

Report on meetings of expert committees and study groups¹

Report by the Secretariat

THE SELECTION AND USE OF ESSENTIAL MEDICINES

**Report of the Expert Committee (including the WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children)
Geneva, 23–27 March 2009²**

Main recommendations

1. The Expert Committee reviewed a number of proposals for additions and deletions to the WHO Model List of Essential Medicines, and made several recommendations for changes. These changes included: amendments to medicines for treating HIV/AIDS, to reflect the latest WHO treatment guidelines; the addition of several medicines for the management of chronic diseases and cancer; and the addition of nicotine replacement therapy as a treatment for tobacco dependence. The new list will be published as the 16th Model List of Essential Medicines.
2. The Expert Committee reviewed the report of the meeting of the subcommittee of the Expert Committee on the Selection and Use of Essential Medicines, held from 29 September to 3 October 2008. The Expert Committee noted the significant progress made by the subcommittee in the further development of the WHO Model List of Essential Medicines for Children, and endorsed the addition of two new sections to the List: medicines for ear, nose and throat disease; and medicines specifically for neonatal care. These medicines are relevant for the paediatric population and will be included in the complete WHO Model List of Essential Medicines.

¹ The Regulations for Expert Advisory Panels and Committees provide that the Director-General shall submit to the Executive Board a report of expert committees containing observations on the implications of the expert committee reports and recommendations on the follow-up action to be taken.

² WHO Technical Report Series, No. 958 (in press).

3. The Committee considered the recommendation of the subcommittee that the Model List for Children should remain a separate publication from the complete Model List for the foreseeable future, and recommended that WHO should publish two products: the WHO Model List of Essential Medicines to facilitate procurement, and the WHO Model List of Essential Medicines for Children to maintain a critical focus on the needs of children and support advocacy for children's health.

4. In its report to the Expert Committee, the subcommittee had concluded that it had satisfied its own terms of reference, recommending that it should be dissolved. The Expert Committee agreed and made the recommendation to the Executive Board and the Director-General that the subcommittee should be dissolved as it had fulfilled its terms of reference regarding the development and revision of the WHO Model List of Essential Medicines for Children. Future Expert Committees should, however, include adequate expertise to consider medicines for children and maintain the Model List for Children.

Significance for public health policies

5. Many Member States have national lists of essential medicines adapted from the WHO Model List of Essential Medicines, and hence changes in the Model List, particularly those concerning inclusion of medicines suitable for children, can have an important impact on the selection of essential medicines at a national level.

6. The publication of the WHO Model List of Essential Medicines for Children is providing significant assistance in identifying the medicines needed to improve health outcomes in relation to the Millennium Development Goals.

7. The WHO Model List of Essential Medicines is a key tool for countries wishing to strengthen their pharmaceutical sector through provision of medicines to their population, especially through primary health care.

Implications for the Organization's programmes

8. The Committee's updating of the Model List of Essential Medicines provides important guidance for other WHO and United Nations programmes (including the WHO-managed United Nations programme on the prequalification of medicines) and for procurement agencies.

9. The updated Model List and the Model List for Children will be used by countries as templates for updating national lists.

10. The transparent process in which applications and expert assessments may be posted on WHO's electronic information service is a model for countries to use in strengthening their pharmaceutical sector.

EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS

Forty-fourth report
Geneva, 12–16 October 2009¹

Main recommendations

11. The Expert Committee on Specifications for Pharmaceutical Preparations advises the Director-General in the area of quality assurance of medicines. It provides recommendations and tools to assure the quality of medicines from their development phase to their final distribution to patients. Detailed recommendations can be found in the relevant sections of the report.

12. The forty-fourth meeting adopted 42 new monographs for inclusion in *The International Pharmacopoeia* and nine related International Chemical Reference Substances. The specifications under development are internationally applicable methods for testing antimalarial, antituberculosis, antiretroviral and radiopharmaceutical medicines, together with, specifically, medicines for children.

13. The Expert Committee adopted the revision of WHO's guidelines on good practices for pharmaceutical quality control laboratories after an intensive process of consultation. The new guidelines will provide a more comprehensive approach for quality control laboratories and related inspections worldwide.

14. In the series of guidelines on good manufacturing practices, a revision of the text for active pharmaceutical ingredients was adopted in line with new international developments. The text on good manufacturing practices for sterile pharmaceutical products was adopted as a newly revised version. In addition, a completely new text was adopted providing guidelines on good manufacturing practices for pharmaceutical products containing hazardous substances. These new guidelines, currently the only ones of their kind, will be valuable in answering the queries that are frequently raised about the manufacture of such products.

15. In order to prevent the further influx of non-authorized or illegal products into the supply chain, thorough reviews of WHO's guidelines on good distribution practices for pharmaceutical products were conducted by the members of both the Regulatory Implementation working group of the International Medical Products Anti-Counterfeiting Taskforce and the Expert Committee on Specifications for Pharmaceutical Preparations. The subsequent joint consultative process culminated in the adoption of a revised text by the Expert Committee.

16. In order to serve the WHO-managed United Nations programme on the prequalification of medicines, a new guideline was adopted on the requalification of prequalified dossiers. Furthermore, upon request by prequalification inspectors, a guideline for the preparation of a contract research organization master file was developed and adopted during this meeting.

¹ WHO Technical Report Series, No. 957 (in press).

17. It was strongly recommended that the series of tests which quality control laboratories undertook as part of the WHO external quality assurance assessment scheme should be continued with the involvement of the WHO regional offices, enabling participating laboratories to improve their performance.

Significance for public health policies

18. Since 1947, when this Expert Committee came into existence, its members have worked towards making available scientifically sound and independent recommendations, written and physical standards, as well as international guidelines for quality medicines. Standards in the area of quality assurance for pharmaceutical preparations are developed by the Committee following a wide international consensus-building process.

19. The international guidelines, specifications, nomenclature and standards developed under the aegis of this Expert Committee serve all Member States, international organizations, bodies within the United Nations system, and regional and interregional harmonization efforts, and they underpin important initiatives, including the prequalification of medicines, the Roll Back Malaria programme, the Stop TB programme, and programmes on essential medicines and medicines for children. The advice and recommendations provided by the Expert Committee are intended to support efforts to enhance access to quality medicines; they are thus aimed at national and regional authorities (in particular national medicines regulatory authorities) and procurement agencies, as well as international organizations like UNICEF and major international bodies and institutions, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria.

20. In recent years policy-makers have increasingly come to recognize that quality of medicines cannot be taken for granted. The growth of trade and the increasing use of modern technologies are posing additional challenges to regulators. There is a clear need for international guidelines and global cooperation to avoid patients' health being compromised through poor-quality medicines; and to avoid public and private resources being wasted on medicines that might be inefficient or harmful, or that might create resistance.

Implications for the Organization's programmes

21. The activities discussed during this Expert Committee meeting concern a broad range of technical programmes within the Organization. There are joint activities, specifically with the Expert Committees on Biological Standardization, and on the Selection and Use of Essential Medicines and its subcommittee on medicines for children. In addition, the Expert Committee serves to develop specific additional guidance and specifications, as needed, for the various medicines recommended by WHO's programmes.

22. The Committee also serves the United Nations programme on the prequalification of medicines, as the programme could not function without the guidelines, standards and specifications adopted by the Committee after its rigorous, international and broad consultative process. The major advantage of this process for the Expert Committee is that, following implementation of these guidelines and specifications, it receives practical suggestions for potential revision or feedback concerning the need for additional guidance.

23. The Expert Committee's recommendations enable WHO, both within the Organization and beyond, to promote the implementation of tools and systems in support of quality assurance for medicines. WHO can thus lead and coordinate international efforts to define and harmonize clear,

independent and practical standards and guidelines for medicines, taking account of increasing globalization and the challenges it poses which can no longer be resolved solely on a national level.

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