

REGULATORY AND CLINICAL REQUIREMENTS FOR PRESCRIPTION TO OTC SWITCHES IN USA AND INDIA

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INTRODUCTION:

Over-the- Counter (OTC) drugs are those which are available directly to the patient through pharmacist without any prescription from the health professional. There are sheer number of OTC drugs in market in various countries. Over the Counter (OTC) drugs are also known as non-prescription drugs which qualifies certain criteria as regulatory point of view. Deciding what qualifies for OTC drug category is not simple. There is always bit confusion between OTC drugs with respect to diet supplements, cosmetics, herbal products.

Rx-to-OTC switches are a means for the pharmaceutical industry to extend the marketing exclusivity which provides the originator company with defence from erosion from generic competitor. The regulations for changing the status of the drug from prescription to non-prescription status are well defined by USFDA. The status of the drug is changed on the basis that the drug is safe and information on the label describing pros and cons of the drug product when it is used without a prescription from the health professional. Labeling comprehension studies are conducted by the sponsor with the key research endpoint to self-recognize the condition. It is also important to determine the ability of the consumer to appropriately select or deselect the medication and ability to demonstrate good judgement about whether the drug is proper to administer for them. There are at least 65 Rx-to-OTC switched drugs in US from 1976 to 2010. Division of Non-prescription Regulation Development (**DNRD**) and Division of Non-prescription Clinical Development (**DNCE**) are the two divisions under FDA with primary responsibility of updating the monographs and handling the NDAs involving OTC drug products respectively.

Finally, in India OTC has no legal recognition, drugs which are not included in prescription only drugs are considered to be in non-prescription drugs. India does not have a well-documented process or a specific regulation on switching Rx to OTC products. Globally many countries have a formal process of transferring prescription (Rx) status to over-the-counter status. Regulators in India will sooner or later need to clearly define OTC formally as a category since in near future switching would be one of the most used strategies to enter OTC by new players.

United States Regulations:^[1]

Prior to the advent of 1938 Food, Drug and Cosmetic Act (FD&C Act), technically all drugs could be marketed without a prescription. After passage of the act, the U.S Food and Drug

Administration (FDA) decided on a case-by case basis which drugs were to be considered prescription only and which could be sold over the counter (OTC).

In 1951 the Durham-Humphrey amendments to the FD&C act saying that a drug requires a prescription if

- ✓ It is one certain habit forming drugs
- ✓ It is not safe for use except under competent professional supervision due to toxicity, potential harmful effects, or method of use
- ✓ It is specifically limited to prescription status by approved New Drug Application (NDA)

Safety of OTC use means a low incidence of adverse reactions or significant side effects under adequate directions for use and warnings against unsafe use, as well as low potential for harm, which may result from abuse under conditions of wide spread availability. FDA recognizes that while no drug can be considered totally safe, an OTC product must have sufficient benefits to justify whatever risks are likely to be connected with its proper use.

The labeling of OTC drug products must be clear and understandable and must be truthful in all respects without being false or misleading in any particular. The labeling must contain adequate directions for proper use as well as warnings against use, side effects and adverse reactions. Label comprehension studies typically constitute an important facet of the decisions involved in allowing drug products to be sold without prescription. Moreover, the use of an OTC drug does not necessarily mean that medical professionals are totally out of picture, as it is not unusual for the initial diagnosis of the condition to be made by a physician. An example is vaginal yeast infections, not frequently first diagnosed by health care professional and then self-medicated with an OTC product.

REASONS FOR INTEREST IN NONPRESCRIPTION DRUGS ^[2]:

Consumer's point of view:

- ✓ There is usually a significant monetary advantage to the consumer since OTCs are considerably less expensive than prescription drugs.
- ✓ Less lost work time and costs saved by not needing to visit a doctor are important considerations.
- ✓ Growing sophistication and self-reliance among consumers, with increasing interest in and knowledge about appropriate self-medication.

- ✓ Older adults in particular tend to experience increased minor medical problems, such as arthritis, sleeping difficulties, muscle aches and pains, headaches and colds, so that as the population ages, the demand for non-prescription drugs is escalating.

Manufacturer's point of view:

- ✓ Increased sales of non-prescription medicines tend to enhance corporate revenue and profitability.
- ✓ Older prescription drugs are losing patent protection; at least some of the lost revenue can be recouped by offering OTC versions of the products through life-cycle product management.

Companies offering health-care insurance encourage use of OTC self-medication by patients as a cost-containment strategy to reduce the more costly compensation of higher priced prescription drugs. There are seven principles which FDA needs to consider before switching. They can be listed as

- 1) Ease/possibility of self-diagnosis
- 2) Self-limited or chronic condition
- 3) Benefit/risk ratio and its evaluation
- 4) Low potential in harm
- 5) Number of adverse drug reactions or interactions and ease of detecting them
- 6) Long term data from prescription use
- 7) Toxicity compared with other drugs in the class.

REASONS FOR RX-TO-OTC SWITCHING

Consumer's point of view

1. Less expensive compared to prescription drugs
2. Time-saving
3. Self-medication
4. Demand for OTC drugs by older patients

Manufacturer's point of view

1. Increase sales to enhance corporate revenue
2. 3 years exclusivity for additional use
3. Lost revenue can be recouped by offering OTC versions of prescription drugs.

OBJECTIVES:

The study highlights are:

- Regulatory Approval Process for Rx to OTC switches in US
- Clinical trials needed for switching prescription drug to non-prescription drug in US
- Labeling differences between prescription drug and OTC switched drug product in US

REGULATORY APPROVAL PROCESS FOR Rx to OTC SWITCHES IN USA ^[3,4]:

The “Prescription-to-OTC switch” movement is a recent trend in which drugs that were previously available only by prescription become available as over-the-counter (OTC) products. More than 600 OTC drugs new use ingredients and dosages are available as OTC today that were available only by prescription 20 years ago. The retail market share of these switched products totals to about 8.8billion USD and will most likely to increase in future.

OTC drug products are approved through either New Drug Approval (NDA) process or OTC drug monograph process. OTC drug monographs are a kind of “recipe book” covering acceptable ingredients, doses, formulations, labelling, and testing. OTC dug monographs are continually updated to add additional ingredients and labeling as needed. Updating the monographs is primary responsibility of **Division of Non-prescription Regulation Development** (DNRD). Those products confirming to a monograph may be marketed without FDA pre-approval, while those that do not, must undergo separate review and approval through NDA process. NDAs involving OTC drug products are handled primarily by **Division of Non-prescription Clinical Development** (DNCE). The primary responsibility of DNCE is review management and over sight of INDs and NDAs for Non-prescription drug products.

The NDA process is also used for new ingredients entering the OTC marketplace for the first time. For example, the new OTC drug products (previously available only by prescription) are first approved through the NDA process and their "**switch**" to OTC status is approved via the NDA process. The switch to OTC is done in a partial or total way. Most switches are partial, a version of the active ingredient remains available on prescription while a specific indication, strength, or dosage form becomes available through the(new NDA) switch application, on the other hand some switches are full, no prescription version of the active ingredient remains which becomes available through (NDA supplement) switch application. The non-sedating antihistamines Zyrtec, Allegra, and Claritin are examples of full switches. Heartburn medicines Pepcid or Tagamet, or the analgesic Aleve would be examples of partial switches.

The Switch Process ^[5]:

The process of reclassifying drugs from prescription to OTC status is referred to as an "**Rx to OTC switch.**" FDA regulations identify processes for initiating consideration of an Rx to OTC switch. A proposal under this regulation to exempt a drug from prescription-only requirements may be initiated by the Commissioner or by "**any interested person**" in the form of a sponsor submitting a supplement to an approved new drug application (NDA) or, as in your case, by a third party petitioning FDA. Regardless of who initiates a request for an OTC switch, however, the evidence must demonstrate that the prescription-only dispensing requirements are no longer necessary to protect the public health due to drug's toxicity or other potentiality for harmful effect, or by reason of the method of the drug's use. Evidence must also demonstrate that the drug is safe and effective for use in self-medication as directed in proposed labelling.

Drugs are commonly switched one of two ways: under the "OTC drug review," or by a manufacturer's submission of additional information to the original new drug application.

The OTC drug review, which began in 1972, is an on-going assessment of the safety and effectiveness of all non-prescription drugs. In the first phase of the OTC drug review, panels of non-government experts review active ingredients in marketed OTC drug products to determine whether they can be classified as safe and effective. The panels also review prescription ingredients to determine whether some are appropriate for OTC marketing. About 40 former prescription-only drug ingredients have been switched by this process.

The second common path to OTC approval is under the new drug application process. Under this process, manufacturers submit data to the FDA showing the drug is appropriate for self-administration. Data are submitted in a new drug application or a supplement to an already approved drug application. Often the submission includes studies showing that the product's labeling can be read, understood, and followed by the consumer without the guidance of a health care provider. The FDA reviews the new data, along with any information known about the drug from its prescription use. Under the new drug application process, some drugs are approved initially as OTC drugs, but most are first approved for prescription use and later switched to OTC.

The most common way to switch a product status for a manufacturer to submit an supplementary NDA, because the NDA holder might get 3 year marketing exclusivity if it is approved by FDA. The crucial part of review process entails 3-year market exclusivity known as Hatch-Waxman exclusivity. For obtaining this exclusivity companies have to prove to FDA that switch drug provides innovations that are not shown by currently available OTC drugs. There are some cases where FDA has denied 3 year market exclusivity for inadequate proof.

When a drug company wants to explore the possibility of Rx-to-OTC switch, the usual first step is to request a meeting with the FDA to discuss the rationale of their proposal & drug development plan, and to get FDA feedback on what data will be necessary to submit in an application to do so. Once the drug company has compiled the data requested by the FDA, they submit either a new OTC drug application or an efficacy supplement to the Rx application (depending on the circumstances and guidance from the FDA). The FDA reviews and approves the application, using the same process and scientific standards as is used to approve an Rx application.

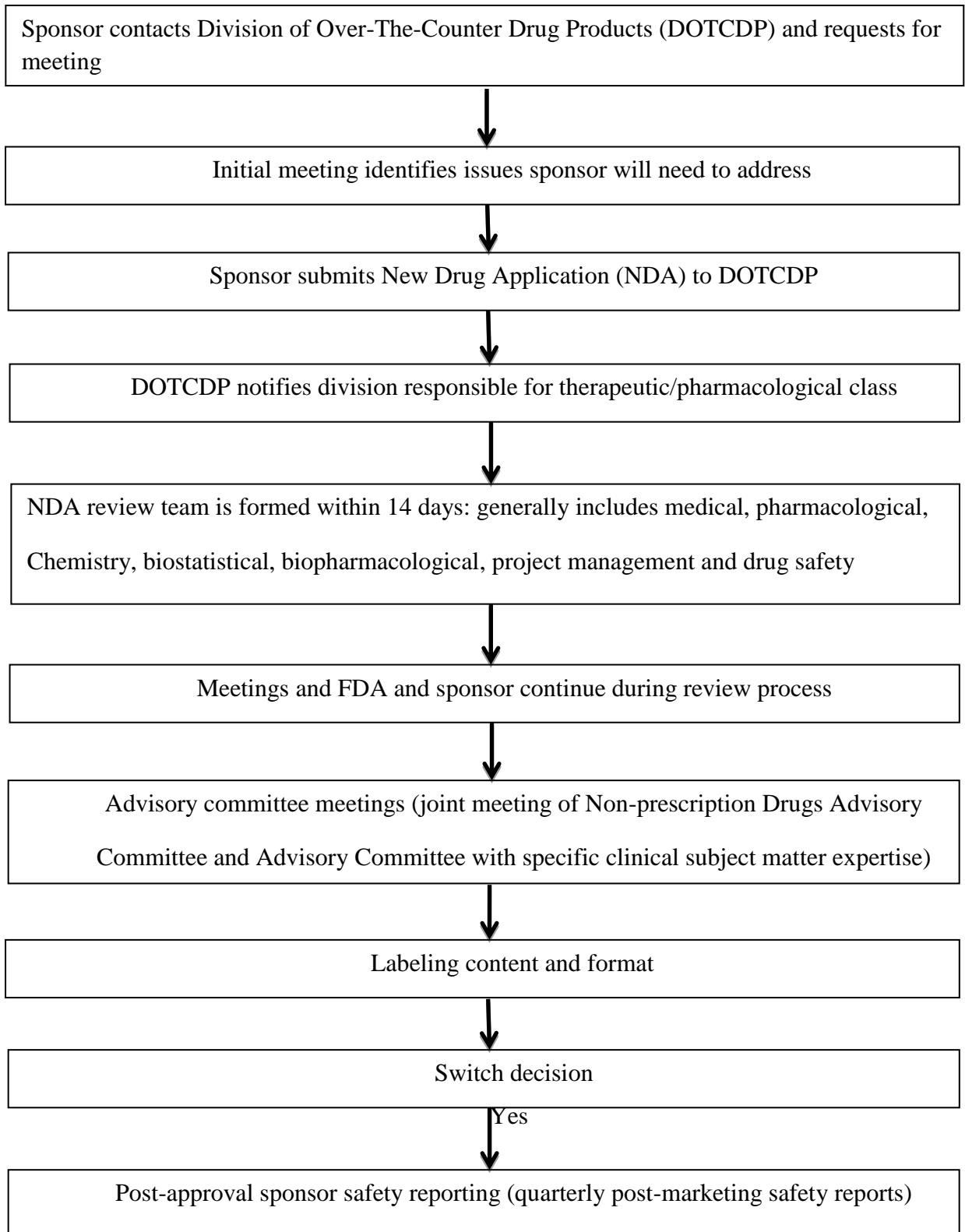


Fig.1 Rx-to-OTC switches Review and Approval process (Source: USFDA, NATURE) ^[6].

ROLE OF ADVISORY COMMITTEE IN Rx-to-OTC SWITCHES ^[7]:

In almost every case for the first drug switched in a drug category, the agency has sought the recommendation of a joint advisory committee made up of members of the agency's Non-prescription Drugs Advisory Committee and another advisory committee with expertise in the type of drug being considered.

While not bound by the advisory committee's counsel, the FDA almost always follows its recommendation.

CLINICAL TRIALS REQUIRED FOR SWITCH PROCESS IN USA ^[8]:

Clinical trials are not a compulsory requirement for Rx-to-OTC switches, but most switch applications include new clinical trial data for the non-prescription indication and almost all the switch applications include label comprehension studies and/or actual use studies to demonstrate that the medicine can be used safely and effectively in the consumer target population. Additional standard efficacy and safety clinical trials are to prove the drug can be used safely in an OTC setting.

FDA's Center for Drug Evaluation and Research (CDER) defines OTC drug actual use study as "a controlled experiment in which a prescription drug or unapproved new drug is used by subjects under OTC-like conditions." OTC studies are intended to support a significant change in labelling for the drug. These studies are considered the most important in assessing a drug's appropriateness for a switch. The main Objectives of an Rx-to OTC study fall into four main categories:

- Safety (prescription safety demonstrated by previous trials)
- Comprehension (demonstrated by label comprehension studies)
- Self-selection and de-selection
- Compliance as the core issue

If the drug has a good safety profile, shown by the studies done to support its marketing as a prescription drug, and if the drug meets the specific criteria for switching which includes ability of selection or de-selection by consumer, there is relatively good chance that FDA will approve it for OTC use.

The key end points of this research include interest or motivation in treating one's condition and ability to self-recognize the condition. It is important to determine the ability of the consumer to appropriately select or deselect the medication and ability to demonstrate good judgement about

whether the drug is proper to administer for them. For example, if the package labels states that one should first see a doctor, actual use research has to be designed to assess whether the consumer complies.

Compliance results are the data that the sponsor, FDA and industry anxiously await. After obtaining consent from the subject, taking background medical histories, collection of blood samples, if necessary, the subjects are given the drug and sent home for a specified period of time to use the drug as they “actually would use it” in “real life” should the drug be available over the counter. Adverse events are compiled during the study period. Every rare adverse event can represent a challenge to sponsor and prevent the switch from being approved, since the doctor or pharmacist may be less involved, safety becomes primary concern.

Models and settings:

A variety of models are used to conduct actual use studies. The OTC-like environment for the studies and the study design components differ depending on the company doing research, but overall objectives do remain the similar.

It is important that the research design ensure a minimized or non-existent role for health care providers such as doctors and pharmacists. The FDA looks for compelling data that demonstrates the consumers can select the potential OTC medication appropriately and comply with its label instructions. During the repurchase cycle the contact with health care professionals should be minimized or completely eliminated. These studies can be conducted in independent pharmacies, rented or leased storefronts or market research facilities in shopping malls.

The study should be conducted in OTC like environment, in the absence of a “learned intermediary”, with the main objective, to asses’ consumer self-selection and to gather consumer compliance data based on label instructions. Actual use studies generally involve about 800-5000 subjects for duration of 4-12 months. It is important that the design specifies adequate minority population representation. For Pravachol switch, Bristol-Myers Squibb was praised for a study population that included 21% African-Americans, 5% Hispanics, 3% Asians, and 1% Native Americans in its enrolment.

Short-term compliance:

In an actual use study, consumer compliance is commonly assessed over a period of weeks or months. The compliance stage of study is the point at which evidence of self-management or lack of self-management become critical in evaluating the suitability of the drug for OTC use. If

the consumers cannot demonstrate compliance in short term, there will be considerable concern about long-term compliance.

Long-term compliance:

These studies are mainly to evaluate compliance over time after the new OTC product is on market. Post marketing surveillance information on prescription product is an important adjunct to the OTC research.

Evaluating Risk:

The FDA, sponsor and consumer evaluate how much risk they are willing to take to move a product to over-the-counter status. There is unavoidably some degree of risk, but there is also risk in taking prescription medications. The baseline for compliance in the OTC setting should be set against the compliance for the drug and the particular condition in prescription setting.

LABELING REQUIREMENTS FOR OTC DRUGS ^[9]:

For many years FDA has had regulations on the required labelling of OTC drug products, both to be in conformity to the FD&C (Food, Drug and Cosmetic) Act and the Fair Packaging and Labelling Act (FPLA). As per these regulations labels are required to show dosage strength, as well as the name and address of the manufacturer, packer, or distributor. The FDA Modernization Act amended Section 502(e)(1) which states OTC labels to list quantity or proportion of each active ingredient present and an alphabetical list of inactive ingredients must appear on the outside container of the retail package and also on immediate container if determined by FDA.

In 1997 FDA proposed to establish a standard format for labeling of OTCs to make key information clear, simple and user friendly. The new format appeared as a final regulation in the *Federal Register* for March 17, 1999. This requires “drug facts” box along with other details. The box lists the active ingredient, purpose of the product, uses, directions, inactive ingredients, warnings and other information. Any OTC drug product that is not in compliance with these requirements is subject to regulatory action as a misbranded drug.

Most OTCs require an expiration date. There are specific exceptions for certain products like creams or ointments intended for itching if their labeling does not bear limitations and they are established as being stable for at least 3 years. Out-of-date drug products are considered by FDA to be adulterated, and any sale of adulterated products may result in regulatory action such as seizure or injunction.

OTC DRUG LABEL REQUIREMENTS ^[10]:

21 CFR 201.66 requires that all OTC drug product labeling contain the following information about the drug product. This information must be organized according to the following headings and must be presented in the following order:

1. Title (Drug Facts or Drug Facts (continued))
2. Active ingredient(s)
3. Purpose(s)
4. Use(s)
5. Warning(s)
6. Directions
7. Other information
8. Inactive ingredients
9. Questions? Or Questions or comments? (Optional)

S.No	CATEGORY	DESCRIPTION
1	Title(drug facts or drug facts continued)	The title Drug Facts must appear on the first panel and the title Drug Facts (continued) must appear on each subsequent panel to ensure that the person reading the labeling can follow through to the end of the labeling.
2	Active ingredient(s)	An active ingredient is any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.
3	Purpose(s)	Each active ingredient of the drug product should describe its general pharmacological activity and principal intended action(s) of the drug. If the drug product contains two active ingredients for the same purpose, then the purpose can be stated only once as long as purpose is clearly associated with both active ingredients.
4	Use(s)	Includes specific indications or approved uses for the drug product. For the drug-cosmetic product only drug related indications are included in this section.
5	Warning(s)	Includes specific warning statements in the order of impact

		or importance. Information must be under subheadings like “Do not Use for/if”, “Ask a Doctor/pharmacist if you have”, “when using this product you may experience”, “pregnancy and related warnings”, “Keep out of reach of children”.
6	Directions	Includes how to use the product for optimal effect like “shake well”, “drink full glass of liquid with each dose”, “do not use more than directed”. A tabular representation is used if the drug product is used for different age groups or populations.
7	Other information	Information under this heading must contain information not included under the other headings or subheadings. It includes, quantity of ingredients present in each dose, storage information and tamper evident statement.
8	Inactive ingredients	This section contains a list of inactive ingredients, using their established names. For OTC drug products the established names of inactive ingredients must be listed in alphabetical order.
9	Questions or Comments	The telephone number or a source to answer questions about the drug product must be included in this section.

Fig.2 Labeling content requirements for all OTC products, which includes OTC products under final OTC drug monograph, an approved NDA or ANDA, and OTC drug products for which there is no final monograph or approved drug application^[10]. (Source: USFDA)

Standard and Modified Labeling Formats^[11]:

According to the US regulations 21 CFR 201.66(d), this contains a formula that allows use of modified labeling format. When required drug facts content information in paragraph, plus other FDA required information for drug or drug-cosmetic products, requires more than 60 per cent of the total surface area available to bear labeling, the drug facts labeling must appear in modified labeling format.

Labeling Element	Standard Format	Modified Format
Drug Facts box	Set off by barline	Barline may be omitted if color contrast used to set off from the rest of the labeling
Drug Facts	Larger than largest type size used in Drug Facts box or similar enclosure	Larger than largest type size used in the Drug Facts box or similar enclosure
Drug Facts (continued)	No smaller than 8-point type	No smaller than 7-point type
Headings	≥8-point type, or 2-point type > point size of text	≥7-point type, or 1-point type > point size of text
Subheadings	No smaller than 6-point type	No smaller than 6-point type
Bulleted text	No smaller than 6-point type	No smaller than 6-point type
Leading	Minimum 0.5-point type	Smaller than 0.5-point type can be used, provided the ascenders and descenders do not touch
Bullets	Minimum 5-point type Vertical alignment	Minimum 5-point type No alignment required

Fig.3 Describes the selected format requirements used in standard and modified labeling formats. (Source: USFDA)

Label Modifications

Label changes were made to increase awareness of messages regarding who should use the drug that were conveyed as strongly as other messages. In addition, results of additional clinical studies and consumer use trials, as well as the FDA final rule on Labeling Requirements for Over the Counter Human Drugs (Drug Facts), were considered in developing layout changes.

Fig.4 Labeling differences between Rx drug product and Rx-to-OTC switched drug product
 [12]: (Source: USFDA)

Prescription drug label:

TAVIST-D®

Antihistamine/Nasal Decongestant

12 Hour Relief of Sinus & Nasal Congestion

NEW DOSAGE FORM

Indications: For the temporary relief of nasal congestion associated with upper respiratory allergic or sinusitis when accompanied by other symptoms of hay fever or allergies, including runny nose, sneezing, itching of the nose or throat, or itchy watery eyes.

Directions:	Dose
Age	
Adults and children 12 years of age and over	Swallow 1 caplet whole every 12 hours, not to exceed 2 caplets in 24 hours or as directed by a doctor.
Children under 12 years of age	Consult a Doctor

Warnings: Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately. May cause drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery. May cause excitability especially in children.

Do not exceed recommended dosage. If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor. If symptoms do not improve within 7 days, or are accompanied by fever, consult a doctor. Do not take this product if you have heart disease, high blood pressure, thyroid disease, diabetes, glaucoma, a breathing problem such as emphysema or chronic bronchitis, or difficulty in urination due to enlargement of the prostate gland unless directed by a

doctor. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

Drug Interaction Precaution: Do not take this product if you are presently taking another product containing phenylpropanolamine. Do not use this product if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product.

Active Ingredients: Each Tavist-D Caplet contains clemastine fumarate, USP, 1.34 mg (equivalent to 1 mg clemastine) immediate release and phenylpropanolamine hydrochloride, USP, 75 mg extended release.

Inactive Ingredients: Carnauba wax, hydroxypropyl methylcellulose, lactose monohydrate, methylparaben, polydextrose, polyethylene glycol, silicon dioxide (colloidal), starch (pregelatinized), stearic acid, titanium dioxide, triacetin. Sodium free.

Store at Controlled Room Temperature, 20°- 25°C (68°- 77°F).

3 0043-0131-08 5

Non-prescription drug label:

Drug Facts	
Active ingredients (in each caplet) Clemastine fumarate 1.34 mg (equivalent to 1 mg clemastine) Phenylpropanolamine HCl 75 mg extended release	Purpose Antihistamine Nasal Decongestant
Uses temporarily relieves these symptoms of the common cold, hay fever, or other upper respiratory allergies: - nasal congestion - runny nose - sneezing - itchy, watery eyes - itching of the nose or throat - temporarily relieves nasal congestion associated with sinusitis	
Warnings Do not use if you are now taking - another product containing phenylpropanolamine - a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product. Ask a doctor before use if you have - high blood pressure - heart disease - glaucoma - thyroid disease - diabetes - a breathing problem such as emphysema or chronic bronchitis - trouble urinating due to an enlarged prostate gland Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers When using this product - do not use more than directed - avoid alcoholic drinks - drowsiness may occur - alcohol, sedatives, and tranquilizers may increase drowsiness - be careful when driving a motor vehicle or operating machinery - excitability may occur, especially in children Stop use and ask a doctor if - nervousness, dizziness, or sleeplessness occurs - new symptoms occur - symptoms do not get better within 7 days or occur with a fever If pregnant or breast-feeding , ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a poison control center right away.	
Directions - do not crush or chew caplet - adults and children 12 years of age and over: take 1 caplet every 12 hours; not more than 2 caplets in 24 hours unless directed by a doctor - children under 12 years of age: consult a doctor	
Other information - sodium free - store at controlled room temperature 20°-25°C (68°-77°F)	

Drug Facts (continued) Inactive ingredients carnauba wax, hydroxypropyl methylcellulose, lactose monohydrate, methylparaben, polydextrose, polyethylene glycol, silicon dioxide (colloidal), starch (pregelatinized), stearic acid, titanium dioxide, triacetin
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RECENT Rx-TO OTC SWITCH LIST IN US ^[13]

S.No	COMPANY NAME	DRUG NAME	PURPOSE	YEAR OF APPROVAL
1	McNeil Consumer Healthcare	Zyrtec	Anti-histamine and Nasal Decongestant	2007
2	Novartis	Lamisil Derm Gel	Topical Antifungal	2006
3	Merck	MiraLax	Laxative	2006
4	Barr Pharmaceuticals	Plan B	Emergency Contraceptive	2006
5	Novartis	Zaditor	Antihistamine Eye Drop	2006
6	Procter and Gamble	Prilosec	Acid reducer/PPI	2003
7	Merck	Claritin	Antihistamine	2003
8	Merck	Nicotrol TD	Smoking Cessation	2002
9	Insight Pharmaceuticals	Monistat 3 combo pk	Vaginal Antifungal	2001
10	Merck	Lomitrin Ultra	Topical Antifungal	2001

INDIA ^[14]:

In India OTC has no legal recognition, drugs which are not included in the list of prescription-only drugs are considered to be non-prescription drugs (or OTC drugs). Hence, OTC drugs means drugs legally allowed to be sold Over the Counter by pharmacists, i.e. without the prescription of a Registered Medical Practitioner or a physician. Prescription-only drugs are those medicines that are listed in Schedules H and X of the Drug and Cosmetics Act 1940 and Drugs and Cosmetics Rules. OTC drugs registered as “Ayurvedic Medicine” (i.e. traditional Indian system of medicines containing natural / herbal ingredients) are also regulated by the DCA (Drugs and Cosmetics Act) and DCR (Drugs and Cosmetics Rules).

India currently ranks 11th in the global OTC size. It is estimated that it will reach 9th position within five years. The Indian OTC market was estimated at approximately USD 1,813 million (euro 1362 million) with an annual growth rate of 10.7% at the end of calendar year 2009.

SWITCH TREND IN INDIA:

There are many products in the Rx sector which could be revitalised through OTC switches in India. An analytical interpretation of various data places the focus on vitamins, cough & cold, antacids, antipyretics and NSAIDs as opportunity areas for switch in India. India does not have a well-documented process or a specific regulation on switching Rx to OTC products and this is the need of the hour. Globally many countries have a formal process of transferring prescription (Rx) drugs to over-the-counter (OTC) status, known as "Rx-to-OTC switch. In these markets Rx to OTC switch is also seen as an efficient way of reducing healthcare costs by expanding the most inexpensive form of health care with OTC medicines. Regulators in India should clearly define OTC formally as a category because this would help promote access to market and will empower consumers who want to take a more active role in their own health care. In fact, in the near future, switching would be one of the most used strategies to enter OTC by new players.

CONCLUSION:

The success of an Rx-to-OTC switch depends on several factors which includes release of drug into market (timing), providing safe, effective use of the product by consumers and required labeling changes. Changing the status of drug from prescription to non-prescription status mainly requires labeling comprehension studies and studies that prove the drug is safe to administer without prescription from the health professional. Label for Rx-to-OTC switch drugs should contain drug facts, warnings, uses and directions clearly. This switch requires approval from the Division of OTC drug products of Food and Drug Administration and sponsor should periodically report post-approval safety of the product. Pharmaceutical industry representatives agree that easy switches are over and the coming years will be focused on Rx-to-OTC switches for chronic applications like diabetes and hypertension.

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