

## Book Review

**WHO Expert Committee on specifications for pharmaceutical preparations**, Forty-second Report, Technical Report Series No.948 (World Health Organization, Geneva) 2008. 146 pages. Price: US\$ 30.00; in developing countries: US\$ 21.00  
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With a view towards improving healthcare conditions world over, the WHO brings out from time to time, technical reports on a broad range of health related topics. Among these publication series is that of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. The forty second report published in 2008, and the latest in this series as always, presents clear and practical guidelines regarding quality assurance of medicines. A set of four new standards and guidelines have been included in the 42<sup>nd</sup> Report.

The first among these are the Current List of Available International Chemical References and International Infrared Reference Spectra. The International Chemical Reference Substances are mainly intended to be used as primary standards to calibrate secondary standards. Lists giving control numbers for the current batches are issued in the annual reports from the WHO Collaborating Centre for Chemical Reference Substances and new lists may also be obtained on request. In addition to International Chemical Reference Substances, the WHO Collaborating Centre for Chemical Reference Substances is able to supply 69 International Infrared Reference Spectra (e.mail: [who.apl@apoteket.se](mailto:who.apl@apoteket.se); website: <http://www.apl.apoteket.se/who>).

The United Nations takes up the responsibility of providing drugs and associated health products all over the world. To aid the UN in this task the WHO has defined the procedures for assessing the quality, safety and efficacy of not only the male latex condoms but

also that of intrauterine devices for purchase by the UN and other agencies in this Report. The primary aim is to have in place a mechanism by which manufactures of male latex condoms may be prequalified to enable the procurement of quality products that conform to the international standard ISO 4074:2002 and the WHO specifications for the male latex condom and retain their effectiveness throughout their stated shelf-life.

Manufacturers of male latex condoms who undertake the processes of formulation, compounding and dipping, as well as those using pre-vulcanized latex, may apply for this prequalification scheme. Invitations to submit an Expression of Interest (EOI) may be obtained from the United Nations Global Marketplace (UNGM: <http://www.ungm.org>), UNFPA (<http://www.unfpa.org>) and WHO (<http://www.who.int/prequal/>) websites. Additional details regarding submission of EOI and scrutiny of submitted documents and site inspection criteria, aspects taken into consideration for remaining in the prequalification scheme, *etc.*, are clearly described in the 42<sup>nd</sup> WHO Report. Similarly, the scheme to prequalify manufacturers of TCu380A IUDs of assured quality at specific manufacturing sites for procurement by United Nations agencies are also detailed out.

In addition, the Report also presents guidelines on the Active Pharmaceutical Ingredient Master File (APIMF) procedure. The primary purpose of this is to protect the confidential intellectual property of the manufacturer of the active pharmaceutical ingredient (API), while enabling an applicant for prequalification or prequalification variation to take full responsibility for the finished pharmaceutical product (FPP) and the quality and quality control of the API.

These guidelines would be of help in the compilation of the information on APIs in their dossiers

for prequalification or when submitting a variation to a dossier on a prequalified product when the APIMF procedure is used. It is also intended to help APIMF holders in the compilation of their APIMFs. The structure, format as well the steps of APIMF procedure and dossier contents to be provided in the APIMF are described in great detail in this Report.

Finally, the Report presents a comprehensive review of International Nonproprietary Names (INN) for Biological and Biotechnological Substances, which is likely to be of interest to all those dealing with health products. INN or generic names facilitate the identification of pharmaceutical substances or APIs. This section presents an inventory of the policy decisions taken by the INN Expert Group over the

years and the standards adopted while assigning names to biological and biotechnological substances. Considering rapid advances in the number of agents being made available for the treatment of diseases in man, such as monoclonal antibodies, fusion proteins, gene therapy, *etc.*, there is an overwhelming need for uniformity of terminology to enable global identification of health products. This Report is likely to be a valuable document for anyone who wishes to make sense of the complex process of pharmaceutical christening.

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