SECTORAL ANNEX ON
GOOD MANUFACTURING PRACTICES
(GMP)

1. Purpose

1.1. This Mutual Recognition Agreement (MRA) Sectoral Annex on Good Manufacturing Practices (GMP) Compliance Certification pertaining to medicinal products/drugs has been developed by the European Community (EC) and Canada to:

(a) enhance bilateral regulatory cooperation;

(b) establish mutual recognition for GMP compliance certification and acceptance of Manufacturing Authorizations/Licences directly issued by the authorities designated equivalent after the successful completion of a confidence building exercise;

(c) develop an infrastructure for on-going communications/consultations between Canada, the European Commission, and the Regulatory Authorities of the EC Member States to enable regulators to determine and maintain the equivalency of their GMP compliance programmes.

2. General Considerations

2.1. The underlying premise behind a MRA for GMP compliance certification is that it can be demonstrated that Canada and the EC Member States have equivalent GMP compliance programmes, and therefore the issuance of a Certificate of Manufacturing Authorization/Licence by an authority of one Party certifying that a facility is in compliance with GMPs, would be all the evidence required by the other Party to accept that facility as being in compliance for the manufacturing/control of medicinal/drug products or to issue a similar Certificate of Manufacturing Authorization/Licence. It should be understood that equivalent does not mean identical but it does mean leading to the same result.

2.2. The acceptance by an authority of a certificate of manufacturing authorization/licence issued by the other authority will depend on the successful completion of a confidence building exercise and on an evaluation of its results. Only certification by authorities with GMP compliance programmes (including the supporting infrastructure of regulatory requirements, standards, processes, and quality systems, etc.) mutually recognized as equivalent will be accepted.

2.3. The MRA on Medicinal Products/Drug GMP is built on three pillars:

(a) the concept of a GMP compliance programme (Appendix 4)

(b) a "two-way" alert system (Appendix 5)

(c) a transition period including a confidence building exercise (Appendix 6)

3. Scope and Coverage

3.1. The provisions of this Annex will cover all medicinal products/drugs which have undergone one or a series of manufacturing process(es) (e.g. fabrication, repackaging, labelling, testing, wholesaling activities) in Canada and in the European Community, and to which Good Manufacturing Practice (GMP) requirements apply in both jurisdictions. Recognition will be limited to the manufacturing process(es) carried out and subject to inspections in the respective territories of the Parties.

3.2. This Annex may also apply, on a voluntary basis, to products covered by the legislation of one Party but not the other if agreed to by the authorities concerned.

3.3. The product coverage shall be as determined by the relevant legislation of each Party. Appendix 1 names the legislations and contains an indicative list of products concerned.

3.4. For the purpose of this Annex, GMP includes the system whereby the manufacturer receives the specifications of the product and/or process from the Marketing Authorization (MA)/Drug Identification Number (DIN) or Licence holder or applicant and ensures the product is made in compliance with the specifications (equivalent to Qualified Person certification in the EC).

Good Manufacturing Practice (GMP) 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

– required by the Marketing Authorization or product specifications and by assignment procedure of the Drug Identification Number or the Licence.

3.5. Product or process oriented inspections will be carried out by one Party at the request of the other Party. For pre-approval inspections, the Parties agree to exchange pre-approval inspection reports to the extent required under the importing Party's laws and regulations, for the purpose of their respective product approval procedures. Lot-to-lot release for biologicals is excluded from this Agreement.

4. Confidentiality

4.1. Each Party will protect from public disclosure any non-public confidential technical, commercial and scientific information, including trade secrets and proprietary information that is provided by the other Party.

4.2. Each Party reserves the right to make public the results of any conformity assessment, including the conclusions of inspection reports, provided by the other Party, in situations in which public health safety may be affected.

5. Management Mechanisms

5.1. A Joint Sectoral Group will be established for the purposes of the management of this sectoral agreement. The Joint Sectoral Group will establish its composition and determine its own rules and procedures. Its role is described in Appendix 3. The Group will include representatives of the Therapeutic Products Programme in Health Canada, of the European Commission, and of the the relevant EC authorities. It will be co-chaired by a member of each of the two Parties.

6. Resolution of Divergent Views

6.1. Divergent views which have not been resolved between the authorities will be referred to the Joint Sectoral Group for resolution. In the case of inability of the Joint Sectoral Group to resolve these divergent views, either Party may bring the matter to the attention of the Joint Committee.

7. Transition Period

7.1. Time Frame

The confidence building period will commence upon the signing of the MRA and is expected to be completed within 18 months.

7.2. Confidence Building Programme

At the beginning of the transitional period, the Joint Sectoral Group will elaborate a joint Confidence Building Programme. The implementation of this programme will permit the determination of the capability of each Party's authority to perform GMP compliance certification (guidance provided in Appendix 6).

7.3. Budget

Each of the Parties to the MRA will be responsible for the costs of its participation in the confidence building activities.

7.4. Administrative provision

Medicinal products/drugs from manufacturing sites with a good track record of compliance in the importing Party, and that have been placed on a list of qualified sites, will be exempted from retesting requirements. The list will be developed by the Joint Sectoral Group.

7.5. End of Transitional Period

7.5.1. At the end of the transitional period, the Joint Sectoral Group will proceed to a joint evaluation of the equivalency and capabilities of the compliance programmes of the participating authorities (Appendix 2).

7.5.2. Those determined as not being equivalent to the other Party's GMP compliance programme will not be listed in Appendix 2 at the end of the transitional period. Proposals to limit the recognition of the equivalence of an authority or exclude it from the Appendix should be based on objective criteria and documented evidence.

7.5.3. Authorities may be placed in Appendix 2 for specific categories of manufacturing processes (e.g. biologicals, radiopharmaceuticals). Excluded authorities (or not included for a given manufacturing process) may apply for re-consideration of their status once the necessary corrective measures have been taken.

8. Operational Phase

8.1. General provisions

8.1.1. The European Community and Canada agree that, for medicinal products/drugs covered by this Annex, each Party will recognize the conclusions of the GMP compliance programme carried out by the other Party in its territory, and the relevant Certificates of Manufacturing Authorizations/Licences granted by the deemed equivalent authorities of the other Party listed in Appendix 2. In addition, the certification by the manufacturer on the conformity of each batch will be recognised by the other Party without re-control at import.

8.1.2. Manufacturers located in Canada or a Member State of the European Community whose relevant authority is not listed in Appendix 2 or is not included for the relevant category manufacturing processes may ask that an inspection be carried out by any of the authorities listed in Appendix 2 . The batch and the compliance certificates issued according to this procedure will be recognized by the other Party provided that equivalent enforcement procedures against that facility can be subsequently ensured in case of non-compliance.

8.1.3. With respect to medicinal products/drugs covered by the pharmaceutical legislation of the importing Party but not the exporting one, the locally competent inspection service willing to carry out an inspection of the relevant manufacturing operations shall inspect against its own GMPs if relevant, or, in the absence of specific GMP requirements, against the applicable GMPs of the importing Party. This will also be the case when the locally applicable GMPs are not considered equivalent, in terms of quality assurance of the finished products, to the GMPs of the importing Party.

This provision may also apply to the manufacturer of active pharmaceutical ingredients, intermediate products, and products intended for use in clinical trials.

8.1.4. It will be the responsibility of the authorities covered by the Annex to ensure that any suspension or withdrawal (total or partial) of a manufacturing authorization, which could affect the protection of public health, is communicated to the other Party with the appropriate degree of urgency as defined in the "two-way" alert programme.

Contact points will be agreed between both Parties to permit authorities and manufacturers to inform the authorities of the other Party with the appropriate speed in case of quality defect, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the product.

8.1.5. Certification of manufacturers

At the request of an exporter, an importer or of an authority of the other Party, the authorities responsible for granting Certificates of Manufacturing Authorizations/Licences and for the supervision of the manufacture of medicinal products/drugs will certify that the sites used for manufacture and/or control:

(a) are appropriately authorised to manufacture and/or control the relevant medicinal product/drug or to carry out the relevant specified operations,

(b) are regularly inspected by the authorities, and

(c) comply with the GMP requirements recognised as equivalent by the two Parties.

The Certificates of Manufacturing Authorization/Licence will also identify the site(s) of manufacture. A Canadian and a European Community example of such certificates are attached at Appendix 7 for illustrative purposes.

Certificates of manufacturing authorizations/licences will be issued expeditiously, and the time taken should not exceed 30 calendar days. In cases when a new inspection has to be carried out, this period may be extended to 60 calendar days.

8.1.6. Batch certification

Each batch exported will be accompanied by a batch certificate issued by the manufacturer ("self certification") after a full qualitative and quantitative analysis of all active constituents to ensure that the quality of the products complies with the requirements of the Marketing Authorization/Product Approval.

When issuing this certificate, the manufacturer will take into account the provisions of the current WHO certification scheme on the quality of medicinal products/drugs moving in international commerce. This certificate will attest that the batch meets the specifications and has been manufactured in accordance with the relevant Marketing Authorization/Product Approval, detailing the specifications of the product, the analytical methods referenced, the analytical results obtained, and containing a statement that the batch processing and packaging records were reviewed and found in conformity with GMPs.

The batch certificate will be signed by the person responsible for releasing the batch for sale or supply. In the European Community the "qualified person" is referred to in Article 21 of Directive 75/319/EEC, and in Canada, the nominated person responsible for manufacturing quality control is as specified in the Food and Drug Regulations, Division 2, Section C.02.014 (1).

8.1.7. Fees

The regime of inspection/establishment licence fees is determined by the location of the manufacturer. The cost recovery programmes and the fees pertaining to the issuance of Manufacturing Authorizations/Licences in each jurisdiction will remain the responsibility of that jurisdiction.

The Parties shall endeavour to ensure that any fees imposed for services will be cost-oriented and take into account relevant cost factors. If no services are rendered by one Party, fees should not be charged.

8.1.8. Each Party reserves the right to conduct its own inspection for reasons identified to the other Party. Such inspections are to be notified in advance to the other Party, which has the option of joining the inspection. Recourse to this safeguard clause should be an exception.

8.1.9. The decision to suspend or revoke a licence will rest with the issuing Party.

8.2. Information Sharing

8.2.1. In accordance with the general provisions of the Annex, the Parties will exchange all information necessary to determine and maintain the equivalence of GMP compliance programmes. In addition, the relevant authorities in Canada and in the EC will keep each other informed of all new technical guidance, inspection procedures, or changes in regulation (these include: guidance documents, publications of references to standards, forms, documents relating to the application of legal requirements). Each Party will consult the other before adopting these changes to ensure the continued equivalency of the GMP compliance programmes. Concerns will be raised to the Joint Sectoral Group.

8.2.2. Upon reasoned request, the relevant inspection service shall forward a copy of the last inspection report of the manufacturing or control site, in case analytical operations are contracted out. The request may concern a "full inspection report" or a "detailed report". A "full inspection report" comprises a Site Master File (compiled by the manufacturer or by the inspectorate) and a narrative report by the inspectorate. A "detailed report" responds to specific queries about a firm by the other Party. Parties will ensure that such inspection reports are forwarded in no more than 30 calendar days, this period being extended to 60 calendar days should a new inspection be carried out.

8.3. Two-way Alert System

8.3.1. The Joint Sectoral Group will ensure that an efficient and effective "two-way" alert system is in place at all times. Elements of such a system are described in Appendix 5.

8.3.2. It shall be the responsibility of the authorities covered by the Annex to ensure that any suspension or cancellation (total or partial) of certification of compliance is communicated to the other relevant authorities with the appropriate degree of urgency.

8.3.3. Each Party shall notify the other Party of any confirmed problem reports, corrective actions, or recalls related to products covered under the scope of this Annex. Each Party will respond to special requests for information and will ensure that authorities make available relevant information, as requested.

Contact points are identified in Appendix 5.

9. Monitoring of the Agreement

9.1. The continuous monitoring of the GMP compliance programmes determined to be equivalent at the conclusion of the confidence building period and any subsequent decisions concerning that equivalence must be made according to a mutually developed and managed equivalence maintenance programme. This programme will be managed by the Joint Sectoral Group.

9.2. The Parties undertake to hold regular consultations, under the auspices of the Joint Sectoral Group set up under this Annex, to ensure the continued relevancy and accuracy of this annex. Canada and Member State authorities may organize meetings to discuss specific questions and issues.

9.3. Authorities must participate in maintenance activities, as established under the Joint Sectoral Group, in order to maintain their status as listed in Appendix 2.

10. Appendices

10.1. Appendices 1 and 2 constitute integral parts of this annex.

10.2. Appendices 3, 4, 5, 6 and 7 are general guidelines.

Appendix 1

1. List of Applicable Legislation

1.1. For the European Community

Directive 65/65/EEC as modified
Directive 75/319/EEC as modified
Directive 81/851/EEC as modified
Directive 91/356/EEC as modified
Directive 91/412/EEC as modified
Regulation (EC) No 2309/93
Directive 92/25/EEC
Guide to Good Distribution Practice (94/C 63/03)
Current version of the Guide to Good Manufacturing Practice, Volume IV of Rules Governing Medicinal Products in the European Community.

1.2. For Canada:

Food and Drugs Act and Regulations, Health of Animals Act and Regulations for the issuance of permits for materials of animal origin.

2. Indicative list of Products

Recognizing that precise definitions of medicinal products and drugs are to be found in the legislations referred to above, an indicative list of products covered by the agreement is given below:

- human pharmaceuticals including prescription and non-prescription drugs, and medicinal gases;

- human biologicals including vaccines, stable medicinal products derived from human blood or human plasma, biotherapeutics, and immunologicals;

- human radiopharmaceuticals;

- veterinary pharmaceuticals, including prescription and non-prescription drugs, and pre-mixes for the preparation of veterinary medicated feeds;

- where appropriate, vitamins, minerals, herbal remedies and homeopathic medicinal products; and

- active pharmaceutical ingredients or bulk pharmaceuticals (Note: APIs are not GMP regulated)

Appendix 2

AUTHORITIES

For the European Community:

BELGIUM	Inspection générale de la Pharmacie Algemene Farmaceutische Inspectie
DENMARK	Laegemiddelstyrelsen
GERMANY	Bundesministerium für Gesundheit
GREECE	Εθνικός Οργανισμός Φαρμάκου Ministry of Health and Welfare National Drug Organization (E.O.F.)
SPAIN	for medicinal products for human use: Ministerio de Sanidad y Consumo Subdirección General de Control Farmacéutico for medicinal products for veterinary use: Ministerio de Agricultura, Pesca y Alimentación (MAPA) Dirección General de la Producción Agraria

FRANCE	for medicinal products for human use: Agence du Médicament for veterinary medicinal products: Agence Nationale du Médicament Vétérinaire
IRELAND	Irish Medicines Board
ITALY	for medicinal products for human use: Ministero della Sanità Dipartimento Farmaci e Farmacovigilanza for medicinal products for veterinary use: Ministero della Sanità Dipartimento alimenti e nutrizione e sanità pubblica veterinaria – Div. IX
LUXEMBOURG	Division de la Pharmacie et des Médicaments
NETHERLANDS	De Minister van Volksgezondheid, Welzijn, en Sport Inspectie voor de Gezondheidszorg
AUSTRIA	Bundesministerium für Arbeit, Gesundheit und Soziales

PORTUGAL	for human and veterinary (non-immunologicals): Instituto da Farmácia e do Medicamento – INFARMED for veterinary immunologicals: Direcç_o-Geral de Veterinaria
FINLAND	Lääkelaitos/Läkemedelsverket (National Agency for Medicines)
SWEDEN	Läkemedelsverket – Medical Products Agency
UNITED KINGDOM	for human and veterinary (non-immunologicals): Medicines Control Agency for veterinary immunologicals: Veterinary Medicines Directorate
EUROPEAN COMMUNITY	Commission of the European Communities European Agency for the Evaluation of Medicinal Products (EMEA)

For Canada:

Therapeutic Products Programme, Health Canada, Ottawa.
Bureau of Veterinary Drugs, Food Directorate, Health Canada, Ottawa

Appendix 3

JOINT SECTORAL GROUP

A Joint Sectoral Group (JSG) will be established to manage the confidence building process and to monitor the operations of the MRA thereafter.

The JSG will be co-chaired by a member from each Party and will determine its own composition, ensuring, to as great a degree as possible, consistent membership. The role of the JSG will be to ensure communications with the Joint Committee and to manage the transition period and to monitor the continued implementation of this annex including, but not limited to:

– making decisions on activities required to define and establish the equivalence of compliance programmes and the "two way" alert system;

– assessing the results of the confidence building exercise, and determining which regulatory authorities are deemed equivalent. The JSG will prepare a list of the equivalent regulatory agencies and provide its recommendations to the Joint Committee;

– providing directions to experts that will conduct the evaluation of the respective GMP compliances programmes, and undertake joint activities (e.g. inspections, workshops); and

– making decisions on the necessary arrangements of the MRA maintenance programme.

The JSG will meet as needed to adopt the confidence building working plan, resolve issues, and monitor the progress of the confidence building exercise. The Joint Committee will be kept informed of the agendas and conclusions of meetings as well as on the progress made during the transition period.

Appendix 4

COMPONENTS OF A GMP COMPLIANCE PROGRAMME

1. Legislative and Regulatory Requirements and Scope

   – Empowering legislation and regulations including authority to enforce laws and regulations, powers given to inspectors to conduct inspections, authority to remove violative products from the market, etc

   – Suitable controls on conflict of interest

2. Regulatory Directives and Policies

   – Procedures for designating inspectors

   – Enforcement policies/guidelines/procedures (inspection, re-inspection, corrective action)

   – Codes of conduct/ethics

   – Training/certification policies/guidelines

   – Alert/crisis management policies/procedures/guidelines

   – Organizational structure, including roles, responsibilities and reporting relationships

3. Good Manufacturing Practices (GMP) Standards

- Scope/details of GMPs necessary for the control of the manufacturing of drug products
- Process validation requirements

4. Inspection Resources

- Staffing – initial qualifications, certification of inspectors
- Number of inspectors in relation to size of industry (in-house, contract, third Party)
- Training/certification programmes/processes (e.g. frequency of training)
- Quality assurance mechanisms to ensure effectiveness of training programmes

5. Inspection Procedures (pre-inspection, inspection, and post-inspection activities)

- Inspection strategy (type, scope, scheduling, focus of inspection, notification of inspections, risk based inspections)
- Pre-inspection preparation/requirements
- Format and content of inspection reports (including support tools e.g. hardware)
- Inspection methodology (access to and review of firm's files and databases, collection of evidence, data review, sample collection, interviews)
- Standard Operating Procedures (SOPs) for inspection
- Post-inspection activities (procedures for report issuance, follow-up, decision making)
- Storage of inspection data

6. Inspection Performance Standards

- Frequency/number of inspections, quality and timeliness of inspection reports, norms/frequency/procedures for re-inspection and corrective action

7. Enforcement Powers and Procedures

- Provision of written notices of violation to firms
- Non-compliance management procedures/mechanisms (recall, suspension, quarantine of products, licence revocation, seizure, prosecution)
- Appeal mechanisms
- Other measures to promote voluntary compliance by firm

8. Alert and Crisis Systems

- Alert mechanisms
- Crisis management mechanisms
- Alert performance standards (appropriateness and timeliness of alert)

9. Analytical Capability

- Access to laboratories with capacity to handle necessary analysis
- Standard Operating Procedures (SOPs) for analytical support
- Processes for validation of analytical methods

10. Surveillance Programme/Measures (used by firm and by regulatory authority)

- Sampling and audit procedures
- Recall monitoring (including effectiveness controls and verifications of procedures)
- Consumer complaint system/procedures
- Adverse reaction reporting system/procedures
- Drug product defect reporting system/procedures

11. Quality Management Systems

- Quality management/assurance system/procedures to ensure the ongoing suitability and effectiveness of policies, procedures, guidelines and systems used to achieve the objectives of the GMP compliance programme, including establishment of standards and annual audit and review.

Appendix 5

COMPONENTS OF A "TWO-WAY" ALERT PROGRAMME

1. Documentation

   – Definition of a crisis/emergency and under what circumstances an alert is required

   – Standard Operating Procedures (SOPs)

   – Mechanism of health hazards evaluation and classification

   – Language of communication and transmission of information

2. Crisis Management System

   – Crisis analysis and communication mechanisms

   – Establishment of contact points

   – Reporting mechanisms

3. Enforcement Procedures

   – Follow-up mechanisms

   – Corrective action procedures

4. Quality Assurance System

– Pharmacovigilance programme

– Surveillance/monitoring of implementation of corrective action

Contact points

For the purpose of this agreement, the contact points for any technical question, such as exchange of inspection reports, inspectors training sessions, technical requirements, will be:

for Canada,

the Director General, Therapeutic Products Programme, Health Canada , 2nd Floor, Health Protection Building, AL: 0702A, Tunney's Pasture, Ottawa, Ontario, K1A OL2, Canada. Telephone 1-613-957-0369, Fax 1-613-952-7756; and

for the European Community,

the Director of the Evaluation of Medicinal Products Agency, 7, Westferry Circus, Canary Wharf, UK - London E14 4HB, England. Telephone +44-171-418 8400, Fax 418 8416.

Appendix 6

PHASES OF A CONFIDENCE BUILDING PERIOD

The determination of the equivalency of the GMP compliance programmes by the Joint Sectoral Group will be designed around the following three phases:

1. Review and evaluation of documentation (exchange of documentation).

   – Legal Instruments (Regulations/Legislations Directives)/Guidelines on GMPs.

   – Inspection programmes (scope, policies, directives, procedures).

   – Crisis management systems (scope, criteria, policies, directives, procedures).

   – Requirements for inspection reports.

   – Analytical laboratory systems.

   – Alert reports.

2. Evaluation of processes and procedures.

- Audit of systems and procedures.
- Exchange/evaluation of reports.
- Monitoring of alert systems including handling of recalls.
- Joint inspections of manufacturers to determine equivalency of inspection methods.
- Exchange of inspectors or organization of joint workshops (optional).

3. Decision making on the success of the exercise and conclusions.

- Evaluation of results of the confidence building exercise.
- Action to take, development of options and solutions to address issues.
- Determination of competent agencies that meet evaluation criteria.
- Establishment of the conditions and mechanisms for on-going maintenance of the certification programme (develop quality management system, audit mechanism and a consultation/on-going dialogue process).

Appendix 7

CERTIFICATE OF PHARMACEUTICAL MANUFACTURER IN THE FRAMEWORK OF THE AGREEMENT ON MUTUAL RECOGNITION BETWEEN CANADA AND THE EUROPEAN COMMUNITY, SECTORAL ANNEX ON MEDICINAL PRODUCTS GMP INSPECTION AND BATCH CERTIFICATION

As requested by the .....
(*) on ...../...../..... (date) (reference: .....), the Competent Authority of
..... (**) confirms the following:

The company .....
whose legally registered address is: .....
.....
.....
has been authorized, under Directive 75/319/EEC, Article 16, and Directive 81/851/EEC, Article 24, transposed in the national legislation of ..... (**), under the authorization reference number.....
covering the following site(s) of manufacture (and contract testing laboratories, if any):
1 .....
.....
2.....
.....
3.....
.....
to carry out the following manufacturing operations:

+ complete manufacture (***)

+ partial manufacture (***), i.e. (detail of manufacturing operations authorized):
.....
.....
for the following medicinal product: .....

for human use / use in animals (***).

From the knowledge gained during inspections of this manufacturer, the latest of which was conducted on ..../..../.... (date), it is considered that the company complies with the Good Manufacturing Practice requirements referred to in the Agreement on Mutual Recognition between Canada and the European Community.

..../..../.... (date) For the Competent Authority,

(Name and signature of the officer responsible)

(*) : insert exporting or importing firm or Health Canada
(**) : insert European Community Member State or European Community as required
(***) : delete that which does not apply

Health Canada / Santé Canada

Establishment Licence

Licence Number
100001-A
Numéro de la licence

PRODUITS THÉRAPEUTIQUES / THERAPEUTIC PRODUCTS PROGRAMME

Licence d'établissement

This licence is issued in accordance with the Food and Drugs Act & Regulations (Division 1A & 2) for the following activities and categories of drugs:

Cette licence est délivrée conformément à la Loi et aux Règlements sur les aliments et drogues (titres 1A et 2) pour les activités et les catégories de drogues suivantes:

STERILE / STÉRILE NO / NON	Pharmaceutical *Prod. pharmaceutique*	Vaccines *Vaccins*	Blood [3] *Sang*	Schedule D [4] *L'annexe D*	Schedule C [5] *L'annexe C*	[6]
Fabricate *Manufacturer*						
Package / label *Emballer-étiqueter*						
Test[1] *Test*						
Distribute[2] *Distribuer*	X					
Import *Importer*						
Wholesale *Vendre en gros*						

(1) Perform the tests, including any examinations required under Division 2 / *Analyser conformément au titre 2*

(2) Distribute as set out in paragraph C.01.A.003 (a) and/or (b) / *Distribuer à titre de distributeur visé à l'alinéa C.01A.003 (a) et/ou (b)*

(3) Whole blood and its components / *Sang entier et ses composants*

(4) Drugs listed in Schedule D to the Act, other than vaccines or whole blood and its components / *Drogue visée à l'annexe D de la Loi, autre qu'un vaccin ou que le sang entier et ses composants*

(5) Drugs listed in Schedule C to the Act / *Drogue visée à l'annexe C de la Loi*

(6) Drugs listed in the Schedule to Part G of the Food and Drug Regulations, drugs listed in Schedule F to the Food and Drug Regulations, narcotics as defined in section 2 of the Narcotic Control Regulations / Drogue visée à l'annexe de Partie G des Règlements sur les aliments et drogues, drogue visée à l'annexe F des Règlements sur les aliments et drogues, stupéfiants au sens de l'article 2 des Règlements sur les stu

Issued On / Emise le: 1998-01-01

MINISTER OF HEALTH

MINISTRE DE LA SANTÉ

Countersigned: Director General, Therapeutic Products Directorate
Contresigné par: Directeur général, Direction des produits thérapeutiques

Health Canada / Santé Canada

Establishment Licence

Licence Number
100125-A
Numéro de la licence

PRODUITS THÉRAPEUTIQUES / THERAPEUTIC PRODUCTS

Licence d'établissement

This licence is issued in accordance with the Food and Drugs Act & Regulations (Division 1A & 2) for the following activities and categories of drugs:

Cette licence est délivrée conformément à la Loi et aux Règlements sur les aliments et drogues (titres 1A et 2) pour les activités et les catégories de drogues suivantes:

STERILE / STÉRILE NO / NON	Pharmaceutical *Prod. pharmaceutique*	Vaccines *Vaccins*	Blood [3] *Sang*	Schedule D [4] *L'annexe D*	Schedule C [5] *L'annexe C*	6
Fabricate *Manufacturer*						
Package / label *Emballer-étiqueter*						
Test[1] *Test*						
Distribute[2] *Distribuer*	X					
Import *Importer*	X					
Wholesale *Vendre en gros*						

(1) Perform the tests, including any examinations required under Division 2 / *Analyser conformément au titre 2*

(2) Distribute as set out in paragraph C.01.A.003 (a) and/or (b) / *Distribuer à titre de distribuer visé à l'alinéa C.01A.003 (a) et/ou (b)*

(3) Whole blood and its components / *Sang entier et ses composants*

(4) Drugs listed in Schedule D to the Act, other than vaccines or whole blood and its components / *Drogue visée à l'annexe D de la Loi, autre qu'un vaccin ou que le sang entier et ses composants*

(5) Drugs listed in Schedule C to the Act / *Drogue visée à l'annexe C de la Loi*

(6) Drugs listed in the Schedule to Part G of the Food and Drug Regulations, drugs listed in Schedule F to the Food and Drug Regulations, narcotics as defined in section 2 of the Narcotic Control Regulations / Drogue visée à l'annexe de Partie G des Règlements sur les aliments et drogues, drogue visée à l'annexe F des Règlements sur les aliments et drogues, stupéfiants au sens de l'article 2 des Règlements sur les stu

This licence is subject to the additional conditions as indicated in the attached:

Cette licence est assujettie aux conditions supplémentaires indiquées dans le feuillet ci-joint:

Foreign Site Annex / Annexe concernant les sites étrangers

Issued On / Emise le: 1998-01-01

MINISTER OF HEALTH MINISTRE DE LA SANTÉ	Countersigned: Director General, Therapeutic Products Directorate *Contresigné par: Directeur général, Direction des produits thérapeutiques*

This licence is the property of the Therapeutic Products Directorate and must be returned upon demand.
Cette licence appartient à la direction des produits thérapeutiques et doit être retournée sur demande.

Health Canada / Santé Canada

Establishment Licence

Licence Number
100125-A
Numéro de la licence

PRODUITS THÉRAPEUTIQUES / THERAPEUTIC PRODUCTS PROGRAM

Licence d'établissement

Foreign Site Annex / Annexe concernant les sites étrangers

The following sites are considered to be in GMP Compliance:

Les sites suivants sont considérés comme étant conformes aux BPF:

Company Name / Nom de l'entreprise		
Street/Rue:	*City/Ville:*	*Country/Pays:*
Activity/Activite: FABRICATE / FABRICATION PACKAGE / CONDITIONNEMENT		
Category/Catégorie: PHARMACEUTICAL / MEDICAMENT		*Sterile / Stérile* NO / NON

SECTORAL ANNEX
ON
MEDICAL DEVICES

1. PURPOSE

1.1. This Mutual Recognition Agreement (MRA) Annex on conformity assessment and compliance certification pertaining to medical devices has been developed by the European Community and Canada to enhance bilateral medical device regulatory cooperation while facilitating global trade and maintaining the same high standards of health and safety in both jurisdictions.

1.2. Furthermore this Annex calls for the development of an infrastructure for on-going communications/consultations between Regulatory and/or Designating Authorities and Conformity Assessment Bodies of each Party to enable regulators to determine and maintain the equivalence of their medical device conformity assessment capabilities and to develop a cooperative approach to post-market vigilance.

2. SCOPE AND COVERAGE

2.1. This Annex applies to all medical devices which in Canada or the European Community are subject to conformity assessment procedures, including scientific technical evaluations of high risk medical devices and quality systems assessments, by a Conformity Assessment Body.

2.2. The product coverage shall be as determined by the relevant legislation of each Party, which is:

(a) for the European Community

– Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, as amended.

– Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

(b) for Canada

– The Food and Drugs Act and Medical Devices Regulations (proposed for promulgation 1998) as amended from time to time.

– the Canadian Electrical Code (as it relates to medical devices).

– the Radiation Emitting Devices Act and Regulations as amended from time to time (as they relate to medical devices).

It shall not, however, apply to the following products:

– in vitro diagnostic medical devices

– devices incorporating, as an integral part, a substance which, if used separately, may be considered to be a medicinal product

– breast implants

– medical devices incorporating tissues of human or animal origin. However, medical devices incorporating tissues of animal origin and where the device is intended to come into contact with intact skin only, will be included within the scope of this Sectoral Annex.

Both Parties may, however, decide by common agreement, to extend the application of this Annex to the aforementioned or any other medical devices.

3. CONFIDENTIALITY

3.1. Each Party will protect from public disclosure any non-public confidential technical, commercial and scientific information, including trade secrets and proprietary information provided by the other Party.

3.2. Each Party reserves the right to make public the results of any conformity assessment reports in situations where public health may be affected.

4. RESOLUTION OF DIVERGENT VIEWS

4.1. Divergent views which have not been resolved between the regulatory authorities will be referred to the Joint Sectoral Group for resolution. In the event that the Joint Sectoral Group is unable to resolve these divergent views, either Party may bring the matter to the attention of the Joint Committee.

5. MANAGEMENT MECHANISM

5.1. A Joint Sectoral Group will be established for the purposes of management of this sectoral Annex. Its role will be to make decisions concerning the definition, establishment, and evaluation of conformity assessment procedures and programmes, the establishment of the "two-way" alert programme, the management of the confidence building period and the definition of a maintenance programme supporting the continued operation of the MRA. The Group will include representatives of Health Canada and of the European Community’s Competent Authorities and co-chaired by a member of each of the two Parties.

6. TRANSITION PERIOD

6.1. Time Frame

The confidence building period will commence upon the signing of the MRA and is expected to be completed within 18 months.

6.2. Confidence Building Programme

At the beginning of the transitional period, the Joint Sectoral Group will elaborate a joint Confidence Building Programme (guidance provided in Attachment III). The implementation of this programme shall establish each Party's capability to perform conformity assessments in compliance with the requirements and procedures of the other Party. The evidence shall provide practical relevance to the decisions regarding the operational phase.

The Confidence Building Programme should include the following actions and activities:

(a) The organization of seminars aiming to inform Regulatory/Designating Authorities and Conformity Assessment Bodies on each Party's regulatory system, procedures and requirements;

(b) The conduct of workshops aiming to provide, for Regulatory/Designating Authorities, a common understanding and exchange of information regarding requirements and procedures for the designation and surveillance of Conformity Assessment Bodies (CABs);

(c) For scientific technical evaluations, an inter-comparison exercise which would consist of parallel evaluations (double blind evaluations), made by the Conformity Assessment Body in each territory, of a manufacturer's technical submission against the requirements of the intended market for that device, will be undertaken. Full reports and recommendations shall be exchanged for comparison. A certificate of compliance can be issued by the body responsible for the relevant market during this inter-comparison study. The inter-comparison study should take place on a sampling basis comprising a sufficient number of cases spread over the range of different medium to high-risk technologies with the involvement of each Party's Regulatory/Designating Authorities and CABs. Additional evidence with respect to the competency of Regulatory/Designating Authorities or CABs can be requested by either Party;

(d) For quality systems assessments, an inter-comparison exercise which would consist of the participation of Regulatory/Designating Authorities in audits carried out by CABs of the other Party on the basis of requirements of the other Party. Audit management, methods and reports will be compared. The inter-comparison study should take place on a sampling basis comprising a sufficient number of cases spread over the range of different technologies with the involvement of each Party's Regulatory/Designating Authorities and CABs. Additional evidence with respect to the competency of Regulatory/Designating Authorities or CABs can be requested by either Party;

(e) The design, development and testing of a two-way alert system (see guidance in Attachment IV);

(f) The establishment of contact points between Regulatory/Designating Authorities and CABs of both Parties;

(g) The participation in information exchange meetings with particular focus on conformity assessment and vigilance, including participation in staff training sessions. The exchange of staff will also be encouraged; and

(h) During the Confidence Building Programme, where one Party has developed sufficient confidence in the evaluation methods and results of the other, it may at its own discretion, establish the relevant document of compliance permitting market access for its own jurisdiction based on the evaluation reports of the other Party without the full submission.

Participation in activities referenced under (c) and (d) should be understood as means to provide, on an exemplary basis, supplementary evidence in relation to the process of designation and surveillance of CABs.

6.3. Budget

Each of the Parties to the MRA will be responsible for the costs of its participation in the confidence building activities.

6.4. End of Transition Period

No later than eighteen months after the entry into force of this agreement, the Joint Sectoral Group shall proceed to a joint evaluation of the experience gained. This evaluation will cover the adequacy of the Confidence Building Programme, the capabilities of Regulatory/Designating Authorities and the capabilities of the designated Conformity Assessment Bodies.

Recommendations to list CABs in Attachment II of this Annex shall be made by participating Designating/Regulatory Authorities, listed in Attachment I, to the Joint Sectoral Group on the basis of the results of the Confidence Building Programme. Conformity Assessment Bodies that have been accepted by the Joint Sectoral Group will be listed in Attachment II with an indication of their specific conformity assessment expertise and the fields of medical device technologies for which they are recognized. The corresponding Regulatory/Designating Authority responsible for a CAB will also be listed in Attachment II. Proposals to limit the recognition of capabilities of CABs should be based on objective evidence and documented. The Joint Sectoral Group may recommend that a CAB not be listed in Attachment II, provided there is documented evidence demonstrating its lack of capabilities. Excluded CABs may apply for re-consideration of their status once the necessary corrective measures have been taken and confirmed.

Where no agreement on any of the above matters has been reached in the Joint Sectoral Group, the matter will be referred to the Joint Committee under the Framework Agreement.

The Parties shall enter into the operational phase provided that there is representation of each Party's CABs in Attachment II.

The Agreement will also be re-examined at the end of the transitional period to take account of the regulatory evolution of each Party. Consideration shall be given to a single submission/evaluation/quality systems assessment which simultaneously satisfies the requirements of each jurisdiction.

7. OPERATIONAL PHASE

7.1. General Obligations

The provisions of this Section will apply only to conformity assessment carried out in the Parties' respective territories by Conformity Assessment Bodies recognized under this sectoral Annex.

The European Community and Canada agree that, for medical devices covered by this Annex, each Party will recognize the conclusions of the conformity assessment carried out by the other Party and the certificate of compliance granted by the Conformity Assessment Body of the other Party, without further re-assessment.

For evaluation against European requirements, Health Canada or other Conformity Assessment Bodies designated by Canada shall establish the conclusions of completed conformity assessments as referred to in the Active Implantable Medical Device and the Medical Device Directives, and issue the appropriate certificate of compliance. The responsible authorities in the European Community will, without any further re-assessment, accept the certification as evidence of compliance with the premarket requirements of the relevant European Directives.

For evaluating against Canadian requirements, the European CABs shall establish the conclusions of the examination and submit to Health Canada an abbreviated supporting report and certificate of compliance which includes such conclusions. Based on these documents, and without any further re-assessment, Health Canada will accept the certification as evidence of compliance with the premarket requirements of the Canadian Medical Devices Regulations.

Each Party shall make available to the other Party, upon reasoned request, any information which has been reviewed as part of the assessment of a medical device for the purpose of issuing certificates of compliance.

Each Party reserves the right, at any time, to question information with respect to the designation process or the performance of conformity assessments against the requirements of its regulatory regime. Furthermore, each Party reserves the right to conduct its own conformity assessments for reasons identified to the other Party. Justification for such action shall be based on documented evidence and notification is to be provided in advance to the other Party. Recourse to this action should be an exception.

7.2. Procedures for Designation of CABs

The procedures to be followed by the Designating Authorities of each Party in designating CABs shall respect the criteria laid down in the other Party's regulations or guidelines (non-binding guidance is provided in Attachment V).

7.3. Information Sharing

In accordance with the general provisions of the Annex, the Parties will exchange all information necessary to determine and maintain equivalence of conformity assessment procedures. In addition, each Party shall share with the other Party information generated within the framework of its regulatory system which is relevant for the operation of conformity assessment procedures (i.e. guidance documents, publications of references to standards, forms, documents relating to the application of legal requirements). Each Party shall associate Regulatory/Designating Authorities and Conformity Assessment Bodies of the other Party in activities of exchange of information and experience.

In special cases, particularly emergency situations, all those involved in the implementation of this Annex will endeavour to provide all documentation requested by one of the Parties in an expeditious manner.

7.4. Two-way Alert System

The Joint Sectoral Group will ensure that an efficient and effective "two-way" Alert System is in place at all times. Elements of such a system are described in Attachment IV.

Each Party shall notify the other Party of any confirmed problem reports, corrective actions, or recalls related to products that it has evaluated under the terms of this agreement. Each Party will respond to special requests for information on particular devices and will ensure that its Designated Authorities and Conformity Assessment Bodies make available relevant information on these devices, as requested.

It shall be the responsibility of the Regulatory Authorities covered by this Annex to ensure that any suspension or cancellation (total or partial) of a certificate of compliance is communicated to each other with the appropriate degree of urgency.

7.5. Fees

The regime of registration or conformity assessment fees is determined by the location of the manufacturer. The cost recovery programmes and the fees pertaining to the issuance of a certificate of compliance in each jurisdiction will remain the responsibility of that jurisdiction. Conformity assessment fees will not be charged by one Party to manufacturers located on the territory of the other Party, where the conformity assessment was conducted by a Conformity Assessment Body located in the other Party’s territory.

7.6. Monitoring of the Agreement

The continuous monitoring of the equivalency of designation processes and conformity assessments for each Party's requirements that have been determined to be equivalent at the conclusion of the Confidence Building Programme, and any subsequent decisions concerning that equivalence, must be made according to mutually developed and managed equivalence maintenance and implementation activities. This will be managed by the Joint Sectoral Group.

The Parties will undertake to hold regular consultations, within the Joint Sectoral Group set up under this Annex to ensure the continued relevancy and accuracy of this Annex. The Regulatory/Designating Authorities and Conformity Assessment Bodies will organize meetings to discuss specific questions and issues.

Conformity Assessment Bodies and Regulatory/Designating Authorities must continue participation in maintenance activities, as established by the Joint Sectoral Group, within the framework of this Annex in order to maintain their status under this Annex as indicated in Attachment II.

Parties may request the addition of Regulatory/Designating authorities or Conformity Assessment Bodies to Attachment II. The procedure for the acceptance of new Regulatory/Designating authorities will be as described in the Confidence Building Programme. Conformity Assessment Bodies will be added to Attachment II upon recommendation from a Regulatory/Designating Authority and joint decision by the Joint Sectoral Group.

7.7. Contact Points

Contact points are identified in order to permit Regulatory Authorities and manufacturers to inform the Regulatory Authorities of the other Party with the appropriate speed in case of quality defects, recalls, and adverse incidents, which could necessitate additional controls or, suspension of the distribution of the product or, suspension or cancellation of a certificate of compliance.

For the purpose of this agreement, the contact points will be:

for Canada..... and

for the European Community(15 Member States and the Commission)

8. ATTACHMENTS

Attachments I and II constitute integral parts of this Annex. Attachments III, IV and V are general guidelines.

ATTACHMENT I

REGULATORY/DESIGNATING AUTHORITIES ELIGIBLE TO PARTICIPATE IN THIS AGREEMENT

For the Conformity Assessment Bodies Designated by Canada	For the Conformity Assessment Bodies Designated by the European Community
Canada Therapeutic Products Programme, Health Canada	• Belgium Ministère de la Santé publique, de l'Environnement et de l'Intégration sociale Ministerie van Volksgezondheid, Leefmilieu en Sociale Integratie • Denmark Sundhedsministeriet • Germany Bundesministerium für Gesundheit • Greece Υπουργείο Υγείας Ministry of Health • Spain Ministerio de Sanidad y Consumo • France Ministère de l'emploi et de la solidarité Ministère de l'economie, des finances et de l'industrie • Ireland Department of Health • Italy Ministero della Sanità • Luxembourg Ministère de la Santé • Netherlands Staat der Nederlanden • Austria Bundesministerium für Arbeit, Gesundheit und Soziales • Portugal Ministerio da Saude • Finland Sosiaali-ja terveysministeriö/Social-och hälsovårdsministeriet • Sweden Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC), Designating Authority Socialstyrelsen, Regulatory Authority • United Kingdom Department of Health

ATTACHMENT II

DESIGNATED CONFORMITY ASSESSMENT BODIES AND THEIR RESPECTIVE DESIGNATING AUTHORITIES

For Canada	For the European Community
To be completed after the Confidence Building Programme	To be completed after the Confidence Building Programme

ATTACHMENT III

PHASES AND ELEMENTS OF A CONFIDENCE BUILDING PROGRAMME

A. Review and Evaluation of Elements of Conformity Assessment (exchange of documentation).

1. Legislative and Regulatory Requirements and Scope

- Empowering legislation and regulations including authority to enforce laws and regulations, powers given to evaluators and auditors, authority to remove violative products from the market, etc.

- Suitable controls on conflict of interest

2. Regulatory Directives and Policies

- Procedures for determining competency of evaluators/auditors
- Enforcement policies/guidelines/procedures
- Codes of conduct/ethics
- Training/certification policies/guidelines
- Alert/crisis management policies/procedures/guidelines
- Organizational structure, including roles, responsibilities and reporting relationships

3. Quality Audit Management, Methodology and Practices

- Scope/details of operating standards, etc.
- Auditor qualifications, numbers, training, quality assurance, contracting, etc.

4. Scientific Technical Evaluation Methodology and Practices

- Scope/details of operating standards, etc.
- Evaluator qualifications, numbers, training, quality assurance, contracting, etc.

5. Evaluation and Auditing Reports

- Scope and format of reports
- Content requirements
- Storage, retrieval and access to reports
- Scope and format of abbreviated reports, conclusions of conformity assessment and certificates

6. Auditing and Evaluation Procedures

- Audit and Evaluation strategy (type, scope, scheduling, focus, notification, risk)
- Pre-audit or evaluation preparation/requirements
- Methodology (access to and review of firm's files and databases, collection of evidence, data review, sample collection, interviews)
- Post audit and evaluation activities (procedures for report issuance, follow-up, decision making)
- Collection/storage of and access to data

7. Auditing and Evaluation Performance Standards

- Frequency/number, quality and timeliness of reports, norms/frequency/procedures for re-audit or re-evaluation and corrective action

8. Enforcement Powers and Procedures

- Provision of written notices of violations to firms
- Non-compliance management procedures/mechanisms (recall, suspension, quarantine of products, certificate revocation, seizure, prosecution)
- Appeal mechanisms
- Other measures to promote voluntary compliance by firm

9. Alert and Crisis Systems

- Alert mechanisms
- Crisis management mechanisms
- Alert performance standards (appropriateness and timeliness of alert)

10. Analytical Capability

- Access to laboratories with capacity to handle necessary analysis
- Standard Operating Procedures for analytical support
- Processes for validation of analytical methods

11. Surveillance Programme/Measures (used by manufacturers and by regulatory authorities)

- Sampling and audit procedures
- Recall monitoring (including effectiveness controls and verifications of procedures)
- Consumer complaint systems/procedures
- Adverse incident reporting systems/procedures

12. Quality Management Systems

- Quality management/assurance systems/procedures to ensure the ongoing suitability and effectiveness of policies, procedures, guidelines and systems used to achieve the objectives of the conformity assessment programme, including establishment of standards and annual audit and review.

B. Inter-Comparison Exercise

- Audit of Systems and Procedures
- Conduct of Parallel Evaluations (double blind)
- Criteria for Clinical Trial Data
- Exchange/evaluation of reports
- Monitoring of alert systems including handling of recalls.
- Joint audits of manufacturers to determine equivalency of audit methods.
- Exchange of evaluators/auditors or organization of joint workshops (optional).

C. Decision Making on the Success of the Inter-Comparison Study

- Evaluation of results
- Action to take, development of options and solutions to address issues.
- Determination of competent Conformity Assessment Bodies that meet evaluation criteria.
- Establishment of the conditions and mechanisms for on-going maintenance of the MRA (develop quality management system, audit mechanism and a consultation/on-going dialogue process).

ATTACHMENT IV

COMPONENTS OF A "TWO-WAY" ALERT PROGRAMME

1. Documentation

- Definition of a crisis/emergency and under what circumstances an alert is required
- Standard Operating Procedures (SOPs)
- Mechanism of health hazards evaluation and classification
- Language of communication and transmission of information

2. Crisis Management System

- Crisis analysis and communication mechanisms
- Access to manufacturer’s submissions, adverse incident reports and Conformity Assessment Body reports
- Establishment of contact points
- Reporting mechanisms

3. Enforcement Procedures

- Follow-up mechanisms
- Corrective action procedures

4. Quality Assurance System

- Vigilance programme
- Surveillance/monitoring of implementation of corrective action

ATTACHMENT V

GUIDELINES: PROCEDURES FOR THE DESIGNATION AND MONITORING OF CONFORMITY ASSESSMENT BODIES

A. General requirements and conditions

1. Designating Authorities shall only designate legally identifiable entities as Conformity Assessment Bodies.

2. Designating Authorities shall only designate Conformity Assessment Bodies able to demonstrate that they understand, have experience relevant to, and are competent to apply the conformity assessment requirements and procedures of the legislative, regulatory and administrative provisions of the other Party for which they are designated.

3. Demonstration of technical capabilities shall be based on:

   – technological knowledge of the relevant products, processes or services;

   – understanding of the technical standards and the general risk protection requirements for which designation is sought;

   – the experience relevant to the applicable legislative, regulatory and administrative provisions;

   – the physical capability to perform the relevant conformity assessment activity;

– an adequate management of the conformity assessment activities concerned; and

– any other circumstance necessary to give assurance that the conformity assessment activity will be adequately performed on a continuous basis.

4. The technical capability criteria shall be based on internationally accepted documents supplemented by specific interpretative documents developed as appropriate from time to time.

5. The Parties shall encourage harmonization of designation and conformity assessment procedures through cooperation between Designating Authorities and Conformity Assessment Bodies by means of coordination meetings, participation in mutual recognition arrangements, and working group meetings. Where accreditation bodies participate in the designation process they should be encouraged to participate in mutual recognition arrangements.

B. System to determine Conformity Assessment Bodies' capabilities

6. The Designating Authorities may apply the following processes to determine the technical capabilities of Conformity Assessment Bodies. If necessary, a Party will indicate to the Designating Authority the possible ways to demonstrate capabilities.

(a) Accreditation

Accreditation shall constitute a presumption of technical capability in relation to the requirements of the other Party when:

(i) the accreditation process is conducted in conformance with the relevant international documentation (EN 45000 series or ISO/IEC guides); and either,

(ii) the accreditation body participates in mutual recognition arrangements where it is subject to peer evaluation, which involves evaluation by individuals with recognised expertise in the field of the work being evaluated of the capabilities of accreditation bodies and Conformity Assessment Bodies accredited by them, or

(iii) the accreditation body, operating under the authority of a Designating Authority, takes part, in accordance with procedures to be agreed, in comparison programmes and exchanges of technical experience in order to ensure the continued confidence in the technical competence of the accreditation bodies and Conformity Assessment Bodies. Such programmes may include joint assessments, special cooperation programmes or peer evaluation.

When a Conformity Assessment Body is only accredited to evaluate a product, process or service for compliance with particular technical specifications, designation shall be limited to those technical specifications.

When a Conformity Assessment Body seeks designation to evaluate a particular product, process or service for compliance with essential requirements, the accreditation process shall incorporate elements which will permit assessment of the capability (technological knowledge and understanding of the generally stated risk protection requirements of the product, process or service or their use) of the Conformity Assessment Body to evaluate compliance with those essential requirements.

(b) Other means

When appropriate accreditation is not available or when special circumstances apply, the Designating Authorities shall require the Conformity Assessment Bodies to demonstrate their capabilities through other means such as:

- participation in regional/international mutual recognition arrangements or certification systems;
- regular peer evaluations;
- proficiency testing; and
- comparisons between Conformity Assessment Bodies.

C. Evaluation of the Designation System

7. Once the designation systems to evaluate the capabilities of Conformity Assessment Bodies have been defined by each Party, the other Party may, in consultation with the Designating Authorities, check that the systems give sufficient assurance that the designation of the Conformity Assessment Bodies satisfies its requirements.

D. Formal Designation

8. Designating Authorities shall consult the Conformity Assessment Bodies within their jurisdiction in order to determine their willingness to be designated under the terms of this Agreement. Such consultation should include those Conformity Assessment Bodies who do not operate under the respective legislative, regulatory, and administrative requirements of their own Party, but which may, nevertheless, be interested and capable of working to the legislative, regulatory, and administrative requirements of the other Party.

9. Designating Authorities shall inform their Party's representatives on the Joint Sectoral Group, established under this Agreement, of the Conformity Assessment Bodies to be included in or withdrawn from Section XX of the Sectoral Annexes. Designation, suspension or withdrawal of designation of Conformity Assessment Bodies shall take place in accordance with the provisions of this Agreement and the rules of procedure of the Joint Sectoral Group.

10. When advising their Party's representative on the Joint Sectoral Group established under this Agreement, of the Conformity Assessment Bodies to be included in the Sectoral Annexes, the Designating Authority shall provide the following details in respect of each Conformity Assessment Body:

    (a) the name;
    (b) the postal address;
    (c) the facsimile (fax) number;
    (d) the range of products, processes, standards or services it is authorized to assess;
    (e) the conformity assessment procedures it is authorized to carry out; and
    (f) the designation procedure used to determine capabilities.

E. Monitoring

11. Designating Authorities shall maintain, or cause to maintain, ongoing surveillance over designated Conformity Assessment Bodies by means of regular audit or assessment. The frequency and nature of such activities shall be consistent with international best practices or as agreed by the Joint Sectoral Group.

12. Designating Authorities shall require designated Conformity Assessment Bodies to participate in proficiency testing or other appropriate comparison exercises where such exercises are technically possible within reasonable cost.

13. Designating Authorities shall consult as necessary with their counterparts, to ensure the maintenance of confidence in conformity assessment processes and procedures. This consultation may include joint participation in audits related to conformity assessment activities or other assessments of designated Conformity Assessment Bodies, where such participation is appropriate and technically possible within reasonable cost.

14. Designating Authorities shall consult, as necessary, with the relevant regulatory authorities of the other Party to ensure that all regulatory requirements are identified and are satisfactorily addressed.