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DRUG REGULATORY STATUS ASSIGNMENT CRITERIA: A CONTRAST AMONG 2 COUNTRIES

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ABSTRACT

After a laborious and extravagant procedure the drug finally enters the market for use. But who determines the new drug status as a prescription only or an OTC? There is a clear cut contrast between the US and India with respect to their assignment guidelines and the future prospect of a new drug. In the US the regulatory status of the approved drug is determined as per the FDA guidelines (FDCA of 1938) in accordance with the Durham-Humphrey act of 1951 which depicts the criteria required for a pharmaceutical product to be marketed as a prescription drug or an OTC product. CDSCO headed by the DCGI is the authority responsible for determining the regulatory status which acts as per the regulations listed in Drugs and Cosmetics Act of 1940 in India. The US regulatory system stipulates the malleability for the inter conversion of the drugs regulatory status known as "Rx to OTC switch" which is deficient in India. Perfect implementation of regulations in India will promote effective use of OTC's and forestall illicit sale of prescription drugs as OTC's.

INTRODUCTION: A prescription drug is defined as "A medication that can be purchased or given out only with a written instruction from a licensed health care provider such as a Doctor, Dentist, and Nurse to a Pharmacist" [1]. The written instructions are known as prescription. The word prescription is derived from a Latin word "Praescriptus" which means "To write before".

Historically prescription was written before the drug is compounded and administered [2]. The prescription drug is usually denoted by a symbol "Rx" meaning "To Take". The guidelines laid down by the FDA in the FDCA (Food Drug and Cosmetics Act) in 1938 and the amendments followed after monitors and determine the regulatory status of the drugs. This act also emphasizes that no drug is to be marketed until its safety is proven and the directions for its use are specified on the label.

For a drug, in order to be marketed as "Prescription Only" it should comply with any 1 of the following criteria [3];

- It is a habit forming drug or,
- Specified as prescription only during the NDA (New Drug Approval) process or,
- Requires physicians monitoring/ has a very narrow therapeutic range.

OTC Drugs: Over the counter product usually referred as OTC (An Acronym) is defined as a "Medication which is safe and effective for use by the general public without seeking treatment by a health professional" [4]. These medications do not require a prescription. These are usually stocked in the counter cabinets in the Pharmacies, General stores and even in Gas stations (in the U.S.).

There are about 300,000 OTC products with 80 different classes. The FDA reviews of the OTC products are handled by CDER's Office of Drug Evaluation IV [4].

OTC market entry is less restrictive than that for prescription drugs and does not require pre-market clearance. They pose many fewer safety hazards than the prescription drugs because they are designed to alleviate symptoms rather than disease.

Drug regulation criteria in the United States of America (USA): In the U.S., in order to assign "Prescription only" status for a drug it should comply with any of the above mentioned criteria.The criteria for assigning an OTC status to a drug (no prescription required) are:

- Margin of safety
- Method of use
- Benefit-to-risk ratio, and
- Adequacy of labeling for self-medication.

All the injectable drugs are prescription only with Insulin as an exception. All the OTC's active ingredients were reviewed by FDA in 1972 which resulted in the promulgation of a regulation or a monograph, which was a recipe or set of guidelines applicable to all OTC products within a therapeutic category.

Drug regulation criteria in India [5, 6, 7, 8, 9]: India currently ranks 11th in the global OTC market [5]. In India the drug manufacture, import and sales are governed by the Drugs and Cosmetics Act (DCA) 1940, the Drugs and Cosmetics Rules (DCR) 1945 [5] and is implemented by the Central Drug Standard Control Organization (CDSCO) which is headed by Drug Control General of India (DCGI) who in turn functions under Directorate General of Health Services.

The prescription drugs are those that are listed in "Schedule H" and "Schedule X" of the Drugs and Cosmetic Rules. Drugs listed in "Schedule G" (which are mostly antihistamines) do not need prescription to purchase but the DCA emphasizes a mandatory warning label "Caution: It is dangerous to take this preparation except under medical supervision" to be present on all the products.

The drugs listed in the "Schedule K" which are usually treated as "House Hold products" can be sold by a non-pharmacist in remote villages whose population is less than 1000 subject to other conditions. The drugs are categorized into schedules as per the rules published in the official gazette vide notification No. F. 28-10/45-(H) 1 dated 21/12/1945. The phrase "OTC" has no legal recognition in India. The drugs that are not included in the "Prescription only" list are considered as "OTC". Hence all the OTC's do not require a prescription for purchase.

Switch Climate [10]: The process of changing the regulatory status of a drug i.e., from Prescription Only to OTC is usually called as "Rx to OTC switch". In the U.S., the regulatory authority provides flexibility for such switches. Any one of the following criteria is required for initiation and completion of a "Switch";

- The manufacturer requests the switch by submitting a supplemental application to its approved NDA.
- A petition from the manufacturer to the FDA.
- Recommendation from the OTC review panel.

Unfortunately, India lacks a well-documented process or a specific regulation for such switches. The development of regulation for switch process in India was not stressed due the following reasons

- Practically most of the Rx drugs can be bought with a prescription,
- The patient's drug purchase behavior is highly influenced by the physicians and
- The availability of OTC products is restricted mainly to Pharmacies unlike in the U.S., where the OTC's are available even in fuel filling stations.

Drugs which experienced the switch process (Rx to OTC) in the U.S. [11, 12];

- Minoxidil
- Naproxen Sodium
- Cimetidine

- Miconazole
- Nicotine patch, gum, lozenges
- Drugs for Diabetes, Migraine, Asthma and Blood pressure are under review for conversion.

Current Progress in India: The OTC committee of the Organization of Pharmaceutical Procedures of India (OPPI) is currently working towards the promotion of responsible self-medication in order to promote the OTC market. It is also aiming on promoting the importance of responsible self-medication through awareness programs and community education. The committee not only promotes OTC use but also emphasizes on safety. Besides promoting OTC's, establishing a balance between wider access of drugs and their safety should also be focused [13].

CONCLUSION: There are proper drug regulations legislated in India but are rarely accomplished in practice. The regulatory authority along with the state FDA's (Food and Drug Administration) should immensely implement such regulations so that the OTC market is thrived and procurement of prescription drugs over the counter is proscribed eventually knocking off the prescription drug abuse which is the prevailing challenge in India.

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