an authorisation within the meaning of Section 13 sub-section 1 sentence 1.

(2) Any authorisation which is considered as granted pursuant to Section 53 sub-section 1 or Section 56 of the 1961 Drug Law and was still valid on 1st January 1978, shall continue to

be valid to the previous extent as an authorisation within the meaning of Section 13 sub-section 1 sentence 1.

(3) Where the manufacture of medicinal products did not require an authorisation pursuant to the 1961 Drug Law, but requires an authorisation pursuant to Section 13 sub-section 1 sentence 1, such an authorisation shall be deemed to be granted to any person who had been carrying out the activity of manufacturing medicinal products, with an authorisation to do the same, for a period of at least three years on 1st January 1978; however, only in so far as manufacture is restricted to such medicinal products as had been manufactured previously or medicinal products which are similar in composition.

Section 101

(deleted)

Section 102

(1) Any person who exercises the function of Production Manager, with an authorisation to do so, on 1st January 1978 shall continue to exercise this function to the same extent as hitherto.

(2) Any person who, on 1st January 1978, is in possession of the expert knowledge pursuant to Section 14 sub-section 1 of the 1961 Drug Law and does not exercise the function of Production Manager, may exercise the function of Production Manager if evidence of two years of practical experience in the manufacture of medicinal products can be shown. If the practical experience was obtained prior to 10th June 1965, proof shall be submitted of an additional year of practical experience prior to the commencement of this person's activity.

(3) Any person who had commenced university studies pursuant to Section 15 sub-section 1 prior to 10th June 1975 shall be deemed to have acquired expert knowledge as a Production Manager, if he/she completed his/her studies by 10th June 1985 and exercised a function pursuant to Section 15 sub-sections 1 and 3 for at least two years. This shall be without prejudice to the provisions contained in sub-section 2.

(4) Sub-sections 2 and 3 shall apply *mutatis mutandis* to any person seeking to work as a Quality Control Manager.

Section 102a

(deleted)

Section 103

(1) In the case of medicinal products which, pursuant to Section 19a or Section 19d in conjunction with Section 19a of the 1961 Drug Law, are authorised for marketing on 1st January 1978 or which are deemed to have been granted a marketing authorisation on 1st January 1978 pursuant to Article 4 sub-section 1 of the Law on the Establishment of a Federal Agency for Sera and Vaccines of 7th July 1972 (Federal Law Gazette I, p. 1163), a marketing authorisation pursuant to Section 25 shall be deemed to be granted. Sections 28 to 31 shall apply *mutatis mutandis* to the marketing authorisation.

(2) (deleted)

Section 104

(deleted)

Section 105

(1) Finished medicinal products which are medicinal products within the meaning of Section 2 sub-section 1 or sub-section 2 no. 1 and are on the market on 1st January 1978 are deemed to be authorised for marketing if they are on the market on 1st September 1976 or, by virtue of an application submitted by this date, are registered in the register for proprietary medicinal products pursuant to the 1961 Drug Law.

(2) Notification of finished medicinal products pursuant to sub-section 1 must be submitted, within a period of six months from the 1st January 1978, to the competent higher federal authority indicating the designation of the active substances according to their nature and quantity as well as their fields of application. In making a notification regarding a homeopathic medicinal product, the particulars bearing on the fields of application may be omitted. A copy of the notification shall be sent to the competent authority indicating the stipulated particulars. The finished medicinal products may only be kept on the market if the deadline for notification is observed.

(3) The marketing authorisation for a medicinal product, notification of which has been submitted within the deadline pursuant to sub-section 2 shall expire by way of derogation from Section 31 sub-section 1 no. 3, on 30th April 1990 unless an application for a prolongation of the marketing authorisation, or for registration, is submitted prior to the date of expiry, or unless the medicinal product is exempted from the need for a marketing authorisation or registration by ordinance. Section 31 sub-section 4 sentence 1 shall not apply to the marketing authorisa-

tion pursuant to sentence 1 if the renouncement pursuant to Section 31 sub-section 1 sentence 1 no. 2 is submitted by 31st January 2001.

(3a) Until the first prolongation of the marketing authorisation, a modification pursuant to Section 29 sub-section 2a sentence 1 no. 1 in the case of finished medicinal products pursuant to sub-section 1, in so far as it concerns the fields of application, and no. 3 shall only be admissible if it is necessary to correct the flaws, bearing on the efficacy or safety of the medicinal product, indicated to the applicant by the competent higher federal authority; furthermore, Section 29 sub-section 2a sentence 1 nos. 1, 2 and 5 shall not apply to finished medicinal products pursuant to sub-section 1 until the first prolongation of the marketing authorisation. By way of derogation from section 29 sub-section 3, a finished medicinal product pursuant to sub-section 1, which has been manufactured using a manufacturing procedure described in the homeopathic section of the Pharmacopoeia, may be marketed up until the first prolongation of the marketing authorisation:

1. with a change in the composition of the medically active constituents in type and quantity, if the change consists only in the fact that one or several medically active constituents, contained up to that point in the medicinal product, are no longer present after the change or are present in lesser quantities,
2. with a change in the quantity of the medically active constituent and, within the hitherto existing area of application, with a change in indication if the medicinal product is adjusted as a whole to the results published pursuant to Section 25 sub-section 7 sentence 1 in the version in force before 17th August 1994,
3. (deleted)
4. with a change in the quantity of the medically active constituents, in so far as it is a medicinal product with several active ingredients the number of which has been reduced, or
5. with a change in the type or quantity of the medically active constituents without increasing their number within the same area of application and the same school of therapy if the medicinal product, as a whole, is adjusted to a result published pursuant to Section 25 sub-section 7 sentence 1 in the version in force before 17th August 1994 or to a medicinal product model submitted by the Federal Institute for Drugs and Medical Devices and the medicinal product does not become subject to prescription as a result of the adjustment;

a change shall only be admissible in so far as it is necessary for the purpose of correcting the flaw bearing on the efficacy or safety of the medicinal product indicated to the applicant by the competent higher federal authority. The pharmaceutical entrepreneur shall make notification of the change and in the event of a change in the composition, shall cause a clearly differentiating addition, which rules out any possibility of confusion with the previous name, to be made to the previous name of the medicinal product for a period of at least five years. Upon expiry of a period of six months following the notification, the pharmaceutical entrepreneur may market the medicinal product henceforth only in its changed form. In the event that the competent higher federal authority has stipulated the use of a package leaflet with a standard wording for specific medicinal products, by imposition of a condition pursuant to Section 28 sub-section 2 no. 3, the medicinal product may be marketed when changed pursuant to sentence 2 no. 2, by way of derogation from Section 109 sub-section 2, only with a package leaflet pursuant to Section 11.

(4) In applying for a prolongation of the marketing authorisation, documents pursuant to Section 22 sub-section 1 nos. 1 to 6 shall be submitted in derogation of section 31 sub-section 2. The competent higher federal authority shall determine, on a case by case basis, when the documents pursuant to Section 22 sub-section 1 nos. 7 to 15 sub-section 2 no. 1 and sub-section 3a and, in the case of medicated pre-mixes, the documents pursuant to Section 23 sub-section 2 sentences 1 and 2, as well as the analytical expert opinion pursuant to Section 24 sub-section 1 are to be submitted. Upon request by the competent authority, documents shall also be submitted providing evidence that the medicinal product's medically active constituents possess sufficient bioavailability in so far as this is required according to the current state of scientific knowledge. An appraising expertise shall also be submitted. Section 22 sub-section 2 sentence 2 and sub-sections 4 to 7 and Section 23 sub-section 3 shall apply *mutatis mutandis*. The documents referred to in sentences 2 to 5 shall be submitted within a period of four months following the request by the competent higher federal authority.

(4a) In applying for a prolongation of the marketing authorisation pursuant to sub-section 3, documents pursuant to Section 22 sub-section 2 nos. 2 and 3, as well as the expert opinions pursuant to Section 24 sub-section 1 sentence 2 nos. 2 and 3, shall be submitted by 1st February 2001 in cases where these documents have not already been submitted by the applicant; Section 22 sub-section 3 shall apply *mutatis mutandis*. Sentence 1 shall not apply to medicinal products which have been manufactured using a manufacturing procedure described in the homeopathic section of the Pharmacopoeia. In the case of whole blood, plasma and blood cells of human origin, by way of derogation from sentence 1, the documents pursuant to Section 22 sub-section 2 no. 2 and the expert opinion pursuant to Section 24 sub-section 1 sentence 2 no. 2 shall not be required unless substances are contained therein which do not exist naturally in the human body. With the exception of the cases specified in Section 109a,

the marketing authorisation shall expire if the documents stipulated in sentences 1 to 3 are not submitted on time.

(4b) In submitting documents pursuant to Section 22 sub-section 2 no. 2, in the case of veterinary medicinal products which contain pharmacologically active substances which have been tested pursuant to Council Regulation (EEC) No. 2377/90 and listed in one of its Annexes I to III, reference may be made to documents submitted pursuant to that Regulation's Annex V, in so far as a veterinary medicinal product containing this pharmacologically active constituent has already been authorised for marketing in a Member State of the European Communities and the prerequisites for referring to such documents pursuant to Section 24a have been met.

(4c) If the medicinal product pursuant to sub-section 3 has already been authorised for marketing in another Member State of the European Union or another State Party to the Agreement on the European Economic Area, in keeping with Directive 2001/83/EC or Directive 2001/82/EC, the prolongation of the marketing authorisation shall be granted if:

1. the medicinal product is on the market in the other Member State and
2. the applicant
 - a) provides all of the particulars stipulated under Section 22 sub-section 6 and submits the necessary copies and
 - b) declares in writing that the documents submitted pursuant to sub-sections 4 and 4a match the marketing authorisation documents on the basis of which the authorisation was granted in the other Member States,

unless the prolongation of the marketing authorisation could constitute a danger for public health or, in the case of medicinal products intended for administration to animals, a danger to the health of human beings, animals or the environment.

(4d) In applying for registration, documents pursuant to Section 22 sub-section 1 nos. 1 to 4 shall be submitted along with the application in derogation of Section 38 sub-section 2. The documents pursuant to Section 22 sub-section 1 nos. 7 to 15 and sub-section 2 no. 1, as well as the analytical expert opinion pursuant to Section 24 sub-section 1, shall be submitted to the competent higher federal authority upon request. Section 22 sub-sections 4 to 7, with the exception of the draft of the expert information, shall apply *mutatis mutandis*. The documents

stipulated in sentences 2 and 3 shall be submitted within a period of two months following a request by the competent higher federal authority.

(4e) In deciding on an application for prolongation of a marketing authorisation or registration pursuant to sub-section 3 sentence 1, Section 25 sub-section 5 sentence 5 and Section 39 sub-section 1 sentence 2 shall apply *mutatis mutandis*.

(4f) The manufacturing authorisation pursuant to sub-section 1 shall be prolonged upon request pursuant to sub-section 3 sentence 1 for a period of five years if no reason for a refusal pursuant to Section 25 sub-section 2 exists; for additional prolongations, Section 31 shall apply. The particularities of a specific substance group or school of therapy (phytotherapy, homeopathy, anthroposophy) shall be taken into consideration.

(4g) In the case of medicinal products which are blood preparations, Section 25 sub-section 8 shall be applied *mutatis mutandis*.

(5) In the case of flaws, the applicant shall correct the flaws within a reasonable deadline which may, however, not exceed twelve months following the notice of flaws; the correcting of flaws shall be recorded in writing. In the event that the flaws are not corrected within this deadline, the marketing authorisation shall be refused. After a decision has been taken to refuse the marketing authorisation, the submission of documents in order to correct flaws shall not be allowed. In all appropriate cases, the competent authority shall refrain from giving notice of flaws pursuant to sentence 1 first half-sentence and shall instead prolong the marketing authorisation on the basis of sub-section 5a sentences 1 and 2 with a proviso requiring the applicant to correct the flaws within a deadline which it shall set according to its best judgement.

(5a) The competent higher federal authority is empowered to impose conditions on the prolongation of the marketing authorisation pursuant to sub-section 3 sentence 1. Apart from ensuring the requirements stipulated in Section 28 sub-section 2, the contents of conditions may also be geared towards guaranteeing the requirements of quality, safety and efficacy, unless notice must be given of flaws pursuant to sub-section 5 or the prolongation of the marketing authorisation refused as a result of serious deficiencies in the pharmaceutical quality, efficacy or safety. Sentence 2 shall apply *mutatis mutandis* to document requirements pursuant to Section 23 sub-section 1 no. 1. The notice regarding the prolongation shall state whether the condition imposed shall be met immediately or by a deadline to be specified by the competent higher federal authority. Notice shall be given to the competent higher federal authority of the fulfilment of the conditions accompanied by a statutory declaration from an independent counter-expert confirming that the quality of the medicinal product corresponds to the current

state of scientific knowledge. Section 25 sub-section 5 sentences 5, 6 and 8 as well as Section 30 sub-section 2 sentence 1 no. 2 second alternative shall apply *mutatis mutandis*. Sentences 1 to 6 shall apply *mutatis mutandis* to the registration pursuant to sub-section 3 sentence 1.

(5b) No preliminary procedure pursuant to Section 68 of the Rules of the Administrative Court shall be held in the event of an appeal against the decision regarding the prolongation of the marketing authorisation pursuant to sub-section 3 sentence 1. Immediate execution shall be ordered pursuant to Section 80 sub-section 2 no. 4 of the Rules of the Administrative Court, unless the execution would result in undue hardship for the pharmaceutical entrepreneur which is not justified by overriding public interest.

(5c) By way of derogation from sub-section 3 sentence 1, the marketing authorisation for a medicinal product for which a notification was made within the specified time pursuant to sub-section 2 and for which the pharmaceutical entrepreneur declared his intention to withdraw the application to prolong the marketing authorisation pursuant to sub-section 3 sentence 1 by 31st December 1999, shall expire on 1st February 2001 unless the procedure to prolong the marketing authorisation pursuant to sentence 2 is to be resumed. In cases where the pharmaceutical entrepreneur submitted the necessary documents on time in response to a request to that effect issued before 17th August 1994 pursuant to sub-section 4 sentence 2, or if the date of submission of documents for the medicinal product in question was subsequent to that date, or if the request for documents regarding the medicinal product in question was issued after said date, the procedure to prolong the marketing authorisation shall be resumed by the competent federal higher authority upon application by the entrepreneur; the application shall be submitted by 31st January 2001, accompanied by the documents specified in sub-section 4a sentence 1.

(5d) Sub-section 3 sentence 2 and sub-sections 3a to 5c shall apply *mutatis mutandis* to medicinal products for which an application for prolongation was submitted by 30th June 1991, in accordance with Section 4 sub-section 2 of the EC Transition Ordinance of 18th December 1990 (Federal Law Gazette I p. 2915) Annex 3 to Section 2 no. 2, chapter II nos. 1 and 2.

(6) (deleted)

(7) Sub-sections 1 to 5d shall also apply to medicinal products intended for administration to animals which are not finished medicinal products in so far as they are required to have a marketing authorisation or to be registered and are on the market on 1st January 1978.

Section 105a

- (1) (deleted)
- (2) (deleted)

(3) In the case of finished medicinal products, which are not subject to prescription pursuant to Section 49, the competent higher federal authority may, in the first instance, forego the examination of the expert information submitted and exempt the pharmaceutical entrepreneur from his or her duties pursuant to Section 11a, and the pharmaceutical consultant from his or her duty pursuant to Section 76 sub-section 1 sentence 1, until the standardized wording of the expert information for the medicinal products in question is stipulated by imposition of conditions pursuant to Section 28 sub-section 2 no. 3.

(4) Sub-sections 1 to 3 shall not apply to medicinal products which are intended for administration to animals or which fall within the competence of the Paul Ehrlich Institute.

Section 105b

The right to the payment of costs which are to be levied pursuant to Section 33 sub-section 1, in conjunction with an ordinance issued pursuant to Section 33 sub-section 2 or Section 39 sub-section 3 for the prolongation of a marketing authorisation or for the registration of a finished medicinal product within the meaning of Section 105 sub-section 1, shall expire after a period of four years subsequent to informing the applicant of the final decision regarding the prolongation of the marketing authorisation or registration.

Section 106

(deleted)

Section 107

(deleted)

Section 108

(deleted)

Section 108a

Any batch of serum, vaccine, test allergen, test serum or test antigens which was released at the time of the coming into effect of the accession pursuant to Section 16 of the Second Regulations Implementing the Drug Law of 1st December 1986 (Law Gazette I, No. 36 p. 483) shall be deemed to be released within the meaning of Section 32 sub-section 1 sentence

1 in the territory stipulated in Article 3 of the Unification Treaty. Section 32 sub-section 5 shall apply to the release *mutatis mutandis*.

Section 108b

(deleted)

Section 109

(1) Finished medicinal products which are medicinal products within the meaning of Section 2 sub-section 1 or sub-section 2 no. 1 and were on the market on 1st January 1978, shall be governed by section 10 with the proviso that the marketing authorisation number stipulated in Section 10 sub-section 1 sentence 1 no. 3 be replaced, where available, by the registration number recorded in the specialty register pursuant to the 1961 Drug Law with the abbreviation 'Reg.-Nr.'. Finished medicinal products pursuant to sentence 1 and pursuant to Section 105 sub-section 5d may be placed on the market only if the following indication is included in the package leaflet pursuant to Section 11: 'This medicinal product has been placed on the market under the statutory transitional regulations. Official testing to determine pharmaceutical quality, efficacy and safety has not yet been concluded'. The indication pursuant to sentence 2 shall also be included in the expert information pursuant to Section 11a where it is provided. Sentences 1 to 4 shall be valid until the first prolongation of the marketing authorisation or registration.

(2) The text for labels and package leaflets shall be submitted by 31st July 2001 at the latest. Until that date, medicinal products pursuant to sub-section 1 sentence 1 may be placed on the market by the pharmaceutical entrepreneur, thereafter by wholesalers and retailers with labels and package leaflets which are in keeping with the regulations in force up to the date specified in sentence 1.

(3) Finished medicinal products which are medicinal products within the meaning of Section 105 sub-section 1, and are released for trade outside of pharmacies pursuant to Section 44 sub-section 1 or sub-section 2 nos. 1 to 3 or Section 45 and fall under letters a to e may, without prejudice to the provisions contained in sub-sections 1 and 2, be placed on the market from 1st January 1992 by the pharmaceutical entrepreneur if they carry one or several of the following indications on their containers and, if used, on their outer packaging and package leaflet:

'Traditionally used:

a) to strengthen and fortify,

- b) to improve the state of health,
- c) to support the functioning of the organs,
- d) for prevention,
- e) as a mild-action medicinal product.'

Sentence 1 shall not apply in cases where the fields of application are restricted to the results published within the framework of a marketing authorisation pursuant to Section 25 sub-section 1 or a marketing authorisation pursuant to the version in force before 17th August 1994.

Section 109a

(1) In the case of medicinal products specified in Section 109 sub-section 3, as well as medicinal products which are not subject to a prescription and are not excluded from trade outside of pharmacies by virtue of an ordinance issued on the basis of Section 45 or Section 46 as a result of their components, their pharmaceutical forms or because they are chemical compounds with specific pharmacological effects or because such compounds have been added to them, the prolongation of the marketing authorisation can be granted pursuant to Section 105 sub-section 3 and, furthermore, pursuant to Section 31 in accordance with sub-sections 2 and 3.

(2) The requirements in respect of the necessary quality are deemed to be met when the documents pursuant to Section 22 sub-section 2 no. 1, as well as the analytical expert opinions pursuant to Section 24 sub-section 1, have been submitted and the pharmaceutical entrepreneur has made a statutory declaration that the medicinal product has been tested in accordance with the general administrative regulation pursuant to Section 26 and displays the necessary pharmaceutical quality. The form and content of the statutory declaration shall be stipulated by the competent higher federal authority.

(3) The requirements in respect of the efficacy are deemed to be met when the medicinal product claims efficacy in fields of application which are recognized in a list of the fields of application for substances or combinations of substances compiled by the competent higher federal authority after a hearing by a commission set up by the Federal Ministry to which Section 25 sub-section 6 sentences 4 to 6 shall apply *mutatis mutandis*. These fields of application shall be stipulated taking into account the peculiarities of the particular medicinal product and the experience which has been handed down and documented and shall be accompanied by the additional remark: 'Traditionally used'. Such fields of application are: 'to strengthen and fortify the ...', 'to improve the state of health ...', 'to support the functioning of the ...', 'for prevention against ...', 'as a mild-action medicinal product for use in ...'. Fields of application which would

result in the medicinal product being excluded from trade outside of pharmacies may not be recognized.

(4) Sub-sections 1 to 3 shall apply only in cases where the documents pursuant to Section 105 sub-section 4a have not been submitted and the applicant declares in writing that he or she is pursuing a prolongation of the marketing authorisation pursuant to Section 105 sub-section 3 in accordance with sub-sections 2 and 3.

(4a) By way of derogation from sub-section 4, sub-sections 2 and 3 shall apply to medicinal products pursuant to sub-section 1, if the prolongation of the marketing authorisation would normally be refused owing to the fact that one of the published results substantiating the medicinal product's efficacy pursuant to Section 25 sub-section 7 sentence 1 of the version in force prior to 17th August 1994, can no longer be recognised.

Section 110

In the case of medicinal products which are subject to a marketing authorisation pursuant to Section 21, or to registration pursuant to Section 38, and which are on the market on 1st January 1978, the competent higher federal authority can stipulate, by imposing conditions, the affixing of warnings in so far as they are necessary to prevent a direct or indirect health hazard to human beings or animals by the administration of the medicinal product.

Section 111

(deleted)

Section 112

Any person who, on 1st January 1978, places medicinal products within the meaning of Section 2 sub-section 1 or sub-section 2 no. 1, which are released for trade outside of pharmacies, on the market, on a retail basis outside of pharmacies, may continue to pursue this activity in so far as he or she was entitled to do so pursuant to the Act on the Exercise of Professions in the Retail Trade (*Gesetz über die Berufsausübung im Einzelhandel*) of 5th August 1957 (Federal Law Gazette I, p. 1121), amended by Article 150 sub-section 2 no. 15 of the Law of 24th May 1968 (Federal Law Gazette I, p. 503).

Section 113

By way of derogation from Section 58 sub-section 1, medicinal products may be administered if it can be inferred from the labelling or accompanying documents that the medicinal products may continue to be placed on the market pursuant to Section 105 sub-section 1.

Section 114

(deleted)

Section 115

Any person who exercises the function of a pharmaceutical consultant pursuant to Section 75 on 1st January 1978, shall not need to provide the proof of training stipulated therein.

Section 116

Physicians who are entitled, on 1st January 1978, under provisions contained in the legislation of the individual *Land* to manufacture and dispense medicinal products to persons being treated by them, may continue to pursue this activity to the same extent as hitherto. Section 78 shall be applicable.

Section 117

(deleted)

Section 118

Section 84 shall not apply to damage caused by medicinal products which were dispensed prior to 1st January 1978.

Section 119

Finished medicinal products which are medicinal products within the meaning of Section 2 sub-section 1 or sub-section 2 no. 1 and which are on the market in the territory referred to in Article 3 of the Unification Treaty, at the time when accession takes effect, may continue to be marketed by wholesalers and retailers without the package leaflet required under Section 11, in so far as they correspond to the provisions contained in the medical legislation of the German Democratic Republic in force before accession took effect. The competent higher federal authority may, by imposition of conditions, stipulate that warnings must be affixed, in so far as this

is deemed necessary for the prevention of direct or indirect danger to human beings or animals as a result of the application of the medicinal product.

Section 120

In the case of a clinical trial which is being carried out in the territory mentioned in Article 3 of the Unification Treaty at the time when accession takes effect, the insurance policy required under Section 40 sub-section 1 no. 8 shall be taken out.

Section 121

(deleted)

Section 122

The obligation to notify pursuant to Section 67 shall not apply to undertakings, facilities and persons in the territory mentioned in Article 3 of the Unification Treaty who are already pursuing an activity within the meaning of that provision at the time when accession takes effect.

Section 123

A person shall also be deemed to possess the necessary expert knowledge as a pharmaceutical consultant pursuant to Section 75 sub-section 2 no. 2, if he or she has successfully completed a course of studies as a pharmaceutical engineer, a pharmacy assistant or veterinary engineer in the territory mentioned in Article 3 of the Unification Treaty.

Section 124

Sections 84 to 94a shall not be applicable to medicinal products which were dispensed to consumers in the territory mentioned in Article 3 of the Unification Treaty before accession took effect.

Second sub-chapter

Transitional provisions arising out of the First Act Amending the Drug Law

Section 125

(1) After hearing the commissions pursuant to Section 25 sub-sections 6 and 7, the competent higher federal authority shall lay down, in the case of medicinal products which were authorised for marketing on 2nd March 1983, the deadline by which the documents regarding the test method pursuant to Section 23 sub-section 2 sentence 3 are to be submitted.

(2) In the case of medicinal products for which a marketing authorisation was applied after 1st March 1983, and before 4th March 1998, the provisions contained in Section 23 shall apply with the proviso that the documents regarding the test methods do not have to be submitted prior to the deadline referred to in sub-section 1.

(3) In cases where a deadline for the submission of documents regarding the test method pursuant to sub-section 1 has been set, the marketing authorisation may be withdrawn if the documents are not submitted or if they fail to meet the requirements stipulated in Section 23 sub-section 2 sentence 3.

Section 126

In the case of medicinal products intended for administration to animals, and which are authorised for marketing in the territory mentioned in Article 3 of the Unification Treaty at the time when accession takes effect, Section 125 sub-sections 1 and 3 shall apply *mutatis mutandis*.

Third sub-chapter

Transitional provisions arising out of the Second Act Amending the Drug Law

Section 127

(1) Medicinal products which are on the market on 1st February 1987 and are subject to the labelling provisions contained in Section 10, must be placed on the market by the pharmaceutical entrepreneur in accordance with the provision contained in Section 10 sub-section 1 no. 9 within a period of one year after the first prolongation of the marketing authorisation on 1st February 1987, or after the exemption from the marketing authorisation or, in the case of homeopathic medicinal products, five years after the 1st February 1987. Up to this point in time, medicinal products pursuant to sentence 1 may be placed on the market by the pharmaceutical entrepreneur, after this, they may continue to be placed on the market by wholesalers and retailers without indication of an expiry date if the medicinal product's shelf-life is more than three years or, in the case of medicinal products governed by the provisions contained in Section

109, more than two years. This shall be without prejudice to the provisions contained in Section 109.

(2) Medicinal products which are on the market on 1st February 1987 and are subject to the labelling regulations of Section 10 sub-section 1a, may be placed on the market until 31st December 1988 by the pharmaceutical entrepreneur, and even after this deadline by wholesalers and retailers without the particulars stipulated in Section 10 sub-section 1a.

Section 128

(1) In the case of finished medicinal products which are on the market on 1st February 1987, the pharmaceutical entrepreneur shall submit the wording of the expert information to the competent higher federal authority along with the first application for the prolongation of the marketing authorisation or registration filed on 1st February 1987. Sentence 1 shall not apply in so far as the competent higher federal authority has exempted medicinal products which are not subjected to prescription pursuant to Section 49 from the obligations contained in Section 11a until further notice; in this case, the draft of the expert information is to be submitted upon request to the competent higher federal authority.

(2) In the cases described in sub-section 1 Section 11a, Section 47 sub-section 3 sentence 2 and Section 76 sub-section 1 shall apply from the date of the prolongation of the marketing authorisation or the registration or the stipulation of a specific expert information by means of Section 36 sub-section 1, or in the cases described in sub-section 1 sentence 2, six months after the decision of the competent higher federal authorities on the contents of the expert information. Finished medicinal products, the package leaflet of which fails to comply with the provisions contained in Section 11 sub-section 1 in the version of the Second Law Amending the Drug Law, may be placed on the market until this point in time.

Section 129

Section 11 sub-section 1a shall apply to medicinal products which are on the market on 1st February 1987 subject to the proviso that their package leaflet must be forwarded to the competent authority after the next prolongation of the authorisation or registration.

Section 130

Any person who is appointed as a private expert by 1st February 1987 to test samples pursuant to Section 65 sub-section 2, may continue to exercise this function to the same extent as hitherto.

Section 131

In respect of the obligation to submit or pass on expert information pursuant to Section 11a, Section 128 shall apply *mutatis mutandis* to medicinal products which are on the market in the territory stipulated in Article 3 of the Unification Treaty at the time of the coming into effect of accession.

Fourth sub-chapter

Transitional provisions arising out of the Fifth Act Amending the Drug Law

Section 132

(1) Medicinal products which are on the market on 17th August 1994 and are subject to the provisions contained in Sections 10 and 11, must be placed on the market by the pharmaceutical entrepreneur in accordance with the provisions contained in Sections 10 and 11 within a period of one year after the first prolongation of the marketing authorisation granted on 17th August 1994, or in so far as they are exempt from the need for a marketing authorisation, from the time stipulated in the ordinance pursuant to section 36 or, in so far as homeopathic medicinal products are concerned, five years after 17th August 1994. Until such time, medicinal products referred to in sentence 1 may continue to be placed on the market by the pharmaceutical entrepreneur, and thereafter such medicinal products may continue to be placed on the market by wholesalers and retailers with labelling and package leaflets which comply with the provisions in force up to 17th August 1994. The foregoing shall be without prejudice to the provisions contained in section 109.

(2) In the case of finished medicinal products which are on the market on 17th August 1994, the pharmaceutical entrepreneur shall submit the wording of the expert information in compliance with Section 11a of this version of the present Act to the competent higher federal authority along with the first application for the prolongation of the marketing authorisation filed on 17th August 1994. This shall be without prejudice to the provisions contained in Section 128 sub-section 1 sentence 2.

(2a) Marketing authorisations which are not in compliance with section 16 shall be adapted to Section 16 by 17th August 1996. Sentence 1 shall apply to Section 72 *mutatis mutandis*.

(2b) Any person who exercises the function of Production Manager for the manufacture of blood preparations or as (Quality) Control Manager for the testing of blood preparations on 17th August 1994 and fulfils the prerequisites of Section 15 sub-section 3 as contained in the version in force up until 17th August 1994, may continue to exercise this function.

(3) Until the date specified in Article 14 of EEC Council Regulation No. 2377/90, Section 23 sub-section 1 nos. 2 and 3 and Section 25 sub-section 2 sentence 1 no. 6c shall not apply to medicinal products the pharmaceutically active constituent of which was authorised for marketing on 1st January 1992 within the purview of the present Act in a medicinal product which is intended for administration to food-producing animals.

(4) Section 39 sub-section 2 nos. 4a and 5a shall not apply to medicinal products which were registered by 31st December 1993 or for which an application for registration was submitted by that date or for which a notification was made pursuant to Section 105 sub-section 2 and which were placed on the market pursuant to Section 38 sub-section 1 sentence 3 in the version valid before 11th September 1998. Furthermore, Section 39 sub-section 2 no. 4a shall not apply to medicinal products pursuant to sentence 1 in respect of which a re-registration is being applied for because an ingredient is to be removed or several ingredients are to be removed or the degree of dilution of ingredients is to be increased. Furthermore, section 39 sub-section 2 nos. 4a and 5a shall not apply, in the case of decisions bearing on the registration or on its prolongation, to medicinal products which are identical, in the nature and quantity of their components as well as with regard to their pharmaceutical forms, with medicinal products specified in sentence 1. Section 21 sub-section 2a sentence 5 and Section 56a sub-section 2 sentence 5 shall also apply to medicinal products intended for administration to animals whose degree of dilution is below the sixth decimal potency, in so far as they have been registered pursuant to sentence 1 or 2 or have been exempted from registration.

Fifth sub-chapter

Transitional provisions arising of the Seventh Act Amending the Drug Law

Section 133

The obligation to notify pursuant to Section 67 in conjunction with Section 69a shall apply to the enterprises, facilities and persons specified in Section 59c who were already exercis-

ing one of the functions provided for in Section 59c on 4th March 1998 with the proviso that the notification must be made at the latest by 1st April 1998.

Sixth sub-chapter
Transitional provisions arising out of the Transfusion Act

Section 134

Any person who, at the time of the entry into force of the Transfusion Act of 1st July 1998 (Federal Law Gazette I p. 1752), exercises the function of Production Manager in the manufacture of or as Quality Control Manager for the testing of blood preparations or sera from human blood and meets the requirements stipulated by Section 15 sub-section 3 in the version valid until that date, may continue to exercise that function. Any person who, at the time specified in sentence 1 exercises the function of pre-treating persons for the separation of blood stem cells or other blood components according to the technological and scientific state of the art, may continue to exercise this function.

Seventh sub-chapter
Transitional provisions arising out of the Eighth Act Amending the Drug Law

Section 135

(1) Medicinal products which are on the market on 11th September 1998 and are subject to the provisions contained in Sections 10 and 11, must be placed on the market one year after the first prolongation of the marketing authorisation on 11th September 1998 or, in so far as they are exempt from the marketing authorisation, on the date specified in the ordinance pursuant to Section 36 or, in so far as they are homeopathic medicinal products, on 1st October 2003, by the pharmaceutical entrepreneur pursuant to the provisions contained in Sections 10 and 11. Until this date, medicinal products pursuant to sentence 1 may be placed on the market by the pharmaceutical entrepreneur; after this date such medicinal products may continue to be placed on the market by wholesalers and retailers with labelling and package leaflets which are in accordance with the provisions in force up to 11th September 1998. This shall be without prejudice to Section 109.

(2) Any person who on 11th September 1998 exercises the function of Production Manager or Quality Control Manager for the medicinal products or active substances named in Sec-

tion 15 sub-section 3a and is authorised to do so, may continue to exercise this function to the same extent as hitherto. Until 1st October 2001, Section 15 sub-section 4 shall not apply to the practical activities involved in the manufacture of medicinal products and active substances pursuant to section 15 sub-section 3a.

(3) Homeopathic medicinal products which are on the market on 11th September 1998, and for which an application for registration was submitted by 1st October 1999 may, by way of derogation from Section 38 sub-section 1 sentence 3, continue to be placed on the market until a decision has been taken on the application for registration as long as they are in compliance with the provisions in force until 11th September 1998.

(4) In the amended version, Section 41 no. 6 shall not apply to declarations of consent which were made prior to 11th September 1998.

Eighth sub-chapter

Transitional provisions arising out of the Tenth Act Amending the Drug Law

Section 136

(1) In the case of medicinal products for which the prolongation applied for under Section 105 sub-section 3 sentence 1 has already been granted, the documents specified in Section 105 sub-section 4a sentence 1 shall be submitted, at the latest, with the application pursuant to Section 31 sub-section 1 no. 3. In the case of such medicinal products, the marketing authorisation shall be prolonged if no reason for refusal pursuant to Section 25 sub-section 2 exists; Section 31 shall apply to further prolongations.

(1a) With regard to medicinal products pursuant to Section 105 sub-section 3 sentence 1 which are manufactured according to a procedure which is not described in the homeopathic section of the Pharmacopoeia, Section 105 sub-section 3 sentence 2 in the version in force up to 12th July 2000 shall apply until such time as a decision is made by the Commission pursuant to Section 55 sub-section 6 on the inclusion of this manufacturing procedure, insofar as an application has been submitted by 1st October 2000 regarding its inclusion in the homeopathic section of the Pharmacopoeia.

(2) In the case of medicinal products with respect to which the applicant has been informed prior to 12th July 2000 of flaws regarding their efficacy or safety, Section 105 sub-section 3a in the version in force up to 12th July 2000 shall apply.

(2a) Section 105 sub-section 3a sentence 2, in the version in force up to 12th July 2000, shall apply up to 31st January 2001 with the proviso that a notification of flaws is not necessary and a notification is admissible only if it is restricted to the fact that one or several medically active constituents contained up to that point in the medicinal product are no longer present after the notification.

(3) In the case of medicinal products which have been manufactured according to a manufacturing procedure described in the homeopathic section of the Pharmacopoeia, Section 105 sub-section 5c shall continue to apply in the version in force prior to 12th July 2000.

Ninth sub-chapter

Transitional provisions arising out of the Eleventh Act Amending the Drug Law

Section 137

By way of derogation from Section 13 sub-section 2, Section 47 sub-section 1 no. 6, Section 56 sub-section 2 sentence 2 and sub-section 5 sentence 1, medicated feedingstuffs may continue to be manufactured, placed on the market and used until 31st December 2005 according to the regulations in force up to 1st November 2002.

By way of derogation from Section 56 sub-section 2 sentence 1, medicated feedingstuffs may be manufactured using a maximum of three medicated pre-mixes, each of which are authorised for administration to the animal species in question, until 31st December 2005, if:

1. no authorised medicated pre-mix exists for the field of application in question,
2. in individual cases, the medicated feedingstuff does not contain more than two medicated pre-mixes containing antibiotics and
3. a homogenous and stable distribution of the active constituents throughout the medicated feedingstuff is guaranteed.

By way of derogation from sentence 2 no. 2, a medicated feedingstuff may contain only one medicated pre-mix containing antibiotics if the medicated pre-mix contains two or more substances with an antibiotic effect.

Tenth sub-chapter

Transitional provisions arising out of the Twelfth Act Amending the Drug Law

Section 138

(1) With regard to the manufacture and import of active substances of microbial origin, as well as other substances of human origin intended for the manufacture of medicinal products which are manufactured or imported into the territory governed by the present Act, commercially or professionally, for the purpose of distribution to others, Sections 13, 72 and 72a in the version in force until 5th August 2004 shall be applicable until 1st September 2006, unless blood and blood components of human origin destined for the manufacture of medicinal products are concerned. If blood is withdrawn for the processing and multiplication of autologous somatic cells within the framework of tissue engineering for the purpose of tissue regeneration, and if an application has not yet been made for a manufacturing authorisation for this purpose, Section 13 shall not be applicable until 1st September 2006.

(2) Any person who is authorised, on 5th August 2004 to exercise the functions of a Production or Quality Control Manager, may continue to exercise this function, in derogation of Section 15 sub-section 1.

(3) Sections 40 to 42, 96 no. 10 and Section 97 sub-section 2 no. 9, in the version in force until 6th August 2004, shall apply to clinical trials of medicinal products on human beings for which the documents required pursuant to Section 40 sub-section 1 sentence 2 in the version in force until 6th August 2004 were submitted to the Ethics Committee responsible for the chief investigator before 6th August 2004.

(4) Any person who is authorised to exercise the function of wholesaler on 6th August 2004 and submits an application pursuant to Section 52a sub-section 1, for an authorisation to conduct the wholesale distribution of medicinal products, by 1st December 2004, may, in derogation of Section 52a sub-section 1, continue to exercise this function until the decision has been taken with respect to the application; Section 52a sub-section 3 sentences 2 to 3 shall not apply.

(5) An official approval regarding the wholesale distribution of medicinal products intended for administration to animals, granted on the basis of the ordinance pursuant to Section 54 sub-section 2a, shall constitute an authorisation within the meaning of Section 52a for the wholesale distribution of medicinal products intended for administration to animals. The holder

of the approval shall submit the corresponding documents and declarations pursuant to Section 52a sub-section 2 to the competent authority by 1st March 2005.

(6) Any person who was allowed to import substances other than active substances of human or animal origin or those manufactured using genetic engineering, without an import authorisation pursuant to Section 72, into the territory governed by the present Act on 6th August 2004, may continue to pursue this activity until 1st September 2005.

(7) Medicinal products, which are authorised by the competent higher federal authority before 30th October 2005, may continue to be placed on the market by pharmaceutical entrepreneurs, in derogation of Section 10 sub-section 1b, up to the next prolongation but not after 30th October 2007. Medicinal products, which are placed on the market by pharmaceutical entrepreneurs pursuant to sentence 1, may continue to be placed on the market by wholesalers and retailers, in derogation of Section 10 sub-section 1b.

Eleven sub-chapter

Transitional provisions arising out of the First Act Amending the Transfusion Act and the Regulations on Medicinal Products

Section 139

Any person who, on entry into force of Article 2 no. 3 of the First Act amending the Transfusion Act and Regulations on Medicinal Products of 10th February 2005 (Federal Law Gazette I p. 234), carries out the functions of a Production or Control Manager for the testing of blood stem cell preparations and complies with the conditions contained in Section 15 sub-section 3 of the version in force at the time, may continue to exercise these functions.

Twelfth sub-chapter

Transitional provisions arising out of the Thirteenth Act Amending the Drug Law

Section 140

In derogation of Section 56a sub-section 2 and Section 73 sub-section 3, medicinal products not used in food-producing animals may be introduced into the purview of the present Act, prescribed, dispensed or used up to 29th October 2005 pursuant to the regulations in force until 1st September 2005.

Thirteenth sub-chapter

Transitional provisions arising out of the Fourteenth Act Amending the Drug Law

Section 141

(1) Medicinal products that are on the market on 5th September 2005 and are subject to Sections 10 and 11, must be placed on the market by the pharmaceutical entrepreneur two years after the first prolongation of the marketing authorisation or registration following 6th September 2005 or, if they are exempted from the need for a marketing authorisation or registration at the time referred to in the ordinance pursuant to Section 36 or Section 39, or if they do not require a prolongation, on 1st January 2009 in accordance with Sections 10 and 11. Up to the relevant dates referred to in sentence 1, medicinal products may be placed on the market by pharmaceutical entrepreneurs and, after these dates, also by wholesale and retail distributors with labelling and a package leaflet complying with the provisions applicable up to 5th September 2005. This shall be without prejudice to Section 109.

(2) In the case of finished products which are on the market on 5th September 2005, the pharmaceutical entrepreneur shall submit to the Higher Federal Authority the wording of the technical information in accordance with Section 11a with the first application for prolongation submitted after 6th September 2005; if the medicinal products in question do not require prolongation, the requirement shall apply from 1st January 2009.

(3) A person who does not have the experience referred to in Section 15 but who is authorised on 5th September 2005 to engage in the activities of the qualified person described in Section 19, shall be regarded as a qualified person in accordance with Section 14.

(4) Finished medicinal products which are on the market on 5th September 2005 and which, in accordance with Section 4 sub-section 1, require a marketing authorisation pursuant to Section 21, for the first time after 6th September 2005, can still be placed on the market if a marketing authorisation application has been submitted by 1st September 2008.

(5) The periods relating to the protection of documents in accordance with Section 24b sub-sections 1, 4, 7 and 8 shall not apply to reference medicinal products for which the application for marketing authorisation was submitted before 30th October 2005; these medicinal products shall be subject to the protection deadlines referred to in Section 24a in the version applicable until 5th September 2005, amounting to the period of ten years referred to in Section 24b sub-section 4.

(6) Medicinal products with a marketing authorisation that was prolonged before 1st January 2001, shall be subject to Section 31 sub-section 1 no. 3 in the version applicable until 5th September 2005; Section 31 sub-section 1a shall apply to these medicinal products only if their marketing authorisation was prolonged after 6th September 2005. For marketing authorisations with a five-year validity which has expired by 1st July 2006, the deadline referred to in Section 31 sub-section 1 no. 3 in the version applicable on 6th September 2005 shall continue to apply. For medicinal products with a marketing authorisation that was prolonged after 1st January 2001 and before 6th September 2005, the competent higher federal authority can stipulate the requirement of a further prolongation, if this is necessary to guarantee the safe placing on the market of the medicinal product. Marketing authorisation prolongation applications submitted before 6th September 2005 which, according to this sub-section, no longer require prolongation, shall be regarded as settled. Sentences 1 and 4 shall apply *mutatis mutandis* to registrations. Marketing authorisation prolongations or registrations of medicinal products which were considered authorised pursuant to Section 105 sub-section 1, shall be considered prolongations within the meaning of this sub-section. This shall be without prejudice to Section 136 sub-section 1.

(7) The holder of the authorisation for a medicinal product which is authorised on 5th September 2005 but is not on the market at this time shall inform the competent higher federal authority immediately of the fact that the medicinal product will not be placed on the market.

(8) Section 33 in the version applicable until 5th September 2005, shall be applicable to protests which are lodged before 5th September 2005.

(9) Section 25 sub-section 9 and Section 34 sub-section 1a shall not be applicable to medicinal products for which the application for marketing authorisation was submitted before 6th September 2005.

(10) Medicinal products which were registered as homeopathic medicinal products by 6th September 2005 or for which an application for registration was submitted before 30th April 2005, shall still be subject to the provisions applicable up to that date. The same applies to medicinal products, which have been notified and placed on the market pursuant to Section 38 sub-section 1 sentence 3 of the version valid before 11th September 1998.

(11) Section 48 sub-section 1 sentence 1 no. 2 shall apply only from the date of entry into force of an ordinance pursuant to Section 48 sub-section 6 sentence 1 and at the latest on 1st January 2008. The Federal Ministry of Agriculture, Food and Consumer Protection shall publish the date referred to in sentence 1 in the Federal Law Gazette.

(12) Section 56a sub-section 2a shall apply only after the list referred to therein has been drawn up and published by the Federal Ministry of Agriculture, Food and Consumer Protection in the Federal Gazette or, if it is part of a directly applicable legal instrument of the Commission of the European Communities or of the Council of the European Union, after publication in the Official Journal of the European Union.

(13) In the case of medicinal products, which are on the market on 5th September 2005, for which the obligation to report pursuant to Section 63b sub-section 5 sentence 2 exists in the version valid up to 5th September 2005, Section 63b sub-section 5 sentence 3 shall apply to the next report to be submitted on 6th September 2005.

(14) The marketing authorisation for a traditional herbal medicinal product that has been prolonged pursuant to Section 105 in conjunction with Section 109a, shall expire on 30th April 2011 unless an application for a marketing authorisation or registration pursuant to Section 39a is submitted before 1st January 2009.

Fourteenth sub-chapter

Section 142

Transitional provisions arising out of the Tissues Act

(1) Any person who, by 1st August 2007, possesses the expert knowledge required pursuant to Section 15 sub-section 3a, in the version in force up to that date, may continue to exercise the function of qualified person.

(2) Any person who had applied for an authorisation pursuant to Section 20b sub-section 1 or sub-section 2 or Section 20c sub-section 1 or a manufacturing authorisation pursuant to Section 13 sub-section 1 by 1st October 2007, or an authorisation pursuant to Section 21a sub-section 1 by 1st February 2008 or a marketing authorisation pursuant to Section 21 sub-section 1 by 30th September 2008 for tissues or tissue preparations, may continue to harvest these tissues or tissue preparations, test them in laboratories, process, preserve, store or place them on the market until a decision is taken on the application.

(3) Any person who, on 1st August 2007, possesses a manufacturing authorisation pursuant to Section 13 sub-section 1 for tissues or tissue preparations within the meaning of Section 20b sub-section 1 or Section 20c sub-section 1 or a marketing authorisation pursuant to Section 21 sub-section 1 for tissue preparations within the meaning of Section 21a sub-section

1 shall not have to submit a new application pursuant to Section 20b sub-section 1, Section 20c sub-section 1 or Section 21a sub-section 1.

Fifteenth sub-chapter

Transitional provisions arising out of the Act on improving measures against doping in sport

Section 143

(1) Finished medicinal products which have been authorised before 1st November 2007 by the competent higher federal authority and are subject to the provisions contained in Section 6a sub-section 2 sentences 2 to 4, may be placed on the market by pharmaceutical entrepreneurs, also without the warnings on the package insert stipulated in Section 6a sub-section 2 sentences 2 and 3 until the next prolongation of the authorisation, but not longer than 31st December 2008.

(2) If a substance or a group of substances is added to the Appendix of the Anti-Doping Convention of 16th November 1989 (Federal Law Gazette 1994 II, p. 334), medicinal products which, at the time of the publication of the amended appendix in the Federal Law Gazette, are authorised and contain one of these substances, may continue to be placed on the market by pharmaceutical entrepreneurs, even without the warning on the package insert stipulated by Section 6a sub-section 2 sentences 2 and 3, until the next prolongation of the authorisation, but not longer than one year after the publication of the Appendix in the Federal Law Gazette. Sentence 1 shall apply *mutatis mutandis* to substances which are intended for use in prohibited methods.

(3) Medicinal products which have been placed on the market by pharmaceutical entrepreneurs pursuant to sub-section 1, may continue to be placed on the market by wholesalers and retailers without the warnings in the package insert stipulated under Section 6a sub-section 2 sentences 2 and 3.

(4) The deadlines provided for in sub-sections 1 and 2 apply *mutatis mutandis* to the adaptation of the wording of the expert information.

Annex

(to Section 6a subsection 2a)

Substances pursuant to Section 6a subsection 2a sentence 1 are:

I. Anabolic active substances

1. Anabolic androgenic steroids

a) Exogenous anabolic androgenic steroids

1-Androstendiol
1-Androstendion
Bolandiol
Bolasterone
Boldenone
Boldione
Calusterone
Clostebol
Danazol
Dehydrochlormethyltestosterone
Desoxymethyltestosterone
Drostanolone
Ethylestrenol
Fluoxymesterone
Formebolone
Furazabol
Gestrinone
4-Hydroxytestosteron
Mestanolone
Mesterolone
Methandienone
Metenolone
Methandriol
Methasterone
Methyldienolone
Methyl-1-testosteron
Methylnortestosterone
Methyltrienolone
Methyltestosterone
Mibolerone
Nandrolone
19-Norandrostendion
Norboletone
Norclostebol
Norethandrolone
Oxabolone
Oxandrolone
Oxymesterone
Oxymetholone
Prostanozol
Quinbolone
Stanozolol
Stenbolone
1-Testosteron
Tetrahydrogestrinone

Trenbolone

b) Endogenous anabolic androgenic steroids

Androstenediol
Androstenedione
Androstanolone, synonym Dihydrotestosterone
Prasterone, synonym Dehydroepiandrosterone, DHEA
Testosterone

2. Other anabolic active substances

Clenbuterol
Tibolone
Zeranol
Zilpaterol

II. Hormones and related substances

1. Erythropoietin and analogues
2. Growth Hormone and Insulin-like Growth Factors, IGF-1
3. Gonadotrophins
Chorionic Gonadotrophin und Luteinising Hormone
4. Insulin
5. Corticotrophins

III. Anti-estrogenic substances

1. Aromatase inhibitors

Anastrozole
Letrozole
Aminoglutethimide
Exemestane
Formestane
Testolactone

2. Selective estrogen receptor modulators (SERMs)

Raloxifene
Tamoxifen
Toremifene

3. Other anti-estrogenic substances

Clomiphene
Cyclofenil
Fulvestrant.

The list includes the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives.