Explanatory note

Monographs for artemisinin derivatives (Artemether, Artemisinin, Artemotil, Artenimol and Artesunate and their associated dosage forms) were first published in 2003 in Volume 5 of the Third Edition of The International Pharmacopoeia. Certain aspects of these monographs were revised before inclusion in the Fourth Edition. Since publication of the Fourth Edition, the WHO Secretariat has focused resources on the development of new monographs for the fixed-dose combination preparations in line with WHO policy for combination therapy for malaria. Monographs for Lumefantrine and for Artemether and lumefantrine tablets were adopted by the Expert Committee for Specifications for Pharmaceutical Preparations in October 2007 and that for Artemether and lumefantrine oral suspension in October 2008. While, monotherapy is no longer prescribed, the monographs for the monocomponent dosage forms are still of relevance since single component tablets can be co-packaged to provide combination therapy.

Review and revisions

Due to the importance of the published monographs for the APIs and the monocomponent dosage forms and to their wide usage, a large amount of user feedback and comment has been received from, for example, the WHO External Quality Assurance Assessment Scheme, WHO PQ assessors and inspectors, national QC laboratories and manufacturers. It is clear from the comments received and from the development work carried out on the new monographs that further revision of the published monographs is needed, in particular with respect to the chromatographic tests for Related substances and Assay. At its recent meeting the Expert Committee therefore recommended that the monographs should be reviewed in light of all the comments received and proposals for revision should then be circulated for comment. This work is in progress.

Meanwhile, it is clear from comments received and from practical work already carried out that the sample preparation for the HPLC assay as currently described in several of the monographs for tablets and capsules is unsatisfactory. Changes to this aspect of all the relevant monographs will be included in the revision proposals. Meanwhile, the changes that will be proposed with respect to the preparation of solution (A) in Assay Method A for the monographs for Artemether capsules, Artemether tablets and Artesunate tablets are included for information (see separate link).
**Note:** The following correction will be included in the update of the electronic version of the Fourth Edition of the International Pharmacopoeia that will be provided as CD-ROM and online upon publication of the Second Supplement. The graphic formula on page 123 of Volume 1 of the printed publication is correct.

ARTESUNATUM
ARTESUNATE

**Graphic formula.** Replace by: