



WORLD HEALTH ORGANIZATION

EXECUTIVE BOARD
113th Session
Provisional agenda item 3.12

EB113/10
27 November 2003

Quality and safety of medicines, including of blood products

Report by the Secretariat¹

1. The Health Assembly has adopted many resolutions² on the quality, safety and efficacy of medicines, blood products, vaccines and other biologicals, and herbal medicines.³ Despite considerable progress made in the implementation of such directives, urgent action is needed to sustain and expand basic normative and regulatory functions underpinning public health efforts to assure access to quality medicines,⁴ such as those used in the treatment of HIV/AIDS, tuberculosis and malaria.

2. Technological development, increased international trade and the opening of borders are major forces for change with diverse global implications. As a result, many medicines are circulating more freely than ever. Lack of an effective regulatory structure, particularly in special economic zones such as free ports, in some countries raises considerable concern. An absence of appropriate regulatory oversight leads to products that do not comply with quality specifications, whose labelling may make unverified claims, that may have unknown adverse reactions, and which may be counterfeit or substandard and/or contain toxic substances or impurities. Medicinal products derived from blood and plasma, unless they are subject to control, can transmit known and/or emerging pathogens. As access to an ever-expanding array of vaccines increases and sources of manufacture multiply, more effective regulation of the export, import and local use of vaccines is vital to ensure their safety and efficacy.

3. The need, therefore, is urgent to increase political commitment for establishing, maintaining and supporting independent and fully functioning national regulatory authorities in all Member States.

4. Effective regulation of medicines is essential for maintaining product safety, efficacy and quality. Half the Member States are generally considered to lack fully effective regulatory systems,

¹ See also document EB113/37.

² Resolutions WHA24.56 and WHA25.61 on quality, safety and efficacy of drugs; resolution WHA28.72 on utilization and supply of human blood and blood products; resolution WHA45.17 on immunization and vaccine quality; resolution WHA45.28 on harmonizing drug regulations; resolution WHA47.17 on safety, efficacy and quality of pharmaceuticals; resolution WHA50.20 on quality of biological products moving in international commerce; resolution WHA54.11 on WHO medicines strategy; and resolution WHA56.31 on traditional medicine.

³ Collectively referred to in this document as “medicines”.

⁴ In this document “quality” also implies safe and efficacious.

while in a further 30% no regulation exists – yet these are the very countries in most need of effective medicines. In addition, Member States need to recognize the necessity of strong regulatory control for attaining many public health objectives, including provision of safe antiretroviral agents of proven quality to people infected with HIV as part of WHO’s “3 by 5” initiative.

5. The establishment and functioning of national regulatory systems with reference to WHO recommendations, norms and standards are essential in order to protect patients and public health from fraudulent practices and economic waste. A system to regulate medicines must be legally based and its independence assured. It should comprise at least the following functions: (i) to license and control the manufacture, import, export, sale, distribution, promotion and advertising of medicines; (ii) to regulate, supervise and control clinical trials; (iii) to assess the safety, efficacy and quality of medicines; (iv) to conduct postmarketing surveillance and monitoring of adverse reactions or events; (v) to inspect manufacturers, importers, wholesalers and dispensers at regular intervals; and (vi) to provide unbiased information to professionals and the public.

CURRENT ACTIVITIES

6. Over the years, WHO has drawn up extensive normative guidance to form an operational basis on which countries may establish regulatory systems. Its work in the medicines area has been guided in the past four years by the WHO medicines strategy 2000-2003.¹

7. WHO has elaborated methodology for assessing individual regulatory capacity and enabling countries to identify weaknesses in their systems, establish priorities and draw up a plan of action. This activity is strengthened by training programmes for regulatory personnel and support to countries. National regulatory authorities, inspection agencies and other parties with professional knowledge have provided valuable input in the development of these tools.

8. National regulatory authorities and vaccine manufacturers have benefited from the Organization’s support through a global training network enabling countries to use vaccines that meet international standards of quality.

9. Stringent regulatory control is vital in assuring the quality and safety of products derived from human blood. Special effort is needed to strengthen the technical capacity of medicines regulatory authorities to assure the appropriate control of blood products worldwide.

10. Activities also focus on communication networks linking drug regulatory authorities and WHO; provision of authoritative information; support for training and professional development of drug regulatory staff; effective safety monitoring through collaboration among Member States in the WHO Programme for International Drug Monitoring, and on improving the quality of generic medicines, including the “pre-qualification” scheme on medicines for priority diseases.

11. A similar “pre-qualification” process for vaccine manufacturers – both in industrialized and in developing countries – has been in operation for several years, allowing manufacturers to sell products assessed by WHO to global and regional procurement schemes such as those operated by UNICEF and WHO/PAHO, respectively.

¹ WHO medicines strategy: Framework for action in essential drugs and medicines policy 2000-2003, document WHO/EDM/2000.1. See document EB113/10 Add.1 for a report on the WHO Medicines Strategy 2004-2007.

12. WHO fosters international collaboration through forums such as the International Conference of Drug Regulatory Authorities, where regulatory officials report on progress and discuss ways to strengthen cooperation and coordination. Recommendations proposed at the conferences form the basis of future action.

THE WAY FORWARD

13. In order to meet current challenges and strengthen regulation, WHO will need to reinforce partnerships with its stakeholders, including governments, health-care professionals (including prescribers), industry, civil society, patients and other consumers, and academia, while creating new working alliances with regulatory authorities, inspection agencies and other interested parties.

14. Political commitment and support are needed from Member States if WHO is to maintain and expand activities and improve its support to regulatory authorities through:

- updating normative guidance in response to international demand and promoting its effective implementation;
- strengthening mechanisms for efficient exchange of independent regulatory information, sharing experience and maintaining international collaboration among regulatory authorities;
- providing mechanisms and resources to sustain and increase capacity building and training in all aspects of regulatory functions, including the efficient implementation of good regulatory practices.

ACTION BY THE EXECUTIVE BOARD

15. The Executive Board is invited to note the information contained in this report.

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