



Keynote address

Access to essential drugs and vaccines: the role of regulators

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Between 1977 to 1997 — a period spanning only 20 years — the estimated number of people with access to essential drugs doubled from 2000 to 4000 million. Notwithstanding this increase in availability, over one-third of the global population still lacks access to drugs and people are suffering and dying needlessly as a result of unavailability, unaffordability, or misuse. In Africa and South-East Asia, half of the deaths in children are due to acute respiratory infection, diarrhoea, malaria, measles, tuberculosis, or perinatal conditions. Prompt diagnosis and treatment could save over 3 million lives each year.

The role of the drug regulatory authority

The role of drug regulatory authorities (DRAs) is to ensure the quality, safety and efficacy of medicinal products and improve access to essential drugs of good quality. Marketing authorization helps ensure that only those medicinal products which have been approved are available to patients. Timely product authorization with a standard review time will improve access and where generics account for a large majority of the market, they should be regulated first. For smaller, less resourced agencies, accepting and adopting decisions made by regulatory authorities of countries carrying out full product approval can save time and money.

Access to new products can be facilitated by international or regional harmonization of standards. This will result in a reduction of the time frame for product registration and reduced cost to consumers. Prerequisites to successful harmonization of activities are national political commitment, a level of development similar to other participating countries, and adequate human and financial resources. Appropriate product information materials can contribute to rational use. A summary of product characteristics (SPC) document included in the registration certificates can be used as the basis for regulation of drug information. Authorized SPCs should be accessible on the Internet, where they can be updated as new information becomes available. “Fast-track” authorization may be appropriate for products which are needed urgently to meet public health situations, while older products should be periodically re-evaluated to ensure that they meet current registration requirements.

Effective quality control of medicines is carried out through inspection of the manufacturers and distribution channels. Quality control laboratories should also be equipped to detect counterfeit and substandard products. Substandard pharmaceuticals, including antibiotics and antimalarials, may cause prolonged patient suffering and even death, as well as leading to drug resistance. Almost 60% of substandard pharmaceuticals reported to WHO had no active ingredient. Some had the wrong ingredient, or an incorrect amount of the right ingredient.

Regulations should promote research and development (R&D). Between 1975 and 1997, 1223 new chemical entities were launched, of which only 11 were for the treatment of tropical diseases. There is little market incentive to develop drugs in this area, and the public sector therefore needs to invest in R&D on these “neglected diseases”, which are often prevalent in developing countries. At the domestic level, regulations should be in line with country needs. Priority areas for support of R&D should be identified. GLP and GCP standards should be complied with, and collaboration between industry and academia encouraged.

Challenges faced by regulatory authorities include the following:

- In this era of globalization, borders are open for trading and countries with different regulatory, technological or financial backgrounds are connected. This calls for increased attention to potential health implications of newly introduced systems including the Trade-Related Intellectual Property Rights (TRIPS) Agreement, compulsory licensing in countries with no or limited pharmaceutical production capacity, and the control of trade and information on the Internet.
- There is a big challenge for governments to ensure the quality and safety of drugs when regulations are overruled in emergencies and in diseases such as HIV infection.
- There are a number of complex issues enshrined in the control of biological products since they are derived from living materials with inherent variability and complexity. Regulatory authorities are faced with the important issue of keeping up with innovation and technological advancement or enhancement of vaccines, blood derivatives, and therapeutic biological and biotechnology products.
- A potential challenge in terms of information exchange will be the need to have a scientific database for regulatory decisions, which could be shared with other countries or authorities.
- New procedures should be developed and implemented to cope with the introduction and dissemination of new technologies to the benefit of all, and the impact of novel technologies for developing countries should be assessed.
- There are many challenges in the areas of traditional and complementary and alternative medicines (CAMs). In the countries of the Organisation for Economic Cooperation and Development (OECD), the proportion of the population who had used CAMs at least once doubled from 30% to 60% between 1991 and 2000. In developing countries, CAMs are increasingly being used as primary treatment for common symptoms.

Role of WHO

WHO will continue to monitor global developments and to provide international guidelines for pharmaceuticals and their manufacture, quality control and evaluation.

WHO provides support to Member States focused on strengthening national regulatory capacity through human resources development, support in setting up key infrastructures, and in providing standards, tools and technical advice. WHO also promotes technical cooperation among countries and operational research.

WHO's Medicines Strategy for 2000-2003 aims to improve access to essential drugs for poor and vulnerable populations, especially for priority health problems such as malaria, tuberculosis, HIV/AIDS, etc. It also gives priority to ensuring the quality and safety of medicines, rational use by health professionals and consumers, and the implementation of national drug policies as an integral part of national health policies.

In order to improve access to HIV treatments, WHO has initiated a project for prequalification of suppliers of antiretroviral drugs to procurement agencies. Potential suppliers can present a dossier for evaluation by WHO which is followed by inspection of the manufacturing site and an analysis of samples. This prequalification project has led to creation of a WHO Model Quality Assurance System for Procurement which can be extended to other medicines of public health importance, such as those for malaria and tuberculosis.

The WHO Traditional Medicine Strategy for 2002-2005 is to promote the integration of traditional medicine systems with national health care systems, to provide guidance and support for effective regulation to ensure quality, safety and efficacy of products used. The strategy also advocates availability and affordability of traditional, complementary and alternative medicines, including essential herbal medicines, and promotes their safe and rational use.

In conclusion, regulators have a role and responsibility to promote and facilitate access to quality essential medicines and vaccines. WHO is committed to providing assistance, but appropriate action has to be taken at national level.