



Harmonization II

Moderator: Ms Malebona Precious Matsoso, South Africa

It has been stated that the aim of harmonization is to eliminate duplication and to ensure the efficient use of resources in order to allow faster access to safe and effective medicines of good quality. To this end, a number of guidelines have been developed, including those from the ICH. Non-ICH countries have, however, expressed a need to also develop a harmonization process for generic medicines.

A number of regional harmonization initiatives have been developed, and these experiences will be described. There is an understanding that harmonization initiatives should speed up access to medicines, while responding to the forces of international trade and achieving a balance between high technological requirements and public health needs.

Regional harmonization initiatives — the Association of South-East Asian Nations (ASEAN)

Dr Mohd. Zin Che Awang, Malaysia

The idea of harmonizing ASEAN pharmaceutical regulations was first raised in the ASEAN Consultative Committee for Standards and Quality (ACCSQ), which was formed in 1992 to facilitate and complement the Asian Free Trade Area (AFTA). In 1997, ACCSQ authorized the ASEAN regulatory bodies to work towards eliminating technical barriers to trade.

The proposal for pharmaceutical harmonization in ASEAN was agreed by the Senior Economic Officials Meeting (SEOM) in early 1999. Subsequently, a Pharmaceutical Product Working Group (P-PWG) was formed to develop harmonization schemes for pharmaceutical

regulations in the ASEAN member countries, without compromising product quality, safety or efficacy. The countries currently participating in the P-PWG are Brunei Darussalam, Cambodia, Indonesia, Lao People's Democratic Republic, Malaysia, Myanmar, Philippines, Singapore, Thailand and Viet Nam. Malaysia has been assigned as the lead country. P-PWG comprises regulatory and industry representatives, and five meetings have been held since 1999.

The scope of the ASEAN Harmonization Project includes exchange of information on existing regulatory requirements, which vary from country to country, comparative studies on them, and study of other successful models for harmonization (particularly ICH). By consolidating the common technical requirements (CTR) developed by each individual country, a common technical dossier (CTD) is established in order to implement the harmonized ASEAN Pharmaceutical Product Dossier.

The P-PWG has made considerable progress despite limitations in existing capabilities and capacities. It is committed to ensuring the quality, safety and efficacy of pharmaceutical products in the interest of consumers and of public health. The ongoing tasks are to improve global cooperation in pharmaceutical harmonization via an interactive and constructive forum; to implement, monitor and review CTDs in line with current international requirements; to establish mutual acceptance of data and facilitate the development of a single ASEAN pharmaceutical market.

Trade globalization highlights the need for a strategic partnership in pharmaceutical harmonization, with the adoption of ICH as a model. The ASEAN P-PWG will maintain close links and network with various international agencies, particularly WHO, in working towards adopting a harmonized best-practice approach appropriate to the ASEAN pharmaceutical environment.

Harmonization in the Americas **Dr Grandville G. de Oliveira, Brazil**

The Brazilian Sanitary Surveillance Agency (now called ANVISA) is the national regulatory agency in Brazil. It has financial and

administrative independence despite being politically subordinate to the Ministry of Health. There are five directors, appointed for three years, who are responsible for developing plans for the Government. ANVISA has responsibilities in various specific areas, including products (e.g. biologicals, drugs, devices and cosmetics), medical and health services, price monitoring and the borders. It also deals with international affairs and financial and administrative matters. The administration of the health system has three levels: (1) federal, (2) state and (3) municipal/county. The mission is to protect and to promote health, by ensuring the safety of products and services.

The vision of ANVISA is “To be the agent of transformation of the decentralized sanitary surveillance system within a network, holding a distinct position, legitimized by the population, as regulator and promoter of social welfare.” Acting at the national level, ANVISA has as main activities the decentralization of surveillance, interaction with society, and the development of relationships with the regulated sector. The concept of essential drugs was developed in 1971. ANVISA is also responsible for national regulation and international harmonization. Harmonization has been achieved through the Pan American Network for Drug Regulatory Harmonization (PANDRHA) and MERCOSUR, the Southern Common Market.

The participants in PANDRHA are the regulatory authorities from each member state and representatives from industry, academia, professional groups, consumers, regional economic integration groups, global drug harmonization initiatives, and other interested groups. The initiative to support the processes of regulatory harmonization covers the whole of the Americas, with the coordination of the Pan American Health Organization. It deals with issues related to bioequivalence, good manufacturing practices, good clinical practice, counterfeit drugs and the pharmacopoeia. New issues to be taken up include medicinal plants, pharmacovigilance, drug registration and drug classification. Three conferences have already taken place.

MERSOCUR comprises Argentina, Brazil, Paraguay and Uruguay, and is a political and economic grouping. MERCOSUR seeks to harmonize efforts in health, to improve health protection and to eliminate non-tariff barriers to increased flow of goods at national, regional and international levels. Some results are:

- regulation is harmonized among members, and the national legislation of each member state must reflect the agreements and be enacted simultaneously;
- the technical skills of human resources are improved through control and inspection;
- joint inspection programmes are carried out on manufacturing companies;
- sanitary surveillance systems have been improved in all member states;
- there is a common drug policy.

Centralized drug registration system in the Gulf Region Dr Laila A. Rahman, Bahrain

The Gulf Cooperation Council (GCC) represents Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates, which have a shared culture, history and environment. A unified drug purchasing scheme was started in the 1970s by a group of pharmacists, to reduce drug costs and allow procurement of large quantities of drugs. In order to make purchasing more rational, a unified system of registration was also needed. There were complaints from patients about not receiving medications on time and from manufacturers about problems in bureaucratic systems in some countries. The GCC Drug Regulatory Committee was thus established in 1997 to centralize registration. It consists of two representative members from each country and appoints advisers from the academic area when necessary. Meetings are held at least four times a year.

Work has been done in three stages. The first stage was a two-year period, during which all pharmaceutical companies and their

products, and research-based companies, in the countries were registered. In the second stage, the programme was evaluated and generic drugs from local manufacturers were registered. The third stage will begin soon and will cover all complementary products (e.g. cosmetics, health food, herbs, etc.).

Current problems arise from the fact that some multinational companies do not accept the concept. In addition, the Ministers of Health in most GCC countries have expressed their doubts about the need for expertise in registration, and some are afraid of losing sovereignty to the centralized authority. On the positive side, coordination among the six countries has led to the development of human resources and a good inspection team, more international collaboration, and mutual understanding. WHO has been very supportive of this system. In the future, more time will be needed for follow-up and postmarketing activities in the individual countries.

Recommendations

It was recognized that international harmonization is characterized by a number of initiatives undertaken in different parts of the world. Such initiatives reflect specific local or regional needs and circumstances. Although these activities and their products may be useful examples and supply important technical knowledge, no single initiative can currently be considered a model for international application or implementation.

1. Countries should take into account local factors, priorities, possible implications, and implementation capacity when evaluating harmonization initiatives and guidance materials produced elsewhere.
2. The development of international regulatory requirements and guidelines should be based on demonstrated public-health needs and should not be driven by technological progress alone.

3. WHO should continue to support regional and local harmonization initiatives aimed at strengthening regulatory capacity and achieving public health goals.

4. Progress should be reported back to the ICDRA.