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Document for comment

WHO CERTIFICATION SCHEME ON THE QUALITY OF PHARMACEUTICAL PRODUCTS MOVING IN INTERNATIONAL COMMERCE: Questions and answers (Q & A). Proposal for revision

DRAFT FOR COMMENT

Following discussions during the meetings of the WHO Expert Committee on Specifications for Pharmaceutical Preparations, during which an update of the Q & A document was recommended, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Certificate of Pharmaceutical Product (CPP) Network has provided the attached draft proposal. Should you have any comments thereon, please send these to Dr S. Kopp, Group Lead, Medicines Quality Assurance, Technologies, Standards and Norms (kopps@who.int) with a copy to Ms Marie Gaspard (gaspardm@who.int) by **15 August 2015**.

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.

SCHEDULE FOR THE PROPOSED ADOPTION PROCESS OF DOCUMENT QAS/15.623: WHO CERTIFICATION SCHEME ON THE QUALITY OF PHARMACEUTICAL PRODUCTS MOVING IN INTERNATIONAL COMMERCE: Questions and answers (Q & A). Proposal for revision

Recommendation by WHO Expert Committee on Specifications for Pharmaceutical Preparations to update the Q & As	October 2014
Triggered by a WHO survey, proposal by IFPMA CPP Network team to update the Q & As published in *WHO Drug Information*	May 2015
Updated version circulated for comments	June 2015
Compilation of comments received	August 2015
Review of comments by small working group	September 2015
Submission to fiftieth meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations	12–16 October 2015
Any further action, as recommended by the WHO Expert Committee on Specifications for Pharmaceutical Preparations	

Background

The WHO Certification Scheme for Finished Pharmaceutical Products is an international voluntary agreement to provide assurance to countries participating in the Scheme, about the quality of pharmaceutical products moving in international commerce (World Health Assembly resolution WHA22.50 (1969), World Health Assembly resolution WHA28.65 (1975), World Health Assembly resolution WHA41.18 (1988), World Health Assembly resolution WHA45.29 (1992), World Health Assembly resolution WHA50.3 (1997). The primary document of the Scheme was the Certificate of Pharmaceutical Product (CPP). The WHO Expert Committee on Specifications for Pharmaceutical Preparations, during its forty-third meeting, recommended that the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be reviewed 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. Any change of the Scheme will necessitate a discussion by Member States.

In addition, as an interim measure, the Expert Committee also requested that a questions and answers (Q & A) document on the function of the Scheme should be prepared (see WHO Technical Report Series, No. 953, pp. 47–48 (2009)). The previous version of the Q & A document (working document QAS/10.374) was prepared and is available on the web as follows:
http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/qas_certif_scheme_2012.pdf?ua=1.

The following is a collection of questions and answers relating to the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce[1] and specifically to the CPP.

The "WHO Certification Scheme"

- represents WHO activity on the quality, and potentially the safety and efficacy of pharmaceutical products moving into international commerce
- is an administrative instrument which enables WHO Certification Scheme Member States to request certain information from another WHO Certification Scheme Member State by means of defined documents, i.e. a CPP.

The CPP gives a snapshot of the regulatory status of a pharmaceutical product and of the CPP applicant in the certifying country. It is for a single product only, since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

[1] Later also referred to as the "WHO Certification Scheme".

For easier reference, questions have been grouped into the following categories to support the review process.

1. About the WHO Certification Scheme
2. Related to issuing country
3. Related to recipient country
4. GMP status
5. Alternatives to a CPP

Contents

1. ABOUT THE WHO CERTIFICATION SCHEME

1.Q1 What is the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce?

1.A1 *It is a Scheme developed by the World Health Organization (WHO) in response to the request of WHO Member States to facilitate international trade in pharmaceutical products between Member States and it gives guidance to the issuing as well as requesting health authorities.*

1.Q2 Why is it called the WHO Certification Scheme?

1.A2 *It is called the WHO Certification Scheme because it was developed by WHO in response to the request of Member States.*

1.Q3 When was the Scheme developed?

1.A3 *It was first developed in 1975. Since then it has been revised in 1988, 1992 and in 1997.*

1.Q4 How can a WHO Member State or regional organization be eligible for participation in the Scheme?

1.A4 *Any WHO Member State or regional organization intending to participate in the Scheme may do so by notifying the Director-General of WHO in writing, of its willingness to participate in the Scheme; any significant reservations it intends to observe relating to this participation; and by providing the names and address of its national medicines regulatory authority (NMRA) or other competent authority.*

1.Q5 Where can one find the list of organizations and countries party to the Scheme?

1.A5 *WHO publishes the names and addresses of Member States party to the Scheme. The list is available on the WHO website:*

http://www.who.int/entity/medicines/areas/quality_safety/regulation_legislation/certification/contacts/en/index.html.

A hard copy of the list is also published and distributed to Member States. The list is updated from time to time.

1.Q6 Does the list of Member States and organizations party to the Scheme provide the names and addresses of those government organizations authorized to sign and issue a Certificate for a Pharmaceutical Product (CPP)?

1.A6 *Yes, the list provides the names and full addresses of those government organizations authorized to sign and issue a certificate for a pharmaceutical product (CPP). NMRAs receiving a CPP can use this list to check and verify if the certificate they are receiving has been issued by the authorized organization.*

1.Q7 How can the Scheme facilitate trade in pharmaceutical products?

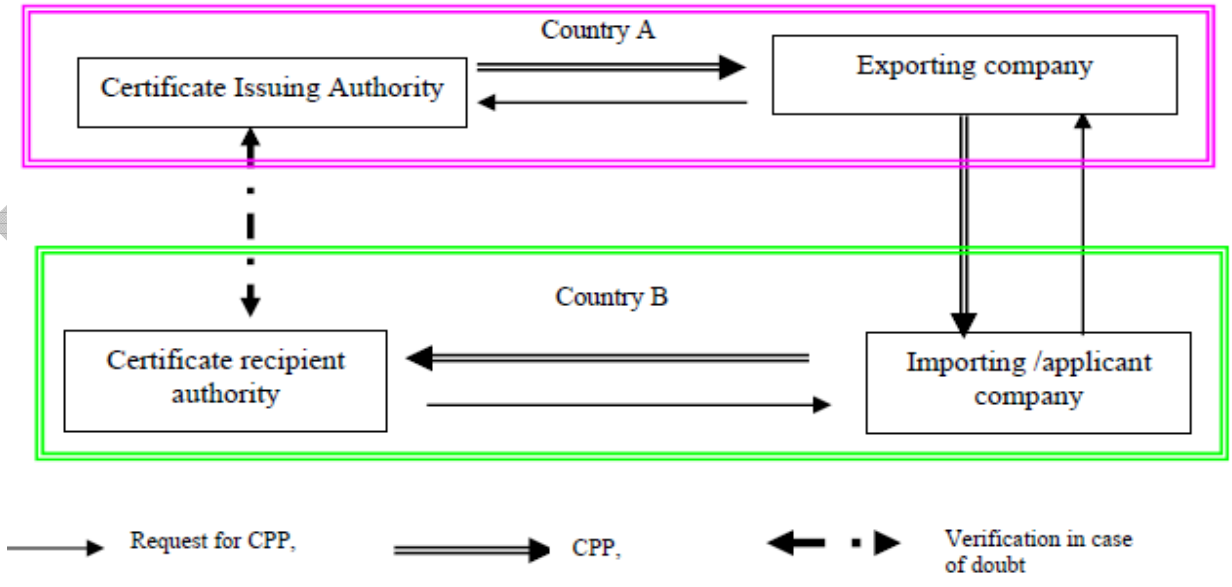
1.A7 *The Scheme is an administrative instrument that requires a competent authority of a participating Member State (the certifying country), upon application by a commercially-interested party (the applicant company), to certify/attest to the competent authority of another participating Member State (the recipient country) that:*

- *a specific pharmaceutical product is authorized for marketing in the certifying country, or if not, the reason why authorization has not been accorded;*
- *confirmation of marketing status in issuing country;*
- *the manufacturing facilities and operations conform to good manufacturing practices (GMP) as recommended by WHO.*

1.Q8 How does the Scheme operate?

1.A8 *The Scheme operates as follows:*

- *the certificate recipient authority has in its national medicine legislation or guidelines a requirement for the submission of a CPP for products being imported into the country as a support to ensure the quality of the product being imported (in most countries the CPP forms part of the dossiers to be submitted to NMRA to have a product registered by the authority);*
- *the applicant/importing company requests a CPP from the certifying authority through the exporting company;*
- *the certifying authority issues a CPP to the importing/applicant company via the exporting company. The practice at present is as shown in the diagram below.*



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At the time of the development of the Scheme the understanding was that the issuing authority would send the CPP directly to the recipient authority

1.Q9 Is the Scheme mandatory?

1.A9 *No, the Scheme is not mandatory. It is a voluntary agreement devised to enable countries with limited medicine regulatory capacity to obtain partial assurance from exporting countries concerning the quality, safety and efficacy of the pharmaceutical product they plan to import.*

1.Q10 Is there any written document that provides detailed information on the WHO Certification Scheme?

1.A10 *Yes, there are published guidelines called "Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce". One can access these guidelines by going to the WHO website:*

http://www.who.int/entity/medicines/areas/quality_safety/regulation_legislation/certification/guidelines/en/index.html.

1.Q11 What products are covered under the WHO Certification Scheme?

1.A11 *Pharmaceutical products covered under the Scheme are:*

- *finished pharmaceutical products (FPPs) intended for administration to human beings;*
- *pharmaceutical products intended for administration to food-producing animals;*
- *active pharmaceutical ingredients (APIs).*

There is now a separate scheme called the WHO pharmaceutical starting materials certification scheme (SMACS) which has guidelines on importation of APIs (http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/qas_certif_scheme_2012.pdf?ua=1).

1.Q12 What are the different types of certificates that can be requested within the scope of the Scheme?

1.A12 *Three types of certificate can be requested for pharmaceutical products within the scope of the Scheme:*

- *a CPP or product certificate;*
- *a statement of licensing status of pharmaceutical product(s);*
- *a batch certificate of pharmaceutical product.*

Further information is given in Section 5, alternatives to the CPP.

1.Q13 Is there a standard format for CPPs?

1.A13 *Yes, there is a standard format. The WHO standard format was last agreed by WHO Member States in 1997 (reference: WHO guidelines, Section 3.2). The template gives a numbering which is followed by almost all certifying countries. They state this on the top of the CPP. Also the explanatory notes attached to the CPP are almost the same in every certifying country:*

- *the standard WHO format for CPPs facilitates understanding and review by the recipient authority. It obliges certifying authorities to disclose important information to the importing country;*
- *by keeping the numbering of the WHO template recipient authorities can easily retrieve the information in the CPP;*
- *since CPPs are often issued bilingually, the text style may look differently by having the national language and the translation organized in columns, or the translation written in italic letters follows every sentence of national language;*
- *there may be different mandatory/optional attachments upon request in addition to the CPP, such as quantitative composition, the summary of product characteristics, the package insert label, etc., depending on the perspective and the legislation of either the certifying or the recipient country;*
- *recipient authorities should refrain from obtaining data other than in the WHO standard format or in addition to the standard CPP format;*
- *certifying authorities should not issue the outdated "free sales certificates". These have been replaced by the WHO format CPP.*

1.Q14 What should recipient countries do in case of any doubt about a CPP?

1.A14 *In case of any doubt the competent authorities of recipient countries should communicate directly with the authorized body that has issued the certificate or contact WHO regional branch to clarify the matter.*

1.Q15 Are certifying authorities penalized if they issue CPPs, but do not meet WHO requirements for self-certification and subsequent issue of CPPs?

1.A15 *No, there is no system to penalize them. WHO does not have the power to certify, inspect or penalize certifying authorities. Since the Scheme is voluntary, Member States party to the Scheme self-certify their compliance.*

1.Q16 What are the main problems encountered in the application of the Scheme?

1.A16 *A number of problems have been encountered in the use of the Scheme, which include:*

- *countries not party to the Scheme issue certificates;*
- *authorities that do not meet the requirements or format stated in the guidelines for the Scheme when they issue CPPs;*

- *some issuing authorities put the WHO emblem, logo or acronym on the certificate, thereby creating the impression that the certificate is authenticated by WHO;*
- *certifying authorities limit the CPP to products manufactured and exported from the certifying country;*
- *the CPP is no longer recognized to substitute the full dossier and QSE;*
- *GMP status given in the CPP is no longer enough for the recipient countries and additional GMP certificates are requested;*
- *there is a lack of understanding that the CPP reflects the approval status of the certifying country only;*
- *CPPs can be a prerequisite for a regulatory submission rather than being provided just prior to approval;*
- *the lead times of the certifying authorities can be very long, sometimes several months;*
- *the way to apply for a CPP is not harmonized as every certifying authority has its own system;*
- *there is a lack of electronic request systems in the certifying authorities and also no possibility of tracking the submitted requests;*
- *some authorities do not allow open discussions about the CPP requests, e.g. prior to a rejection of the CPP application, because of minor mistakes/clarifications;*
- *charging processes vary across certifying authorities which can lead to unnecessary delays in CPP issuance;*
- *there are inconsistencies in listing the trademark of the recipient country on the CPP if different from the certifying country;*
- *required legalizations lead to delays in CPP availability (see Section 3, Q8).*

2. RELATED TO ISSUING COUNTRY

2.Q1 Does WHO issue CPP?

2.A1 *No, WHO does not issue CPPs or any of the certificates described under the Scheme.*

2.Q2 Can any one issue a CPP?

2.A2 *No, only countries and regional organizations, such as the European Medicines Agency (EMA), that are party to the Scheme, can issue CPPs.*

2.Q3 What should Member States and regional organizations possess in order to issue a CPP to support the export pharmaceutical products?

2.A3 *Member States and regional organizations should have the following to issue a CPP:*

- *an effective national licensing system for pharmaceutical products, manufacturers and distributors;*
- *GMP requirements consonant with those recommended by WHO to which all manufacturers of FPPs are required to conform;*
- *effective controls to monitor the quality of pharmaceutical products registered or manufactured within the country, including access to an independent quality control laboratory;*
- *a national pharmaceutical inspectorate having the technical competence experience and resources to assess whether GMP and other controls are effectively implemented and legal power to conduct appropriate investigations;*
- *the administrative capacity to issue the required certificates, to institute inquiries in the case of complaint associated with a potentially serious quality defects or other hazard and to notify WHO and other concerned parties.*

2.Q4 Should a CPP issued by Member States bear the WHO emblem or the acronym "WHO"?

2.A4 *No, certificates should not bear the WHO emblem or the acronym "WHO".*

The use of the emblem or acronym creates the impression that the certificate is issued or endorsed by WHO. It is an illegal act and countries receiving such CPPs should reject them and report to WHO.

The CPP should always appear on the certifying authority's headed paper or emblem.

2.Q5 By whom is a CPP issued and for what requirement in the recipient authority?

2.A5 *A CPP is issued by the authorized body of the exporting country and is intended for use by the competent authority within an importing country:*

- *when a pharmaceutical product is under consideration for a product license/marketing authorization that will authorize its importation and sale in the importing country;*
- *when administrative action is required to renew, extend vary or review such license;*
- *should be provided at the end of the review process for markets that also require the detailed dossier.*

2.Q6 Is the CPP evidence of quality, safety, efficacy review and approval?

2.A6 *Yes, the CPP is based on the assumption that the authorities issuing a CPP have the capacity to assess the quality, safety and efficacy (QSE) of the product they approve for marketing.*

Based on the intention of the Scheme, a recipient authority could require a CPP when it does not undertake a full review of QSE data submitted for registration and evidence of approval in another country is required.

2.Q7 What is the significance of the declaration of marketing status, i.e. whether the product is actually on the market in the exporting country?

2.A7 *Declaration of marketing authorization approval is the aim of the CPP. It is true that the WHO format CPP includes information on marketing status (if the product is actually on the market of the certifying country) but the Scheme also has a provision where the certifying authority can indicate why the product may not be marketed. In circumstances where the product is not actually on the market the issuing authority can indicate that in the certificate.*

The actual presence on the market of the product depends on many other factors. The recipient authority should not require that a product be marketed in the certifying country. The focus of the CPP is to ensure that a full review has been undertaken by the authority to ensure QSE.

2.Q8 Imagine a situation in which a product is authorized for marketing in the country of manufacture, but is not actually available on the market. Can the competent authority of the exporting country issue a CPP to support export?

2.A8 *Yes, it can issue a CPP. What it should do is explain why it is not on the market. One reason for not being on the market could be that the disease/health problem for which the product is indicated may not be prevalent in the country.*

For products approved according to Article 58 (Regulation (EC) No. 726–2004) for diseases/health problems in certain regions, the EMA only can issue the CPPs within the WHO format.

2.Q9 Sometimes a country may wish to import a special dosage form, strength or formulation of a certain known product, and this particular product may not be registered in the manufacturing country. Under such circumstances, can the authority of the exporting country issue a CPP?

2.A9 *Yes, it can issue a CPP, but it should explain on the certificate:*

- *that the particular product is not authorized for marketing in the exporting country;*
- *that it has been produced based on the request of the importing country;*
- *and that the manufacturing is in compliance with GMP.*

The export certificate may look different and have differences in format. However, there may be restrictions on this dependent on individual legislation in the exporting country.

3. RELATED TO RECIPIENT COUNTRY

3.Q1 When would a CPP be required?

3.A1 *When the CPP replaces either a full or partial QSE review, the CPP would be a condition of approval and it would not be required at the time of submission.*

If local legislation stipulates provision of a CPP at the time of submission, the authority review should be a "verification" procedure with published, communicated timelines that should be short and thus not delaying patient access (see Section 1, Q/A 16).

3.Q2 Is it a must that a pharmaceutical product has to be exported from the same country as the certifying authority?

3.A2 *No, it is not necessary for the product to be exported from the certifying country as long as a declaration of GMP assurance appears on the CPP.*

The Scheme was established on the basis that the certifying country was also the country where finished product manufacture took place and was therefore the exporting country. Subsequent revisions to the Scheme have introduced scope for CPPs to be issued by other reference authorities. Most certifying authorities currently provide CPPs when the finished product is not manufactured in the certifying country on the basis that GMP is assured.

Moreover many authorities assume that certifying authorities issue CPPs even when finished product manufacture does not occur in the certifying country. Strict adherence to the above assumption potentially limits licensing and registration options and can delay the introduction, or affect the continued supply, of important medicines.

3.Q3 Is it possible to obtain a CPP from a certifying authority that is not the country where the manufacture of the finished product takes place?

3.A3 *Yes, the Scheme has a provision that when manufacture takes place in a country other than that where the product certificate is issued, an attestation that such manufacture complies with GMP may still be provided as an attachment to the product certificate, on the basis of inspections undertaken for registration purposes.*

The GMP declaration in the CPP will refer to assurance of GMP for the product approved in the certifying country at the stated site, even if the manufacturing site is in a different country than the issuing authority.

3.Q4 Is it necessary for the CPP to come from the country where finished product manufacture takes place?

3.A4 *No, although the Scheme was set up assuming that the certifying country was also the country where finished product manufacture takes place, there is scope within*

the Scheme for CPPs to be issued by other authorities that can provide independent assurance of the GMP compliance status.

There needs to be an appreciation of the complexity of manufacturing and sourcing routes currently employed by companies operating internationally. WHO Member States define the "source" differently:

- *country of finished product manufacture;*
- *country of final packing;*
- *country of final release;*
- *country of main headquarters of the pharmaceutical company, etc.*

The critical element is the confirmation that all production/manufacturing/ quality operations are carried out according to GMP.

Due to complex modern, sourcing routes, together with varying local regulatory processes, the approval in the country where finished product manufacture takes place may be later than in other countries. In this case it is a matter of judgment as to whether it is necessary for the CPP to be issued from the country where finished product manufacture takes place. The preference, in order to speed up patient access, would be to accept the CPP from the earlier approving country – in order to approve the product the certifying authority must also be assured of GMP.

Implementation and compliance with GMP ensures quality of product irrespective of source. Requirement of an additional CPP for the release site if it is different from the product manufacture site, delays patient access since multiple CPPs provide no additional value.

3.Q5 Should recipient authorities require a CPP from more than one certifying authority?

3.A5 *No, under most circumstances they should not require a CPP from more than one certifying authority. A WHO-format CPP from a single certifying authority should provide appropriate evidence of approval and GMP status. However, certain regulations may require provision of more than one CPP.*

3.Q6 Business Process Scenario Questions for when a product is contract manufactured?

3.A6 *Imagine a situation in which a company within Europe produces a pharmaceutical product, and the product is authorized for marketing in that European country. However, the company also produces the product under contract manufacturing in a second country, e.g. in Asia, and wants to export from there to Africa.*

The authority of the importing country should receive the CPP from the European country to prove quality efficacy and safety of the approved product.

Supporting questions

3.Q6.1 Is contract manufacturing accepted?

3.A6.1 *Yes, contract manufacturing is accepted under GMP.*

3.Q6.2 In case of a contract-manufactured product: from which country should the authority in the importing country (recipient authority) accept the Certificate for a Pharmaceutical Product (CPP)?

3.A6.2 *The country where the contract manufacture is taking place can issue a CPP if the product is registered by the authority of that country. If the product is not registered where the contract manufacture is taking place then the authority cannot issue the CPP, but an export certificate (see Section 2, Q/A 9).*

- *If the contract-manufactured product is also authorized for marketing in the European country, then the European country can issue certificate.*
- *If the contract-manufactured product is also authorized by an additional stringent health authority, then this authority can issue a CPP.*

3.Q7 Can a CPP also be used to provide evidence of an administrative review and approval (e.g. as certification of acceptability of a company name change)?

3.A7 *Yes, the CPP can also provide evidence of an administrative review and approval (e.g. as certification of acceptability of a company name change:*

- *for a name change of the owner of a manufacturing or production site), which often happens in the context of company mergers and acquisitions;*
- *for administrative approvals that now involve a QSE review, recipient authorities should use alternatives to a CPP as a preferred and quicker option;*
- *issues related to manufacturing company name change ("administrative review") may indeed create various practical difficulties for exporters–importers, but are not associated directly with safety/quality concerns and should be given less prominence).*

3.Q8 Is it necessary to legalize the CPP?

3.A8 *No, legalization is not part of the WHO Scheme and this is not considered to provide additional assurance of authenticity. Approval statuses in key reference countries are currently available as public information.*

Legalization should not be necessary since an official governmental authority of the certifying country signs the CPP.

Legalization does not add value to the CPP, as it confirms only the signatures on the CPP but does not confirm any details of the CPP content.

Legalization delays availability of the CPP and therefore delays access to medicines for patients. If a recipient authority has any doubts about the validity of a CPP it should contact the certifying authority directly. In addition, cash payment required by certain embassies could cause unnecessary delays to the CPP availability.

A number of recipient countries are no longer asking for legalization as long as the CPP strictly follows the WHO format.

4. GMP STATUS

4.Q1 Is it necessary for recipient authorities to require GMP certificates in addition to a CPP?

4.A1 *No, the CPP includes a GMP declaration, so additional GMP certificate is not necessary.*

- *Following the introduction of the WHO CPP some authorities no longer issue GMP certificates (e.g. US-FDA).*
- *In the CPP context separate GMP certificates are redundant and are therefore discouraged. CPPs should be accepted (in particular from the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and International Conference on Harmonisation (ICH) regions) as evidence of GMP status.*
- *Outside of the Scheme, there are occasions when it is appropriate to require a GMP certificate.*

4.Q2 Does the CPP provide evidence of GMP?

4.A2 *Yes, the GMP declaration in the CPP refers to assurance of GMP for the product approved in the certifying country at the stated manufacturing site(s).*

In addition, CPPs issued by NMRAs party to the PIC/S and ICH regions (European Union, Japan and United States of America) provide evidence of GMP status.

When a CPP is provided it is not necessary to provide additional GMPs for finished products.

4.Q3 What is the difference between approval of the quality data in the submission and evidence of GMP?

4.A3 *The approval of the quality information in a submission is an approval of how the applicant company proposes to manufacture and control the quality of the product at the time of manufacture and throughout the product's life. The evidence of GMP compliance shows, that the applicant company has been able to demonstrate that the manufacturing site fulfills the underlying GMP principles.*

4.Q4 When a CPP forms part of a regulatory review, is it necessary to conduct a site inspection as well?

4.A4 *An inspection should not be necessary when the GMP declaration on the CPP covers the product to be approved in the recipient country.*

- *Inspections outside of this condition are a matter of judgment and decision by the recipient country. Membership of PIC/S, ICH or other means of recognizing inspections by other authorities is encouraged.*
- *The acceptance of the GMP status in the CPP helps to reduce unnecessary inspections.*
- *CPPs should be accepted (in particular from PIC/S and ICH regions) as evidence of MP status. The decision to inspect should be made after a risk-based assessment of the facility, taking into account GMP and inspection status from other authorities.*

5. ALTERNATIVES TO A CPP

5.Q1 Are there any alternatives to a CPP as evidence of approval by a national medicine regulatory authority (NMRA)?

5.A1 *Outside the WHO Certification Scheme other forms of evidence include:*

- *product approval letters (or copies of licenses) from well-established NMRAs, e.g. Australia, Canada, People's Republic of China, Denmark, Finland, Germany, India, Japan, Norway, Republic of Korea, Spain, United Kingdom, United States of America;*
- *positive scientific opinion from EMA;*
- *decisions of the European Commission;*
- *European public assessment report;*
- *licensing/approval information on regulatory authority websites and evidence of approval on the United States Food and Drug Administration website.*

5.Q2 When and by whom is a statement of licensing status of pharmaceutical product(s) (SLSPP) issued?

5.A2 *An SLSPP is issued by the competent authority of the exporting country and is intended for use by importing agents when considering bids in an international tender. It is requested by the importing agent as a condition for bidding. The SLSPP is not intended for use for regulatory submissions.*

5.Q3 What is a batch certificate?

5.A3 *A batch certificate is a certificate that accompanies and attests to the quality and expiry date of a specific batch or consignment that has already been licensed/ approved for marketing in the importing country.*

- *A batch certificate is usually issued by the manufacturer.*
- *In case of biological products, a lot certificate is issued by the competent authority of the exporting country.*

6. GLOSSARY

Terms

Competent authority	A medicines regulatory authority which has the legally delegated or invested authority, capacity, or power to perform a designated function
Stringent authority	The same as competent authority, but related to a certain reputation and generally an authority of a developed market, such as the Food and Drug Administration, European Medicines Agency, Therapeutic Goods Administration, etc.

The following terms are used with the same meaning:

Certifying/issuing country Certifying/issuing (health) authority Exporting country	These terms always refer to the competent authority – in most cases of a developed market which issues the CPP
Requesting country Recipient country Importing country	These terms always refer to the emerging market which needs the CPP from a developed market, as stipulated in the regulatory requirements

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