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RX TO OTC SWITCH – FDA

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ABSTRACT

Over-the-counter (OTC) medications are those that can be purchased by consumers without a prescription from a medical professional. The "prescription-to-OTC switch" movement refers to a recent development in which pharmaceuticals that were previously only available with a prescription are now offered as over-the-counter (OTC) items. They are frequently used to treat common illness symptoms that don't always need to be monitored closely by a doctor. If the prescription version of the drug's post-marketing safety data confirms its efficacy, safety, and ease of use, it may be possible to "switch" the product from its initial prescription marketing to an over-the-counter one. This refer as a "Prescription-to-OTC Switch." It is evident that the lower pricing has reduced profits, nonetheless, this is an minor cost to incurto keep the required market share until the drug's patent expires. In the end, the consumer gains as the new product is more affordable. Safety comprehension, Self-selection and de-selection Compliance as the core issue Kinds of security and effectiveness and real-world Utilize information that can utilized to bolster the switch application, there is no "one-size-fits-all" strategy. In the end, the consumer gains since the new product is more affordable & ensure patient safety.

Keywords: Efficacy, OTC drugs, Rx-To-OTC, Safety

INTRODUCTION:

Pharma firms can prolong the life cycle of a drug that faces intense competition by using **Rx-to-OTC** changes. Strength revenue and earnings due to generic introduction to the prescription drug market and consequently a typically transition from Rx to OTC status takes place either right before or right at Rx conclusion of a patent. OTC sales can last for a long time with less negative effects from private label competition, even if they usually only made up a small portion of prescription sales prior to generic arrival.

When a prescription medication's patent expires and generic versions enter the market, the original maker of the drug is protected against generic competitors by a Rx-to-OTC transfer. When it comes to protecting a company's brand, going from prescription to over-the-counter medication can often be a far better long-term strategy than moving patients to more recent medications, introducing formulations with extended release, extending patents for line extensions like pediatric uses, leveraging new drug delivery technologies, forming partnerships to form "authorized" generics, or manufacturing the generic versions themselves **[1]**.

A drug product that is marketed for consumer use without requiring a prescription from a medical professional is known as an **over-the-counter (OTC)** drug product. For the lawful marketing of these products, there are two regulatory avenues available:

Promoting a medicine in accordance with an OTC monograph

Marketing carried out in compliance with

- **Biologics License Application (BLA),**
- **Abbreviated New Drug Application (ANDA), or**
- **New Drug Application (NDA)**

that is specific to a product **[2]**.

An **Rx** is a symbol for a prescription drug. Its root word, recipe, is Latin and means "**take thou**" or "**take this**." Rx can also be used to denote a drugstore or pharmacy. Rx may have come from the Eye of Horus, an ancient Egyptian healing symbol, according to some sources **[3]**.

There are various reasons why the Rx-to-OTC switch is advantageous.

- It can increase consumer **access to safe and effective** treatments, reduce healthcare costs, and improve patient outcomes.
- It also **empowers clients** to take control of their health by providing them with additional self-care options.
- It's important to keep in mind, though, that the switch **cannot be used for self-medication** as advised

by the proposed label until the FDA approves it **[4]**.

The Rx-to-OTC switch benefits patients, retailers, the health economy, and manufacturers by offering reduced expenses and treatment independence. Companies may choose this for life cycle extension and patent expiration threats from generic manufacturers **[5]**.

A manufacturer has several options for extending the life of a product. Among them might be:

- **Changing a product's recipe.**
  Example: making an extended-release version of an already-existing product
- **Altering a product's dosage or delivery mechanism.**
  Example: going from an oral tablet to an implantable system that elutes drugs.

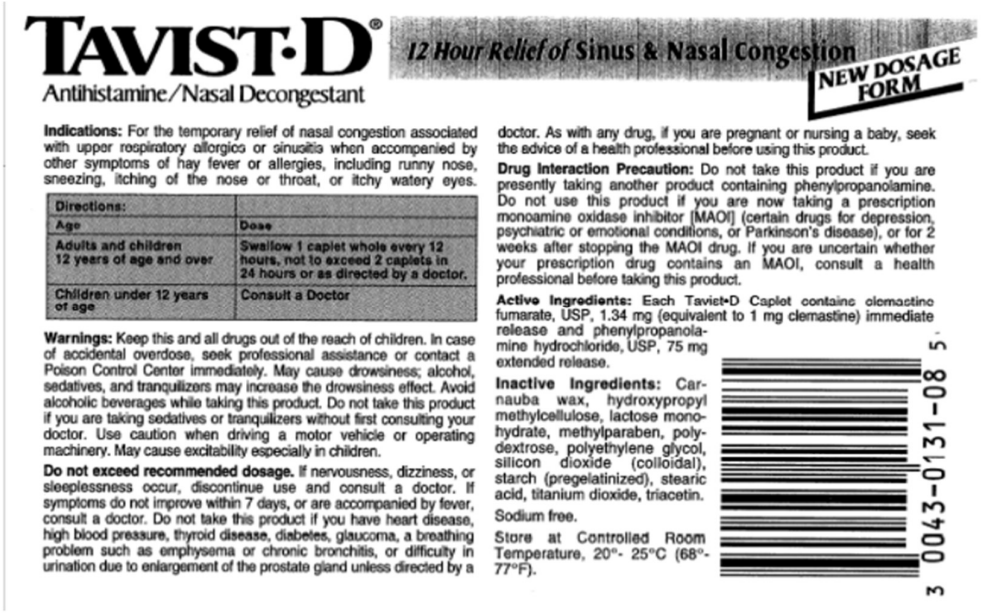
The FDA is required to review and approve the Rx-to-OTC switch procedure, which applies to both prescription and over-the-counter products, depending on the full or partial switch.[4]

The FDA uses this procedure to assess if a drug is safe and suitable for over-the-counter use. To put it another way, users ought to be able to use it to treat their symptoms without the assistance of a healthcare professional. Labelling should be straightforward, understandable, and uncomplicated. In certain instances, the prescription product might still be necessary for a particular purpose [6]. When a drug's prior prescription status is deemed "**not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use or the collateral measures necessary to its use, and the drug is safe and effective for use in self-medication as directed in proposed labelling**," the FDA will **approve a Rx-to-OTC switch application**.**[1]**

The FDA finalized **21 CFR 201.66 on March 17, 1999**, establishing uniform content and format for over-the-counter drug product labels. This regulation applies to all OTC drugs and drug-cosmetic products, regardless of their application status **[4]**.

Rx-to-OTC (RTO) switches the process of reclassifying an existing prescription medication as over-the-counter (OTC) during the preceding 20 years. Increased accessibility to over-the-counter (OTC) Public health issues and healthcare costs could be addressed by medications with proven safety and efficacy **[7]**.

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 allergies 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:	
Age	**Dose**
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.

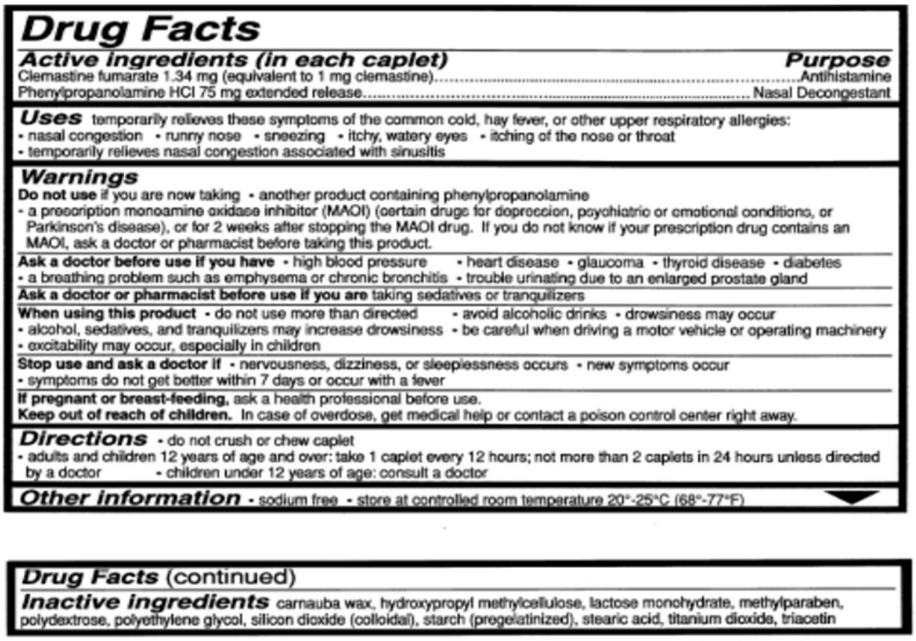
Inactive Ingredients: Carnauba wax, hydroxypropyl methylcellulose, lactose monohydrate, methylparaben, polydextrose, polyethylene glycol, silicon dioxide (colloidal), starch (pregelatinized), stearic acid, titanium dioxide, triacetin.

Sodium free.

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

3 0043-0131-08 5

Figure 01: Prescription drug label



Drug Facts

Active ingredients (in each caplet) — **Purpose**

Clemastine fumarate 1.34 mg (equivalent to 1 mg clemastine) ..... Antihistamine

Phenylpropanolamine HCl 75 mg extended release ..... 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

Figure 02: Non-Prescription drug label

The FDA does not need to preapprove OTC drug products before they can be sold. Title 21 of the Code of Federal Regulations contains additional guidelines for the marketing of pharmaceutical products intended for human use. About 10% of medications sold worldwide, according to the World Health Organization, are faked in developing and impoverished nations. These low-quality medications endanger patients' health and put the world economy at risk. To improve the quality of drugs, several analytical methods have been reported for screening Rx to OTC drugs for

counterfeiting. In addition to having sufficient usage instructions and warnings against misuse, safety in over-the-counter medicine refers to the low risk of abuse that could arise from widespread availability of the product combined with a low incidence of major side effects or adverse reactions. FDA is aware of this Despite the fact that no medication is completely safe, over-the-counter products must provide enough advantages to explain away any hazards that might arise from using it properly. Customers can now obtain an increasing number of medications over-the-counter (OTC) thanks to a strictly regulated, scientifically rigorous process. The FDA approves over-the-counter medications if they meet safety, effectiveness, and user-friendly labelling requirements, including consumer choice and good safety profile, as demonstrated by studies supporting their prescription drug marketing **[15]**.

Objectives:

1. To provide an **overview of Rx to OTC Switch** – FDA
2. To **determine whether a medicine is suitable and safe** for use over-the-counter.
3. To **reduce healthcare expenses and improving patient access to efficacious** treatments are the benefits of Rx-to-OTC shift.

Advantages of switching

- During a **lengthy, difficult**, and **expensive** process involving appointments, medical consultations, medication acquisition, and pharmacy visits, missing work is common.
- Through over-the-counter medication, patients can self-treat their minor ailments in a much more convenient manner, avoiding almost all of these laborious steps.
- Moreover, doctors can save time by not needlessly spending it diagnosing conditions that are clear-cut and easily treated on their own when using OTC medication.
- Over-the-Counter (OTC) products are typically purchased by the consumer and are not covered by insurance. To guarantee greater sales volumes, pharmaceutical companies typically price OTC products far less than their prescription counterparts.
- Profits are clearly lower as a result of the lower pricing, However, this is a minor cost to incur to maintain the necessary market share after the drug patent expires. Because the new product has lower prices, the consumer ultimately benefits.
- The possibility of only for the organiser providing clinical data deemed sufficient to support the

product's downregulation could provide another powerful incentive to switch. Beneath the auspices regarding the Hatch-Waxman Act, the US has a 3-year exclusivity period; in the EU, Article **74a of Directive 2004/27/EC** grants a 1-year exclusivity period. This helps the sponsor even more in this brief window of time to protect himself against generic erosion.

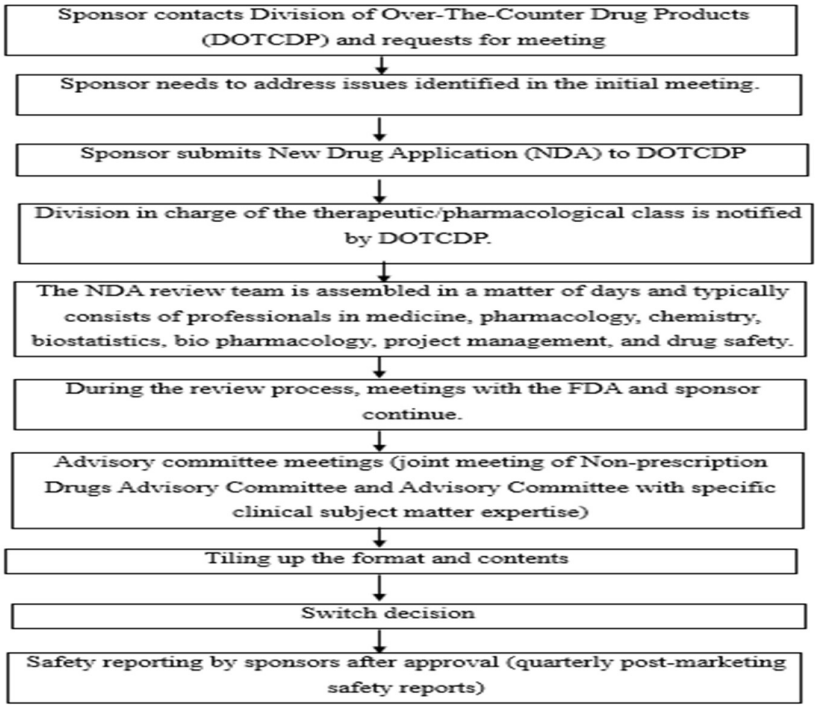
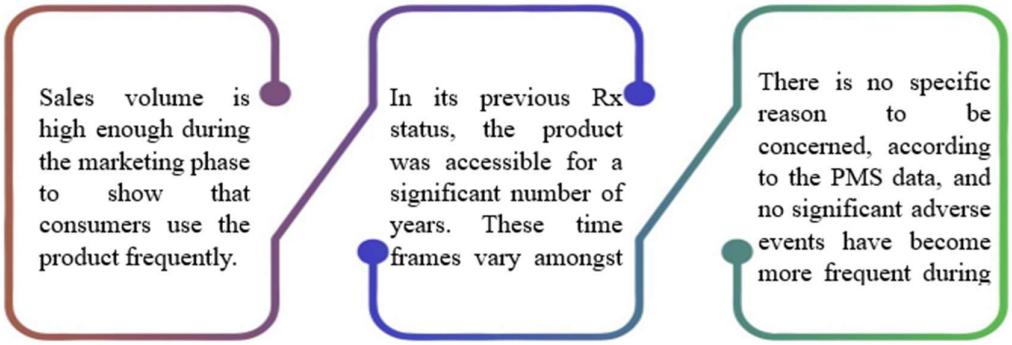


Figure 03: Procedure for reviewing and approving Rx-to-OTC switch

RESULTS & DISCUSSIONS:

Workings of a Rx to OTC switch

The Rx-to-OTC switch was initially introduced in **1976,** and since then, its operation has changed **[14]**. Sponsors may find it useful to consult a guideline released by the WHO when making this determination. Generally speaking, the product needs to have the following features.



Sponsor conducted clinical trials for over-the-counter class, referencing data in initial NDA. No **"one-size-fits-all"** method is recommended. Frequent meetings with OTC sector and Authority on Health Care are recommended for information understanding. In order to influence the outcome of the switch application, sponsors must also engage in lobbying with important **opinion leaders, medical professionals, patient organizations,** and **pharmacists**.

The US, UK, Singapore, and China are four major countries whose regulatory processes and paper work must be adhered to in order to convert a pharmaceutical item to over-the-counter status. These sections provide a brief summary of these processes **[8]**.

For some brands, switching from an RX to an OTC is a viable option, particularly if the medication treats a sizable patient population that is untreated, is in a therapeutic area where OTC switching has precedent, has non-parenteral regimens, has limited safety concerns, and has a long competitive runway. Rx to OTC conversion may make sense if a brand can satisfy at least some of these requirements **[9]**.

Prescription to OTC switch: This is the term used to describe the marketing of a once prescription drug product for the same patient demography that uses the same administration route, and dosage form but now available over-the-counter. A first-party notification (NDA) must be filed if the sponsor plans to market a novel over-the-counter product with an active ingredient, indication, dosage form, etc. that has never been marketed. If the organizer

wants to change certain, but not all, of the authorized treatment conditions of use to OTC commercial standing, an NDA needs to be filed **[4]**.

Review Process for OTC

Process of Administrative Orders:

Drugs Any individual or group involved in the marketing, manufacturing, processing, or development of a drug may start the administrative order process to add, remove, or modify a monograph, or the FDA may do so first. In the US, a nonprescription drug can be approved for sale through one of two regulatory channels: the Over-the-Counter (OTC) Drug Review process or the drug application process **[10]**.

In other nations, many medications that are currently only available with a prescription are already available over-the-counter. Erythromycin cream, for instance, is available over-the-counter in Belgium and Poland but is prescribed in the US. Furthermore, whereas this is not the case in some European nations, many indications, like high cholesterol and irritable bowel syndrome, have few or no over-the-counter treatment options available in the US. These data encourage and put pressure on the US to keep growing the OTC treatment options and investigating Rx-to-OTC switches, as

doing so will propel the market's expansion **[5]**.

Guidance from the applicable FDA regulations.

- To convert a medicine from a Rx to an OTC, the FDA in the US offers precise guidelines with step-by-step instructions. Fundamentally, the goal is to make sure that patients are capable of using the product correctly and safely on their own.
- Sponsors will be required to submit documentation demonstrating that:
- The product has generated a comfortable providing support to safety and efficacy data.
- Customers should be competent in making accurate self-diagnoses and product selections.
- Customers can benefit from the treatment without suffering any harm if they correctly follow the instructions.
- New consumer behavioral studies, additional clinical trials, or historical data can all provide evidence **[11]**.

Medication without a prescription but with an additional requirement for nonprescription use (ACNU)

When labelling by itself is inadequate to certify that the customer is capable of making appropriate use of either or both of these options in a nonprescription setting, the applicant may, in accordance with the proposed rule, submit an application proposing an ACNU that a consumer must successfully fulfill in order to acquire the over-the-counter medication with an ACNU **[13]**.

Indicate that in the event that the application does not meet the requirements that apply to it or if the applicant cannot show that labelling alone will not guarantee that the consumer can correctly usage or both, a medication product outside of a prescription, the FDA will not approve the NDA or ANDA for a nonprescription drug product with an ACNU.

An extensive analysis of FDA advisory committee discussions of first-in-class switches resulted in the development of a consolidated and updated framework of OTC Considerations for Rx-to-OTC switches. Prior to OTC approval, these OTC Considerations provide as a helpful benchmark to track the development of the evidence base for regulatory evaluations of drug safety and efficacy by the FDA and industry.

The OTC Considerations for Rx-to-OTC Switch may also function as a model for the development of OTC drugs and the education of new OTC regulatory employees **[13]**.

The FDA has moved over 106 ingredients and dosages to OTC availability since the formal review of OTC medicine safety,

efficacy, and **labeling began in 1972**. A major product of this process is a codified framework for using data from science and medicine. OTC Factors for Rx-to-OTC Conversion . This kind of evolving framework derived from experience has the benefit of applying the most recent data and scientific viewpoint to OTC decisions.

Additionally, from the perspective of regulations for the government and business OTC Considerations of switch can be approached in a predictable and consistent manner thanks to the framework. Establishing equity in a cutthroat drug development system **[13]**.

CONCLUSION:

The potential for a more methodical evaluation of Rx-To-OTC switches may be highlighted by the creation of superior, all-inclusive models to evaluate the effects of Rx-To-OTC switches on public health and the payer's budget. Numerous arguments have been made, such as reducing the cost of healthcare, utilizing the education and experience of pharmacists, encouraging the idea of prevention and self-care, and boosting pharmaceutical sales. Reducing healthcare costs and improving patient access to effective treatments are two benefits of the Rx-to-OTC switch. While making Rx-to-OTC decisions, pharmaceutical companies must carefully consider regulatory, educational, pricing, and competitive factors. In future will see a greater adoption of technologies like smartphone apps to support Rx-to-OTC switches and enable patient self-care and education for common medical conditions.

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CONFLICT OF INTEREST:

The authors declared that there is no conflict of interest

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