GOOD PHARMACOPOEIAL PRACTICES

CONCEPT PAPER ON PURPOSE AND BENEFITS

(MAY 2013)

DRAFT FOR COMMENT

Please address any comments on this proposal by 12 July 2013 to Dr S. Kopp, Medicines Quality Assurance Programme, World Health Organization, 1211 Geneva 27, Switzerland, fax: (+41 22) 791 4730 or e-mail: kopps@who.int with a copy to gaspardm@who.int.

We are sending out our working documents electronically only and they are also placed on the Medicines web site for comment. If you do not already receive our documents please let us have your e-mail address (to bonnyw@who.int) and we will add it to our electronic mailing list.

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Please send any request for permission to:

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# SCHEDULE FOR THE PROPOSED ADOPTION PROCESS OF DOCUMENT QAS/13.518:

**GOOD PHARMACOPOEIAL PRACTICES CONCEPT PAPER ON PURPOSE AND BENEFITS**

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Date(s)</th>
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<tr>
<td>Need for good pharmacopoeial practices (GPhP) stated during first international meeting of world pharmacopoeias, Geneva, and other related events with stakeholders</td>
<td>28 February-1 March 2012</td>
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<td></td>
<td>7-8 October 2012</td>
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<td>9-12 October 2012</td>
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<td>21-22 October 2012</td>
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<tr>
<td>First draft of good pharmacopoeial practices (GPhP) sent out for comment (QAS/12.516)</td>
<td>17 October 2012</td>
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<tr>
<td>Compilation of feedback and comments received</td>
<td>November-December 2012</td>
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<td>Circulation of GPhP to drafting group on good pharmacopoeial practices with comments, as well as Concept paper on scope and background (QAS/13.518)</td>
<td>18 January 2013</td>
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<tr>
<td>Formation of initial drafting group (IDG), including representatives from each pharmacopoeia, as per self-nomination, to review draft concept paper via teleconference call</td>
<td>February 2013</td>
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<tr>
<td>Preparation of new skeleton and first draft with more detailed structure</td>
<td>February 2013</td>
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<tr>
<td>Mailing to world pharmacopoeias for additional feedback, preparation of draft chapters by drafting group</td>
<td>February-March 2013</td>
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<tr>
<td>Compilation of feedback</td>
<td>April 2013</td>
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<tr>
<td>Discussion of draft working document on good pharmacopoeial practices at second international meeting of world pharmacopoeias, New Delhi, India</td>
<td>18-19 April 2013</td>
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<tr>
<td>Revised version of GPhP concept paper prepared and mailed out for comments</td>
<td>May 2013</td>
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<tr>
<td>Discussion of any feedback during informal consultation to discuss new medicines, quality control and laboratory standards</td>
<td>12-14 June 2013</td>
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<tr>
<td>Compilation of feedback</td>
<td>August-September 2013</td>
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<tr>
<td>Presentation to forty-eighth meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations</td>
<td>October 2013</td>
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<tr>
<td>Sharing of feedback with world pharmacopoeias in next face-to-face meeting, i.e. Third international meeting of world pharmacopoeias</td>
<td>… (dates tbd)</td>
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1. BACKGROUND

Harmonization efforts in the area of pharmacopoeias started more than a century ago. WHO was mandated with its Secretariat in 1948. This led to the creation of The International Pharmacopoeia.

Pharmacopoeias are embedded in their respective national or regional regulatory environment. Retrospective harmonization has proven difficult to achieve. Prospective harmonization may be easier but presents certain challenges after the initial work has been done, as the maintenance process over time of the pharmacopoeial standards (pharmacopoeial texts and reference standards) needs to be viewed within a long-term perspective.

Complete pharmacopoeial harmonization is only possible once regulatory systems have also been harmonized. Developments in science and medical practice, globalization and the presence of adulterated products require pharmacopoeias to constantly revise. Convergence and reinforced collaboration among pharmacopoeial committees and regulators, supported by adequate interaction with industry, will assist in facing new challenges and resource constraints.

A first initiative to reopen the discussion on international harmonization of quality control specifications on a global scale was taken in a side meeting of the 10th International Conference of Drug Regulatory Authorities (ICDRA) entitled: "Pharmacopoeial Specifications – Need for a Worldwide Approach?" in Hong Kong on 24 June 2002. This further led to discussions among regulators during the 11th ICDRA meeting held in Madrid in 2004.
Other international events during the following years enabled discussions with and among pharmacopoeias on this topic.

In 2012 a series of meetings and events focused on and reopened this debate worldwide among the pharmacopoeias and their stakeholders. These events included:

- 28 February-2 March 2012: the first international meeting of world pharmacopoeias held at WHO, Geneva, Switzerland;

- 7-8 October 2012: joint FIP-WHO Conference during the FIP Centennial Congress, Amsterdam, Netherlands;

- 9-12 October 2012: 47th meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations, Amsterdam, Netherlands;

- 21-22 October 2012: pre-ICDRA meeting on *Quality of medicines in a globalized world: focus on active pharmaceutical ingredients*, Tallinn, Estonia;


The main emerging suggestion from all these events was the development of good pharmacopoeial practices to favour prospective harmonization facilitated by WHO. A number of pharmacopoeias agreed to participate in an initial drafting group.

It was agreed to develop the harmonized good pharmacopoeial practices under the auspices of the WHO Expert Committee on Specifications for Pharmaceutical Preparations, benefiting from its well-established international standard-setting processes and procedures. These processes include an international wide consultation process,
which enables participation of all stakeholders and users in the development process. The final guidance would then be presented, in line with the procedure, to WHO’s 194 Member States and pharmacopoeial authorities.

2. **PURPOSE OF GOOD PHARMACOPOEIAL PRACTICES**

The primary objective of the *WHO Good Pharmacopoeial Practices* (GPhP) guidance is to harmonize approaches and policies in establishing pharmacopoeial standards, which will support regulatory authorities in controlling the quality of pharmaceutical ingredients and their finished products, and other materials provide a tool by which the user or procurer can make an independent judgement regarding quality, thus safeguarding the health of the public.

GPhP describes a set of principles that provides guidance for national (NPAs) and regional pharmacopoeial authorities (RPAs) which facilitates the appropriate design, development, maintenance, publishing and distribution of pharmacopoeial standards.

3. **BENEFITS OF GOOD PHARMACOPOEIAL PRACTICES**

GPhP is designed to facilitate collaboration among pharmacopoeias leading to possibilities for work sharing, prospective harmonization of standards and the recognition of published standards between NPAs and RPAs, increasing access to and availability of quality medicines.

In addition to the above, the establishment of GPhP may result in the following:

- strengthening of global pharmacopoeial cooperation;
- providing stakeholders with a better understanding of how pharmacopoeial standards are developed and maintained in a transparent manner;
– improving cooperation between NPAs/RPAs and stakeholders (e.g. regulators, industry) with a view to facilitating the global harmonization of pharmacopoeial standards, to reduce duplication of work.

Pharmacopoeial standards that are developed following GPhP can be relied upon for adequately validated analytical procedures and suitable reference standards in support of compliance determination. Adherence to GPhP can foster exchanges, work sharing and acceptance of monographs among pharmacopoeias.

GPhP should ultimately enable harmonization of pharmacopoeial standards.

4. IMPLEMENTATION

While the implementation of GPhP by NPAs and RPAs is voluntary, it is recommended and encouraged, as a high level of participation will result in greater benefit to the stakeholders and ultimately to patients.

[Note from the Secretariat: Nomenclature may change with different pharmacopoeias and use of legal terms.]

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