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BOOK REVIEW*

WHO EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS. Thirty-ninth Report. Geneva, World Health Organization, 2005. 142p. ilus. (WHO Technical Report Series 929). ISBN 92 4 120929 1

This report presents the recommendations of an international group of experts convened by the World Health Organization to consider matters concerning the quality assurance of pharmaceuticals and specifications for drug substances and dosage forms. Important topics were addressed, such as regulatory guidance on interchangeability of medicines, fix-dose combinations: how to regulate them, new guidance in the area of good manufacturing practices (GMP) and stability testing and counterfeit medicines. In addition some 12 new monographs for antiretrovirals, 6 new ones on TB drugs, including 2-, 3- and 4-fixed-dose preparations, as well as monographs for anti-malarial medicines are discussed in detail. Seven new specifications for antiretrovirals were adopted.

The report also includes newly International Chemical Reference Substances for the series of artemisinin derivatives. The following new WHO guidelines were adopted and are annexed to the report: GMP: requirement for the sampling of starting materials, (amendment to current text), GMP: water for pharmaceutical use, guideline for sampling of pharmaceuticals and related materials, guidelines for registration of fixed-dose combination medicinal products.

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ANNEXES

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*This book is available at the Library of the Instituto de Medicina Tropical de São Paulo