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Over-the-counter medicines: Global perspective and Indian scenario

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Abstract

Patients often approach a pharmacist instead of visiting a doctor for minor ailments such as cough, cold, allergies, pain, fever, acidity, diarrhea, and skin-related conditions. Purchase of specific medicines over the counter is legally recognized in most countries. 'Over-the-Counter (OTC) Medicines' means drugs which are legally allowed to be sold by pharmacists without need for a prescription. The term does not have a legal definition in India. Technically, drugs are OTC unless they are specifically stated as prescription only drugs. OTC drugs allow faster and cheaper access to healthcare; however, their misuse and adverse health effects cause concerns. This article describes concept of OTC medicines and practices in India against the background of globally prevalent regulations and practices. A recognized category of OTC medicines by law, patient awareness programs, and support of pharmacists and pharmaceutical companies are required to optimize the use of OTC medicines in India.

KEY WORDS: Drugs and cosmetics act, nonprescription drugs, over-the-counter, self-medications

Introduction

The trend of 'Over-the-Counter (OTC) Medicines' use has grown steadily in the last few years. Various reasons such as easy availability, affordability, and increased awareness among patients are responsible for this trend. OTC medicines or nonprescription medicines are terms used interchangeably to refer to medicines that can be bought without a prescription.[1,2] Many countries recognize OTC medicines as a separate category of drugs and have established regulations for their use. In India, till date there are no guidelines for licensing of OTC medicines. There is no separate category allotted for OTC medicines in India and the drugs which do not come under the prescription medicines schedule are generally sold as over-the-counter medicines.[3] This review article makes an attempt to throw light on the regulatory and clinical scenario of "OTC medicines" in India against the globally prevalent practices.

Methods

The literature search for this review article was performed on three databases: MEDLINE, Scopus, and Science Direct and one search engine: Google Scholar, with the terms “over the counter,” “OTC,” “self-medication,” “nonprescription,” and “without prescription.” A total of 10833 articles containing the above search terms in their title were obtained. Among these, the articles fulfilling the following criteria were chosen: Articles with the above-mentioned search terms in their title, studies in English language published in peer-reviewed journals, and studies that mentioned about the regulatory and/or clinical scenario pertaining to OTC medicines. There were no restrictions on the date of publication. The search was conducted by 2 independent authors; both of them screened the articles independently for relevance and completeness. Articles containing overlapping or duplicate information were excluded. Only a limited number of articles ($n = 49$) fulfilling the above stated criteria were finally selected. Of these, 46 were full text articles, 1 was an editorial, and 2 were conference proceedings. The information available from electronic media (newspapers and websites) has been quoted occasionally. The search was conducted in May–July, 2019.

Results

Use of over the counter medicines (OTC): Scenario across different countries

A report on global OTC markets states that countries such as the United States, Japan, Germany, and the United Kingdom contribute maximally to the worldwide OTC sales.[4] The USA, UK, Australia, and Japan have formulated guidelines regarding classification, regulation, and uses of OTC. Distinction between OTC and prescription medicines may not always be obvious. For instance, in New Zealand, low-dose ibuprofen (200 mg) is OTC to treat minor pains such as headache, while high-dose ibuprofen (400, 600, and 800 mg) is a prescription-medicine used for the treatment of severe pain associated with arthritis.[5,6] OTC medicines can be classified into two categories: First category of OTC medicines are the ones which have been under the category of nonprescription medicines since the time they were introduced. The second category of OTC medicines are those that had been prescription medicines initially but were later shifted to the OTC category.[7] According to WHO, for a product to be an OTC medicine, it should be marketed on prescription for at least 5 years. Time period for change of category from prescription to OTC varies from country to country (e.g., European Union—no time specified, New Zealand—3 years, Japan—6 years, and Philippines—upto 10 years). Before accepting switch of a given drug into OTC category, it is important to ensure that the drug did not cause serious adverse drug reactions with increasing frequency during the marketing period till then.[2]

Status of OTC medicines in the United States In the U.S., there are more than 80 classes of OTC medications amounting to up to 1,00,000 marketed products. It is estimated that every year, OTC drugs save \$102 billions in US of which 25 billion is saved due to their use and \$77 billion is saved as unnecessary hospital visits are avoided.[8] According to the US FDA, OTC drugs should fulfil the following criteria: favorable benefit-risk ratio, low potential for misuse and abuse, consumer awareness regarding its use, and adequate labeling. The switch to OTC category needs an elaborate OTC medicine review process. Some examples of medicines that experienced a switch from prescription medicine to OTC in the US include triamcinolone acetonide, fluticasone (spray), loratidine, fexofenadine, topical antifungals, pseudoephedrine, loperamide, and ketoconazole.[9] In the US, OTC medicines are marketed under regulations referred to as “OTC monographs.”[10] The medicines that do not fit within a specific monograph require approval via the New Drug Application (NDA) process.[4,11] Some of the accepted OTC Drug Categories as per USFDA are antacids, antidiarrheal products, antiemetic, antiperspirants, cough and cold products, wart removers, sleep medications, ophthalmic products, products for piles, dandruff, dental caries, and analgesics. In the US, OTC drug advertising in media is permitted by law.[4,12]

Status in European union (EU) countries European Medicines Agency (EMA) has classified medicinal products into two categories as per article 70 (1): prescription medicines and nonprescription medicines.[13] Nonprescription medicines are divided into pharmacy medicines and general sales medicines in UK and Germany. Although pharmacy medicines are sold without a prescription, they are not available for self-selection and should be sold under the supervision of a registered pharmacist. Germany contributes maximum shares to the OTC market in Europe. All nonprescription medicines can be advertised in these 2 countries. In France, nonprescription medicines are divided into those that can be advertised to the public and those that cannot be advertised. In the year 2004, United Kingdom became the very first country in the world to include statins in the category of pharmacy-supervised OTC medicines. Since the availability of Simvastatin 10 mg tablets over the counter, its use in the UK has increased significantly.[14] A policy guidance document published in 2006 states that OTC medicines should have a low risk of serious type A reactions and very low risk of serious type B reactions. In addition, they should not have interactions with commonly used medicines, which can produce serious adverse reactions.[15]

In contrast to UK's decision, US FDA did not approve the use of any of the statins as OTC drugs because of concerns over their safety.[4,16] The American Society of Health-System Pharmacists (ASHP) then proposed OTC reclassification for statins so as to introduce low-dose statins as OTC drug products. This was done to allow pharmacists to provide low-dose statins directly to patients without a prescription in addition to preserving the prescription status of the statins as a class.[17] It is interesting to see how different countries' regulations differ with respect to OTC status of medicines.

Japan The country has an extensive OTC market and it has contributed significantly to the worldwide OTC sales. Just like other consumer goods, OTC medicines in Japan can be freely advertised. Nonprescription medicines are further divided into those requiring guidance (postmarketing surveillance is needed), type 1 (high potential risk), type 2 (less potential risk), and type 3 (relatively low risk). Type 1 OTC medicines can only be sold under the supervision of a registered pharmacist. Information about type 2 OTC medicines can be provided by a pharmacist or even by a qualified drug seller. Type 3 OTC medicines can be purchased at convenience stores and supermarkets.[18,19]

Australia In Australia, OTC medicines are a separate category in the drug regulations and they are further divided into 3 categories: Pharmacy medications, pharmacist only medications, and general sales medications. The sale of pharmacy medications has to be restricted to registered pharmacies but the sales process can be shouldered by a nonpharmacist employee. Pharmacist only medications require a direct involvement by the pharmacist in the form of advice given on the appropriate use of medication. General sales medicines can be sold in nonpharmacy outlets.[20] Advertising is allowed for OTC medicines in Australia.[21]

China Since 1999, China has regulated the administration of OTC medicines. There is a separate manual for OTC medicines with a logo to mark this as a special category.[22] In China, OTC drug advertisements are permitted on any kind of media, provided prior approval for the same has been obtained.[23]

India In India, the medicines are listed under different schedules in the Drugs and Cosmetics Act and Drugs and Cosmetics Rule. Drugs listed in Schedules H, H1, and X should carry a label stating that these drugs are to be sold by retail only on prescription of a registered medical practitioner. The drugs listed in Schedule G (mostly antihistamines) must carry a mandatory text on the label stating, "Caution: it is dangerous to take this preparation except under medical supervision." Surprisingly, certain important drug categories such as diuretics and aminosaliclates (sulfasalazine, mesalamine) are not included under any drug schedule creating a confusion for pharmacists whether to sell these drugs as OTC or prescription medicines.[24] It has to be stressed that in India, the phrase "OTC" has no legal

recognition. Here, the term OTC is used for the way drugs are used (self-medication without prescription or allowed to be sold by pharmacists without the prescription of a Registered Medical Practitioner) rather than being a recognized official category of medicines unlike other countries.[25]

Schedule K of the Drug and Cosmetics Act and its Rules includes household remedies such as paracetamol, liquid paraffin, eucalyptus oil, tincture iodine, and various formulations for the treatment of cough and cold and are the potential OTC drugs. Currently, nondrug-licensed stores (e.g., nonpharmacists) can sell a few medicines classified as “Household Remedies” in Schedule K of the D and C Rules in villages whose population is below 1000 subject to certain other conditions.[24] Under the provision of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules, 1955, the advertising and misleading promotion of some drugs/classes is kept under control to avoid self-medication by people.[26] Topical or external use of certain schedule G and H category drugs (except ophthalmic and ear/nose preparations containing antibiotics and/or steroids) is exempt from the schedule. For example, topical diclofenac is not a schedule H drug though diclofenac is included in schedule H. The State Government of Delhi announced in 2015, that aspirin which was earlier included in the list of household remedies (Schedule K) should be sold only with a prescription in Delhi. This was in view of the fact that there were increased number of deaths in dengue patients who bought aspirin OTC.[27]

The medicines which do not fall under the category of schedule H, H1, and X can be given without prescription through pharmacists and drugstores in India. Moreover, it is a common observation that prescription drugs are also sold without a prescription akin to over the counter medicines.[28] Ayurvedic drugs and traditional medicines are manufactured under a manufacturing licence issued by the State Licensing Authorities. These drugs are sold over the counter freely by non-pharmacists.[25] Thus, till date, there are no specific unifying regulations related to use and sale of OTC products and this impacts both the accessibility to better health care and patients' safety due to inappropriate use.[29]

A study by Phalke *et al.* reported prevalence of self-medication in rural population of state of Maharashtra in India to be 81.5%.[30] However, in Tamil Nadu, only 23% of the rural population resorted to self-medication or household remedies and almost 77% consulted a doctor for their ailment.[31] The prevalence of self-medication in Urban Delhi was found to be 92.8%,[32] whereas a study conducted at Behrampur in Odhisha found the prevalence of OTC medication use to be 18.72%.[33] Overall, 52% Indians were estimated to self-medicate in India according to a web portal-based survey of 20000 people across 10 cities. The reasons given were lack of time, need to avoid doctors' fees, and dependence of internet.[34] One Indian study reported that more than 90% of the qualified pharmacists interviewed in their study were aware about the concept of OTC drugs, 96.5% asked the patients their complaints when they were approached for purchase of OTC drugs, but only 51% counselled the patients regarding instructions for use.[35]

A study from Nepal reported reasons such as mild illness, previous experience of treating a similar symptoms, and nonavailability of health personnel for seeking OTC medicines.[36] In a survey conducted by Manohar and Manohar, 44% of participants stated cost-effectiveness as the main reason for choosing OTCs.[37] Nagaraj and Srinivashave reported that increased healthcare cost and inaccessible healthcare have led to growing use of drugs over the counter in India.[38] Availability of earlier prescriptions, recommendation from a friend/relative, advice by pharmacist, previous use, and advertisements were the factors reported to be responsible for use of OTC medicines,[39] especially in the upper educated class.[40]

The Indian pharma market generated total revenues of 1.8 billion in 2009 from the drugs presumed to be OTC with an annual growth rate of 10.7%.[25] Organization for Pharmaceutical Producers of India (OPPI) has proposed that policies should be developed for drug classification, labeling, licensing, distribution, and pricing of OTCs.[29]

Benefits of using approved OTC medicines

OTC medicines allow greater access to treatment of people at large at lower cost for minor or self-limiting illnesses.[41] Moreover, General Practitioners (GPs) do not have to write prescriptions for minor ailments and in turn have more time for dealing with serious health problems. This is extremely useful for countries like India where the doctor to patient ratio is less (1:1800) than other countries.[42] For ensuring optimum use of OTC medicines, pharmacists can provide a valuable interface by using their professional knowledge to guide patients.[43]

Common concerns about OTC medications: Inappropriate use and adverse effects

The concerns about misuse, adverse effects including dependence (especially to sedatives, analgesics, antacids, laxatives), drug resistance, and delayed diagnosis of underlying conditions due to use of OTC medicines pose formidable challenges.[1,34]

As per the National survey data submitted by Substance Abuse and Mental Health Services administration (SAMHSA) in US, about 3.1 million people aged 12 years and older have misused OTC medications at least once in their lifetime (3.7% in < 18 years old).[44] A meta-analysis by Frei *et al.*, threw light on the fact that over half a million Australians use analgesics over the counter for nonmedical purpose and OTC medicines are the third most common form of substance abuse in Australia.[45] Similarly, in Canada, it was found that OTC medicines were widely abused.[46,47] In India, abuse of OTC medicines is not well documented. One report mentions that cough syrups and antihistamine medications sold over the counter are a prevalent form of drug abuse in India.[48]

Despite their importance, instructions for use mentioned on the labels of OTC medicines are often not adequate, filled in small space and are missed by patients. As a result, patients do not follow the instructions.[1] An interesting study from India assessed whether labels of 100 nonprescription medicines complied with the requirements mentioned in the US FDA guidelines. It was found that 87% of the labels lacked information regarding contraindications. In 90% of the labels, adverse effects and in 96% information about their use during pregnancy and breastfeeding were missing. Overall, the label instructions were inadequate and had the potential harming the health of patient.[49]

In another study using deception conducted by Salunkhe *et al.*, a total of 263 pharmacies were visited. The investigators concealed their identity and pretended to suffer from sore throat/acute diarrhea. The questions asked to the pharmacists were whether they can get some strong medication to relieve symptoms and also antibiotics? In 76% of participants, antibiotics were dispensed (azithromycin for sore throat and nitroimidazoles for diarrhea).[50] Even though antimicrobials belong to the category of prescription drugs in India, they are dispensed without a prescription raising the concern regarding antimicrobial resistance.[51] The ready availability of OTC drugs places the weakest individuals at greatest risk—these are the patients from low socio-economic strata, the elderly and others taking multiple medications, and some illiterate individuals who are incapable of evaluating safety information mentioned on the drug label. Studies in US have shown that more than 60% of people cannot identify the active ingredient in the OTC drugs. In addition, about 40% of Americans believe that OTC medicines are too mild to cause any real harm. They also fail to report use of OTC medicines to health care providers. In a study done in UK on use of ibuprofen, 555 patients were followed up and surprisingly one fourth of the patients were found to use it for more than 8 weeks. Among them 4% had active peptic disease and 7% had asthma.[1] Since the doctor's prescription is not required, the term OTC gives a false sense of safety to the patients. There are no proper documented studies regarding awareness about nonprescription drugs in India and no regulatory act for OTC medicines, but even in western world, there is inadequate awareness among masses about optimum use of OTC medications. [52]

Optimizing use of OTC medicines

The following are a few approaches used in other countries in order to smoothen self-medication with OTC medicines. Also in India, the government is taking positive steps toward formalizing the use of OTC medicines.

Prescription monitoring programs Prescription monitoring programs (PMPs) collect, monitor, and analyze electronically transmitted prescribing and dispensing data submitted by pharmacies and dispensing practitioners. This data is then used to support to prevent OTC drug abuse. This strategy was implemented in Canada in the year 2013 as part of “First Do No Harm” in response to Canada’s prescription drug crises. In 2016, PMP was extended with the idea of giving pharmacists real time information on the potential abuse of OTCs at the time of purchase. After PMP program, double doctoring and poly-pharmacy reduced.[53]

Spreading awareness through news and electronic media In a survey that enrolled 1872 viewers of television advertisements in USA, 70% opined they had learned little or nothing more about the health condition requiring treatment, while 59% were of the notion that they knew little about the drug being advertised.[54] Use of advertisement may be legally allowed once a separate category of OTC is recognized. The content should be complete and approved by the concerned authority as it is done in some countries. Use of in the UK, websites such as overcount.org.uk and codeinefree.me.uk explain about the importance of appropriate use of OTC analgesia for pain such as back injury or menstrual cramps. In addition, patients share their personal experiences with OTC medicines on these sites.[55]

Adequate labeling Due to the diversity in languages spoken throughout India, apart from English, it will be useful to have labels in local languages for OTC drugs. Label instructions have to be simple and understandable by common and less educated people. Specification of dosage, especially for children, is most important. It is also important to clearly specify the indications, warnings, and directions for use since the drugs are administered without medical guidance. In 2008, FDA passed a law which requires that OTC medicines must have a new label called “Drug Facts.”[56] This label shows people the best, safest way to use OTC medicines and is written in large print in a language that can be read easily and understood by a lay person. It includes information on active ingredients, purposes, uses, warnings, directions for use, and inactive ingredients. This ensures that patient uses the OTC medicine in a right way and also helps to avoid potential adverse effects. Similar guidelines for labeling OTC medicines can be made in India by specially appointed committees. Tamper proof packaging can be introduced which will ensure easy identification of any tampering done with the OTC drug package labels. Adding a pictorial description on label may be useful to patients especially those who are less educated.

Distribution and delivery of OTC drugs India is still struggling to provide essential health care to remote places. New ways to deliver the OTC drugs to the rural population have to be conceived. India has almost 1,50,000 post offices and 9,00,000 pharmacy shops. If the services of post offices are used, the reach will dramatically increase.[57,58,59] Conversely if the drugs are provided in places other than the pharmacy shop, then conditions necessary for proper storage need to be strictly followed.

Establishment of a subcommittee to categorize OTC drugs The Drugs Consultative Committee (DCC) on 18th September 2017 recommended the creation of a separate category for OTC drugs which can be legally sold over the counter. A subcommittee was formed with an intention to examine the various schedules to which the drugs marketed in India belonged to, i.e., Schedule H, H1, G, X, and K. In addition, the committee was also assigned the role of suggesting a list of drugs that could be considered for marketing as OTC, along with conditions to be followed. The OTC medicines for conditions like allergy, fever, vomiting, muscle pain, inflammatory conditions, antacids, external preparations for skin, and hormonal contraceptives have been considered for inclusion in the list.[60] The subcommittee examined the matter and prepared a report which was submitted to the DCC for review. The report dealt with various aspects of OTC drugs such as definition of OTC drugs, their basic

characteristics, classification, list of OTC drugs, regulation of prescription drug to OTC drug switch process, regulation of new OTC drug approval and manufacturing, labeling, distribution, sale, advertisement as well as pricing of OTC drugs. At the meeting held on 20th February 2019, the DCC opined that there is a need to conduct a detailed examination of the report submitted by the subcommittee. Currently, the report is under review.[61] This is indeed a welcome move. Misuse of prescription-only drugs sold over the counter is rampant in India. Hence, in addition to allowing a separate category of OTCs; strict rules are needed to prevent illegal sale of prescription-only medicines without prescriptions.[62] There needs to be clarity in instructions about contents and uses on the label and, hence, labeling norms will have to be developed.[60]

Along with making OTC drug schedule available officially, a number of other regulatory measures are being implemented. The DCC is introducing a “Behind the counter medicines” category. These medicines do not require a prescription but can be sold “only under the supervision of a qualified pharmacist.” This new category of drugs has already been introduced in few European countries with success.[63] In view of rampant use of topical steroids over the counter, an online petition was started by Indian Association of Dermatologists, Venereologists, and Leprologists Taskforce Against Topical Steroid Abuse (ITATSA) against the OTC availability of topical steroids. The petition laid emphasis on problems associated with the indiscriminate sale of nonprescription topical steroids in India and made an effort to sensitize the general population about risks associated with their use.[64] In early 2018, a positive response was seen when the Ministry of Health and Family Welfare announced its intention to regulate over the counter sale of fairness creams containing corticosteroids. In a notification issued on 23rd March 2018, the ministry announced inclusion of 14 steroid based creams under Schedule H (prescription drug list) of Drugs and Cosmetics Rules, 1945.[65,66] To regulate the use of depigmentation creams further, the Central Drugs Standards and Control Organization (CDSCO) recently urged a ban on over the counter sales of topical medications containing Hydroquinone, effective from 1st April 2019.[67] The recent move by the Indian government regarding banning of irrational FDCs will curb the indiscriminate use of OTC medications.[68] With the advent of online pharmacies in India since 2016, the use of OTC medications has further increased. There is a need to develop stringent regulatory mechanisms to avoid misuse and abuse of the medicines sold online.[69] The OTC medicines committee of the Organization of Pharmaceutical Procedures of India (OPPI) is working toward promotion of responsible self-medication through awareness programs and community education.[70]

Conclusion

The need to recognize OTC medicines as a separate category of drugs in India is evident. However, OTC medicine can act as a double-edged sword and due consideration has to be given to safety, abuse, and patient education. Strict regulation for classification, distribution, and sale of OTC medicines is the need of the hour. Strategies may be developed by the Health ministry of India to enhance patient education by launching national educational campaign. The pharmacists can be asked to strengthen the educational movement. Manufacturers should also consider including pictorial description to allow safe use of these products especially by the less educated population. Surveillance for reporting of adverse effects of OTC drugs needs to be strengthened. All stakeholders need to come together and join hands to rationalize use of OTC medicines in India.

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Conflicts of interest

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