World Health Organization
Organisation mondiale de la Santé

FIFTIETH WORLD HEALTH ASSEMBLY

Provisional agenda item 19

A50/INF.DOC./3
27 February 1997

Guidelines on the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce

This document contains revised Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce[1] which the Executive Board, in resolution EB99.R21, recommends that the Health Assembly should endorse.

[1] WHO Technical Report Series, No. 863 (1996), Annex 10 (attached).

WHO Technical Report Series, No. 863, 1996

Annex 10
Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce

1. Provisions and objectives

1.1 A comprehensive system of quality assurance must be founded on a reliable system of licensing[1] and independent analysis of the finished product, as well as on an assurance obtained through independent inspection that all manufacturing operations are carried out in conformity with accepted norms referred to as "good manufacturing practices" (GMP).

1.2 In 1969, the Twenty-second World Health Assembly, by resolution WHA22.50, endorsed requirements for "Good practices in the manufacture and quality control of drugs"(*1*) (referred to henceforth as "GMP as recommended by WHO"). These comprise internationally recognized and respected standards that all Member States are urged to adopt and to apply. These requirements have since been revised twice. The first revision was adopted by the Health Assembly in 1975 in

[1] Throughout this document licensing refers to any statutory system of approval required at national level as a precondition for placing a pharmaceutical product on the market.

resolution WHA28.65 (*2*), and a second revision of the requirements is included in the thirty-second report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (*3*).

1.3 These standards are fully consonant with those operative within the countries participating in the Convention for the Mutual Recognition of Inspection in Respect of the Manufacture of Pharmaceutical Products, and other major industrialized countries. They also provide the basis for the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (referred to henceforth as "the Scheme") recommended initially in resolution WHA22.50 (*1*). The Scheme is an administrative instrument that requires each participating Member State, upon application by a commercially interested party, to attest to the competent authority of another participating Member State that:

- a specific product is authorized to be placed on the market within its jurisdiction or, if it is not thus authorized, the reason why that authorization has not been accorded;
- the plant in which it is produced is subject to inspections at suitable intervals to establish that the manufacturer conforms to GMP as recommended by WHO; and
- all submitted product information, including labelling, is currently authorized in the certifying country.

1.4 The Scheme, as subsequently amended in 1975 (*2*) and 1988 (*4*) by resolutions WHA28.65 and WHA41.18, is applicable to finished dosage forms of pharmaceutical products intended for administration to human beings or to food-producing animals.

1.5 Provision for the certification of active ingredients is also included within the scope of the Scheme. This will be the subject of separate guidelines and certificates.

2. Eligibility for participation

2.1 Any Member State intending to participate in the Scheme may do so by notifying the Director-General of WHO, in writing, of:

- its willingness to participate in the Scheme;
- any significant reservations it intends to observe relating to this participation; and
- the name and address of its national drug authority or other competent authority.

2.2 These notifications are subsequently announced in the monthly *WHO pharmaceuticals newsletter.* An updated consolidated list will be published annually in the newsletter and will be available to governments at other times from the Division of Drug Management and Policies, WHO, 1211 Geneva 27, Switzerland. (See also section 3.3).

2.3 A Member State may opt to participate solely to control the *import* of pharmaceutical products and active substances. This intention should be stated explicitly in its notification to WHO.

2.4 A Member State intending to use the Scheme to support the *export* of pharmaceutical products should first satisfy itself that it possesses:

- An effective national licensing system, not only for pharmaceutical products, but also for the responsible manufacturers and distributors.
- GMP requirements, consonant with those recommended by WHO, to which all manufacturers of finished pharmaceutical products are required to conform.
- Effective controls to monitor the quality of pharmaceutical products registered or manufactured within the country, including access to an independent quality control laboratory.
- A national pharmaceuticals inspectorate, operating as an arm of the national drug regulatory authority, and having the technical competence, experience and resources to assess whether GMP and other controls are being effectively implemented, and the legal power to conduct appropriate investigations to ensure that manufacturers conform to these requirements by, for example, examining premises and records and taking samples.
- The administrative capacity to issue the required certificates, to institute inquiries in the case of complaint, and to notify expeditiously both WHO and the competent authority in any Member State known to have imported a specific product that is subsequently associated with a potentially serious quality defect or other hazard.

2.5 Each Member State assumes the responsibility to determine, through a process of self-evaluation, whether it satisfies these prerequisites. The Scheme contains no provision for external inspection or assessment under any circumstances, either of a competent national authority or of a manufacturing facility. However, should a Member State so wish, it can approach WHO, or a well recognized drug regulatory authority, occasionally to delegate consultants to act as advisers in the course of both national inspections and inspector training activities.

3. Requesting a certificate

3.1 Three documents can be requested within the scope of the Scheme:

– a Certificate of Pharmaceutical Product (product certificate);
– a Statement of Licensing Status of Pharmaceutical Product(s); and
– a Batch Certificate of a Pharmaceutical Product.

3.2 Proposed formats for these documents are provided in Appendices 1, 2 and 3 of these guidelines. To facilitate their use, they are presented in forms suitable for generation by computer. All participating countries are henceforth urged to adopt these formats to facilitate the interpretation of certified information. Requests for the provision of certificates offering

more limited attestations – for instance, that the manufacturer complies with GMP or that the product is authorized for "free sale" within the country of export – are discouraged. Similarly, requests should not be made for the certification of information going beyond the scope of the Scheme. When manufacture takes place in a country other than that where the product certificate is issued, an attestation that such manufacture complies with GMP may still be provided as an attachment to the product certificate on the basis of inspections undertaken for registration purposes. The explanatory notes attached to the three documents referred to above are very important. While they are not part of the documents, they should always be attached to them.

3.3 A list of addresses of competent national regulatory authorities participating in the Scheme that are responsible for the registration of pharmaceutical and/or veterinary products, together with details of any reservations they have declared regarding their participation in the Scheme may be obtained from WHO as indicated in section 2.2.

3.4 The competent authority in each country participating in the Scheme should issue guidelines to all agents responsible for importing pharmaceutical products for human and/or veterinary use that operate under its jurisdiction, including those responsible for public sector purchases, to explain the contribution of certification of the drug regulatory process and the circumstances in which each of the three types of documents will be required.

Certificate of a Pharmaceutical Product

3.5 The Certificate of a Pharmaceutical Product (Appendix 1), issued by the exporting country, is intended for use by the competent authority within an importing country in two situations:

- when the product in question is under consideration for a product licence that will authorize its importation and sale;
- when administrative action is required to renew, extend, vary or review such a licence.

3.6 All requests for certificates should be channelled through the agent in the importing country (see section 3. 4) and the product-licence holder or other commercially interested party in the exporting country ("the applicant"). The applicant should submit the following information for each product to the authority issuing the certificate:

- the name and dosage form of the product;
- the name and the amount of active ingredient(s) per unit dose (the International Nonproprietary Name(s), where such exist(s), should be used);
- the name and address of the product-licence holder and/or manufacturing facility;

– the formula (the complete qualitative composition including all excipients); this is particularly important when no product licence exists or when the formulation differs from that of the licensed product;
– product information for health professionals and for the public (patient information leaflets) as approved in the exporting country.

For product information to be attached to the certificate, see section 4.7.

3.7 The certificate is a confidential document. As such, it can be issued by the competent authority in the exporting country ("the certifying authority") only with the permission of the applicant and, if different, of the product-licence holder.

3.8 The certificate is intended to be incorporated into a product-licence application in the importing country. Once prepared, it is transmitted to the requesting authority through the applicant and, when applicable, the agent in the importing country.

3.9 When any doubt arises about the status or validity of a certificate, the competent authority in the importing country should request a copy directly from the certifying authority, as provided for in section 4.9 of these guidelines.

3.10 In the absence of any specific agreement, each certificate will be prepared exclusively in the working language(s) of the certifying authority. The applicant will be responsible for providing any notarized translation that may be required by the requesting authority.

3.11 Since the preparation of certificates imposes a significant administrative load on certifying authorities, the service may need to be financed by charges levied upon applicants.

3.12 Supplementary attestations are obtainable only at the discretion of the certifying authority and with the permission of the applicant. The certifying authority is under no obligation to supply additional information. Requests for supplementary information should consequently be referred to the applicant, and only in exceptional circumstances to the certifying authority.

Statement of Licensing Status

3.13 The Statement of Licensing Status of Pharmaceutical Product(s) (Appendix 2) attests only that a licence has been issued for a specified product, or products, for use in the exporting country. It is intended for use by importing agents when considering bids made in response to an international tender, in which case it should be requested by the agent as a condition of bidding. It is intended only to facilitate the screening and preparation of information. The importation of any product that is provisionally selected through this procedure should be determined on the basis of a Certificate of a Pharmaceutical Product.

Batch Certificate

3.14 A Batch Certificate of a Pharmaceutical Product (Appendix 3) refers to an individual batch of a pharmaceutical product, and is a vital instrument in drug procurement. The provision of a Batch Certificate is usually a mandatory requirement in tender and procurement documents.

3.15 A Batch Certificate is normally issued by the manufacturer and only *exceptionally,* as in the case of vaccines, sera and some other biological products, by the competent authority of the exporting country. The Batch Certificate is intended to accompany and provide an attestation concerning the quality and expiry date of a specific batch or consignment of a product that has already been licensed in the importing country. The Batch Certificate should include the specifications of the final product at the time of batch release and the results of a full analysis undertaken on the batch in question. In most circumstances these certificates are issued by the manufacturer to the importing agent (i.e. the product-licence holder in the importing country), but they must be made available at the request of – or in the course of any inspection made on behalf of – the competent national authority.

4. Issuing a certificate

4.1 The certifying authority is responsible for assuring the authenticity of the certified data. Certificates should not bear the WHO emblem, but a statement should always be included to confirm whether or not the document is issued in the format recommended by WHO.

4.2 When the applicant is the manufacturer of the finished dosage form, the certifying authority should satisfy itself, before attesting compliance with GMP, that the applicant:

(a) applies identical GMP standards to the production of *all* batches of pharmaceutical products manufactured within the facility, *including those destined exclusively for export;*

(b) consents, in the event of identification of a quality defect consonant with the criteria set out in section 5.1, to relevant inspection reports being released, in confidence, to the competent authority in the country of import, should the latter so require.

4.3 When the applicant is not the manufacturer of the finished dosage form, the certifying authority should similarly satisfy itself – in so far as it has authority to inspect the records and relevant activities of the applicant – that it has the applicant's consent to release relevant reports on the same basis as described in section 4.2 (b) above.

4.4 GMP as recommended by WHO assigns to the manufacturer of the finished dosage form responsibility for assuring the quality of active ingredients. National regulations may require that suppliers of active ingredients be identified in the product licence, but the competent authority may have no power to inspect them.

4.5 Notwithstanding this situation, a certifying authority may agree, on a discretionary and voluntary basis, and at the request of a manufacturer, to undertake an inspection of a manufacturer of active ingredients to satisfy specific requirements of a requesting authority. Alternatively, pending the development of specific guidelines for active pharmaceutical ingredients, the certifying authority may be able to attest that the manufacturer is an established supplier of the substance in question to manufacturers of finished dosage forms licensed for marketing under its jurisdiction.

4.6 Whenever a product is purchased through a broker or another intermediary, or when more than one set of premises has been involved in the manufacture and packaging of a product, the certifying authority should consider whether it has received sufficient information to satisfy itself that those aspects of the manufacture of the product for which the applicant is not directly responsible have been undertaken in compliance with GMP as recommended by WHO.

4.7 The certifying authority should officially stamp and date all copies of product information submitted to it in support of an application for a certificate and intended to be appended to the certificate. Every effort should be made to ensure that certificates and all annexed documentation are consonant with the version of the product licence operative on the date of issue. When available, the certifying authority will add a summary basis of approval or any other material that it may deem relevant. Translation by an applicant of these materials into a widely used language, preferably English, shall be deemed to satisfy the provisions of section 3.10.

4.8 Any additional attachment to a certificate submitted by the applicant, such as price lists of products for which bids are offered, should be clearly identified as not forming part of the attestation made by the certifying authority.

4.9 To avert potential abuse of the Scheme, to frustrate attempts at falsification, to render routine authentication of certificates by an independent authority superfluous, and to enable the certifying authority to maintain comprehensive records of countries to which specific products have been exported, each certificate should identify the importing country and be stamped on each page with the official seal of the certifying authority. If requested by the importing country, an identical copy, clearly marked as duplicate, should be forwarded by the certifying authority directly to that country's authority.

5. Notifying and investigating a quality defect

5.1 Each certifying authority undertakes to institute enquiries into any quality defect reported in a product exported in accordance with the provisions of the Scheme, on the understanding that:

– the complaint is transmitted, together with the relevant facts, through the competent authority in the importing country;

– the complaint is considered to be of a serious nature by the latter authority; and
– the defect, if it appeared after delivery of the product into the importing country, is not attributable to local conditions.

5.2 In the case of obvious doubt, a participating national authority may request WHO to assist in identifying an independent quality control laboratory to carry out tests for the purposes of quality control.

5.3 Each certifying authority undertakes to inform WHO and, as far as is possible, all competent national authorities, of any serious hazard newly associated with a product exported under the provisions of the Scheme or of any criminal abuse of the Scheme directed, in particular, to the export of falsely labelled, spurious, counterfeited or substandard pharmaceutical products. On receipt of such notification, WHO will transmit the message immediately to the competent national authority in each Member State.

5.4 WHO stands prepared to offer advice should difficulty arise in implementing any aspect of the Scheme or in resolving a complaint, but it cannot be a party to any resulting litigation or arbitration.

References

1. Quality control of drugs. In: *Twenty-second World Health Assembly, Boston, Massachusetts, 8-25 July 1969. Part I: Resolutions and decisions, annexes.* Geneva, World Health Organization, 1969: 99-105 (Official Records of the World Health Organization, No. 176).
2. Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. In: *Twenty-eighth World Health Assembly, Geneva, 13-30 May 1975. Part 1: Resolutions and decisions, annexes.* Geneva, World Health Organization, 1975: 94-95 (Official Records of the World Health Organization, No. 226).
3. Good manufacturing practices for pharmaceutical products. In: *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-second Report.* Geneva, World Health Organization, 1992: 14-79 (WHO Technical Report Series, No. 823).
4. WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. In: *Forty-first World Health Assembly, Geneva, 2-13 May 1988. Resolutions and decisions, annexes.* Geneva, World Health Organization, 1988: 53-55 (document WHA41/1988/REC/1).

Appendix 1

Model Certificate of a Pharmaceutical Product

Certificate of a Pharmaceutical Product[1]

This certificate conforms to the format recommended by the World Health Organization (*general instructions and explanatory notes attached*).

No. of Certificate: _____

Exporting (certifying) country: _____

Importing (requesting) country: _____

1. Name and dosage form of product:

_____

1.1 Active ingredient(s)[2] and amount(s) per unit dose:[3]

_____

_____

_____

For complete qualitative composition including excipients, see attached.[4]

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5] yes/no (*key in as appropriate*)

1.3 Is this product actually on the market in the exporting country? yes/no/unknown (*key in as appropriate*)

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue with section 2B.[6]

2A.1 Number of product licence[7] and date of issue:

_____

2A.2 Product-licence holder (name and address):

_____

_____

_____

2A.3 Status of product-licence holder:[8] a/b/c (*key in appropriate category as defined in note 8*)

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are:[9]

_____

2A.4 Is Summary Basis of Approval appended?[10] yes/no
(*key in as appropriate*)

2A.5 Is the attached, officially approved product information complete and consonant with the licence?[11] yes/no/not provided
(*key in as appropriate*)

2A.6 Applicant for certificate, if different from licence holder (name and address):[12]

_____

_____

2B.1 Applicant for certificate (name and address):

_____

_____

2B.2 Status of applicant: a/b/c (*key in appropriate category as defined in note 8*)

2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form are:[9]

_____

2B.3 Why is marketing authorization lacking?

not required/not requested/under consideration/refused
(*key in as appropriate*)

2B.4 Remarks:[13] _____

_____

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

yes/no/not applicable[14] (*key in as appropriate*)

If no or not applicable proceed to question 4.

3.1 Periodicity of routine inspections (years): _____

3.2 Has the manufacture of this type of dosage form been inspected? yes/no (*key in as appropriate*)

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?[15]

yes/no/not applicable[14] (*key in as appropriate*)

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[16]

yes/no (*key in as appropriate*)

If no, explain: _____

_____

Address of certifying authority:

_____

_____

Telephone number: _____ Fax number: _____

Name of authorized person:

_____

Signature:

_____

Stamp and date:

_____

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

[1] This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

[2] Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.

[3] The formula (complete composition) of the dosage form should be given on the certificate or be appended.

[4] Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-licence holder.

[5] When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

[6] Sections 2A and 2B are mutually exclusive.

[7] Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

[8] Specify whether the person responsible for placing the product on the market:

(a) manufactures the dosage form;
(b) packages and/or labels a dosage form manufactured by an independent company; or
(c) is involved in none of the above.

[9] This information can be provided only with the consent of the product-licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information.

It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence must be updated or it will cease to be valid.

[10] This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.

[11] This refers to product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SPC).

[12] In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission must be provided to the authority by the applicant.

[13] Please indicate the reason that the applicant has provided for not requesting registration:

(a) the product has been developed exclusively for the treatment of conditions – particularly tropical diseases – not endemic in the country of export;
(b) the product has been reformulated with a view to improving its stability under tropical conditions;

(c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
(d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
(e) any other reason, please specify.

[14] Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

[15] The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series, No. 823, 1992, Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).

[16] This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

The layout for this Model Certificate is available on diskette in WordPerfect from the Division of Drug Management and Policies, World Health Organization, 1211 Geneva 27, Switzerland.

Appendix 2

Model Statement of Licensing Status of Pharmaceutical Product(s)

No. of Statement _____

Exporting (certifying) country:

Importing (requesting) country:

Statement of Licensing Status of Pharmaceutical Product(s)[1]

This statement indicates **only** whether or not the following products are licensed to be put on the market in the exporting country.

Applicant (name/address):

Name of product	Dosage form	Active ingredient(s)[2] and amount(s) per unit dose	Product-licence no. and date of issue[3]

The certifying authority undertakes to provide, at the request of the applicant (or, if different, the product-licence holder), a separate and complete Certificate of a Pharmaceutical Product in the format recommended by WHO, for each of the products listed above.

Address of certifying authority:

Telephone/fax numbers:

Name of authorized person:

Signature:

Stamp and date:

This statement conforms to the format recommended by the World Health Organization (*general instructions and explanatory notes below*).

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

[1] This statement is intended for use by importing agents who are required to screen bids made in response to an international tender and should be requested by the agent as a condition of bidding. The statement indicates that the listed products are authorized to be placed on the market for use in the exporting country. A Certificate of a Pharmaceutical Product in the format recommended by WHO will be provided, at the request of the applicant and, if different, the product-licence holder, for each of the listed products.

[2] Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.

[3] If no product licence has been granted, enter "not required", "not requested", "under consideration" or "refused" as appropriate.

The layout for this Model Statement is available on diskette in WordPerfect from the Division of Drug Management and Policies, World Health Organization, 1211 Geneva 27, Switzerland.

Appendix 3

Model Batch Certificate of a Pharmaceutical Product

Manufacturer's/Official[1] Batch Certificate of a Pharmaceutical Product

This certificate conforms to the format recommended by the World Health Organization (*general instructions and explanatory notes attached*).

1. No. of Certificate: _____

2. Importing (requesting) authority: _____

3. Name of product: _____

3.1 Dosage form: _____

3.2 Active ingredient(s)[2] and amount(s) per unit dose: _____

_____

_____

3.2.1 Is the composition of the product identical to that registered in the country of export? yes/no/not applicable[3] (*key in as appropriate*)

If no, please attach formula (including excipients) of both products.

4. Product-licence holder[4] (name and address):

_____

_____

_____

4.1 Product-licence number:[4] _____

4.2 Date of issue:[4] _____

4.3 Product licence issued by:[4] _____

4.4 Product-certificate number :[4, 5] _____

5.1 Batch number: _____

5.2 Date of manufacture: _____

5.3 Shelf-life (years): _____

5.4 Contents of container: _____

5.5 Nature of primary container: _____

5.6 Nature of secondary container/wrapping: _____

_____

5.7 Specific storage conditions: _____

_____

5.8 Temperature range: _____

6. Remarks:[6]

_____

7. Quality analysis

7.1 What specifications apply to this dosage form? Either specify the pharmacopoeia or append company specifications.[7]

_____

7.1.1 In the case of a product registered in the exporting country, have the company specifications[7] been accepted by the competent authority? yes/no *(key in as appropriate)*

7.2 Does the batch comply with all parts of the above specifications? yes/no *(key in as appropriate)*

7.3 Append certificate of analysis.[8]

It is hereby certified that the above declarations are correct and that the results of the analyses and assays on which they are based will be provided on request to the competent authorities in both the importing and the exporting countries.

Name and address of authorized person:

_____

_____

Telephone number: _____ Fax number: _____

Signature of authorized person: _____

Stamp and date: _____

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

These forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

Certification of individual batches of a pharmaceutical product is only undertaken exceptionally by the competent authority of the exporting country. Even then, it is rarely applied other than to vaccines, sera and biologicals. For other products, the

responsibility for any requirement to provide batch certificates rests with the product-licence holder in the exporting country. The responsibility to forward certificates to the competent authority in the importing country is most conveniently assigned to the importing agent.

Any inquiries or complaints regarding a batch certificate should always be addressed to the competent authority in the exporting country. A copy should be sent to the product-licence holder.

[1] Strike out whichever does not apply.

[2] Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.

[3] "Not applicable" means that the product is not registered in the country of export.

[4] All items under 4 refer to the product licence or the Certificate of a Pharmaceutical Product issued in the exporting country.

[5] This refers to the Certificate of a Pharmaceutical Product as recommended by the World Health Organization.

[6] Indicate any special storage conditions recommended for the product as supplied.

[7] For each of the parameters to be measured, the specifications give the values that have been accepted for batch release at the time of product registration.

[8] Identify and explain any discrepancies from specifications. Government batch release certificates issued by certain governmental authorities for specific biological products provide additional confirmation that a given batch has been released, without necessarily giving the results of testing. The latter are contained in the manufacturer's certificate of analysis.

The layout for this Model Certificate is available on diskette in WordPerfect from the Division of Drug Management and Policies, World Health Organization, 1211 Geneva 27, Switzerland.

Appendix 4
Glossary and index

In order to facilitate understanding, terms used in the guidelines are explained here and/or reference is made to relevant sections. This appendix provides supplementary information and is not a formal part of the Scheme.

For the sake of clarity, all definitions taken from the glossary of "Good manufacturing practices for pharmaceutical products" (*1*) are preceded by an asterisk.

abuse of Scheme
See sections 4.9 and 5.2 of the guidelines.

active ingredients
See sections 1.5, 4.4 and 4.5 of the guidelines.

addresses of competent authorities
See sections 2.2 and 3.3 of the guidelines.

applicant
The party applying for a Product Certificate. This is normally the product-licence holder. Because certain data are confidential for commercial reasons, the competent authority in the exporting country must always obtain permission to release these data from the product-licence holder or, in the absence of a product licence, from the manufacturer.

authentication of certificates
See section 4.9 of the guidelines.

** batch (or lot)*
A defined quantity of a starting material, packaging material, or product processed in a single process or series of processes so that it can be expected to be homogeneous. In the case of continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch.

batch certificate
A document containing information, as set out in Appendix 3 of the guidelines, will normally be issued for each batch by the manufacturer. Furthermore, a batch certificate may exceptionally be validated or issued by the competent authority of the exporting country, particularly for vaccines, sera and other biological products. The batch certificate accompanies every major consignment (see also section 3.14 of the guidelines).

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

** bulk product*
A product that has completed all processing stages up to, but not including, final packaging.

certifying authority
The competent authority that issues product certificates. It must ensure that it possesses the capacities listed in section 2.4 of the guidelines.

charges for product certificates
See section 3.11 of the guidelines.

competent authority
The national authority as identified in the formal letter of acceptance in which each Member State informs WHO of its intention to participate in the Scheme. The extent of its participation should be indicated in the letter of acceptance (see section 2.1 of the guidelines). The competent authority can issue or receive certificates.

WHO makes available on request a continuously updated list of addresses of competent authorities and, when applicable, the specific conditions for participation.

competence and evaluation of national authority
See sections 2.4, 2.5 and 4.2 of the guidelines.

dosage form
The form of the completed pharmaceutical preparation, e.g. tablet, capsule, elixir, suppository.

drug regulatory authority
An authority appointed by the government of a Member State to administer the granting of marketing authorizations for pharmaceutical products in that country.

** finished product*
A product that has undergone all stages of production, including packaging in its final container and labelling.

free sale certificate
See section 3.2 of the guidelines.

GMP certificate
See section 3.2 of the guidelines.

importing agents, guidelines for
See section 3.4 of the guidelines.

language of product certificate
See section 3.10 of the guidelines.

licence holder
An individual or a corporate entity possessing a marketing authorization for a pharmaceutical product.

licensee
An individual or corporate entity responsible for the information and publicity on, and the pharmacovigilance and surveillance of batches of, a pharmaceutical product and, if applicable, for their withdrawal, whether or not that individual or corporate entity is the holder of the marketing authorization.

limits of certificate by competent authority
See sections 3.12 and 4.8 of the guidelines.

lot
See *batch.*

* *manufacture*
All operations of purchase of materials and products, production, quality control, release, storage, shipment of finished products, and related controls.

* *manufacturer*
A company that carries out at least one step of manufacture. (For the different categories of manufacturer, see Appendix 1, explanatory note no. 7.)

marketing authorization
See *product licence.*

pharmaceutical product
Any medicine intended for human use or administered to food-producing animals, presented in its finished dosage form or as an active ingredient for use in such dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.

product
See *pharmaceutical product.*

product certificate
A document containing the information as set out in Appendix 1 of the guidelines that is validated and issued for a specific product by the competent authority of the exporting country and intended for use by the

competent authority in the importing country or – in the absence of such an authority – by the drug procurement authority (see also section 3.5 of the guidelines).

Transmission of product certificate: see sections 3.8 and 4.9 of the guidelines.

Validity of product certificate: see section 3.9 of the guidelines.

When to request a product certificate: see section 3.5 of the guidelines.

product information
The approved product information referred to in section 4.7 of the guidelines and item 2A.5 of the Product Certificate. It normally consists of information for health professionals and the public (patient information leaflets), as approved in the exporting country and, when available, a data sheet or a Summary of Product Characteristics (SPC) approved by the regulatory authority.

product licence
An official document issued by the competent drug regulatory authority for the purpose of the marketing or free distribution of a product. It must set out, *inter alia*, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using International Nonproprietary Names or national generic names, where they exist), the shelf-life and storage conditions, and packaging characteristics. It also contains all the information approved for health professionals and the public (except promotional information), the sales category, the name and address of the licence holder, and the period of validity of the licence.

product-licence holder
See *licence holder*.

** production*
All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing and packaging, to completion of the finished product.

registration
Any statutory system of approval required at national level as a precondition for introducing a pharmaceutical product on to the market.

registration certificate
See *product licence*.

specifications
See Appendix 3, explanatory note 7.

statement of licensing status
See section 3.13 of the guidelines and Appendix 2.

Summary Basis of Approval
The document prepared by some national regulatory authorities that summarizes the technical basis on which the product has been licensed (see section 4.7 of the guidelines and explanatory note 9 of the Product Certificate contained in Appendix 1).

Summary of Product Characteristics (SPC)
Product information as approved by the regulatory authority. The SPC serves as the basis for production of information for health personnel as well as for consumer information on labels and leaflets of medicinal products and for control of advertising (see also *Product information*).

tenders and brokers
See section 4.6 of the guidelines.

WHO responsibility
See section 5.4 of the guidelines.

Reference

1. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-second report.* Geneva, World Health Organization, 1992:18-22 (WHO Technical Report Series, No. 823).