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Expert committees and study groups[1]

Report by the Secretariat

WHO EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS

Forty-second report
Geneva, 15–19 October 2007[2]

Main recommendations

1. The WHO Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for quality assurance of medicines. It develops standards through worldwide consultation and an international consensus-building process.

2. The forty-second meeting adopted 11 new monographs for inclusion in *The International Pharmacopoeia* and seven related new International Chemical Reference Substances. The specifications elaborated under the aegis of the Expert Committee refer to internationally applicable methods for testing antimalarial, antituberculosis and antiretroviral medicines and specifically also paediatric formulations of medicines.

3. The Expert Committee recommended the application of new approaches in the manufacture of medicines and maintenance of good manufacturing practices and the development of a new guide on technology transfer. In view of the numerous tragic incidents involving diethylene glycol over the past 70 years, the Committee also recommended that WHO should provide further advice to various target audiences.

4. The Committee recommended that the Secretariat should act as a catalyst in the sharing of regulatory information between drug regulatory authorities in order to conserve resources in assessment dossiers and inspection. It was strongly recommended that the databases on International

[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. 948, in press.

Nonproprietary Names and quality assurance nomenclature should be maintained. The main principles for selection of International Nonproprietary Names for biological materials were endorsed.

5. In the context of the WHO-managed prequalification programme, two new procedures were adopted, on prequalification of intrauterine devices and of male latex condoms, together with new guidance on the assessment of active pharmaceutical ingredients for use in medicines.

6. Cooperation with the WHO departments working on clinical and quality aspects of paediatric formulations, and with the Expert Committee on Biological Standardization on reference preparations and other quality assurance-related topics, was deemed to be essential in order for WHO to fulfil its mandate in these cross-cutting areas. On the basis of the results of an external quality assurance assessment scheme carried out under the auspices of the Committee, it was recommended the WHO regional offices should be more closely involved in building capacity in laboratories reporting questionable or non-satisfactory results.

7. The following new standards and guidelines were adopted and recommended for use: list of available International Chemical Reference Substances and International Infrared Reference Spectra; procedure for assessing the acceptability, in principle, of male latex condoms for purchase by United Nations and other agencies; procedure for assessing the acceptability, in principle, of TCu380A intrauterine devices for purchase by United Nations and other agencies; the Active Pharmaceutical Ingredient Master File procedure; and main principles for selection of International Nonproprietary Names for biological materials.

Significance for public health policies

8. The international guidelines, specifications and nomenclature developed under the aegis of the Expert Committee on Specifications for Pharmaceutical Preparations serve all Member States, international organizations, United Nations agencies, and regional and interregional harmonization efforts, and underpin important initiatives, including the prequalification of medicines, the Global Malaria Programme, the Stop TB Partnership, essential medicines and medicines for children. The advice and recommendations provided by this Expert Committee are intended to help national and regional authorities (in particular drug regulatory authorities), procurement agencies, major international bodies and institutions such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and UNICEF to combat problems of counterfeit and substandard medicines and to work towards ensuring access to good-quality medicines used in the treatment of large populations, for which international quality requirements are not generally available.

9. The independent international standards developed under the aegis of this Expert Committee are freely available for use and WHO has no commercial stake in their development. Special efforts are made to keep implementation costs low, while ensuring that quality is not compromised, for example by keeping the number of physical reference standards needed for an *International Pharmacopoeia* monograph to a minimum.

10. The standards developed by this Committee, such as the International Nonproprietary Names for pharmaceutical substances, are often built into Member States' health policies and legislation and are used by health professionals and patients who are not necessarily aware of their origin.

11. Quality of medicines is all too often taken for granted. The outputs of this Expert Committee help to ensure that patients' health is not compromised through the use of poor-quality medicines, and

that public and private resources are not wasted on medicines that might be ineffective or even harmful.

Implications for the Organization's programmes

12. The Expert Committee enables WHO to fulfil its constitutional responsibilities in developing standards for quality assurance of medicines. Its observations, conclusions and recommendations have significant implications for all WHO programmes dealing with medicines, and are used by all specific disease and human reproduction programmes, by major WHO initiatives such as the Global Malaria Programme and the HIV/AIDS programme, the Stop TB Partnership and the International Medical Products Anti-Counterfeiting Taskforce.

13. The WHO-managed prequalification programme for priority essential medicines produces a list of prequalified medicinal products in the areas of HIV/AIDS, malaria, tuberculosis and reproductive health, which is used principally by United Nations agencies to guide their procurement decisions, and also assesses quality control laboratories for pharmaceuticals. The Programme could not function without the guidelines, standards, specifications and new guidance texts adopted by this Committee after the usual rigorous consultative process. In turn the prequalification programme provides valuable feedback to the Expert Committee and gives staff from the drug regulatory authorities practical experience in joint inspections and joint regulatory assessment activities with the participation both of developed and of developing countries.

14. The Expert Committee's recommendations provide the Organization with a tool to ensure the availability of robust, internationally harmonized quality standards. WHO will continue to promote their implementation both within and outside the Organization. These independent standards and guidelines will enable Member States and other parties to meet the challenges posed by increasing globalization and help to ensure that all, including resource-poor patient populations, have access to good-quality medicines.

THE SELECTION AND USE OF ESSENTIAL MEDICINES

Report of the Expert Committee (including the WHO Model List of Essential Medicines for Children) Geneva, 16–17 October 2007[1]

Main recommendations

15. 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 9 to13 July 2007. The report included the deliberations held by the subcommittee in accordance with the terms of reference decided upon by the Executive Board in resolution EB121.R2, and a proposed list of essential medicines for children.

16. The Expert Committee recommended that WHO should adopt its first Model List of Essential Medicines for Children, as one of the activities needed to implement resolution WHA60.20.

[1] WHO Technical Report Series, No. 949, in press.

17. The Expert Committee recognized that there were many gaps in the Model List, and noted the report of an informal consultation on research needs for children's medicines. More work is needed for a full definition of essential medicines for children. The Committee therefore proposed that the subcommittee should meet again before the next meeting of the Expert Committee (scheduled for March 2009) and further refine the Model List of Essential Medicines for Children.

Significance for public health policies

18. The Sixtieth World Health Assembly in resolution WHA60.20 identified a need for the Secretariat and Member States to take action to ensure better medicines for children. The WHO Model List of Essential Medicines for Children can be used by Member States as a basis for developing national lists appropriate to their needs.

19. The Model List will provide an opportunity to advocate for better medicines for children; it can be linked with procurement and supply in order to improve access to medicines. It also offers an opportunity to identify gaps in the List and to advocate for the development of essential medicines.

Implications for the Organization's programmes

20. The WHO Model List of Essential Medicines for Children can provide important guidance for other WHO and United Nations programmes, including the WHO/United Nations prequalification programme, and for procurement agencies.

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