Fourth Edition, *Second Supplement*

Similarly as for the First Supplement, the Second Supplement, published in 2011, contains new and revised monographs for pharmaceutical substances and dosage forms together with additions and amendments to the texts already published in the Fourth Edition.

The Second Supplement is published in two electronic formats – as a CD-ROM and online. The replacement CD-ROM is, therefore, a cumulative version of the current Fourth Edition, comprising Volumes 1, Volume 2 and the First Supplement as amended and augmented by the text of the Second Supplement.

With the publication of this Second Supplement, the Fourth Edition sees its collection of monographs expanded for both active substances and dosage forms, notably for antiretroviral, antimalarial, antituberculosis and anti-infectives medicines, including specifications for paediatric preparations as recommended in the EMLs. In collaboration with the International Atomic Energy Agency (IAEA), the texts devoted to radiopharmaceuticals have also been revised and replaced by a comprehensive section which is now composed of general texts and a great number of specific monographs for radiopharmaceutical preparations.

New monographs. New monographs are included for the following pharmaceutical substances, including antiretrovirals, antimalarials, antituberculosis dosage forms, including dispersible tablets for paediatric use. Such specifications support the joint UNICEF-WHO-UN Prequalification Team. In developing these monographs WHO has worked closely with manufacturers, national authorities and national quality control laboratories. The new monographs include the following:

NEW MONOGRAPHS

Pharmaceutical substances

- -Lumefantrine
- -Zinc sulfate

Dosage forms

Specific monographs

- -Artemether + lumefantrine tablets
- -Magnesium sulfate injection
- -Rifampicin + isoniazid + ethambutol tablets
- -Rifampicin + isoniazid dispersible tablets
- -Rifampicin + isoniazid + pyrazinamide dispersible tablets
- -Zinc sulfate oral solution (paediatric)
- -Zinc sulfate tablets (paediatric)

REVISION

- -Heparins (interim)
- -Mebendazole
- -Nevirapine

Radiopharmaceuticals. The Second Supplement includes an extensive section on radiopharmaceuticals; this section comprises a general monograph, individual monographs for 29 radiopharmaceutical preparations and supporting texts for methods of analysis and supplementary information. Publication of this substantial section of *The International Pharmacopoeia* is the result of joint work carried out by WHO and IAEA. Radiopharmaceuticals are unique medicinal formulations containing radioisotopes which are used in major clinical areas for diagnosis and/or therapy. As such they require compliance both with regulations governing pharmaceutical preparations and with those governing radioactive materials.

Methods of analysis. As in the First Supplement, in the interests of improved transparency, a specific cross-reference has been given within the monographs published in this supplement in all cases where a general method text is available. Such cross-references are usually in the form of the number of the method text given in parentheses, for example "(1.13)" for the method text for "Determination of pH".

Infrared reference spectra. Many monographs in *The International Pharmacopoeia* include an identification test using infrared spectroscopy; these tests usually allow comparison either with a spectrum obtained from the ICRS or with a reference spectrum. A new section was introduced in the First Supplement which included the majority of the infrared reference spectra required. Additional spectra are published in this supplement.