Over the Counter Drugs

Organisation of Pharmaceutical Producers of India

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OPPI and its member companies are committed to empowering citizens with responsible self-medication. They aim to provide access to self-care options and timely medication through clear information, enhancing health outcomes and reducing the national health system's burden.

FAQs

1. 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.

2. 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.

3. 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 or that are required to be sold only with a prescription as part of the approval conditions.

4. What differentiates prescription drugs from OTC drugs in India?

Prescription drugs are categorized into Schedules H, H1, and X of the Drugs Rules, 1945 (DR, 1945). Newly approved drugs by the 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.

5. Why is there a need for a well-defined prescription-to-nonprescription (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.

7. 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.

8. 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.

10. 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), and
- Establish a clear procedure for switching prescription drugs to over-the-counter status
- Well-defined labelling requirements

11. 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.