



Quality and safety of medicines: regulatory systems

Report by the Secretariat

1. At its 113th session in January 2004 the Executive Board reviewed and noted the report on quality and safety of medicines, including of blood products.¹ This present report responds to the suggestion of members for a progress report in the light of the Eleventh International Conference of Drug Regulatory Authorities (Madrid, 16-19 February 2004).

2. Because of the international dimensions of regulation and trade in medicines and cross-border public health issues, it is important for regulatory officials of different nations to cooperate. For more than 20 years, WHO has provided the secretariat to the International Conferences of Drug Regulatory Authorities. The conferences foster the strengthening of regulatory systems and offer a unique and independent forum in which regulators can work towards and reach international consensus. The meetings are also instrumental in guiding regulatory authorities, WHO and interested stakeholders in issues of national and international regulation of medicines.²

3. The role of the regulatory system is to ensure that the manufacture, trade and use of medicines are controlled effectively in order to protect and promote public health. Medicines regulation encompasses many activities aimed at promoting the availability of safe, effective high-quality medicines. The scope and scale of regulatory authorities, always operating within a legal framework, vary according to country or region. Their major functions include:

- assessing the safety, efficacy and quality of medicines and approving products for the market;
- licensing and inspecting manufacturers, retail outlets and pharmacies, wholesalers, importers and exporters of medicines;
- calling on independent testing or expertise whenever required to assess and/or release products;
- authorizing clinical trials and monitoring their conduct in order to ensure that clinical data are of an acceptable standard for use in the regulatory assessment process;
- monitoring and reporting on the safety, efficacy and quality of products circulating on the domestic market; and
- providing information on medicines to health-care professionals and the public.

¹ Document EB113/10.

² Within the context of this document, “medicines” is understood to include medicines, herbal medicines, blood-derived products, vaccines, biotechnology products and other biologicals including tissues.

RECOMMENDATIONS FROM THE CONFERENCES AND REGULATORY CHALLENGES

4. The International Conferences of Drug Regulatory Authorities make recommendations to both Member States and WHO on regulatory issues. Over time, these recommendations have significantly helped the evolution of regulatory systems in many countries and provided direction for WHO in this area. At the Eleventh Conference, which was attended by representatives of 113 regulatory authorities, participants reviewed achievements since the Tenth Conference (Hong Kong Special Administrative Region, China, 24-27 June 2002) and identified regulatory matters that need urgent action. They issued major recommendations concerning access to safe medicines, development of new medicines and good clinical practices.¹

5. Accessible and safe, high-quality medicines improve human health and promote well-being. The need for high quality has been underlined by the repeated finding in many countries of substandard medicines and the devastating consequences of their use. Vigorous implementation of good manufacturing practices is a prerequisite for ensuring the high quality and safety of medicines, especially at all stages of the preparation of blood products from the blood donor to the recipient.

6. WHO is undertaking special efforts to raise awareness of the need for regulatory measures, such as those covering trade in starting materials, active pharmaceutical ingredients and excipients, and assuring the implementation of viral inactivation procedures in the manufacture of blood products. Monitoring safety of medicines continues to be important, and new methods of gathering safety information on medicines are being explored.

7. Diseases of public health concern sometimes primarily affect poor populations. Medicines for these diseases are commercially unattractive because the populations at risk cannot afford them. As a result, effective mechanisms are needed to bridge the gap in research and development. Regulators can play an important role in supporting initiatives aimed at creating such new medicines that hold little commercial incentive. However, there is also a regulatory capacity gap, as regulators from developing countries have limited capability to advise on drug development or assess the safety, efficacy and quality of new products. Authorities lacking that capability could benefit from assessment advice provided by highly developed regulatory authorities, in cooperation with WHO.

8. Application of good clinical practices ensures that clinical trials and studies on medicines meet quality and ethical requirements. Given the increasing numbers of participants in research, the regulators' role in good clinical practice should be strengthened. Member States need to share knowledge and experience in new areas of clinical research, such as biotechnology, since data on safety, efficacy and quality may be limited.

9. Member States can contribute to attaining the goal of improving regulatory systems through partnership with WHO in the following actions:

- updating their national regulations to meet international standards and collaborating in activities that harness resources and focus on optimal strategies;

¹ The recommendations are available on request.

- actively seeking ways to increase collaboration and implement the institutional development plans of national regulatory authorities with WHO and other regulatory authorities or regional networks from both developed and developing countries;
- collaborating in regulatory capacity building by ensuring implementation of internationally accepted requirements, norms and standards, and by supporting and strengthening education and training in all areas of medicines regulatory activity, and, moreover, identifying channels to increase capacity building across boundaries;
- using the principles of the International Conferences of Drug Regulatory Authorities as a catalyst for action and framework to strengthen regulatory systems.

ACTION BY THE HEALTH ASSEMBLY

10. The Health Assembly is invited to take note of the report.

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