PROPOSAL FOR REVISION OF THE WHO CERTIFICATION
SCHEME ON THE QUALITY OF PHARMACEUTICAL
PRODUCTS MOVING IN INTERNATIONAL COMMERCE

(April 2018)

DRAFT FOR COMMENT

Should you have any comments on the attached revision, please send these to Dr S. Kopp, Group Lead, Medicines Quality Assurance, Technologies Standards and Norms (kopps@who.int), with a copy to Mrs. Xenia Finnerty (finnertyk@who.int), by 15 May 2018.

Our working documents will be sent out electronically only and will also be placed on the Medicines website for comment under “Current projects”. If you do not already receive our draft working documents please let us have your email address (to bonnyw@who.int) and we will add it to our electronic mailing list.

© World Health Organization 2018

All rights reserved.

This draft is intended for a restricted audience only, i.e. the individuals and organizations having received this draft. The draft may not be reviewed, abstracted, quoted, reproduced, transmitted, distributed, translated or adapted, in part or in whole, in any form or by any means outside these individuals and organizations (including the organizations’ concerned staff and member organizations) without the permission of the World Health Organization. The draft should not be displayed on any website.

Please send any request for permission to:
Dr Sabine Kopp, Group Lead, Medicines Quality Assurance, Technologies Standards and Norms, Department of Essential Medicines and Health Products, World Health Organization, CH-1211 Geneva 27, Switzerland. Fax: (41-22) 791 4730; email: kopps@who.int.

The designations employed and the presentation of the material in this draft do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers’ products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this draft. However, the printed material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

This draft does not necessarily represent the decisions or the stated policy of the World Health Organization.
### SCHEDULE FOR THE PROPOSED ADOPTION PROCESS OF DOCUMENT QAS/18.768:

**PROPOSAL FOR REVISION OF THE WHO CERTIFICATION SCHEME ON THE QUALITY OF PHARMACEUTICAL PRODUCTS MOVING IN INTERNATIONAL COMMERCE**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendation by 52nd WHO Expert Committee on Specifications for Pharmaceutical Preparations to prepare a proposal for revision of the scheme for public consultation</td>
<td>16–20 October 2018</td>
</tr>
<tr>
<td>Preparation of working document by WHO Secretariat</td>
<td>February–March 2018</td>
</tr>
<tr>
<td>Circulation of working document for public comments</td>
<td>April 2018</td>
</tr>
<tr>
<td>Consolidation of comments received</td>
<td>May 2018</td>
</tr>
<tr>
<td>Discussion of working document and feedback received during the informal consultation on regulatory tools for medicines</td>
<td>19–20 May 2018</td>
</tr>
<tr>
<td>Circulation of revised working document for public consultation</td>
<td>June–July 2018</td>
</tr>
<tr>
<td>Consolidation of comments received and review of feedback</td>
<td>August 2018</td>
</tr>
<tr>
<td>Presentation to the 18th International Conference of Drug Regulatory Authorities</td>
<td>3–7 September 2018</td>
</tr>
<tr>
<td>Presentation to the 53rd meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations</td>
<td>22–26 October 2018</td>
</tr>
<tr>
<td>Any further action, as recommendation by the WHO Expert Committee on Specifications for Pharmaceutical Preparations</td>
<td></td>
</tr>
</tbody>
</table>
PROPOSAL FOR IMPROVEMENT OF THE WHO CERTIFICATION SCHEME ON
THE QUALITY OF PHARMACEUTICAL PRODUCTS MOVING IN
INTERNATIONAL COMMERCE

1. INTRODUCTION

The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (the “Scheme”) is an international voluntary agreement to provide assurance to countries participating in the Scheme, about the quality of pharmaceutical products moving in international commerce. The primary document of the Scheme is the certificate of a pharmaceutical product (CPP).

The fifty-second WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) in 2017 was informed about the current situation of the Scheme, including the fact that the forty-third Expert Committee in 2008 had recommended that “the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be revised” in line with recent developments. The Expert Committee in 2017 recommended that the “WHO Secretariat should prepare a proposal for revision of the Scheme for public consultation”.

The objective of this working document is to compile key issues on the Scheme and provide a proposed revision of the Scheme for consideration during the upcoming fifty-third ECSPP meeting in 2018.

2. BACKGROUND

The Scheme has been in operation since 1969 (World Health Assembly resolution WHA 22.50) and was amended in 1975 (WHA 28.65), 1988 (WHA 41.18), 1992 (WHA 45.29) and 1997 (WHA 50.3) (1–5). The current Scheme provides following three types of certificate:

- CPP;
- statement of the licensing status of pharmaceutical product;
- batch certificate.
In 2007, the forty-second ECSPP discussed and identified a number of perceived problems with the operation of the Scheme (6).

In 2008, a WHO consultation was held to make recommendations for consideration during the forty-third ESPCC, taking account of the WHO working document QAS/07.240 which contains key issues and possible action (7). The forty-third ECSPP in 2008 discussed the report of the consultation (working document QAS/08.279) (8). In light of the changing environment, including the rapid globalization of the pharmaceutical manufacturing sector, coupled with changes in the make-up of both the regulators and the groups involved in procurement, the forty-third ECSPP endorsed the following recommendations (9):

1. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be revised;
2. The proposal for revision of the Scheme and modification of the guidelines should be discussed by the relevant WHO Governing Bodies – the Executive Board and the World Health Assembly – and in consultation with WHO’s Legal Counsel.
3. In the interim a question and answer (Q&A) paper should be prepared on the function of the Scheme.”

Based on the above recommendation, as an interim measure, a Q&A document on the function of the Scheme was developed in 2010 and it was revised in 2015 (10, 11). However, the Scheme has not been revised since 1997.

In 2017, the fifty-second ECSPP recommended that the “WHO Secretariat should prepare a proposal for revision of the scheme for public consultation” (12).

The draft working document which includes the proposed revision of the Scheme was prepared by the WHO Secretariat and it will be discussed during an informal consultation planned to be held on 19 to 20 May 2018. In addition, the draft working document will be circulated, including
to the Member States and other interested parties, for public consultation to prepare a version of the working document for possible endorsement by the fifty-third ECSPP.

3. PROPOSED REVISION OF THE SCHEME

Since the last revision of the Scheme in 1997 it has been discussed on various occasions and key issues and possible actions have been identified. These are roughly classified into the following two aspects:

(a) issues related to the revision of the Scheme;
(b) issues related to implementation/operational aspects of the Scheme.

The objective of this working document is to provide a proposed revision of the scheme for consideration [endorsement/adoption] during the upcoming fifty-third ECSPP. Therefore, possible action related to implementation and operational aspects of the Scheme (e.g. promotion of the Scheme, making use of IT) would be considered after adoption of the revision of the Scheme.

3.1 Summary of key issues and proposed actions related to the revision of the Scheme

The table below outlines key issues and possible actions. These were prepared mainly based on the report of the forty-third ECSPP and on working documents QAS/07.240 and QAS/08.279 and the Q&A document¹ as well as comments from the Member States and interested parties during public consultation (6, 7, 9, 12).

¹ Q16 is “What are the main problem encountered in the application of the Scheme”
<table>
<thead>
<tr>
<th>Key issues</th>
<th>Proposed actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>The Scheme is formally at present directed to individual Member States, whereas regulatory and procurement groupings of multistate organizations also need to be able to operate within the Scheme; this applies to both issuing and receiving parties</td>
</tr>
</tbody>
</table>
| | • The wordings in the Scheme should be changed so that regional organizations, such as the European Union can formally participate in the Scheme  
**[Note from Secretariat: Member State(s)” => “Member State(s) and/or regional authority(ies)”]** |
| b | The list of competent authorities is out of date; details of some authorities have changed. The current list of countries that participate in the Scheme in its present form is not readily available |
| | • Memberships as “certificate-issuing” countries should be renewed every five years  
**[Note from Secretariat: Added new para. as section 2.5; See below for more detail.]** |
|  | • Member States should inform any update of the name and address of competent authorities to the WHO secretariat  
**[Note from Secretariat: Added new paragraph as section 2.7.]** |
| c | Exporting countries that do not fulfil the prerequisites required by the Scheme issue certificates to support export |
| | • Memberships as “certificate-issuing” countries should be renewed every five years. Member States intending to continue to participate in the Scheme as “certificate-issuing” countries should resubmit notification to the Director-General of the World Health Organization (WHO) in the same way as section 2.1  
**[Note from Secretariat: Added new paragraph as section 2.5.]** |
|  | • Member States intending to participate in the Scheme as certificate-issuing countries should declare that the competent authority meets the requirements in the notification to the WHO Director-General  
**[Note from Secretariat: Added new paragraph as section 2.4.]** |
|  | • In case that WHO does not receive the notification for renewal of membership for a long time period, the Director-General may delete such a Member State’s name from the participant list in consultation with the relevant Expert Committee |
d The CPP is no longer provided to substitute the full dossier quality safety and efficacy (QSE) review

- CPPs should not be requested in countries that have the capability to conduct full QSE reviews

[Note from Secretariat: Added new paragraph as section 2.8.]

e Information on who released the batch for marketing is not disclosed in certificates issued by exporting countries

- The certificate should include batch release site information in the CPP as a new option (in section 2A.3, explanatory note 8 in model certificate of the guidelines) (“option c” will become the new “d” and a new “c” will be created)

[Note from Secretariat: Added new words in Appendix 1 of the Annex.]

f There have been cases in which forged certificates have been supplied to competent authorities of importing countries

- Email address, telephone and fax numbers should be provided as contact information so that the requesting authority can request confirmation to the certifying authority countries easily

[Note from Secretariat: Added new words in section 2.4.]

g Lead times of the certifying authorities can be very long, sometimes several months

- Certifying authority should provide a certificate without undue delay

[Note from Secretariat: Added new paragraph as section 4.10.]

h Importing countries require legalization of certificates, additional stamps, etc.

- Unnecessary legalization should not be requested

[Note from Secretariat: Added new paragraph as section 4.7.]

3.2 Proposed revision of the Scheme

The proposal for revision of the Scheme is attached as an annex. The amendments of the Scheme in the annex are presented in track-change mode. Moreover, it should be noted that this revision includes not only an amendment related to 3.1 in this working document but also editorial changes such as:
• updating some definitions in “Glossary and index” in conformity with latest version of relevant guidelines;
• replacing some words (e.g. “license” by “market authorization”).

4. OTHER ISSUES RELATED TO OPERATION OF THE SCHEME

The table below outlines key issues not related to revision of the Scheme. As described in section 3 of this document, possible actions regarding implementation/operation of the Scheme (e.g. promotion of the Scheme, making use of IT) should be considered after adoption of the revision of the Scheme.

<table>
<thead>
<tr>
<th>Key issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
</tr>
<tr>
<td>b</td>
</tr>
<tr>
<td>c</td>
</tr>
<tr>
<td>d</td>
</tr>
<tr>
<td>e</td>
</tr>
<tr>
<td>f</td>
</tr>
</tbody>
</table>

5. REFERENCES

2. World Health Assembly resolution WHA28.65 (1975).
3. World Health Assembly resolution WHA41.18 (1988).
5. World Health Assembly resolution WHA50.3 (1997).
7. Proposal for improvement of the WHO Certification Scheme on the Quality of
Pharmaceutical Products Moving in International Commerce (working document QAS/07.240).


10. WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce: Question and Answer (Q&A) (QAS/10.374, 2010)

11. WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce: Questions and Answers (Q & A) (WHO Drug Information Vol. 30, No. 3, 2016)

1. PROVISIONS AND OBJECTIVES

1.1 A comprehensive system of quality assurance must be founded on a reliable system of 
marketing authorization and independent analysis of the finished pharmaceutical 
product, as well as upon 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 several times. The first revision was adopted by the 
Health Assembly in 1975 in resolution WHA28.65 (2). A second revision of the requirements is 
included in the Thirty-second report of the WHO Expert Committee on Specifications for 
Pharmaceutical Products (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 or regional authority, upon application by a commercially 
interested party, to attest to the competent authority of another participating Member State or 
regional authority 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 the World Health 
Organization (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 (3), 1992 (4) and 1997 (5), 
by resolutions WHA28.65 and WHA41.18, WHA45.29 and WHA50.3, is applicable to finished
dosage forms of pharmaceutical products intended for administration to human beings or to food-producing animals.

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

2. **MEMBERSHIP: ELIGIBILITY FOR PARTICIPATION**

[Note from Secretariat: the new text in section 2 includes rearrangement of the order of paragraphs and such change is NOT presented in track-change mode except for the section number.]

2.1 Any Member State as well as regional authority that has legal right to control the regulation of pharmaceutical products are eligible to participate in the Scheme as a certifying member and/or a requesting member if it complies with the requirements stipulated in section 2.2 or 2.3.

2.2 A Member State intending to use the Scheme as a certifying member to support the export of pharmaceutical products should first satisfy itself that it possesses:

- an effective marketing authorization 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 its 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;
- 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.

2.3 A regional authority intending to become a certifying member should possess by itself or through its legal framework:

- an effective marketing authorization 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 its region, including access to an independent quality control laboratory;

- a pharmaceuticals inspectorate, operating as an arm of the 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;

- 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 and regional organization known to have imported a specific product that is subsequently associated with a potentially serious quality defect or other hazard.

2.4.1 Membership as a certifying member and/or requesting member can be applied by Any Member State intending to participate in the Scheme may do so by notifying in writing to the WHO Director-General of:

- its willingness to participate in the Scheme as a certifying member and/or a requesting member (Member States and regional authorities may participate only as a certifying member to control the import of pharmaceutical products and APIs);

- any significant reservations it intends to observe relating to this participation; and

- the name and address (including email address, telephone and fax numbers) of its national drug regulatory authority or other competent authority; and

- declaration to comply with the requirements for a certifying member stipulated in section 2.2 or 2.3, if applicable.

2.5 A Member State and regional authority that has a membership of a certifying member should resubmit the notification in section 2.4 at least once every five years, in order to ensure that it continues to comply with the requirement stipulated in section 2.2 or 2.3 and that contact information keeps updated.

2.6.2 Consolidated list of information on the notification submitted by Member States and regional authorities in accordance with provision in sections 2.4, 2.5 and 2.7 will be available through WHO’s official website. (See also section 3.3). These notifications will be subsequently announced in the monthly WHO Pharmaceutical 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)

2.6 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 the World Health Organization.

2.7 A Member State and regional authority should inform WHO of any change of information notified to the WHO Director-General.
2.8 Membership as a certifying member may be disqualified by the Director-General after consultation with the ECSPP in the case that a Member State or regional authority would fail to resubmit a notification in accordance with provision in section 2.5 for a long period.

2.95 Each Member State and regional authority assumes the responsibility to determine, through a process of self-evaluation, whether it satisfies these prerequisites. The Scheme contains no provision, under any circumstance, for external inspection or assessment, either of a competent national authority or of a manufacturing facility. However, should a Member State or regional organization so wish, it could approach WHO, or a well-recognized drug regulatory authority, to occasionally delegate consultants to act as advisers in the course of 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 a 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, these documents are presented in forms suitable for generation by computer. All participating Member States and regional authorities are henceforth urged to adopt these formats to facilitate 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 certification of information going beyond the scope of this Scheme. When manufacture takes place in a country other than that from which the product certificate is issued, an attestation relevant to compliance of the manufacture 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. Whilst they are not part of the document to be certified, they should always be attached to the certificate.

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 will be available at the WHO official website may be obtained from WHO as indicated in section 2.62.

3.4 Each competent authority in certifying members 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 to 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 competent authority in the exporting country or regional authority ("the certifying authority") exporting country, is intended for use by the competent authority within an importing country and regional organization in two situations:

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

3.6 The Certificate of a pharmaceutical product should not be required by the Member States or regulatory authorities where they undertake full quality, safety and efficacy review by themselves.

3.7 All requests for certificates should be channeled through the agent in the importing country (see section 3.4) and the product licence marketing authorization holder or other commercially-interest party in the exporting country ("the applicant"). The applicant should submit the following information for each product to the authority issuing the certificate:

- name and dosage form of product
- name and amount of active ingredient(s) per unit dose (International Nonproprietary Name(s) where such exist(s)),
- name and address of product licence marketing authorization holder and/or manufacturing facility,
- formula (complete composition including all excipients; also particularly when no product licence marketing authorization exists or when the formulation differs from that of the authorized licensed product),
- product information for health professionals and for the public (patient information leaflets) as approved by the certifying authority in the exporting country.

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

3.8 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 marketing authorization holder.

3.9 The certificate is intended to be incorporated into a product licence marketing authorization application in the competent authority in the importing country and regional authority ("the requesting authority"). Once prepared, it is transmitted to the requesting authority through the applicant and, when applicable, the agent in the importing country.
3.109 When any doubt arises about the status or validity of a certificate, the requesting competent authority in the importing country should request a copy directly from the certifying authority, as provided for under section 4.9 of these guidelines.

3.110 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.

3.124 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.

3.132 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 marketing authorization/licensing status

3.143 Model statement of marketing authorization Statement of Licensing Status (Appendix 2). This attests only that a marketing authorization/license 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 CPP.

Batch certificate

3.154 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 element in tender and procurement documents.

3.165 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 in the exporting country or regional authority. 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 obtained marketing authorization 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 license 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:

- applies identical GMP standards to the production of all batches of pharmaceutical products manufactured within the facility, including those destined exclusively for export;
- 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 requesting authority/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 APIs. National or regional regulations may require that suppliers of APIs be identified in the product licence/marketing authorization, 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 APIs to satisfy specific requirements of a requesting authority. Alternatively, pending the development of specific guidelines for APIs, 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 authorized/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/marketing authorization operative on the date of
Nevertheless, requesting authorities should not request unnecessary legalization procedure that may cause undue delay of certificates.

When available, the certifying authority will add a summary basis of approval or any other material the authority deems relevant. Translation by an applicant of these materials into a widely used language, preferably English, shall be deemed to satisfy the provision of 3.1 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 comprising 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, an identical copy, clearly marked as duplicate, should be forwarded by the certifying authority on demand directly to the requesting importing country authority.

4.10 The certifying authority should establish standard period of time for issue of certificates. It should endeavor to make each issue of certificate completed within this period as far as the applicant submits sufficient documents.

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 requesting 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 or falsified pharmaceutical products. On receipt of such notification, WHO will transmit the message immediately to the competent national authority in each Member State and regional organization.
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


APPENDIX 1

MODEL CERTIFICATE OF A PHARMACEUTICAL PRODUCT

CERTIFICATE OF A PHARMACEUTICAL PRODUCT\textsuperscript{1}

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

No. of Certificate: ________________________________________________

Certifying member\textsuperscript{2} Exporting (certifying) country): ____________________________________________

Requesting member\textsuperscript{2} Importing (requesting) country): ____________________________________________

1. Name and dosage form of the product:

____________________________________________________________________________

1.1. Active ingredient(s)\textsuperscript{2} and amount(s) per unit dose\textsuperscript{3}:

____________________________________________________________________________

____________________________________________________________________________

For complete composition including excipients, see attached.\textsuperscript{4}

1.2. Is this product authorized\textsuperscript{2} licensed to be placed on the market for use in the exporting country?\textsuperscript{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\textsuperscript{6}:

2.A.1. Number of product licence\textsuperscript{2} marketing authorization\textsuperscript{7} and date of issue:

____________________________________________________________________________

2.A.2. Product licence\textsuperscript{2} Marketing authorization\textsuperscript{7} holder (name and address): ______________________

____________________________________________________________________________

2.A.3. Status of product licence\textsuperscript{2} marketing authorization\textsuperscript{7} holder\textsuperscript{8}: a/b/c/d

(key in appropriate category as defined in note 8)

2.A.3.1. For categories b\textsuperscript{2} c and d\textsuperscript{2} e, the name and address of the manufacturer producing the dosage form is\textsuperscript{7}:

____________________________________________________________________________
2.A.3.2. For categories d, the name and address of the manufacturer certifying the finished
pharmaceutical product batch is:  

2.A.4. Is a summary basis for approval appended?  yes/no (key in as appropriate)

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

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

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

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

2.B.2.1. For categories b, c and d, the name and address of the manufacturer producing the
dosage form is:

2.B.2.2. For categories d, the name and address of the manufacturer certifying the finished
pharmaceutical product batch is:

2.B.3. Why is marketing authorization lacking?
not required/not requested/under consideration/refused (key in as appropriate)

2.B.4. Remarks:

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in
which the dosage form is produced? yes/no/not applicable (key in as appropriate)
If not 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 WHO?  yes/no/not applicable (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? \( \text{yes/no (key in as appropriate)} \)

If no, explain: ________________________________________________________________
___________________________________________________________________________

Address of certifying authority: _____________________________________________
___________________________________________________________________________

Telephone number: _______________________ Fax number: _________________________
E-mail address: __________________________

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.
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;
(c) certifies the finished pharmaceutical product batch; or
(d) is involved in none of the above.

This information can only be provided with the consent of the product licence marketing authorization 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 marketing authorization. If the production site is changed, the licence marketing authorization has to be updated or it is no longer valid.

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

This refers to product information approved by the competent national drug regulatory authority, such as summary product characteristics (SPC).

In this circumstance, permission for issuing the certificate is required from the product licence marketing authorization holder. This permission has to be provided to the authority by the applicant.

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; any other reason, please specify.

Not applicable means 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.

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).

This section is to be completed when the product licence marketing authorization holder or applicant conforms to status (b) or (c) as described in note 8 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 MARKETING AUTHORIZATION

LICENSING STATUS OF PHARMACEUTICAL PRODUCT(S)

No. of Statement: _____________________________________________

Certifying member Exporting (certifying) country: ______________________

Requesting member Importing (requesting) country: ______________________

Statement of marketing authorization 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): _____________________________________________

<table>
<thead>
<tr>
<th>Name of product</th>
<th>Dosage form</th>
<th>Active ingredient(s)² and amount(s) per unit dose:</th>
<th>Product licensee Marketing authorization no. and date of issue³</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The certifying authority undertakes to provide, at the request of the applicant (or, if different, the product licensee marketing authorization holder), a separate and complete certificate of a pharmaceutical product (CPP) in the format recommended by the World Health Organization (WHO), for each of the products listed above.

Address of certifying authority: _____________________________________________

Telephone number: __________________________ Fax number: __________________________

Email address: __________________________

Name of authorized person: _____________________________________________

Signature: _____________________________________________

Stamp and date: _____________________________________________

This statement conforms to the format recommended by WHO.

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 (CPP) 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 Certificate 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 PRODUCTS

MANUFACTURERS/OFFICIAL\(^1\) BATCH CERTIFICATE OF A PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization (WHO) (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 If the composition of the product identical to that registered in the country of export? (yes/no/not applicable)\(^3\)
      If no: please attach formula (including excipients) of both products.
4. Product licenceMarketing authorization holder\(^4\) (name and address): ______________
   4.1 Product licenceMarketing authorization number\(^4\): ______________________
   4.2 Date of issue\(^4\): ______________________
   4.3 Product licenceMarketing authorization 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: ________________________________________________________________

7. Quality analysis:

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

7.1.1 In the case of a product registered in the exporting country, have these company specifications been accepted by the competent authority? (yes/no)

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

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 exporting countries.

Name and address of authorized person: _______________________________________

Telephone number: __________________________ Fax number: ________________________

E-mail address: ______________________________

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 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 marketing authorization 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 marketing authorization 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 marketing authorization or the certificate of a pharmaceutical product (CPP) issued in the exporting country.
5. This refers to the Certificate of a Pharmaceutical Product (CPP) as recommended by WHO.
6. Indicate any special storage conditions recommended for the product as supplied.
7. For each of the parameters to be measured, 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.
GLOSSARY AND INDEX

In order to facilitate understanding, this glossary explains terms in the guidelines and/or refers to relevant sections. It is considered as supplementary information and not as being a formal part of the Scheme.

For clarity, all definitions that have been taken from the glossary of the WHO Technical Report Series No. 823, 1992 are preceded by an asterisk.

**abuse of Scheme**
See section 4.9 and 5.2 of the guidelines.

**active pharmaceutical ingredients**
Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body. See section 1.5, 4.4 and 4.5 of the guidelines.

**addresses of competent authorities**
See item 2.62 and 3.3 of the guidelines.

**applicant**
The party applying for a product certificate. This is normally the product licencemaking authorization holder. In all instances, having regard to commercial confidentiality of certain data, the competent authority in the exporting country must obtain permission to release these data from the product licencemaking authorization holder, or, in the absence of a product licencemaking authorization, 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. 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. In the case of terminal sterilization, the batch size is determined by the capacity of the autoclave. In the case of continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. The batch size can be defined either as a fixed quality or as the amount produced in a final time interval. 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 Annex 3 of the guidelines for use, will normally be issued for each batch by the manufacturer. Furthermore, exceptionally a batch certificate may be validated or issued by the competent authority of the exporting country, particularly for vaccines, sera and other biological products. The batch certificate travels with every major consignment (see also section 3.14 of the guidelines).

**Batch number (or lot number).**
A distinctive combination of numbers and/or letters which uniquely identifies a batch on the labels, its batch records, and corresponding certificates of analysis, etc.

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

**Certifying authority.**
This is the competent authority that issues product certificates. It shall ensure that it possesses the capacities listed in section 2.2 and 2.3 of the guidelines.

**Charges for product certificates.**
See section 3.11 of the guidelines.

**Competence and evaluation of national authority.** See sections 2.2, 2.3, 2.9 and 4.2 of the guidelines.

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

WHO makes available upon request a continuously updated list of addresses of competent authorities and, when applicable, the specific conditions for participation (see section 2.6 of the guideline).

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

**Drug regulatory authority.**
An national or regional authority responsible for the registration of and other regulatory activities connecting pharmaceutical products, appointed by the government of a Member State to administer the granting of Marketing Authorizations for pharmaceutical products in that country.

**Expiry date.**
The date given on the individual container (usually on the label) of a product up to and including which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf life to the date of manufacture.

*finished pharmaceutical product.*
A finished dosage form of a pharmaceutical product that has undergone all stages of manufacture, including packaging in its final container and labelling.

free sale certificate,
See section 3.2 of the guidelines.

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

good manufacturing practices certificate,
See section 3.2 of the guidelines.

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

International Nonproprietary Name (INN).
The shortened scientific name based on the active ingredient. WHO is responsible for assigning INNs to pharmaceutical substances.

language of product certificates,
See section 3.10 of the guidelines.

License holder
An individual or a corporate entity being in the possession of a marketing authorization of a pharmaceutical product.

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

limits of certification by competent authority,
See section 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, distribution, and shipment of pharmaceutical finished products, and related controls.

*Manufacturer.*
A company that carries out operations such as production, packaging, repackaging, labelling and relabelling of pharmaceuticals, at least one step of manufacture. (for categories of manufacturer, see Appendix 1, Explanatory Note No. 7).

**Marketing authorization.**
A legal document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using INNs or national generic names where they exist), the shelf-life and storage conditions and packaging characteristics. It specifies the information on which authorization is based (e.g., “The product(s) must conform to all the details provided in your application and as modified in subsequent correspondence.”). It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization and the period of validity of the authorization. Once a product has been given marketing authorization, it is included on a list of authorized products – the register – and is often said to be “registered” or to “have registration”. Market authorization may occasionally also be referred to as a “licence” or “product licence”.

See product licence.

**Marketing authorization holder.**
An individual or a corporate entity being in the possession of a marketing authorization of a pharmaceutical product.

*Pharmaceutical product.*
Any material and product intended for human use or veterinary use, administered to food-producing animals, presented in its finished dosage form, or as a starting material, an active ingredient for use in such a dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and/or 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 or regional authority 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).

**Product information.**
This is the approved product information referred to in section 4.7 of the guidelines and item 2.A.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 approved by the drug regulatory authority.

**Product licence**

A legal document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using INNs or national generic names where they exist), the shelf life and storage conditions and packaging characteristics. It specifies the information on which authorization is based (e.g., “The product(s) must conform to all the details provided in your application and as modified in subsequent correspondence.”). It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization. Once a product has been given marketing authorization, it is included on a list of authorized products—the register—and is often said to be “registered” or to “have registration”. Market authorization may occasionally also be referred to as a “licence” or “product 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, and repackaging, labelling and relabelling, to completion of the finished product.

**Registration.**

Any statutory system of approval required at national or regional level as a precondition for introducing a pharmaceutical product onto the market.

**Registration certificate**

See product licence

**Specifications.**

A list of detailed requirements with which the products or materials used or obtained during manufacture have to conform. They serve as a basis for quality evaluation. See Appendix 3, Batch Certificate, explanatory note 7.

**Statement of licensing status.**

See section 3.13 of the guidelines and Annex 2

**Summary basis of approval.**

This refers to 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 Annex 1).
Summary product characteristics (SPC)
Product information as approved by the drug 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.
- transmission of product certificate: See section 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 item 3.5 of the guidelines.
- WHO responsibility: See item 5.4 of the guidelines.

REFERENCES

***