



Regulatory challenges: health sector reform and drug regulatory capacity

Moderator: Dr Jorge Bermudez, Brazil

Regulatory control is a state and government responsibility. Within the pharmaceutical sector, regulation must take account of three essential aspects: public health, policy-making, and harmonization.

Strengthening regulatory capacity during reform Mr Xiaoyu Zheng, China

The economic reform which was initiated in the late 1970s in China has affected the pharmaceutical sector. Drug laws have been improved and revised. Some of the challenges facing China now are: to implement the Drug Administration Law and regulations; to promote the development of the pharmaceutical industry; to safeguard people's health; to reduce bureaucracy and improve the service standard of the agency; and to enhance exchange and cooperation with WHO and other countries

The creation of a trans-Tasman therapeutic products regulatory agency: a case study in cooperation Dr Stewart Jessamine, New Zealand, and Mr Graham Peachey, Australia

The creation of a joint trans-Tasman agency is intended to ensure that both Australia and New Zealand are able to manage the regulation of an expanding range of increasingly complex products, and to enhance the influence of each country in regional and global regulatory activities. It will also facilitate trans-Tasman trade.

Various models were considered for the collaboration, and it was concluded that a true joint agency, performing the full range of

regulatory activities, was the preferred one. Discussions have been wide-ranging, covering issues of sovereignty, control of advertising of pharmaceuticals, and cost recovery. The governance principles have essentially been agreed by the regulatory authorities, but have yet to receive formal government endorsement.

The South African experience

Ms Malebona Precious Matsoso, South Africa

One of the main aims of health sector reform in South Africa is to integrate a very fragmented health service and to develop a national drug policy and essential drugs programme, neither of which existed before 1994. The Medicines Control Council is moving towards performance-based units. It will base its work on an electronic regulatory system and is planning to acquire more in-house regulators. Improvements in the legislative framework are planned in relation to complementary medicine and harmonization. South Africa's regulatory changes on parallel importation and generic substitution have already caused controversy. Other recent achievements of the agency include audits for clinical trials, setting-up of a law enforcement unit, GMP inspections of foreign manufacturers and safety monitoring of antiretrovirals.

Drug registration and importation control in Tunisia

Professor Amor Toumi, Tunisia

In developing countries and countries with emerging economies, it is not sufficient for the regulatory authority to ensure safety, quality and efficacy of medicines alone. The authorities should also play a fundamental role with regard to the economic aspects of medicines. Tunisia uses a computerized system with WHO software for drug registration. The system automatically generates all the necessary correspondence, reports and statistics and assists the regulators with decision-making. Another computerized system is used to control the import of drugs. The system is based on close collaboration between the Drug Regulatory Authority and the customs officials, and delivers or refuses permits automatically. It helps the Drug Regulatory Authority in building databases on drug registrations, epidemiological studies, consumption and drug price. With such data, the Drug Regulatory Authority is able to make evidence-based decisions.

Health reform and drug regulation in Venezuela

Dr Esperanza Briceño, Venezuela

In order to improve the Health Services in Venezuela, which were previously highly centralized and inefficient, a new health law has been developed. The aims of the reform were to improve surveillance, strengthen the role of the public sector, decentralize operational and enforcement work, and improve access to medicines. It seeks to do this through a unified, decentralized health system, directed by the Ministry of Health, with institutional and legal autonomy and participation from the community sector. Apart from ensuring the safety, efficacy and quality of medicine, the new law requires drug manufacturers and distributors to be competent, health professionals to be highly qualified, and information to be complete and impartial. The new health act makes the work of the regulatory authority transparent and participatory. It has also enabled the setting-up of independent advisory committees for the regulatory authority and gives the authority power to impose sanctions.

Drug regulation is an essential function of the state, and public health interests should prevail over professional or commercial interests. Health authorities should ensure the availability of essential medicines.

Economic regulation of pharmaceuticals in Brazil

Dr Marcelo Liebhardt, Brazil

In the early 1990s, the market for pharmaceuticals in Brazil was liberalized. In the mid-1990s, it was realized that drug prices had risen substantially and some controls needed to be reintroduced.

The failure of market forces in relation to pharmaceuticals is attributable to the fact that pharmaceuticals are essential products with inelastic demand and high technical complexity. There is also brand loyalty among prescribers. Substitution is low and there is little vertical mobility inside one therapeutic class. All these factors limit the capacity of the consumer to choose.

Recent experience in Brazil shows that competition policy is inadequate to control the pharmaceutical market. The alternatives are technical and economic regulations. Technical regulations monitor the quality and safety of medicine while economic regulations reduce the market power of the pharmaceutical industry and increase consumer access. In Brazil, a mixture of technical and economic regulations is employed.

The instruments used for economic regulations are country-specific and are affected by the characteristics and epidemiological situation of the country, patterns of consumption, distribution of the population and the relationship between state and industry.

Recommendations

Health sector reform, especially in developing countries, has been driven more by financial constraints than by health needs. This is an important challenge for drug regulatory authorities that are confronted with reduction in public funding and the need to develop new mechanisms to finance their activities.

Globalization of economies and intensification of international commerce have created new challenges for drug regulatory authorities. Most authorities — especially the less resourced ones — are confronted with regulatory decisions made elsewhere under diverse circumstances.

1. It is in the paramount interest of public health that drug regulation remains a fundamental responsibility of the public sector, is not left to market forces alone, and is not subordinated to commercial interests.
2. New dimensions should be considered in the regulatory assessment of drug quality, safety, efficacy, and information. This must continue to be based on solid scientific evidence, while taking into account the implications of regulatory decisions on public health goals and on access to medicines by the majority of the population.
3. The resources necessary to ensure full regulatory assessment of pharmaceuticals cannot be available to all countries. In order to contribute to strengthening national regulatory capacity, WHO should study existing experience and undertake research in order to develop models for intensified collaboration and, where appropriate, joint decision-making among national regulatory authorities.
4. Availability of information is a crucial tool to achieve appropriate regulatory decisions. WHO should further support national authorities to introduce or improve data management systems in order to produce and interchange information and to achieve evidence-based decision-making.
5. Progress should be reported back to the ICDDA.