Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

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FDA Advisory

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SUBJECT: REVIEW OF GUIDELINES FOR OVER-THE-COUNTER DRUGS

The pillars of Universal Health Care are founded on a consistent regulatory regime that ensures the safety and efficacy of health products. Secretary Enrique T. Ona has prioritised access to medicines that are safe, pure and effective. Every drug has a risk profile defined in terms of adverse events, margin of safety[1], and interactions with other molecules. In 2000, then Secretary Alberto Romualdez enforced guidelines for drugs that can be dispensed without a prescription, promoting greater accessibility while ensuring public safety. To ensure that Filipinos are protected, labelling standards were reinforced to reflect the total information necessary to guide the public into making an informed decision. For the regulators, this means comparing the risks with the benefits in regular cycles, and with supporting information from the consumers and health professionals. Thus pharmacovigilance was established to provide the feedback mechanism allowing the Health Department to review approvals and revise labels if necessary. Off-label use has altered the situation for health regulators – consumers are taking risks with administering multiple doses for unapproved indications. Coupled with the dynamics of multiple drugs given to an individual to treat different disorders, taking into account the causation of adverse events requires epidemiologic surveillance.

The Department of Health is looking into revising Administrative Order number 23-C issued in 2000 prescribing the guidelines for classification of drugs as over-the-counter. The Food and Drug Administration will apply pharmacovigilance principles such as risk management planning in decision points as it reviews current guidelines for over-the-counter medicines.

For more information and inquiries, email us at info@fda.gov.ph

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[1] Related to the concept of therapeutic index, a ratio derived when the dosage that will cause toxicity in half of the population is divided by the dosage that will cause the intended effect in half of the population. Values less than one indicate that the drug is likely to cause adverse effects before it is effective. Higher values suggest a wider margin of safety.

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