

General Policy Topics

Role of the International Conference of Drug Regulatory Authorities

One of the primary functions of the World Health Organization is to serve as the directing and coordinating agency in international health work. Among a wide range of technical functions, WHO's Constitution requires the secretariat to "develop, establish and promote international standards for food, biological, pharmaceutical and similar products". In no other domain does the Organization work in such direct collaboration with the governments of Member States. Currently, over 160 countries have designated a senior official to be responsible for disseminating technical advice received from WHO on the safety and efficacy of drugs, and who also arranges for WHO to be kept informed of national drug regulatory decisions that are of international relevance and concern. It is this initiative that has established WHO as the international focus for drug regulatory affairs and has helped to establish and maintain the International Conferences of Drug Regulatory Authorities (ICDRA).

The first of these conferences was convened in Annapolis in the USA in 1980, as a joint initiative of the WHO Secretariat and officials of the US Food and Drug Administration. For the first time within a global context, representatives of drug regulatory authorities in both developed and developing countries were provided with a forum for debate. Conferences have since been held biennially, each one being sponsored by the Ministry of Health of a host country and the agenda is proposed by a regionally-representative group of drug regulatory officials and the WHO Secretariat.

At the first meeting, both the acronym ICDRA and the objectives of the conference were established. The principle aims are to:

- promote collaboration between national drug regulatory authorities;
- forge a consensus on matters of mutual interest;
- facilitate timely and adequate exchange of technical information; and

- discuss contemporaneous issues of international relevance.

The objective is, above all, to offer practical support to decision-makers in drug regulatory authorities. The conferences have been looked upon with benevolence by the governing bodies of WHO, and they have been actively supported by an increasing number of Member States that arrange to be represented at the meetings. It is gratifying that the conferences have now been formally recognized by the World Health Assembly in which resolution WHA45.28 defines WHO's role in intergovernmental harmonization of drug registration and control. The resolution urges all Member States to support and participate in sessions of the ICDRA concerning the harmonization process. It also invites the pharmaceutical industry "to continue to collaborate with drug regulatory authorities and with WHO, where appropriate, in order to ensure that the advantages of harmonization benefit all concerned".

The ICDRA has helped to create a commitment within drug regulatory authorities to address international responsibilities. Certain obligations towards collaboration are manifest. They include the need to exorcise trade in counterfeit, spurious and substandard products; to assure broad international respect for good manufacturing practices in all circumstances; to establish efficient approaches to drug registration and other aspects of control in all countries; and to sensitize law enforcement and customs authorities to their role in control mechanisms.

Other concerns are more recent. One sign of changing times is a general acceptance of the need to validate all data that contribute to the drug development process. Hence the need to develop globally-recognized standards of good clinical and good laboratory practice. This need is uncontested, but the requirements will have to be interpreted with sensitivity and with concern for practicability. There is always a danger that overzealous commitment to standards may serve only to frustrate the process that they are intended to protect.

Extensive discussion within the ICDRA has resulted in better understanding of underlying problems. At

the same time, in the course of debate, the frailty of the drug registration process in many countries has become evident. This has stimulated WHO to develop Guiding Principles for Small Drug Regulatory Authorities and to complement this text with a computer software package for drug registration. One of the most encouraging experiences of ICDRA, thus far, has been the frequency with which discussion of one topic has brought into focus other important subjects.

Regulatory authorities, like pharmaceutical companies, have many interests that merit frank and confidential discussion. The informality and spontaneity of debate that characterizes the ICDRA is one of its greatest strengths. It accepts the need for dialogue between drug regulatory officials and their counterparts in the pharmaceutical industry. Opportunity has thus been offered in the past to international pharmaceutical industry associations to provide luncheon speakers. During the last Conference in Ottawa in 1991 a panel of speakers was invited from the industry to a special session to discuss various topics with drug regulatory authorities. The issues that attracted attention included detection of counterfeiting; harmonization of registration requirements; transfer of summary-basis-of-approval documents; criteria for designation of prescription and non-prescription medicines; and control of pharmaceutical products moving in international commerce.

The next conference, which is co-sponsored by the Government of the Netherlands, will take place in April 1994 immediately prior to the World Health Assembly. This will offer a timely occasion to discuss the outcome of a meeting held by WHO and the Council of International Organizations of Medical Sciences (CIOMS) on the implementation

of WHO's Ethical Criteria for Medicinal Drug Promotion and the responsibilities of the various parties involved, including pharmaceutical companies, consumers and governments, in assuring standards of promotional practice.

These are but examples of the work and influence of the ICDRA. In fact, the agenda of each meeting is overloaded to the extent that much time is devoted to small parallel workshop discussions, each of which has a global focus. Topics that have captured attention range from the assessment and control of traditional and herbal medicines to the prevention and treatment of HIV infection and the prospects of improving the management of the disease in developing countries.

One particularly encouraging feature of the conferences is that the single afternoon reserved to discuss current topics is appreciated to the extent that both selection of subjects and time for debate have to be rigorously controlled. Regulators working in strikingly different environments and grappling with totally different situations meet to discuss common responsibilities from their various perspectives. They are given a unique opportunity to understand at first hand the challenges faced by their counterparts around the world, and the need for collective approaches to issues, both technical and administrative, that cannot be solved effectively from an isolated position.

The ICDRA has already celebrated its first decade of existence and its future is assured for many years ahead. Its success is a reflection of its symbiotic value in promoting the complementary interests of national authorities and the international community. Its recent formal recognition by the World Health Assembly provides proof of its relevance and vitality.