PROCEDURE FOR THE DEVELOPMENT OF WHO MEDICINES QUALITY ASSURANCE GUIDELINES
(July 2018)

DRAFT FOR COMMENTS

Please send any comments you may have to Dr S. Kopp, Group Lead, Medicines Quality Assurance, Technologies Standards and Norms (koppins@who.int), with a copy to Mrs Xenia Finnerty (finnertyk@who.int) by 30 September 2018.

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**SCHEDULE FOR THE PROPOSED USE OF DOCUMENT QAS/18.760 Rev.1:**

**PROCEDURE FOR THE DEVELOPMENT OF QUALITY GUIDANCE GUIDELINES**

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<tr>
<td>First draft developed by the WHO Secretariat.</td>
<td>February 2018</td>
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<tr>
<td>Circulation of working document to the Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations (EAP) for comments.</td>
<td>February 2018</td>
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<tr>
<td>Consolidation of comments received and review of feedback.</td>
<td>April 2018</td>
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<tr>
<td>Discussion during informal consultation on quality control laboratory tools and specifications for medicines.</td>
<td>2-4 May 2018</td>
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<tr>
<td>Review of feedback and revision of the text from the informal consultation and EAP.</td>
<td>July 2018</td>
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<tr>
<td>Circulation of working document and posting it on the Medicine Quality Assurance website.</td>
<td>August - September 2018</td>
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<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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PROCEDURE FOR THE DEVELOPMENT OF QUALITY GUIDANCE GUIDELINES

1. INTRODUCTION

The process described below is designed to ensure wide consultation and transparency when developing the World Health Organization (WHO) norms and standards for medicines quality assurance. These quality assurance (QA) guidelines include good “X” practices (GXPs) and technical regulatory guidance. The steps outlined below are designed to ensure that these texts are made available in a timely manner. The QA guidelines are developed and maintained up-to-date under the aegis of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP), in line with WHO’s rules and procedures governing Expert Committees, adopted by WHO Member States. The steps involved in the development of specifications and monographs for inclusion in The International Pharmacopoeia are addressed separately (1, 2, 3).

QA guidelines are the recognized WHO technical standards to support the whole life cycle of medicines, from development through to their production (for example, good manufacturing practices (GMP), quality control, inspectorates guidelines), provision of their marketing authorization (for example, stability and bioequivalence) and distribution (good distribution practices (GDP)) until the post-marketing phase (for example, WHO Guidelines on the Conduct of Surveys of the Quality of Medicines, and Guidance on Testing of “Suspect” Falsified Medicines).

To reflect the constant technical progress in pharmaceutical development, production, regulatory science and quality control, it is crucial that the QA guidance texts are kept up-to-date, reflect science and that the WHO procedures to elaborate or review them are flexible enough to allow rapid interventions by regulators, whilst maintaining a rigorous public consultation process with all stakeholders.

QA guidelines provide an important element of the quality dimension for the medicines (included on the basis of their efficacy and safety) in the WHO Model List of Essential Medicines and in WHO treatment guidelines. Major WHO programmes, such as the Prequalification Team-Medicines, and others managed by partner organizations, such as the United Nations Children’s
the quality specifications set out in *The International Pharmacopoeia* and in the QA guidelines.

### 2. PURPOSE AND SCOPE

The primary objective of this guidance document is to establish a standardized policy when developing new QA guidelines. By increasing transparency and communication, the aim is to involve a wide range and a large number of stakeholders able to bring different perspectives to common issues.

In addition, the transparency and promotion of internationally standardized practices could improve the cooperation between national medicines regulatory authorities and stakeholders when developing quality standards leading to an optimization of resources on a global scale and reducing duplication of work.

### 3. GUIDELINES DEVELOPMENT

QA guidelines are developed following recommendations by the WHO Governing Bodies (such as, the Executive Board and the World Health Assembly), the International Conferences of Drug Regulatory Authorities (ICDRA), the ECSPP, other WHO Programmes or major public health needs, and are adopted by the ECSPP. The procedural steps to follow when developing a new QA guidance are outlined below:

- Phase 1: search for information on the identified QA topic available in the public domain.
- Phase 2: identify relevant expert(s) in that field applying conflict of interest screening.
- Phase 3: contact the experts suitable for the task, sharing the relevant WHO confidentiality rules and policy. Confirm the core experts team; it can be composed by experts internal and/or external to the Organization. The core experts group is coordinated by the WHO Secretariat.
- Phase 4: make arrangements with the expert(s) for developing the first draft QA guideline text.
• Phase 5: follow the ECSPP consultative process: circulate widely for public consultation; this will last for a period of between eight to twelve weeks, depending on the topic.
• Phase 6: collect and collate the comments received during the global consultative process.
• Phase 7: discuss and review the comments received during the consultation process in the ECSPP meetings/in an informal consultation with experts and specialists.
• Phase 8: incorporate all changes agreed during the discussion in the ECSPP meeting leading to adoption, together with any editorial corrections. Present the final text to the ECSPP for possible formal adoption.
• Phase 9: if no consensus is reached in the ECSPP, repeat steps 5–8 until the agreed draft is suitable for adoption.
• Phase 10: when consensus is reached, the guidance is adopted by the ECSPP and included as an annex in the meeting report. It is recommended by the Director-General to Member States as new WHO guidelines, GXP guidances, etc.

The different steps leading to the development of a new WHO QA guideline for medicines are reported in the Note “schedule for the adoption process” outlining the development history of a text from its draft to its adoption, which is included in each working document that is circulated and posted on the Medicine Quality Assurance website for comments.

4. THE WHO QA TECHNICAL REPORT SERIES

In accordance with the WHO rules and procedures, the Secretariat publishes the QA guidelines adopted by the ECSPP in WHO’s Technical Report Series (TRS) after every meeting of the Committee. The report of the ECSPP includes all the newly adopted guidelines, including GXP and regulatory guidances. It provides recommendations to the WHO Director-General and to WHO Member States. The report is presented to WHO Governing Bodies (such as, the Executive Board) for final comments, endorsement and implementation by Member States. The report of the ECSPP constitutes the WHO technical guidance in Medicine Quality Assurance and regulatory matters.
REFERENCES

1. Procedure for the development of monographs and other texts for The International Pharmacopoeia (WHO TRS, No. 992, 2015, Annex 1).
