

Annex 2

Updating mechanism for the section on radiopharmaceuticals in *The International Pharmacopoeia*

Introduction

In line with the proposal to revise the procedure for the development of monographs and other texts for *The International Pharmacopoeia*, similar changes have been made to the Updating mechanism for the section on radiopharmaceuticals in *The International Pharmacopoeia* (published as Annex 1 of the forty-eighth report of the World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series, No. 986, 2014).

Subject to the availability of the necessary resources, the Secretariat aims to publish adopted monographs or general texts for inclusion in *The International Pharmacopoeia* (Ph.Int.) after each meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. The changes to the process for updating the section on radiopharmaceuticals reflect this new approach.

Updating mechanism for the section on radiopharmaceuticals

Based on the official process for developing monographs for inclusion in the Ph.Int. as outlined in WHO Technical Report Series, No. 992, 2015 (Annex 1), the following process was elaborated to fulfil the specific purpose of development and updating of radiopharmaceutical specifications, a joint project carried out by the International Atomic Energy Agency (IAEA) and WHO, in close collaboration with the Council of Europe (CoE) and other parties wishing to join.

- Phase 1: Identify a specific radiopharmaceutical specification that needs to be revised and/or developed in a joint meeting of IAEA, WHO and CoE experts, following confirmation by IAEA and WHO. Identify radiopharmacy experts to review the material and suggest additions, deletions or modifications as appropriate. Include and update the current workplan on the Ph.Int. website accordingly.
- Phase 2: Identify the information on specifications available in the *European Pharmacopoeia*, other pharmacopoeias and nuclear medicine resources. Arrange for draft monographs to be prepared.

This work, supported by IAEA, will be undertaken by individual experts and consultants through research contracts and/or supporting consultancy

meetings. IAEA should invite suitable experts with pharmacopoeia experience to strengthen the process.

- Phase 3: Mail draft specifications to the IAEA Technical Officers and to members of the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations and to specialists; provide drafts on the Ph.Int. website in accordance with the WHO Expert Committee on Specifications for Pharmaceutical Preparations and IAEA consultative processes.
- Phase 4: WHO forwards any feedback received to IAEA for review by IAEA experts.
- Phase 5: If applicable, discuss comments received during the consultation process with IAEA specialists, contract laboratories and, if relevant, with the International Chemical Reference Standards (ICRS) custodian centre (this arrangement to be confirmed by the European Directorate for the Quality of Medicines & HealthCare (EDQM)) and a specialized agency, as necessary (to be further reviewed with IAEA and EDQM).
- Phase 6: Communicate the outcome of the IAEA review to WHO
- Phase 7: Recirculate draft monograph for comments as in Phase 3.
- Phase 8: Repeat Phases 3–7 until the agreed draft is suitable for adoption.
- Phase 9: Present the drafts to the WHO Expert Committee on Specifications for Pharmaceutical Preparations for possible formal adoption. If not adopted, repeat Phases 3–7 as often as necessary. If the draft is adopted, proceed to Phase 10.
- Phase 10: Incorporate all changes agreed during the discussion leading to adoption together with any editorial corrections.
- Phase 11: In all cases, confirm the amended text by correspondence with the IAEA experts before making it available on the Ph.Int. website or publishing it in a new edition or supplement of *The International Pharmacopoeia*.
- Phase 12: Include adopted text in *The International Pharmacopoeia*.