

WORKING GROUP ON DRUG CLASSIFICATION

DEFINITION AND CRITERIA TO APPLY TO OTC DRUGS¹

1. Definition of Non Prescription Drug or Over the Counter (OTC):

“An OTC is a pharmaceutical product, drug, or medicinal specialty whose dispensing or administration does not require medical authorization, and it can be used by the consumers under its own initiative and responsibility to prevent, relieve or to treat symptoms or mild diseases and that its use, in the form, conditions and authorized dosages are safe for the consumer”;
2. Criteria to classify drugs as OTC: OTC drugs are those that fulfill with the following characteristics:
 - 2.1 Drugs which are effective and safe in order to be used in the prevention, relief of symptoms, or treatment of mild diseases, and are easy to identify;
 - 2.2 Drugs with broad safety range, in such a way that the voluntary or involuntary administration of dosage higher than those recommended, or where are not indicated, does not represent a serious danger for the health of the patient;
 - 2.3 Have a broad dosage margin, so it can be adapted at the age and weight of the patient;
 - 2.4 Drugs that does generate tolerance or dependency when are used and that are not susceptible of abuse;
 - 2.5 When it is used in accordance with the instructions do not mask serious diseases, nor delay the diagnosis and treatment of a condition that requires of medical care;
 - 2.6 Drugs of safe utilization in all the age groups of the population;
 - 2.7 Dosage forms usually of oral or topical route, of easy management and storage and that are not of IV or IM administration;
 - 2.8 Drugs whose active ingredient has been marketed under medical prescription at least 5-10 years, time during which has demonstrated a favorable index of safety and efficacy through the data of drug surveillance;
 - 2.9 The adverse reaction reports have not increased during the marketing period.

¹ *Approved by the IV Pan American conference on Drug Regulatory Harmonization. March 2005*

3. Criteria for promotional material for the publicity of OTC drugs:
 - 3.1 That OTC drugs are promoted only with the information and arguments approved by the Ministry of Health or Regulatory Authority;
 - 3.2 That they do not suggest that the use of these drugs can delay or avoid seeing the doctor;
 - 3.3 That do not suggest that the drug is to be used permanently, but that the drug is only to be administered (used) for the authorized limited time;
 - 3.4 That the words, content or sentences used do not exaggerate the benefits of the product;
 - 3.5 That the content are written using expression in colloquial language, without using medical or technical terms that may confuse the consumer; and
 - 3.6 That testimonial argument of people or notable entities in the education, research or health sciences should not be used since it can induce to consumption of the drug.