

Drug Classification: Prescription and OTC drugs

Background

The classification of drugs sold over the counter (without prescription) has become a technical subject and hence a strategy affecting drug access. However, this can be successful only if the drugs are adequately classified according to scientific criteria and are accompanied by information that is clear enough to allow the consumer to make useful decisions.

The World Health Organization has analyzed this subject from several standpoints. One of them concerns the role of the pharmacist in the health system¹ and also in self-care and self-medication. This analysis was done through an advisory group that emphasized both the importance of the patient having knowledge of the practice of self-care and the need for suitable training and continuing education of pharmacists so that they can respond to the various health requirements of the public.² The point of view of the regulatory authorities was also analyzed by WHO; in the reclassification of drugs sold without prescription those authorities should consider the types of drugs for which the reclassification is appropriate, safe, and in the interest of public health. In this regard, WHO has produced guidelines for the DRA for evaluation of medicinal products for use in self-medication.³

One organization of the pharmaceutical industry, the World Self Medication Industry (WFPMM), a nongovernmental organization with an official connection to WHO that represents manufacturers of drugs sold without prescription, consolidated a survey on self-medication and self-care that included 14 countries globally. In its conclusions it pointed out that although the legislation and the health systems are different for over-the-counter drugs, consumers rely on them. The use of such drugs is greater in population groups with more education and publicity does not seem to have an impact on their use.⁴ In a study of the capability of the consumer and the attitude toward drugs sold without prescription in several countries of the region, conducted by the Latin American Industry for Responsible Self-medication (ILAR), the results were similar. Among the actions recommended were development of policies on drug classification and making information on these products more accessible to the consumer.⁵

It has been recognized that proper drug classification can contribute effectively to public health, and several countries of the region have included in their

¹ *The Role of the Pharmacist in the Health Care System: Pharmaceutical Care. Report of the WHO Meeting. Tokyo, 1993.*

² *The Role of the Pharmacist in self-care and self-medication. Report of the IV Meeting of the WHO Working Group on the Role of the Pharmacist. The Hague, The Netherlands. 1998.*

³ *Guidelines for the Regulatory Assessment of Medicinal Products for Use in Self-medication. WHO/EDM/QSM/00.1. Geneva, 2000.*

⁴ *Health Care, self-care, and self-medication. WFPMM Survey and Self Medication*

⁵ *Actitud hacia los medicamentos de venta sin receta y el cuidado de la salud en América Latina. Resultado de investigación en 8 países. IPSOS. 2004.*

pharmaceutical policies modification of their legislation to make drugs that can be sold without a prescription more accessible to the population. In some initiatives for integration, such as in the Andean community and in Central America, this issue has been discussed and some agreement has been reached on harmonized requirements that have served as a basis for the formulation of a regional proposal.

In the First Pan American Conference on Drug Regulatory Harmonization (1997) the need for standardized criteria for changes in drug classification from sale under medical prescription to sale over the counter was recognized.⁶

In the Second Pan American Conference on Drug Regulatory Harmonization (1999) a panel on drug classification which involved the United States of America, Canada, producers of over-the-counter drugs, and the drug regulatory authorities of Costa Rica and Venezuela was established. The panel demonstrated the differences in legislation existing in the countries of the sub-region. However, among the conclusions of the meeting was agreement that the subject of drug classification would be treated as involving not harmonization, but rather cooperation.⁷

In the Third Conference, in April 2003, the subject of Drug Classification stood out again; it was given priority and a working group on Drug Classification was established (WG/DC). That same year the Conference Steering Committee analyzed the agenda for that group and, although the regulations in the areas of food and cosmetics required attention, it granted priority to the preparation of a proposal for criteria for classification of over-the-counter and prescription drugs, leaving addressing the subjects of nutrients and cosmetics for later.⁸

In 2003 the Working Group on Drug Classification met and decided to perform a comparative analysis of current legislation. The study was to constitute the basis for the formulation of an integrated proposal for criteria for drug classification.⁹

The study compared current legislation in 18 countries and covered, among other aspects, categories of products and their official definitions, criteria for classification of each of the identified categories, and regulation of advertising and the information content of labels and leaflets.¹⁰

In 2004 at the second meeting of the working group on classification, the results of the "Comparative Initial Analysis of Legislation on Drug Classification in the Region of the Americas" were analyzed. Criteria for definition of over-the-counter drugs (OTC), criteria for classification, information on labels and inserts or leaflets, and criteria for publicity were harmonized for the purpose of preparing the proposal for classification criteria to be presented at the Fourth Pan American Conference on Drug Regulatory Harmonization.¹¹ The content of labels and leaflets were compared and adjusted with that proposed by the Working Group on Drug registration.

⁶ *Report of the First Pan American Conference on Drug Regulatory Harmonization, Washington, D.C. November, 1997.*

⁷ *Report of the Second Pan American Conference on Drug Regulatory Harmonization, Washington, D.C. November, 1999.*

⁸ *Report of the Third Meeting of the Executive Committee of the Pan American Network for Drug Regulatory Harmonization. Mexico, 2003.*

⁹ *Report of the I Meeting of the Working Group on Drug Classification. Mexico, 2003.*

¹⁰ *Estudio Comparativo de Legislaciones Nacionales sobre Clasificación de Medicamentos. GT/CM. PANDRH. November 2004.*

¹¹ *Informe de la II Reunión del Grupo de Trabajo de Clasificación de Medicamentos, Guatemala, 2004.*