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

(June 2018)

DRAFT FOR COMMENTS

Should you have any comments on the attached revision, please send these to Dr Sabine Kopp, Group Lead, Medicines Quality Assurance, Technologies, Standards and Norms, e-mail: kopps@who.int, with a copy to Mrs Xenia Finnerty, e-mail: finnertyk@who.int, by 30 August 2018.

Our working documents will only be sent out electronically and will also be placed on the Medicines website for comments under the “Current projects” link. If you have not already received our draft working documents, please send your e-mail address to jonesi@who.int and we will add you to our electronic mailing list.

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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 4856, e-mail: kopps@who.int.

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### SCHEDULE FOR THE PROPOSED ADOPTION PROCESS OF DOCUMENT QAS/18.768:

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

<table>
<thead>
<tr>
<th>Activity</th>
<th>Date</th>
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<tbody>
<tr>
<td>Recommendation by the 52nd WHO Expert Committee on Specifications for Pharmaceutical Preparations to prepare a proposal for the revision of the scheme for public consultation</td>
<td>16-20 October 2017</td>
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<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>
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<tr>
<td>Consolidation of comments received</td>
<td>May 2018</td>
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<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>
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<tr>
<td>Circulation of revised working document for public consultation</td>
<td>June-August 2018</td>
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<tr>
<td>Consolidation of comments received and review of feedback</td>
<td>August 2018</td>
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<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>
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<tr>
<td>Any further action, as recommendation by the WHO Expert Committee on Specifications for Pharmaceutical Preparations</td>
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PROPOSAL FOR IMPROVEMENT OF THE WHO CERTIFICATION SCHEME ON
THE QUALITY OF PHARMACEUTICAL PRODUCTS MOVING IN
INTERNATIONAL COMMERCE

1. INTRODUCTION

The World Health Organization (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) that took place 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 to 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 three types of certificate as outlined in the following table:
<table>
<thead>
<tr>
<th>Name of certificates</th>
<th>Outline</th>
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| Certificate of a pharmaceutical product (CPP) | A CPP is issued by the authorized body of the certifying country or regional authority and is intended for use by the competent authority of an importing country in two situations:  
  - when the product in question is under consideration for a marketing authorization that will authorize its importation and sale; and  
  - when administrative action is required to renew, extend, vary or review such a marketing authorization.  
  In most circumstances, CPPs are used as evidence that certifying authorities conducted a quality, safety and efficacy (QSE) review of pharmaceutical products and authorized them to be marketed. |
| Statement of the marketing authorization status of a pharmaceutical product | A statement of the marketing authorization status of a pharmaceutical product is intended for use by importing agents when considering bids made in an international tender.  
It is not intended for use for regulatory submission.                                                                                     |
| Batch certificate                              | A 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. A batch certificate is normally issued by the manufacturer. |

73 In 2007, the forty-second ECSPP discussed and identified a number of perceived problems with the operation of the Scheme (6).

74 In 2008, a WHO consultation was held to make recommendations for consideration during the forty-third ECSPP, taking account of the WHO working document QAS/07.240 which contains key issues and possible action (7). The report of the consultation (working document QAS/08.279) was discussed during this consultation (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 recommendations, as an interim measure, a Q&A document on the function
of the Scheme was developed in 2010 and revised in 2015 (10, 11). However, the Scheme has
not been revised since 1997.

In 2017, the fifty-second ECSPP recommended that “the 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 was discussed during an informal consultation that took place
from 19 to 20 May 2018. In addition, the draft working document will be circulated 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 publication of the Scheme in 1997, a number of key issues and possible actions have
been identified and these can be divided into the following two aspects:
(a) revision and requirements of the Scheme; and
(b) implementation/operational requirements 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 the implementation/operational requirements 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 and requirements 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 document\(^1\), as well as comments from experts of the informal consultation and from the Member States and interested parties during public consultation (6, 7, 9, 12).

\(^{1}\) Q16 is “What are the main problems encountered in the application of the Scheme?”. 
<table>
<thead>
<tr>
<th>Key issues</th>
<th>Proposed actions</th>
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<tbody>
<tr>
<td>a  The Scheme is formally at present directed to individual Member States,</td>
<td>• The wordings in the Scheme should be changed so that regional organizations, such as the European Union, can formally participate in the Scheme.</td>
</tr>
<tr>
<td>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>
<td>[Note from Secretariat: Member State(s)] =&gt; “Member State(s) and/or regional authority(ies)”.</td>
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<td>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.</td>
<td>• Memberships as “certificate-issuing” countries should be renewed every five years.</td>
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<td>[Note from Secretariat: Added new paragraph as section 2.4; See below for more detail.]</td>
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<td></td>
<td>⇒ Membership can be voluntarily withdrawn any time by notification to the Director-General of the WHO.</td>
</tr>
<tr>
<td></td>
<td>[Note from Secretariat: Added new words in section 2.1.]</td>
</tr>
<tr>
<td>c  Certifying countries that do not fulfil the prerequisites required by the Scheme issue certificates to support approval of marketing authorization.</td>
<td>• Member States should inform any update of the name and address of competent authorities to the WHO secretariat.</td>
</tr>
<tr>
<td></td>
<td>[Note from Secretariat: Added new paragraph as section 2.6.]</td>
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<tr>
<td></td>
<td>• As an “example” of an indicator for possessing an “effective marketing authorization system”, the WHO Global Benchmarking Tool (GBT) can be made use of.</td>
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<tr>
<td></td>
<td>⇒ GBT maturity level 3 should be added as</td>
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</table>
- 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 WHO in the same way as section 2.1.

[Note from Secretariat: Added new paragraph as section 2.4.]

- 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 2.3.]

[Note from Secretariat: Draft of model notification to the WHO Director-General has been added as Annex 2 to this working document. (This model notification is not a part of the Scheme.)]

- In case WHO does not receive the notification for renewal of membership for a long period of time, the Director-General may delete such
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| **d** | The CPP is no longer provided to substitute QSE reviews. | • CPPs should not be requested in countries that have the capability to conduct full QSE reviews unless they have a rationale to request one. Examples of the rationale to request one are as follows:  
- A competent authority which conducted QSE reviews does not disclose the product registry information or it discloses the list only in its local language.  
- CPPs can facilitate a “fast track” approval by the requesting authority.  

*Note from Secretariat: Added new paragraph as section 2.7.* |
| **e** | Information on who released the batch for marketing is not disclosed in certificates issued by exporting countries. | • The certificate should include, as a minimum, information on manufacturers responsible for:  
(a) manufacturing of dosage forms, (b) certificates of the finished pharmaceutical product batch (batch release), and (c) packaging and/or labelling of the dosage form. In addition, CPPs should allow to include other manufacturing site information (e.g. quality control of finished pharmaceutical products, primary packaging, secondary packaging).  

*Note from Secretariat: Revised model* |
<table>
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<tr>
<th>№</th>
<th>Description</th>
<th>Comments</th>
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| f | There have been cases in which forged certificates have been supplied to competent authorities of importing countries. | • E-mail address, telephone, fax numbers and website addresses should be provided as contact information so that the requesting authority can easily request confirmation to the certifying authority countries.  
*Note from Secretariat:* Added new words in section 2.3. |
| g | Lead times of the certifying authorities can be very long, sometimes several months long. | • The certifying authority should establish a standard time frame, ideally within 30 working days, and should endeavor to issue them within the established period as far as the applicant submits sufficient documents.  
*Note from Secretariat:* Added new paragraph as section 4.11. |
| h | Importing countries require legalization of certificates, additional stamps, etc. | • Legalization should not be requested.  
*Note from Secretariat:* Added new paragraph as section 4.8. |
| i | Sometimes there are inconsistencies in the trade name of the product between the importing country and the certifying country. The current template of CPPs does not have a column for entering the trade name in the importing country. | • The model template of CPPs should be revised so that a proposed trade name in the importing country can be stated. (The certifying authority will state it as provided by the applicant.)  
*Note from Secretariat:* Added new words in section 1.1 of Appendix 1 of the Annex. |
“Statement of marketing authorization” (Appendix 2 of the Scheme) may not be used anymore. CPPs seem to be usually requested for tender application.

- “Statement of marketing authorization” (Appendix 2) should be removed to simplify the Scheme if it has not been used anymore.

[Note from Secretariat: In this round of consultation, comments are welcomed on this proposal.]

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 the latest version of relevant guidelines; and
- replacing some words (e.g. “license” replaced by “marketing authorization”).

4. OTHER ISSUES RELATED TO THE IMPLEMENTATION/OPERATIONAL REQUIREMENTS OF THE SCHEME

The table below is a non-exhaustive list of examples of key issues not related to the revision of the Scheme. As described in section 3 of this document, possible actions regarding the implementation/operational requirements of the Scheme (e.g. promotion of the Scheme, making use of IT) should be considered after adoption of the revision of the Scheme. In addition, it should be noted that other key issues are also described in the answer to Q16 of the Q&A document (11)
### Key issues

<p>| | |</p>
<table>
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<tbody>
<tr>
<td>a</td>
<td>Member States not party to the Scheme issue certificates to support the approval of pharmaceutical products.</td>
</tr>
<tr>
<td>b</td>
<td>Not all of certifying authorities adhere to the WHO template.</td>
</tr>
<tr>
<td>c</td>
<td>Member States do not issue certificates for products not manufactured under but approved in their jurisdiction.</td>
</tr>
<tr>
<td>d</td>
<td>Certifying authorities issue certificates for products not authorized for marketing in their countries.</td>
</tr>
<tr>
<td>e</td>
<td>Certifying authorities issue other certificates, such as free sale certificates.</td>
</tr>
<tr>
<td>f</td>
<td>Applying for a CPP is not harmonized, with each certifying authority having its own system. (It would be helpful to work towards the global harmonization of this, along with a standard electronic submission.)</td>
</tr>
</tbody>
</table>

### REFERENCES

5. World Health Assembly resolution WHA22.50 (1969).
7. World Health Assembly resolution WHA41.18 (1988).
8. World Health Assembly resolution WHA50.3 (1997).

10. WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce: Question and Answers (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)

ANNEX 1

[Note from Secretariat: Based on proposed action on pages 7-10; the new text in Annex 1 is presented in track-change mode.]

Guidelines on the 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 marketing authorization and independent analysis of the 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.

1.3 These standards 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 manufacturing site 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 product information submitted, including labelling, is currently authorized by the certifying authority.

1.4 The Scheme, as amended in 1975 (2), 1988 (3), 1992 (4) and 1997 (5), by resolutions WHA28.65, 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 Provisions for certification of starting materials (active pharmaceutical ingredients (APIs) and excipients) for exporting purposes that are provided in separate guidelines and certificates are issued. (6)

2. MEMBERSHIP

[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, is eligible to participate on a voluntary basis in the Scheme as a certifying member and/or a requesting member if it complies with the requirements stipulated in section 2.2. Membership can be voluntarily withdrawn any time by notification to the WHO Director-General.

2.2 A Member State or a regional authority intending to become a certifying member should possess:

• an effective (i.e. “functional” as defined for example in the Global Benchmarking Tool (GBT) maturity level 3 (7)) marketing authorization system for pharmaceutical products, including the responsible manufacturers and licensing of distributors;
• GMP requirements, consistent 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 or region, including access to an independent quality control laboratory;
• a pharmaceuticals inspectorate, operating as an arm of the national or regional medicines 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 or to coordinate 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 or region known to have imported a specific product that is subsequently associated with a potentially serious quality defect or other hazard.

2.3 Membership as a certifying member and/or requesting member can be declared 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;
• any significant reservations it intends to observe relating to this participation;
• the name and address (including e-mail address, telephone, fax numbers and website address) of its medicines regulatory authority or other competent authority; and
• a declaration to comply with the requirements for a certifying member stipulated in section 2.2, if applicable.

[Note from the Secretariat: Model notification to the WHO Director-General has been added as Annex 2 to this working document.]
2.4 A Member State and regional authority that has a membership of a certifying member should resubmit the notification in section 2.3 at least once every five years, in order to ensure that it continues to comply with the requirement stipulated in section 2.2 and that contact information remains updated.

2.5 Consolidated list of information on the notification submitted by Member States and regional authorities in accordance with provision in sections 2.3, 2.4 and 2.6 will be available through WHO’s official website (see also section 3.3).

2.6 A Member State or regional authority should inform the WHO of any change of notified information to the WHO Director-General.

2.7 Membership as a certifying member may be disqualified by the Director-General after consultation with the WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) in the case that a Member State or regional authority would fail to resubmit a notification in accordance with provision in section 2.4 for twelve months.

3. REQUESTING A CERTIFICATE

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

- a certificate of a pharmaceutical product (CPP);
- a statement of marketing authorization status of pharmaceutical product(s); and
- a batch certificate of a pharmaceutical product (for more details, please see section 3.15 and 3.16 and the Explanatory notes in Appendix 3)

3.2 The proposed formats for these documents are provided in Appendices 1, 2 and 3 of these guidelines. All participating Member States and regional authorities are henceforth urged to adopt these formats without deletion to facilitate the harmonization and interpretation of certified information. A CPP with any deleted sections is no longer considered a “CPP”.
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 authorities participating in the Scheme that are responsible for the registration of pharmaceutical products for human and/or veterinary use, together with details of any reservations they have declared regarding their participation in the Scheme, will be available at the WHO official website as indicated in section 2.5.

3.4 Each certifying authority 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 medicine regulatory process and the circumstances in which each of the three types of documents will be required.

Certificate of a pharmaceutical product (CPP)

3.5 The CPP (Appendix 1), issued by the certifying authority, is intended for use by the requesting authority in two situations:

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

3.6 The CPP should not be requested by the Member States or regulatory authorities where they undertake a full QSE review internally, unless they have a rationale to request.

3.7 All requests for CPPs should be channeled through the applicant. The applicant should submit the following information for each product to the certifying authority:

- name and dosage form of finished pharmaceutical product;
• name and amount of active ingredient(s) per unit dose (International Nonproprietary Name(s) (INN(s)) where such exist(s));
• name and address of marketing authorization holder and manufacturing site;
• formula (complete quantitative composition including all excipients);
• product information for health professionals and for the public (patient information leaflets) as approved by the certifying authority; and
• packaging of finished pharmaceutical product.

Additional information, such as sites of manufacturing of bulk finished product, manufacturer of diluents, sites of quality control, batch release, primary and secondary packaging, could also be submitted to the certifying authority.

For product information to be attached to the certificate, please see section 4.8

3.8 The certificate is a confidential document. As such, it can be issued by the certifying authority only with the permission of the applicant and, if different, of the marketing authorization holder.

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

3.10 When any doubt arises about the status or validity of a certificate, the requesting authority should request verification of the validity of the certificate from the certifying authority, as provided for under section 4.10 of these guidelines.

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

3.12 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.
3.13 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**

[Note from Secretariat: In this round of consultation, there was a proposal to delete this section as industries said this certificate had never been requested. Comments are welcome on such a proposal].

3.14 The model statement of marketing authorization (Appendix 2) attests only that a marketing authorization has been issued for a specified product, or products, for use in the certifying country or within the jurisdiction of the certifying regional authority. 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**

3.15 A batch certificate of a pharmaceutical product (Appendix 3) refers to an individual batch of a pharmaceutical product and is a vital instrument in the procurement of medicines. The provision of a batch certificate is usually a mandatory element in tender and procurement documents.

3.16 A batch certificate is normally issued by the manufacturer and only exceptionally, as in the case of biological products: vaccines, blood and plasma derivatives, by the competent authority in the certifying 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 all the parameters (attributes), with acceptance
criteria, of the release specification of the pharmaceutical 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 marketing
authorization 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 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 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 should
still be provided (as an attachment to the CPP or within the CPP) on the basis of inspections
undertaken for registration purposes by the same authority or by another authority.

4.3 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 site, including those destined
exclusively for export; and

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

4.4 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 4.3 (b) above.
4.5 GMP, as recommended by WHO, assigns to the manufacturer of the finished pharmaceutical product responsibility for assuring the quality of APIs. National or regional regulations may require that suppliers of APIs be identified in the marketing authorization (product dossier) and the competent authority should have the power to inspect them.

4.6 If the API site has not been inspected, 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, 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 for marketing under its jurisdiction.

4.7 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.

4.8 The certifying authority should officially stamp and date (or certify using a secure electronic system/electronic certificate) [Note from Secretariat: Feedback on this point will be welcome] 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 consistent with the version of the marketing authorization operative on the date of issue. Nevertheless, requesting authorities should not introduce legalization procedures 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 3.11.
4.9 Any additional attachment to a certificate submitted by the applicant, such as price lists of products for which bids are offered, are not in the scope of the Scheme and may be attached to the certificate only at the discretion and specific agreement by the certifying authority. [Note from Secretariat: If we take out Appendix 2, this point might not be applicable anymore.]

4.10 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 requesting authority and be stamped on each page with the official seal of the certifying authority (or certify using a secure electronic system/electronic certificate). [Note from Secretariat: Feedback on this point will be welcome.]

If requested, an identical copy, clearly marked as duplicate, should be forwarded by the certifying authority on demand directly to the requesting authority without undue delay, ideally within 30 working days.

4.11 The certifying authority should establish a standard time frame for issue of certificates, ideally within 30 working days. 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 investigate 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 requesting authority;
- 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 climatic or storage conditions.
5.2 In the case of obvious doubt, a participating national or regional 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 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. In the case of substandard or falsified pharmaceutical products, the WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products and/or Medical, should be used to send the notification to the WHO (8). Upon receipt of such notification, WHO will inform the competent authority as appropriate and/or issue a WHO Medical Product Alerts (9).

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

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

No. of Certificate: ________________________________________________________________
Certifying country or regional authority: ____________________________________________
Requesting country or regional authority: ____________________________________________

1. **Basic information**

1.1. Name (and proposed trade name in the importing country as provided by the requester, if applicable) and dosage form of the finished pharmaceutical product:

_____________________________________________________________________________

1.2. Active pharmaceutical ingredient name(s) and quantity(ies) per unit dose:

_____________________________________________________________________________
_____________________________________________________________________________

For complete composition including excipients, see attached.

1.3. Is this product authorized by the certifying authority to be marketed in the certifying country or within the jurisdiction of the certifying regional authority? yes/no (key in as appropriate)
1.4. Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority? yes/no/unknown *(key in as appropriate)*

If the answer to 1.3 is yes, continue with section 2A and omit section 2B.
If the answer to 1.3 is no, omit section 2A and continue with section 2B*:

2. **Information on marketing authorization**

2.A. Product that is authorized for marketing by the certifying authority.

2.A.1. Number of marketing authorization\(^7\) and date of issue:
____________________________________________________________________________

2.A.2. Marketing authorization holder (name and address): __________________________
____________________________________________________________________________

2.A.3. Status of marketing authorization holder\(^8\): a/b/c/d
*(key in appropriate category as defined in note 8)*

*Note from Secretariat: Is the section 2.A.3. still needed? Status of marketing authorization holder can be identified based on the information in the section 2.A.2 and 3.1.]*

2.A.4. Is a summary basis for approval appended?\(^9\) yes/no *(key in as appropriate)*

2.A.5. Is the attached officially approved product information complete and consistent with the marketing authorization?\(^10\) yes/no/not provided *(key in as appropriate)*

2.A.6. Is a packaging of finished pharmaceutical product attached? yes/no *(key in as appropriate)*
2.A.7. Applicant for certificate, if different from marketing authorization holder (name and address)\textsuperscript{11}.


2.B. Product that is not authorized for marketing by the certifying authority.

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

_____________________________________________________________________________

_____________________________________________________________________________

2.B.2. Why is marketing authorization lacking?

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

2.B.3. Remarks\textsuperscript{12}: _______________________________________________________________________


3. Information on manufacturing

3.1. List of manufacturers

(At least specify the manufacturer responsible for: (a) manufacturing of dosage forms, (b) certificates of the finished pharmaceutical product batch (batch release) and (c) packaging and/or labelling of the dosage form and)\textsuperscript{13,14}.

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>e.g. manufacturing of the finished product, batch release of the finished pharmaceutical product</td>
</tr>
<tr>
<td></td>
<td></td>
<td>e.g. packaging and labelling</td>
</tr>
</tbody>
</table>

Draft for comments
3.2. Does the certifying authority arrange for periodic inspection of the manufacturing site in which the dosage form is produced? yes/no (*key in as appropriate*)

If not, proceed to question 4.

3.3. Periodicity of routine inspections (years): ________________________________

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

3.5. Do the facilities and operations conform to GMP as recommended by WHO? 15 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? 16 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 (electronic when possible): __________________________________
General instructions

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

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 certifying country or within the jurisdiction of the regional authority. 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 marketing authorization holder.

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

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

7. Indicate, when applicable, if the marketing authorization is provisional.

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

(a) manufactures the dosage form;

(b) certifies the finished pharmaceutical product batch;
(c) packages and/or labels a dosage form manufactured by an independent company; or
(d) is involved in none of the above.

This refers to the document, prepared by some medicines regulatory authorities, that summarizes the technical basis on which the product has been authorized to be marketed.

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

In this circumstance, permission for issuing the certificate is required from the 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; the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
(c) the product has been reformulated to meet a different maximum dosage limit for an active ingredient; any other reason, please specify.
(d) Any other reason, please specify.

The following information on the manufacturing site may be included in the list of manufactories:

- Manufacture of the finished pharmaceutical product: solvent and diluents.
- Stability studies.
- Quality control of the finished pharmaceutical product.
- Primary packaging.
- Secondary packaging.

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


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.
APPENDIX 2

MODEL STATEMENT OF MARKETING AUTHORIZATION

STATUS OF A PHARMACEUTICAL PRODUCT(S)

No. of Statement: ________________________________________________________________

Certifying country or regional authority: ___________________________________________

Requesting country or regional authority: ___________________________________________

Statement of marketing authorization of a pharmaceutical product(s) ¹

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

This statement indicates only whether or not the following products are authorized by the certifying authority to be marketed in the certifying country or within the jurisdiction of the certifying regional authority.

Applicant (name/address):_________________________________________________________________

<table>
<thead>
<tr>
<th>Name of product (and trade name in the importing country, if applicable)</th>
<th>Dosage form</th>
<th>Active ingredient(s)³ and quantity(ies) per unit dose:</th>
<th>Marketing authorization no. and date of issue⁴</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹ Only used where certification of marketing is conducted on a country or regional basis.

² Trade name in the importing country, if applicable.

³ Only active ingredient(s) necessary for the identification and distinction of the product.

⁴ Where applicable.

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

Address of certifying authority: ___________________________________________________

Telephone number: _______________________ Fax number: _________________________

E-mail address: ________________________________________________________________

Name of authorized person: _____________________________________________________

Signature: ____________________________________________________________________

Stamp and date (electronic when possible):

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.

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 by the certifying authority to be marketed in the certifying country or within the jurisdiction of the certifying regional authority. 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 marketing authorization holder, for each of the listed products.

2. The Certifying authority stated trade name in the importing country as provided by the applicant, if applicable.

3. Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.

4. If no marketing authorization has been granted, enter "not required", "not requested", "under consideration" or "refused" as appropriate.
APPENDIX 3

MODEL BATCH CERTIFICATE OF PHARMACEUTICAL PRODUCTS

MANUFACTURERS/OFFICIAL¹ BATCH CERTIFICATE OF A PHARMACEUTICAL PRODUCT

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

1. No. of Certificate: ________________________________

2. Importing (requesting) authority: ________________________________

3. Name of product: ________________________________

3.1. Dosage form: ________________________________

3.2. Active ingredient(s) name² 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

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

4. Marketing authorization holder⁴ (name and address): ________________________________

___________________________________________________________________________________

Draft for comments
4.1 Marketing authorization number^{4}: 

4.2 Date of issue^{4}: 

4.3 Marketing authorization issued by^{4}: 

4.4 Certificate of a pharmaceutical product (CPP) 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. Quality analysis: 

6.1 What specifications apply to this dosage form? Either specify the pharmacopoeia or append company specifications.^{6}
6.1.1 In the case of a product registered by the certifying country or regional authority, have these company specifications\textsuperscript{6} been accepted by the competent authority? (yes/no)

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

6.3 Append certificate of analysis.\textsuperscript{7}

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: _________________________

Signature of authorized person:

Stamp and date (electronic when possible):
General instructions

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

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. Even then, it is rarely applied other than to biological products: vaccines, blood and plasma derivatives. For other products, the responsibility for any requirement to provide batch certificates rests with the marketing authorization holder in the certifying country or within the jurisdiction of the certifying regional authority. 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 certifying competent authority. A copy should be sent to the 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 marketing authorization or the CPP issued in the certifying country or within the jurisdiction of the certifying regional authority.
5. This refers to the CPP as recommended by WHO.
6. 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.
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.
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.

abuse of Scheme.
See section 4.10 of the guidelines.

active pharmaceutical ingredients.
Any substance or mixture of substances intended to be used in the manufacture of a finished pharmaceutical product (FPP) and that, when used in the production of a pharmaceutical product, becomes an active ingredient of the pharmaceutical product. 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.

addresses of competent authorities.
See item 2.5 and 3.3 of the guidelines.

applicant.
The party applying for a CPP. This is normally the agent responsible for importing pharmaceutical products, the marketing authorization holder or other commercially-interested party. In all instances, having regard to commercial confidentiality of certain data, the certifying authority must obtain permission to release these data from the marketing authorization holder, or, in the absence of a marketing authorization, from the manufacturer.

authentication of certificates.
See section 4.10 of the guidelines.
batch.  
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 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 quantity or as the amount produced in a fixed time interval.

batch certificate.  
A document containing information, as set out in Appendix 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, particularly for vaccines, sera and other biological products. The batch certificate travels with every major consignment (see also section 3.15 of the guidelines).

batch 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.

certificate of a pharmaceutical product (CPP).  
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 issuing country or regional authority and intended for use by the competent authority in the importing country/region or – in the absence of such an authority – by the procurement agency.
certifying authority.
This is the competent authority in the Member State and regional authority that issues certificates. It shall ensure that it possesses the capacities listed in section 2.2 of the guidelines.

charges for CPPs.
See section 3.12 of the guidelines.

competent authority.
This is the national or regional authority, as identified in the formal notification to the WHO Director-General stipulated, 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 notification to the WHO Director-General stipulated in section 2.3 of the guidelines. WHO makes available a continuously updated list of addresses of competent authorities and the specific conditions for participation (see section 2.5 of the guideline).

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

expiry date.
The date given on the individual container (usually on the label) of a pharmaceutical product up to and including the date on 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.

falsified pharmaceutical product.
Pharmaceutical product that deliberately/fraudulently misrepresent their identity, composition or source. Any consideration related to intellectual property rights does not fall
within this definition. Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration, reproduction of an authorized pharmaceutical product or the manufacture of a pharmaceutical product that is not an authorized product.

“Identity” shall refer to the name, labelling or packaging or to documents that support the authenticity of an authorized pharmaceutical product. “Composition” shall refer to any ingredient or component of the pharmaceutical product in accordance with applicable specifications authorized/recognized by national or regional regulatory authority (NRRA).

“Source” shall refer to the identification, including name and address, of the marketing authorization holder, manufacturer, importer, exporter, distributor or retailer, as applicable.

Pharmaceutical product should not be considered as falsified solely on the grounds that they are unauthorized for marketing in any given country.

**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.

**Global Benchmarking Tool (GBT).**
A means by which WHO evaluates regulatory systems through a comprehensive and systematic benchmarking. The tool and benchmarking methodology:
- identifies strengths and areas for improvement;
- facilitates the formulation of an institutional development plan (IDP) to build upon strengths and address the identified gaps;
- aids in the prioritization of IDP interventions; and
- helps to monitor progress and achievements.
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.

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 3.11 of the guidelines.

limits of certification by competent authority.
See section 3.13 of the guidelines.

manufacture.
All operations of purchase of materials and products, production, quality control, release, storage, distribution of pharmaceutical products, and related controls.

manufacturer.
A company that carries out operations such as production, packaging, repackaging, labelling and relabelling of pharmaceuticals. (for categories of manufacturer, see Appendix 1, section 3.1 and Explanatory Note No. 12).
marketing authorization.

A legal document issued by the competent medicines 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”. Marketing authorization may occasionally also be referred to as a “licence” or “product licence”.

marketing authorization holder.

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

medicines regulatory authority.

A national or regional body that administers the full spectrum of medicine regulatory activities, including at least all of the following functions in conformity with national or regional medicine legislation:

- marketing authorization of new products and variations of existing products;
- quality control laboratory testing;
- monitoring of adverse drug reactions;
- provision of information on medicines and promotion of rational use of medicines;
- good manufacturing practice (GMP) inspections and licensing of manufacturers, wholesalers and distribution channels;
- enforcement operations;
- monitoring of drug utilization.
pharmaceutical product.
Any material and product intended for human or veterinary use presented in its finished
dosage form or as a starting material for use in such a dosage form, that is subject to control by
pharmaceutical legislation in exporting state and/or the importing state.

product.
See pharmaceutical product.

product information.
This is the approved product information referred to in section 3.7 of the guidelines and
item 2.A.4 of the product certificate. It normally consists of information for health professionals
and the public (patient information leaflets) as approved by the related medicines regulatory
authority, and when available, a data sheet or a summary of product characteristics approved by
the medicines regulatory authority.

production.
All operations involved in the preparation of a pharmaceutical product, from receipt of
materials, through processing, 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.

regional authority.
A group of countries in the same geographical region to achieve an integrated marketing
authorization system. A regional authority that is willing to participate in the Scheme as a
certificating member need to possess a legal authority stipulated in section 2.2 by itself or
through its legal framework.
requesting authority.
This is the competent authority in the Member State and regional authority that requests certificates.

specifications.
A list of tests, references to analytical procedures and appropriate acceptance criteria that are numerical limits, ranges or other criteria for the test described. It establishes the set of criteria to which a material should conform to be considered acceptable for its intended use. “Conformance to specification” means that the material, when tested according to the listed analytical procedures, will meet the listed acceptance criteria.

statement of marketing authorization.
See section 3.14 of the guidelines and Appendix 2.

substandard pharmaceutical product.
Also called “out of specification”, these are authorized pharmaceutical products that fail to meet either their quality standards or their specifications, or both. When the authorized manufacturer deliberately fails to meet these quality standards or specifications due to misrepresentation of identity, composition, or source, then the pharmaceutical product should be considered “falsified”.

summary basis of approval.
This refers to the document prepared by some medicines regulatory authorities that summarizes the technical basis on which the product has been licensed (see section 4.7 of the guidelines and Explanatory note 8 of the product certificate contained in Appendix 1).

Summary product characteristics (SPC).
Product information as approved by the medicines 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 4.7 of the guidelines.

**transmission of a certificate.**

See section 3.9 and 4.10 of the guidelines.

**validity of a CPP.**

See section 3.10 of the guidelines.

**when to request a CPP.**

See item 3.5 of the guidelines.

**WHO responsibility.**

See item 5.4 of the guidelines.
REFERENCES


ANNEX 2

(DFAFT) MODEL NOTIFICATION TO THE DIRECTOR-GENERAL OF THE WORLD HEALTH ORGANIZATION

[Note from the Secretariat: This Annex 2 is not a part of the “Guidelines on the implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce”. ]

The Ministry of Health of the Government of ……………………………. (Name of country) / …………………………… (Name of regional authority) would like to inform the Director-General of the World Health Organization that ……………………………. (Name of country or regional authority) would like to participate/continue to participate in the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (referred to henceforth as the “WHO Certification Scheme”) as:

☐ Certifying member;
☐ Requesting member;
☐ Certifying member and requesting member. (choose only one)

The Ministry of Health of the Government of ……………………………. (Name of country) / …………………………… (Name of regional authority) hereby confirms that the competent authority(ies) mentioned in the Attachment is(are) the legally established authority(-ies) to regulate/control pharmaceutical products.

(Only for certifying members)

Also, we hereby declares that our certifying authority(-ies) in the Attachment possess(es):

• an effective (i.e. “functional” as defined for example in the Global Benchmarking Tool (GBT) maturity level 3 (7)) marketing authorization system for pharmaceutical products, including the responsible manufacturers and licensing of distributors;
GMP requirements, consistent 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 or region, including access to an independent quality control laboratory;

a pharmaceuticals inspectorate, operating as an arm of the national or regional medicines 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 or to coordinate 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 or region known to have imported a specific product that is subsequently associated with a potentially serious quality defect or other hazard;

willingness to abide by the WHO Model Certificates and provision of the certificates when requested by a requesting member.

The Ministry of Health of the Government of ……………………………. (Name of country) / …………………. (Name of regional authority) once more would like to express its gratitude to the World Health Organization for this opportunity to participate/continue to participate in the WHO Certification Scheme.
We also confirm that any changes of information in the Attachment will be promptly communicated to the WHO secretariat.

<table>
<thead>
<tr>
<th>Signature</th>
<th>Date</th>
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<tbody>
<tr>
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</tr>
</tbody>
</table>

Name and Title

Stamp
## Information on certifying/requesting authority(-ies)

- **Certifying authority**
- **Requesting authority**
- **Certifying and requesting authority**

(choose only one)

<table>
<thead>
<tr>
<th>Name of the authority</th>
<th>Address of the authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone number</td>
<td>Fax number</td>
</tr>
<tr>
<td>E-mail address</td>
<td></td>
</tr>
<tr>
<td>Website address</td>
<td></td>
</tr>
<tr>
<td>Reservation as per section 2.3 of the Scheme for posting on the WHO website (if any)</td>
<td></td>
</tr>
<tr>
<td>Other remarks (if any)</td>
<td></td>
</tr>
</tbody>
</table>

(Add tables as necessary)