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REVIEW ARTICLE

Cosmetics as QUASI and OTC drugs

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ABSTRACT

Over the Counter (OTC) products can be called some of the cosmetics with drug claims and some others that contain chemicals with the ability to change the physiology and biochemistry of in particular skin and nails. A product is either a cosmetic or a medicine, according to the Cosmetic Directive of the EU. In Europe, cosmetics are considered to be several products which are listed under OTC in the US. With the latest changes in the EU Cosmetic Legislation, the regulation of cosmetics is tighter than that of cosmetics in the USA. Similar labeling standards to those of the US Cosmetic Regulations are required by the VI Amendment to the Cosmetic Directive. The Cosmetic Directive also mandates that a 'Dossier' be prepared and made available for each product to be put on the market, including, but not limited to, details on the safety evaluation and evidence of the product's effectiveness. The production, distribution and importation of cosmetics are not permitted in the US and the EU, although they are licensed in Japan. Under the Pharmaceutical Affairs Rule, cosmetics are regulated. They can be known as narcotics, quasi-drugs, or cosmetics. The ones that have a "mild effect" on the body are quasi-drugs. Cosmetics are categorized into a group of goods and are approved accordingly. Although the criteria for labeling and dossiers could still cause problems, harmonization of the US Cosmetic Regulations may be possible with EU regulations. However, the analysis of the harmonization measures taken by the US, the EU and Japan shows that, in order to achieve harmonization, Japan needs a more serious commitment.

INTRODUCTION

Over-the-counter (OTC) drugs are medicines marketed directly to a customer without a healthcare professional's prescription requirement, as opposed to prescription medicines that can only be supplied to patients that have a legitimate prescription [1]. OTC medicines are chosen by a regulatory agency in many countries to ensure that they contain ingredients that are safe and effective when used without the supervision of a physician. OTC drugs are typically regulated instead of final products according to their active pharmaceutical ingredient (API). Governments give manufacturers the freedom to formulate ingredients, or combinations of ingredients, into proprietary mixtures by controlling APIs instead of particular drug formulations [2]. The over-the-counter (OTC) concept refers to a drug that can be bought without a medical prescription. Instead of final products, OTC drugs are generally governed according to their active pharmaceutical ingredient (API). By regulating APIs instead of individual drug formulas, governments grant manufacturers the right to formulate ingredients, or combinations of ingredients, into proprietary mixtures. The definition of over-the-counter (OTC) refers to a drug which can be obtained without a medical prescription [3].

Cosmetics as Quasi Drugs

Quasi-drugs are one of South Korea's main types of beauty products. The other beauty product group is cosmetics. Among medications and cosmetics, there is a thin line that can be known

as quasi-drugs. The health authority of South Korea (HA) and the Ministry of Food and Drug Protection (MFDS) have listed them as skin care products such as acne for skin dullness, because their advantages are not as suitable as drugs. Quasi drugs are generally classified into two types [4]:

Group 1

Things such as sanitary pads, tampons and menstrual pads are used for sanitary purposes. Textiles for the manufacturing of masks; such as dust and surgical masks, wet oral hygiene wipes. Sanitary items used for the safety, preservation and care of infected areas, including various forms of bandages, bandages of plastic.

Group 2

Odour inhibitors, such as toothpaste, bath products and antiperspirants. Hair care pieces that are intended for external use only. Products for those who smoke which do not contain nicotine. Ointments and anti-inflammatory drugs for external use,. The registration procedure for quasi-drugs is rigorous and has few qualifying protocols. Submission-the data for product approval must be sent to the HA. The substance will then be sent for safety and efficacy assessment to the Cosmetics Evaluation Division (CED) and the National Food and Drug Safety Evaluation Institute (NIFDS). Lastly, it will be handed over to the regional food and drug safety division for the safety and efficacy assessment of medical products. Review-the standards are reviewed after HA receives the protection and effectiveness tests. Meanwhile, the manufacturing sites will also be inspected to determine the condition and quality of the production. Approval/Notification-Both if it qualifies in the Korean pharmacopoeia and other MFDS recognised pharmacopoeia compendia, HA will issue approval and notification.

Cosmetics as OTC Drugs

OTC medicines are medicines marketed directly to patients without a healthcare provider prescription. OTC medicines are typically regulated by the active pharmaceutical ingredient (API), rather than finished products [5]. The government gives manufacturing the right to formulate ingredients by regulating API rather than drug formulation. Cosmetic goods can be viewed as OTCs in a similar way. The meanings of both cosmetics and drugs are fulfilled by certain products. Those statements, even if the product is advertised as a cosmetic, can cause a product to be considered a drug. OTC products conforming to the OTC Drug Monograph may be put on the market without prior approval by the FDA [6]. In the U.S., for instance, antidandruff shampoos and sunscreen products are known as OTC. In compliance with cGMP criteria for pharmaceuticals for human use, OTCs must be produced and regulated. 73% of Americans would rather treat themselves at home than see a doctor, according to the Consumer Healthcare Products Association (CHPA). Each year, Americans purchase more than 5 billion OTC drug products, 60% of the drugs used [7].

Advantages of OTC Drugs

- ✓ More benefits less risk.
- ✓ Low misuse and abuse potential.
- ✓ Consumer are able to self diagnose,self treat, self manage.
- ✓ Adequately labeled.
- ✓ Health practitioner are not needed [8].

Disadvantages of OTC Drugs

- ✓ Reduced opportunities to receive counseling about possible lifestyle therapies.
  Poorer compliance.
- ✓ Misdiagnose patients won't benefit from the drug but will be exposed to its risks.
  More difficult to study a drug's effects [9].

Global Perspective and Indian Scenario

Instead of seeing a doctor for minor illnesses such as cough, cold, asthma, pain, fever, acidity, diarrhea, and skin-related disorders, patients often approach a pharmacist. In most nations, the buying of particular drugs over the counter is legally recognised. 'Over-the-Counter (OTC) Medicines' means medicines that are legally approved to be marketed without a prescription by pharmacists. In India, the word doesn't have a legal meaning. Technically, unless they are explicitly indicated as prescription drugs only, drugs are OTC. OTC medicines make for easier and cheaper access to healthcare, but their abuse and adverse health effects are alarming. Against the context of globally prevalent regulations and practices, this article explains the definition of OTC medicines and practices in India. To maximize the use of OTC medicines in India, a recognized category of OTC medicines by law, patient awareness campaigns, and pharmacist and pharmaceutical company support are required [10].

Use of Over the Counter Medicines (OTC): Scenario across Different Countries

A global OTC market study reports that, countries such as the United States, Japan, Germany, and the United Kingdom contribute most to global OTC providing security. The United States, United Kingdom, Australia, and Japan have formulated guidelines on OTC classification, regulation, and use. It may not always be apparent to distinguish between OTC and prescription drugs. In New Zealand, for example, low-dose ibuprofen (200 mg) is OTC for the treatment of mild pain such as headache, while high-dose ibuprofen (400, 600, and 800 mg) is a prescription drug used to treat serious arthritis-related pain. OTC drugs can be divided into two categories: The first category of OTC medicines is the category of non-prescription medicines [11]. The second category of OTC drugs were those that were been previously prescribed, but were later transferred to the OTC category. According to the WHO, for a medication to be an OTC drug, it should be sold for a minimum of 5 years on a prescription basis. The time span for changing the category from prescription to OTC varies from country to country (e.g., no time stated for the European Union, 3 years for New Zealand, 6 years for Japan and, 10 years for the Philippines). Before approving the transfer of the medication to the OTC group, it is necessary to ensure that the drug has not induced severe, increasingly regular adverse drug reactions during the marketing period up to then.

Status of OTC Medicines in the United States

There are over 80 types of OTC drugs in the U.S., amounting to up to 1, 00,000 items marketed. OTC medications are expected to save $102 billion per year in the US, of which 25 billion is saved because of their use, and $77 billion is saved as unnecessary hospital visits are avoided. OTC drugs should meet the following requirements, according to the US FDA: favorable benefit-risk ratio, low abuse and misuse potential, customer knowledge of their use, and appropriate labeling. An extensive OTC medicine analysis process is required for the move to the OTC group. Triamcinolone acetonide, fluticasone (spray), loratidine, fexofenadine, topical antifungals, pseudoephedrine, loperamide, and ketoconazole are several examples of drugs that have undergone a transition from prescription medication to OTC in the US. In the US, OTC medicines are sold under legislation known as "OTC monographs." The New Drug Application (NDA) procedure requires approval for medicines that do not fit into a particular monograph. Antacids, antidiarrheal products, antiemetics, antiperspirants, cough and cold products, wart removers, sleep drugs, ophthalmic products, pile products, dandruff, dental caries, and analgesics are some of the approved OTC Drug Categories as per USFDA. OTC drug advertisement in the US is allowed by law in the media [2, 12].

Status in European Union (EU) Countries

As per Article 70(1), the European Medicines Agency (EMA) has categorized medicinal products into two categories: prescription and non-prescription medicinal products. In the UK and Germany, non-prescription drugs are split into pharmacy medicines and general sales medicines. While medicinal products for pharmacy use are sold without a prescription, they are not eligible for self-selection and should be sold under the supervision of a licensed pharmacist. In Europe, Germany contributes maximum shares to the OTC market. In these 2 countries, all nonprescription drugs can be marketed. Non-prescription pharmaceutical items in France are broken down into those that can be sold to the public and those that cannot be advertised. In 2004, the United Kingdom became the world's first country to include statins in the pharmacy-supervised OTC drug category. Due to the over-the-counter availability of Simvastatin 10 mg tablets, its use in the UK has increased significantly.

A policy guidance document published in 2006 notes that the risk of serious type A reactions and the very low risk of serious type B reactions should be low for OTC medicinal products. Furthermore, they should not interfere with widely used drugs that are capable of causing severe adverse reactions. In contrast to the UK decision, owing to concerns about their safety, the US FDA did not allow the use of any of the statins as OTC products. In order to incorporate low-dose statins as OTC drug products, the American Society of Health-System Pharmacists (ASHP) then introduced OTC reclassification for statins. In addition to maintaining the prescription status of statins as a class, this was done to allow pharmacists to supply low-dose statins directly to patients without a prescription. It is important to see how the laws of various countries vary with regard to the OTC status of drugs [7, 13].

Benefits of using Approved OTC Medicines

OTC medicines provide greater access to care for minor or self-limiting diseases for people in general, at lower costs. In addition, General Practitioners (GPs) do not have to write prescriptions for mild diseases and have more time to deal with severe health conditions in turn. For countries like India, where the doctor-to-patient ratio is lower (1:1800) than other countries, this is extremely useful. Pharmacists may have an useful interface by using their clinical experience to direct patients to ensure efficient use of OTC medicines [8, 9].

Optimizing use of OTC Medicines

A few methods used in other countries to smooth self-medication with OTC medicines are as follows. The government is also taking positive measures in India towards formalizing the use of OTC medications [14].

Prescription Monitoring Programs

Prescription tracking systems (PMPs) capture, track and analyze electronically transmitted data provided by pharmacies and dispensing practitioners for prescribing and dispensing. This information is then used to promote OTC opioid abuse prevention [15]. In response to the prescription drug crisis in Canada, this policy was adopted in Canada in 2013 as part of "First Do No Harm." PMP was expanded in 2016 with the idea of providing real-time information to pharmacists on the possible misuse of OTCs at the time of purchase. Double doctoring and poly-pharmacy decreased after the PMP program [16].

Transitions between Prescription and OTC

Over-the-counter medications must, as a general rule, be used exclusively to treat a disease that does not need a physician's direct supervision and must be demonstrated to be relatively safe and well tolerated. OTC drugs are often commonly required to have little or no potential for abuse, while OTC drugs such as codeine are available in some areas (usually in strictly limited formulations or requiring paperwork or identification to be submitted during purchase). Over time, sometimes 3-6 years, it is possible to move medications that prove safe and suitable as prescription medicines from prescription to OTC [17]. Diphenhydramine (Benadryl), an anti-histamine that once needed a prescription but is now available almost anywhere, is an example of this. In the United States, cimetidine and loratadine are more recent examples, and in Australia, ibuprofen [18-23]. As a result of safety issues, rather than market forces, it is somewhat rare for an OTC drug to be withdrawn from the market, although it does happen occasionally. Phenylpropanolamine, for example, was withdrawn from sale in the United States because of concerns about strokes in young women. A research has been carried out to explore the views of customers about the risk of non-prescription drugs and access to them [24, 25]. The study concluded that a small number of consumers choose to have access to medications over the possible risks of taking non-prescribed drugs. Ranitidine has been removed from many markets because of concerns about the carcinogen N-nitrosodimethylamine (NDMA). It was revealed in February 2007 in the United Kingdom that Boots the Chemist will attempt to market Viagra over-the-counter in shops in Manchester, England (previous available as prescription only). After a consultation with a pharmacist, men between the ages of 30 and 65 may purchase four tablets [26-29].

CONCLUSION

Instead of visiting a doctor for minor illnesses such as cough, cold, asthma, pain, fever, acidity, diarrhea, and skin-related disorders, patients often approach a pharmacist. In most nations, the buying of particular drugs over the counter is legally recognised. 'Over-the-Counter (OTC) Medicines' means medicines that are legally approved to be marketed without a prescription by pharmacists. In India, the word doesn't have a legal meaning. Technically, unless they are explicitly indicated as prescription drugs only, drugs are OTC. OTC medicines make for easier and cheaper access to healthcare, but their abuse and adverse health effects are alarming. Against the context of globally prevalent regulations and practices, this article explains the definition of OTC medicines and practices in India. To optimize the use of OTC medicines in India, a recognized category of OTC medicines by law, patient awareness campaigns, and pharmacist and pharmaceutical company support are required. In India, the need to consider OTC medicines as a separate group of drugs is obvious. OTC medicine, however, may act as a double-edged sword and protection, violence, and patient education have to be given due consideration. The need for an hour is a strict regulation for the classification, distribution, and selling of OTC medicines. By launching a national education campaign, strategies can be developed by the Health Ministry of India to improve patient education. It is possible to ask

pharmacists to improve the educational movement. In order to enable safe use of these items, particularly for the less educated population, manufacturers should also consider including a pictorial description. There is a need to improve monitoring for the detection of adverse effects of OTC products. To rationalize the use of OTC drugs in India, all stakeholders need to come together and join hands. A variety of other regulatory initiatives are being introduced, along with making the OTC prescription schedule publicly available. The DCC is adding the category "Behind the counter medicines." These drugs do not need a prescription, but can only be sold "under the supervision of a qualified pharmacist." This new drug category has already been successfully implemented in a few European countries. In view of the widespread usage of topical steroids over the counter, an online petition was launched by the Task Force Against Topical Steroid Misuse (ITATSA) of the Indian Association of Dermatologists, Venereologists and Leprologists against the OTC availability of topical steroids. The petition stressed issues related to the indiscriminate selling of non-prescription topical steroids in India and made an attempt to raise awareness among the general population of the risks associated with their use In early 2018, when the Ministry of Health and Family Welfare declared its intention to control the counter sale of fairness creams containing short creams, a positive response was seen.

The ministry declared the inclusion of 14 steroid-based creams under Schedule H (prescription drug list) of the Drugs and Cosmetics Rules, 1945, in a notification released on 23 March 2018. The Central Drug Standards and Control Organization (CDSCO) recently urged a ban on counter-sales of topical medications containing hydroquinone, effective from 1 April 2019, to better restrict the use of depigmentation creams. The Indian government's recent decision to prohibit unreasonable FDCs will curb the indiscriminate use of OTC drugs. Since 2016, with the advent of online pharmacies in India, the use of OTC drugs has increased further. Strict regulatory frameworks need to be established to prevent the misuse and abuse of medicines sold online. The Organization of Pharmaceutical Procedures of India's (OPPI) OTC Medicines Committee is working through awareness campaigns and community education to encourage responsible self-medication.

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