

## Annex 6

# Guidelines for inspection of drug distribution channels

Introductory note	72
General considerations	74
Glossary	75
1. Drug inspectors	78
1.1 Qualifications	78
1.2 Organizational aspects	79
1.3 Methods of inspection	80
1.4 Reference/information sources	81
2. Inspection of establishments in the drug distribution chain	82
2.1 Broad objectives	82
2.2 Establishments	82
2.3 Inspections	82
2.4 Special categories of drugs	83
References	83
Selected further reading	83
Appendix 1 Checklist for inspection and the preparation of a report	85
Appendix 2 Guidance on sampling	89
Appendix 3 Guidance for inspection when pharmaceutical products are suspected to be counterfeit, spurious or substandard	90
Appendix 4 Sample receipt form	92

### Introductory note

The quality assurance of drugs at the level of the manufacturer is outlined in the guidelines on good manufacturing practices for pharmaceutical products (GMP) published by WHO (1). Compliance with these guidelines will ensure that products released for distribution are of the appropriate quality. However, if this is to be

realized in practice, it is essential that an established drug regulatory authority exists in a Member State, which complies at least with the “Guiding principles for small national drug regulatory authorities” (2).

In addition, the holder of a marketing authorization for a pharmaceutical product, or alternatively the (legal) person responsible for the initial marketing of a product, who ideally should be a pharmacist or a pharmaceutical company authorized to practise in the Member State, should ensure that the product is only released for distribution after it has been established that it conforms with the product specification lodged with the drug regulatory authority.

This level of quality should be maintained throughout the pharmaceutical supply system or distribution network. Basic principles of GMP are applicable to wholesale operations and (to some extent) to retail outlets. These principles may be summarized as follows:

- only authorized products are distributed;
- a quality system is in place which includes quality policy, quality management, appropriate analytical controls, self-inspection;
- personnel are quality-conscious, adequately trained and motivated;
- premises and equipment are suitable for their intended use, and kept in a good sanitary condition;
- all products are received, stored and handled appropriately (protected against contamination, cross-contamination, mix-ups, environmental factors such as heat, severe cold, moisture, light);
- all drug-related operations are performed in accordance with written procedures, are properly supervised and adequately documented; documentation ensures complete traceability of receipt of all materials, quality testing processes (if any) and shipping;
- adequate provisions exist to handle complaints, recalls, and returned goods.

At the same time, many provisions of the GMP guidelines published by WHO are clearly not addressed to wholesalers and retail pharmacies where specific rules and requirements apply. These rules are determined partly by pharmaceutical science and common sense, and partly by national (regional) regulations and standards. In this context reference is made particularly to the guidelines entitled “Good pharmacy practice in community and hospital pharmacy settings” (3). It follows then that the “Provisional guidelines on the inspection of pharmaceutical manufacturers” (4), which are directed to

government GMP inspectors, are not adequate to cover inspection in the distribution system. The present document addresses this specific issue.

These guidelines are intended for use by pharmaceutical inspectors in national drug regulatory authorities. They are therefore presented in a format that will allow for easy reference in the field. They should, however, be adapted by national drug regulatory authorities to suit their national legal requirements and available resources.

This document discusses the “simplified” situation when there is a single authority, the drug regulatory authority, where all kinds of drug inspections are located, ranging from those of drug manufacture to the inspections of pharmacies. In reality, these tasks, requiring different inspection skills are usually distributed among different (national and local) authorities.

### **General considerations**

A comprehensive system to assure the safety, efficacy and quality of pharmaceutical products at a national level has the following elements:

- Legal: drug legislation
- Administrative:
  - drug regulatory authority with functions of product registration, licensing of manufacturers, importers and distributors (wholesale, retail and for institutional supply), inspection and independent testing of samples
  - enforcement
- Technical:
  - regulations
  - standards and norms
  - guidelines
  - independent quality control laboratory(ies)

This document focuses on one element—inspection—and in particular on inspection in the pharmaceutical supply system.

The usefulness of drugs in the treatment of ailments, diseases and disorders is well recognized and appreciated. It is also recognized that the inappropriate use of drugs can produce severe toxic effects, some of which may be fatal. National drug laws have therefore been introduced to reduce risks associated with the use, misuse and abuse of pharmaceutical preparations.

Drugs differ in the severity of their side-effects and toxicity and these differences are taken into consideration in the classification of drugs in national drug laws. Drugs may be classified into four types as follows: over-the-counter drugs, pharmacy-only drugs, prescription-only drugs and prohibited drugs.

The distribution, supply, import, export, sale, storage, advertisement and dispensing of drugs are normally regulated by national drug laws, which provide for a system of licences to be issued by a drug regulatory authority for such drug-related activities. The drug laws may identify a ministry/department/agency that would function as the drug regulatory authority as well as provide for the enforcement of the drug laws, using a system of inspections organized through an inspectorate(s).

The inspectorate advises on whether applicants and premises should be issued licences to engage in drug-related activities. The inspectorate ensures that counterfeit, spurious and substandard pharmaceutical products are not found in the national pharmaceutical supply system or outside it, and that licensed premises and authorized persons adhere to existing laws and regulations. To do this, the inspectorate gathers information on the working of the drug laws by liaising with other law enforcement agencies and health institutions, including health-care professional associations.

## **Glossary**

The definitions given below apply to the terms used in these guidelines. They may have different meanings in other contexts.

### *batch*

A defined quantity of any drug product processed in a single process or series of processes such that it can reasonably be expected to be uniform in character and quality.

### *batch number*<sup>1</sup>

A distinctive combination of numbers and/or letters which specifically identifies a batch on the labels, the batch records, the certificate of analysis, etc.

### *controlled drugs*

Narcotic drugs and psychotropic substances regulated by provisions of national drug laws.

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<sup>1</sup> As defined in "Good manufacturing practices for pharmaceutical products" (1).

***counterfeit pharmaceutical product***

A pharmaceutical product which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, with the wrong ingredients, without active ingredients, with an insufficient quantity of active ingredient or with fake packaging.

***drug (pharmaceutical product)***

Any substance or mixture of substances that is manufactured for sale or distribution, sold, supplied, offered for sale or presented for use in:

- (i) the treatment, mitigation, cure, prevention or diagnosis of disease, an abnormal physical state or the symptoms thereof and abnormal physiological conditions in human or animal; or
- (ii) the restoration, correction or modification of organic functions in human or animal.

***finished pharmaceutical product***

A pharmaceutical product that has undergone all stages of production and quality control, including being packaged in its final container and labelled.

***good manufacturing practice<sup>1</sup>***

Good manufacturing practice is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

***good pharmacy practice***

The practice of pharmacy aimed at providing and promoting the best use of drugs and other health care services and products, by patients and members of the public. It requires that the welfare of the patient is the pharmacist's prime concern at all times.

***over-the-counter drugs***

These are drugs that can be sold from licensed dealers without professional supervision and without prescriptions. These drugs are suitable for self-medication for minor diseases and symptoms.

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<sup>1</sup> As defined in "Good manufacturing practices for pharmaceutical products" (1).

*pharmacist*

A pharmacist is a holder of a degree or diploma in pharmacy from a recognized higher institution of learning and is registered or licensed to practise pharmacy.

*pharmacy-only drugs*

These are drugs authorized to be sold only in licensed pharmacies under the supervision of licensed and registered pharmacists; they may be sold without a prescription.

*poison*

A preparation or substance defined by a national drug law as a poison.

*prescription-only drugs*

These are drugs supplied only in licensed pharmacies on the presentation of signed prescriptions issued by a licensed and registered medical practitioner, licensed and/or registered dentist (for dental treatment only), and/or licensed and/or registered veterinarian (for animal treatment only), and the supply and dispensing of these drugs must be carried out by a pharmacist or under the supervision of a pharmacist. Prescription drugs are further subdivided into controlled drugs (narcotic drugs and psychotropic substances) and non-controlled drugs.

*product recall*

Product recall is a process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product or complaints of serious adverse reactions to the product. The recall might be initiated by the manufacturer/importer/distributor or a responsible agency.

*prohibited drugs*

These are drugs with toxicity or side-effects that outweigh their therapeutic usefulness, so that public health and welfare are protected by prohibiting their production, manufacture, export, import, trade, distribution, supply, possession or use, except in amounts required for medical and scientific research. Prohibited drugs are normally determined by the national or supranational registration/licensing authority.

*quality assurance*<sup>1</sup>

Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the

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<sup>1</sup> As defined in "Good manufacturing practices for pharmaceutical products" (1).

totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.

*quality control*

Quality control covers all measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.

*unauthorized market (in some countries called parallel market)*

The unauthorized market consists of wholesale establishments and retail outlets distributing or selling drugs without authorization from a competent authority.

**1. Drug inspectors**

**1.1 Qualifications**

Inspectors should normally be pharmacists who have working experience in community and/or hospital pharmacy. Where persons other than pharmacists are employed as drug inspectors, they should be adequately experienced in drug control affairs and suitably trained in inspectorate functions. The possibility of having part-time inspectors with specialist knowledge as part of inspection teams should also be considered.

The inspector should possess the following attributes:

- good knowledge of pharmacy, drugs, and poisons
- good knowledge of the laws and regulations to be enforced
- good command of technical terms and excellent communication skills
- awareness of the probable methods of using forged or false documents for transactions in pharmaceutical preparations and skill in determining the genuineness of documents presented for examination
- maturity, honesty and integrity
- responsible conduct which commands respect
- willingness to accept challenges
- ability to organize their own work with minimum supervision
- ability to assess facts quickly and take rational and sound decisions without delay

- ability to assess character and honesty of persons being interviewed
- good public relations image with key personnel/pharmacists in charge of premises while remaining firm, fair and resolute
- ability to hold discussions with company management at the completion of inspection
- ability to motivate others
- commitment to hard work and long hours
- ethical approach to any potential conflict of interest.

## 1.2 **Organizational aspects**

Inspectors should be embedded in an organization, usually called an inspectorate, which ensures the following aspects:

- A job description which describes the duties of the inspector.
- Proper reporting: inspectors should report either to the drug regulatory authority or to the pharmaceutical department (chief pharmacist) of the ministry of health.
- Uniformity of approach:
  - (a) Regular meetings of inspectors, in which experiences on the job are exchanged, will help promote a uniform approach to inspection as well as enhance the performance of the inspectors.
  - (b) Inspectors should work according to a work plan and to Standard Operating Procedures (SOPs).
  - (c) Inspection reports should preferably be in three or four parts:
    - (i) date of inspection and general information on the establishment inspected,
    - (ii) description of the inspection activities undertaken, including analytical data of samples taken,
    - (iii) observations and recommendations,
    - (iv) conclusions.
  - (d) Inspectors should be encouraged to submit weekly reports of work to headquarters.
- Total coverage of the country. This can be achieved by:
  - (a) dividing the country into defined areas for the purpose of inspection and placing an inspector in charge of a defined area for the purpose of inspecting wholesale, community and hospital pharmacies, and clinics,
  - (b) inspection of ports and border posts in a defined area.
- Total coverage of the field. The inspector will be expected to inspect establishments such as:



- (a) pharmaceutical manufacturers in respect of drug distribution,
- (b) pharmaceutical importers/exporters,
- (c) pharmaceutical wholesalers and retailers,
- (d) hospital pharmacies/clinics,
- (e) ports and international border posts,
- (f) drug warehouses, stores and unauthorized markets.

(Note: The existence of unauthorized markets for the distribution of drugs poses considerable health hazards. The inspectors should, with the assistance of task forces if necessary, investigate the extent of the unauthorized market, the types of drugs distributed and supplied, and the sources of the drugs. Where possible, unauthorized markets for drugs should be prohibited through effective inspectorate activities. Inspectors should also investigate the sources of supply of suspect counterfeit or substandard pharmaceutical products.)

- Cooperation with other agencies. The inspector will be expected to interact and cooperate with other interested parties such as:
  - (a) industrial, community and hospital pharmacists,
  - (b) management and supervisory staff of pharmaceutical establishments and hospitals,
  - (c) medical practitioners, dentists, veterinarians, nurses and midwives and other health workers,
  - (d) public analysts,
  - (e) ministry of justice officials and court officials,
  - (f) drug law enforcement officers including the police and customs,
  - (g) officers of port authorities, clearing agents at the ports, importers and exporters,
  - (h) members of the public,
  - (i) staff of faculties of medicine/pharmacy,
  - (j) foreign drug regulatory authorities.
- Independence. Inspectors should, for example, have the use of official vehicles.
- Adherence to a code of inspection.

### 1.3 **Methods of inspection**

The inspector uses different methods to check compliance with the national, supranational or international drug laws and regulations. Among these methods are:

- *Comprehensive/routine inspection.* This form of inspection is generally reserved for a new pharmaceutical establishment, when an

establishment is applying for permit to extend its scope of operations beyond that for which it was originally licensed, has made important changes in key personnel or is changing premises, has not been inspected for a long time (3–5 years), or when there is information (even of an informal nature) of serious lapses. Where the inspection is for a new establishment or for extension of scope of operation or because of changes in key personnel, the inspection should be announced.

- *Concise inspection.* This is reserved for establishments that have previously been inspected with a view to assessing standards of good pharmacy practice. The outcome of the inspection will help in the proper assessment of the establishment. The inspection may be unannounced.
- *Follow-up inspection.* This is normally carried out to ensure that corrective measures have been undertaken following advice and notice given during a previous inspection. Where a time limit was given for applying the corrective measures, the inspection may be unannounced.
- *Special inspection.* This is undertaken to deal with specific complaints received about lapses or non-compliance with standards of professional practice. The inspection should preferably be unannounced.
- *Investigative inspection.* This type of inspection is used to assess the performance of a new establishment whose scope of operation was previously unknown.

Any of these methods may be applied with or without prior announcement. Normally inspections should be announced but it serves a useful purpose to undertake some unannounced inspections. Follow-up, special and investigative inspections should preferably be unannounced.

Inspections should be held regularly. Premises should be inspected at least once every 12–18 months. Where contravention is often noticed, the inspection should be more frequent (e.g. every six months). For premises with a good record, less frequent inspections may be needed.

#### 1.4 **Reference/information sources**

The reference/information sources of an inspector should include:

- Existing national and international drug laws and regulations, covering such aspects as:

- licensing
  - GMP
  - good distribution practice
  - good pharmacy practice
  - promotion of pharmaceutical products
  - controlled drugs
  - counterfeit, spurious or substandard pharmaceutical products.
- Codes of inspection (national and regional), where in existence.
  - Codes of professional ethics.
  - Health consequences of drug abuse and misuse.
  - Available data on imports/exports/prohibited drugs.

## 2. **Inspection of establishments in the drug distribution chain**

### 2.1 ***Broad objectives***

The welfare of patients and other members of the public is of prime concern in the distribution chain of drugs, either manufactured within the country or imported. Inspections of establishments are therefore undertaken to ensure:

- Protection of patients and members of the public from malpractice by distributors and suppliers of drugs.
- Adherence to the drug laws and regulations governing compounding, distribution, importation, export and storage of drugs.
- High ethical and professional standards of pharmaceutical practice.

### 2.2 ***Establishments***

In the drug distribution chain several kinds of establishments can be distinguished:

- production sites
- storage or warehouse facilities
- establishments for the supply, sale, dispensing and distribution of drugs, such as pharmacies, hospitals, clinics, ports and stores.

### 2.3 ***Inspections***

When inspecting these establishments the inspector uses the appropriate references. The method of inspection should be laid down in a SOP which also contains the requirements for a specific type of establishment. The inspection SOP may be in the format of a checklist (see Appendix 1 for an example applicable to most drug distribution establishments). When sampling is part of the inspection procedure, the

SOP should contain detailed guidance for the inspector; an example of this guidance is to be found in Appendix 2.

#### 2.4 **Special categories of drugs**

When special categories of drugs are present the inspector may require a modified SOP. This situation is likely to occur with controlled drugs, pharmaceutical products moving in international commerce, or with counterfeit, spurious or substandard pharmaceutical products. For this last category an example of extra guidance is given in Appendix 3.

### **References**

1. Good manufacturing practices for pharmaceutical products. *In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-second report.* Geneva, World Health Organization, 1992, Annex 1 (WHO Technical Report Series, No. 823).
2. Guiding principles for small national drug regulatory authorities. *In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-first report.* Geneva, World Health Organization, 1990, Annex 6 (WHO Technical Report Series No. 790).
3. Good pharmacy practice in community and hospital pharmacy settings. *In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-fifth report.* Geneva, World Health Organization, 1999, Annex 7 (WHO Technical Report Series, No. 885).
4. Provisional guidelines on the inspection of pharmaceutical manufacturers. *In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-second report.* Geneva, World Health Organization, 1992, Annex 2 (WHO Technical Report Series, No. 823).

### **Selected further reading**

- ASEAN good manufacturing practice guidelines*, 2nd ed. Jakarta, Technical Cooperation on Pharmaceuticals, 1988.
- Basic tests for pharmaceutical substances.* Geneva, World Health Organization, 1986.
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## Appendix 1

# Checklist for inspection and the preparation of a report

### Inspection applicable to all drug distribution establishments

#### 1. *General information*

- (a) name of establishment inspected
- (b) date of inspection
- (c) name(s) of the inspector(s)
- (d) date of last inspection.

#### 2. *Type of inspection*

Comprehensive, concise, follow-up, special, investigative, announced, unannounced.

#### 3. *Licensing*

- (a) licensing of premises
- (b) person with supervisory role in establishments handling prescriptions and pharmacy sale-only drugs (is normally a registered pharmacist or a person so prescribed by national legislation)
- (c) personnel authorized to sell only over-the-counter drugs (licensed, where such licensing is required)
- (d) adherence to licensing provisions.

#### 4. *Activities undertaken on premises*

Manufacturing, wholesale, importation, export, retail, hospital pharmacy, clinic, nursing and maternity homes.

#### 5. *Adequacy and suitability of premises*

- (a) premises clean, tidy and in good state of repair
- (b) premises secure
- (c) floor durable and easily cleaned
- (d) premises constructed to prevent infestation by vermin and pests
- (e) clean shelves in retail pharmacy and premises for sale of over-the-counter drugs
- (f) changing rooms and toilet available
- (g) adequacy of lighting and ventilation
- (h) appropriate layout of premises.

#### 6. *Warehouse/store*

- (a) adequacy and suitability of warehouse/store
- (b) warehouse/store clean and uncluttered

- (c) warehouse/store inaccessible to unauthorized persons
  - (d) temperature and humidity control
  - (e) enforcement of stock rotation
  - (f) adequacy of shelving
  - (g) existence of areas for returned drugs, recalled drugs, expired drugs, and drugs in quarantine
  - (h) warehouse/store free from vermin and insects.
7. **Special storage**
- (a) availability of cold room storage or refrigerator for vaccines and biological products
  - (b) suitability of the cold storage facilities
  - (c) standard written procedure prepared by an appropriate national regulatory agency for the maintenance of cold chain
  - (d) special storage area for controlled drugs and other prescription drugs
  - (e) suitable and secure storage facility for controlled drugs and poisons.
8. **Record-keeping**
- (a) name and address of supplier of each drug product with date
  - (b) name and address of purchaser of each drug product with date
  - (c) supplier or purchaser licensed
  - (d) retention of order forms, copy of delivery notes, stores receipt and issue vouchers, and book of records (controlled drugs book/prescription drugs book) on the premises as provided for in the drug laws
  - (e) accuracy of records kept.
9. **Conditions for sale and supply**
- (a) sale and supply of prescription and pharmacy sale-only drugs under the control of a registered pharmacist
  - (b) sale and supply prescription and pharmacy sale-only drugs effected from registered/licensed premises
  - (c) sale of prescription drugs on the basis of valid prescription
  - (d) sale and supply of over-the-counter drugs undertaken in registered premises under the supervision of a pharmacist or premises licensed for the purpose of sale and supply of over-the-counter drugs only, where such registration or licence is required by law.
10. **Diversion of controlled drugs**
- Diversion of controlled drugs prevented by examining the records and by physical examination of stock.

11. **Returned and expired drugs**  
Procedures in place for handling returned and time-expired drugs.
12. **Product recall**  
Procedures in place for recall of drugs and handling recalled drugs.
13. **Product complaints**  
Procedures in place for dealing with complaints about drugs.
14. **Promotional activities**  
Assess promotional materials for compliance with drug laws.
15. **Personnel**
  - (a) person responsible for supervising sale in a wholesale/retail pharmacy is a registered/licensed pharmacist
  - (b) name of the pharmacist in continuous personal control noted
  - (c) personnel wear clean protective clothing.
16. **Labelling of drug products and package inserts**  
Check adequacy of labelling of drug and information on package inserts.
17. **Physical examination and sampling of drugs**  
Conduct physical examination of drugs in stock and take samples of drugs for quality assessment.
18. **Reference books**  
Check existence of reference books on premises, where they are required.

**Specific inspection applicable to individual establishments**

19. **Importer**
  - (a) all drugs accompanied by import documents such as bill of lading, export authorization, product licence and batch certificate
  - (b) controlled drugs also accompanied by export authorization certificate or export declaration, whichever is applicable
  - (c) imported drugs are in original packs, except for drugs imported in bulk for repackaging and/or manufacturing drug formulations.
20. **Retail and hospital pharmacy**
  - (a) compounding of drugs carried out by or under the supervision of a pharmacist



- (b) quality of raw materials used in compounding complies with pharmacopoeial specifications
  - (c) dispensing of prescription drugs, carried out by or under the supervision of a pharmacist
  - (d) entries of dispensed prescription drugs made in prescription book and for controlled drugs in controlled drugs book
  - (e) prescriptions for prescription drugs retained on premises for periods provided in the drug laws
  - (f) dispensed drugs labelled appropriately with name of drug, name of patient, name and address of pharmacy, clinic or hospital, instructions for using the drugs and, where appropriate, warning labels
  - (g) counselling of patients on use of dispensed drugs
  - (h) adequacy of containers for dispensed drugs
  - (i) personnel observe high standard of personal hygiene and wear clean protective clothing
  - (j) dispensing area clean, adequate and has necessary equipment
  - (k) walls in dispensing area easily cleaned
  - (l) quality of extemporaneous preparations
  - (m) sources of drugs sold and supplied from the pharmacy
  - (n) suitable cabinets for storage of controlled drugs and poisons.
21. ***Clinics, nursing and maternity homes***
- (a) sources of drugs used, supplied and administered
  - (b) records of controlled drugs used, supplied and administered
  - (c) storage facilities and security for controlled drugs.
22. ***Unauthorized markets***
- (a) investigate sources of drugs in the unauthorized market
  - (b) sample drugs for quality assessment
  - (c) seize drugs in the unauthorized market.

## Appendix 2

### Guidance on sampling

This guidance is applicable to collecting samples of drugs to be tested by the official quality control laboratory. The collection may be aimed either at assessing the quality of products on the market, in which case adequate sampling plans should apply (see, for example, “Sampling procedures for industrially manufactured pharmaceuticals” (1, 2)), or at detecting substandard, spurious and counterfeit pharmaceutical products. In this case sampling shall be based on information and may involve confiscation of entire stocks to prevent further distribution. Compliance with legal procedures for sample collection, analysis and documentation is obligatory.

- (a) Check that the sample is properly labelled with the following:
  - (i) name of sampled pharmaceutical preparation
  - (ii) batch number
  - (iii) date and source of sample; the original manufacturer’s label may be helpful.
- (b) Check that the records contain the following:
  - (i) number of samples
  - (ii) types of packaging and storage conditions
  - (iii) circumstances of sampling that may include suspected quality defects.
- (c) Place seals on containers of the samples.
- (d) Hand over one-third of the samples to the representative of the inspected establishment.
- (e) Confirm in writing that samples were taken from the premises and have the confirmation countersigned by an appropriate official of the inspected establishment (see, for example, the sample receipt form in Appendix 4).

#### References

1. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-first report.* Geneva, World Health Organization, 1990, Annex 2 (WHO Technical Report Series, No. 790).
2. *Quality assurance of pharmaceuticals. A compendium of guidelines and related materials, Vol. 1.* Geneva, World Health Organization, 1997.

## Appendix 3

### **Guidance for inspection when pharmaceutical products are suspected to be counterfeit, spurious or substandard**

This section addresses specifically the situation in which the inspector suspects counterfeit, spurious or substandard pharmaceutical products to be present during an inspection. This may be during either a regular inspection or an investigation aimed at detecting such products.

#### **1. Broad objective**

The presence of counterfeit, substandard and spurious pharmaceutical products in the drug distribution channels may present a danger to public health, and it is imperative that suspect products are effectively and rapidly taken out of the distribution channels and quarantined. In order to facilitate the work of the inspector, the help of capable and experienced persons involved in the distribution of products should be obtained on a proactive basis to help identify such products.

#### **2. Standard operating procedures**

(a) A written SOP for inspectors should be drawn up and made available to them.

This SOP should include at least the following information:

- (i) how the suspect product should be isolated to prevent its further distribution
- (ii) the size of the samples required for testing purposes
- (iii) the manner in which the samples should be taken
- (iv) the record-keeping procedure to be followed in recording the details of the action taken
- (v) the details which should be recorded on the receipt issued for the embargoed product and/or samples taken
- (vi) the type of materials which should be used for sealing samples or for embargoing or confiscating suspect products
- (vii) the names, addresses and telephone numbers of persons who should be contacted to report on the action taken
- (viii) special precautions to be noted by the person initiating the sampling or seizure procedure, with particular reference to correct legal procedures to be followed
- (ix) where appropriate, the manner in which the suspect product should be destroyed.

- (b) Where other persons are involved in the detection of counterfeit pharmaceutical products they shall operate on the basis of a suitable SOP. In any case of suspicion of counterfeit pharmaceutical products an inspector shall be notified immediately.

3. **Counterfeit products**

The following applies specifically to counterfeit products:

- (a) When examining a possible counterfeit pharmaceutical product the inspector shall first screen the product by looking, smelling, touching and listening to the sound of the packing and its contents. The inspector shall look for anything, in particular its labelling and packing, that makes the product look different from an original reference sample. A SOP may assist in examining the product in this way.
- (b) When the organoleptic examination does not give conclusive evidence the inspector shall have a sample tested using appropriate simple screening methods, such as the basic tests recommended by WHO or a suitable thin-layer chromatography method.
- (c) In addition to any full analytical testing, the drug regulatory authority of the country of origin stated on the label of the product may be asked to establish whether the product is counterfeit.
- (d) Proven cases of counterfeit pharmaceutical products shall be fully documented and communicated to all other inspectors, to increase their level of expertise. Information on counterfeit products shall also immediately be made available to drug regulatory authorities of other countries concerned and to WHO.

Appendix 4  
**Sample receipt form**

Institution/company (under inspection) .....

Address .....

.....

Date of inspection .....

Name of representative of the inspected establishment .....

Name of inspector .....

Name of the drug and description of sample .....

.....

Dosage form .....

Batch no. ....

Place sampled (warehouse, production line, packaging section, etc.)  
.....

No. of samples taken (tins, packets, etc.) .....

.....

Signature	Signature
Inspector	Representative of the inspected establishment