

Annex 1

Procedure for the development of monographs and other texts for *The International Pharmacopoeia*

Introduction

The process described below is designed to ensure wide consultation and transparency during monograph development and that the adopted texts are made available in a timely manner.

Subject to the availability of the necessary resources, the Secretariat aims to publish adopted monographs or general texts for inclusion in *The International Pharmacopoeia* after every meeting of the World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations. The proposed changes to the process for the development of monographs reflect this new approach.

Monographs in *The International Pharmacopoeia* provide an important element of the quality dimension for the medicines (included on the basis of their efficacy and safety) in the WHO model lists of essential medicines and in WHO treatment guidelines.

Major WHO programmes such as the Prequalification Team – Medicines (funded by the Bill & Melinda Gates Foundation and UNITAID) and others funded or managed by partner organizations such as the United Nations Children’s Fund and the Global Fund to Fight AIDS, Tuberculosis and Malaria, rely heavily upon the quality specifications set out in *The International Pharmacopoeia*.

The procedure for the development of monographs and other texts for *The International Pharmacopoeia* is outlined in the Note “schedule for the adoption process” outlining the development history of a draft monograph, which is included in each working document that is circulated for comment. The phases of the development procedure are as follows.

- Phase 1: Identify specific pharmaceutical products for which quality control (QC) specifications need to be developed, following confirmation by all WHO parties concerned (including the Department of Essential Medicines and Health Products, specific disease programmes and the Prequalification Team – Medicines). Establish whether monographs also need to be developed for the active pharmaceutical ingredients (APIs) contained in the pharmaceutical products identified. Update the current workplan of *The International Pharmacopoeia*.

- Phase 2: Obtain the contact details for the manufacturers of the selected APIs and pharmaceutical products, as applicable, in collaboration with all parties concerned.
- Phase 3: Contact manufacturers to ask for QC specifications and samples to be provided.
- Phase 4: Identify and contact QC laboratories to collaborate in the project (the number of laboratories contacted will depend on how many APIs and pharmaceutical products have been identified in Phase 1).
- Phase 5: Make arrangements with the collaborating laboratories for drafting the specifications and undertaking the necessary laboratory work.
- Phase 6: Search for information on QC specifications available in the public domain.
- Phase 7: Perform laboratory testing, development and validation, if needed, of QC specifications.
- Phase 8: Follow the WHO Expert Committee consultative process: mail draft specifications to the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations and to specialists; provide drafts on the website.
- Phase 9: Contact collaborating manufacturers to ascertain the availability of the respective substances to establish International Chemical Reference Substances (ICRS), as necessary.
- Phase 10: Support the WHO host organization (European Directorate for the Quality of Medicines & HealthCare, Council of Europe) responsible for the establishment of ICRS.
- Phase 11: Collect and collate the comments received during the global consultative process.
- Phase 12: Discuss comments received during the consultation process with contract laboratories, WHO collaborating centres, and if relevant with the ICRS host organization; conduct additional laboratory testing to add, verify and/or validate specifications.
- Phase 13: Discuss the comments received during the consultation process and test results received as feedback from the collaborating laboratories in an informal consultation with experts and specialists.
- Phase 14: Recirculate draft monograph widely for comments.
- Phase 15: Repeat Phases 8–15, until the agreed draft is suitable for adoption.

- Phase 16: Present the drafts to the WHO Expert Committee on Specifications for Pharmaceutical Preparations for possible formal adoption. If not adopted, repeat Phases 8–14 as often as necessary. If the draft is adopted, proceed to Phase 17.
- Phase 17: Incorporate all changes agreed during the discussion leading to adoption together with any editorial corrections.
- Phase 18: Where necessary, also take into account any further comments that may be received after the consultation or meeting, owing to comment deadlines for recirculated texts (Phase 12 and subsequent phases) falling shortly after the relevant consultation or meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations.
- Phase 19: In all cases, confirm the amended text by correspondence with the relevant experts and/or contract laboratory before making it available on *The International Pharmacopoeia* website or publishing it in a new edition or supplement of *The International Pharmacopoeia*.
- Phase 20: Include adopted text in *The International Pharmacopoeia*.

