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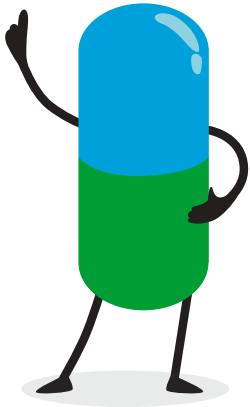
Organisation of Pharmaceutical Producers of India

OVER THE COUNTER (OTC) DRUGS

Putting Health Within Reach

OVER THE COUNTER DRUGS



In India, the role of self-medication is becoming increasingly significant, particularly due to the growing prevalence of chronic and lifestyle diseases such as diabetes and cardiovascular conditions, which require continuous management and preventive care. Over-The-Counter (OTC) drugs play a critical role in facilitating self-care by providing individuals with timely access to safe medications without the need for a prescription. OTC drugs are a crucial component in advancing consumer health because they allow people to treat or manage many health conditions conveniently and successfully save valuable resources of the healthcare systems.

Despite the importance of OTC drugs, India currently lacks a formal legal framework for these medications. Prescription drugs are regulated under specific schedules of the Drugs Rules, 1945, while OTC drugs remain undefined in law, creating regulatory ambiguity. A robust OTC policy is particularly important in the Indian healthcare context, due to the over-burdened Indian healthcare system and a very high percentage of out-of-pocket healthcare expense.

There is a recognized need for a clear and structured OTC framework that includes a formal definition of OTC drugs, a procedure for transitioning prescription drugs to OTC status, and specific regulations governing their manufacture, distribution, advertisement and sale. Establishing such a framework would enhance public access to safe medications, promote responsible self-medication, and reduce the burden on the healthcare system.

FAQs

What is the importance of self-medication in India?

In India, the importance of self-medication is heightened due to the rise in chronic and lifestyle diseases such as diabetes and cardiovascular conditions, which can be managed and prevented through self-care. Factors like pollution, lack of physical activity, and poor dietary habits contribute to these conditions, making informed use of OTC products crucial. Self- medication is influenced by education, societal norms, and availability of drugs, which can alleviate the economic burden of healthcare by focusing on prevention rather than treatment. Thus, establishing a robust regulatory framework and promoting self-care is essential for improving public health and reducing healthcare costs.

Why is there a need for a separate category of OTC drugs in India?

Pharmacists and various pharmaceutical associations have long advocated for a distinct category of OTC drugs to streamline their regulation and availability. Despite numerous discussions and draft reports by various committees, including the Drugs Consultative Committee (DCC) and the Drugs Technical Advisory Board (DTAB), no formal category or comprehensive list of OTC drugs exists in India.

What is the current legal status of OTC drugs in India?

The term "Over-The-Counter" is not legally recognized in India. From a drug regulatory perspective, OTC drugs could include non-prescription drugs that are not classified as prescription drugs (Rx) under the relevant Schedules of the Drugs Rules, 1945 (DR, 1945) or that are required to be sold only with a prescription as part of the approval conditions.

What differentiates prescription drugs from OTC drugs in India?

Prescription drugs are categorized into Schedules H, H1, and X of the Drugs Rules, 1945. Newly approved drugs by the Central Drugs Standard Control Organization (CDSCO) are usually required to be sold only on prescription as a part of the drug approval condition. Drugs listed in Schedule G do not require a prescription but must carry a cautionary label. On the other hand, Over-The-Counter (OTC) drugs are not explicitly classified and can include allopathic drugs not listed in these schedules.

What is the current status of Rx-to-OTC switches for drugs in India?

Currently, there is no formally defined Rx-to-OTC switch procedure in India.

Why is there a need for a well-defined prescription-to-non prescription (Rx-to-OTC) switch procedure in India?

Establishing a clear procedure for transitioning prescription drugs to Over-The-Counter status in India is essential. This would help eliminate regulatory ambiguity, make safe and effective medicines more accessible for common ailments, and enable consumers to make well-informed health decisions about such medicines/ treatment options. A formal process will ensure consistency and clarity in transitioning prescription drugs to over-the-counter status.

What elements should a well-defined OTC regulation framework include in India?

A well-defined OTC regulation framework in India should encompass:

- A formal definition of Over-The-Counter drugs;
- Specific regulations for their import, manufacture, distribution, and sale;
- An approved "Positive List" of OTC active ingredients, directives for Fixed Dose Combinations (FDCs) containing these ingredients, inclusion of these ingredients and FDCs in the Indian Pharmacopoeia and National Formulary of India (NFI)
- Establish a clear procedure for switching prescription drugs to Over-The-Counter status, and
- Well-defined labelling requirements

Can new drugs be classified as OTC in India?

Any new active ingredient or fixed-dose combination approval by CDSCO is issued with the condition that the drug must be sold only on prescription.

What changes are ideal to regulate OTC drugs in India better and align with patient interests?

The regulatory framework should provide for a separate chapter in the DR, 1945 for OTC drugs. Such chapter should include clear definitions; classifications; labelling requirements; guidelines for advertising; and procedures for licensing and selling OTC medicines. This structured regulation would ensure safety, proper usage, and expanded access to OTC drugs.

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