



KNOWLEDGE AND UNDERSTANDING OF NON-PRESCRIPTION (OTC) DRUGS

Medical Education

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ABSTRACT

Introduction: Over the counter (OTC) or non-prescription drugs sold directly to a consumer without the doctor's prescription. As compared to prescription drugs, which requires a medical prescription to be dispensed. So, over the counter (OTC) drugs are mainly used for self-medication because such medicines are easily accessible at pharmacies without the doctor's prescription. In India 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. The aim behind this study is to assess the knowledge and understanding regarding Non- prescription (OTC) drugs. **Material & methods:** A cross-sectional questionnaire-based study conducted among undergraduates and postgraduate medical students, medical officer, specialist, super-specialist nursing students, staff nurse to assess the Knowledge and Understanding of Non-prescription (OTC) drugs. In present study data was collected by Google form over a period of 3 months. 212 responses were received and entered into Microsoft office excel & statistical analysis was done. **Result** 212 responses were evaluated, Male: Female ration was 120:92. Out of 212 responses, 74 (34.9%) Undergraduate medical students, 44 (20.8%) Postgraduate medical students, 31 (14.6%) Medical officer, 21 (9.9%) Specialist, 6 (2.8%) Nursing students, 36 (17%) Staff nurses gave response in this study. Most respondents (n=144, 67.9%) believed that 'OTC/Non-prescription drug' mentioned in Drug and Cosmetics Act. (104, 49.1%) respondents believed that in India OTC/Non-prescription drugs are included in a separate category of drugs and have established regulations for their use. Significant gaps were noticed in the responses from the respondents with regards to the knowledge about OTC drugs in India. **Conclusion** General awareness and knowledge of OTC is very good but few are aware about rules with regard to OTC/Non-Prescription and "Household remedies" under Drugs and Cosmetics Act, 1940. In India, there is a committee for OTC/Nonprescription drugs and regulations are still being framed.

KEYWORDS

OTC drug, Nonprescription drug

INTRODUCTION

Over the counter (OTC) or non-prescription drugs sold directly to a consumer without the doctor's prescription. As compared to prescription drugs, which requires a medical prescription to be dispensed.¹ They are mainly used for self-medication because they are easily accessible at pharmacies without the doctor's prescription.² Self-medication using OTC drugs may be safe and acceptable if the consumer has adequate knowledge of the drug and the illness.³ For minor illness like cold, cough, pain, fever, gastritis, diarrhoea, etc patient use OTC/Non- prescription drugs. However, inappropriate self-medication with OTC drugs can have serious implications, especially in extremes of ages (paediatrics and geriatrics), pregnant and lactating mothers, and patients with co-morbidities. Moreover, their inappropriate use in developing countries is high due to inadequate knowledge, lack of exposure to medical information, inadequate infrastructure, and weak laws and regulations. They are legally recognized in most countries. The USA, UK, Australia have formulated guidelines regarding regulation, and uses of OTC.⁴

In India, there are no regulations regarding Non- prescription (OTC) drugs. 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.⁵ India, Drugs and Cosmetics Act, 1940(amended up to 2016) and its subordinate legislation, the Drugs and Cosmetics Rules, 1945 (amended up to 2020) regulate the import, manufacture, distribution and sale of the drugs and cosmetics. "Prescription only drugs" have been placed in Schedule H, H1, G, and X of the Drugs and Cosmetic Act (1940) but non- prescription (OTC) drugs are not included as a separate category. Draft regulations to amend Schedule K – containing household remedies was issued in May 2022. OTC regulations in India are still under process of being framed.

The aim behind this study is to assess the knowledge and understanding regarding Non- prescription (OTC) drugs among health care professionals.

Objective:

To assess the knowledge and understanding regarding Non-prescription (OTC) drugs.

MATERIAL & METHODS:

Type of study: Cross-sectional questionnaire-based study

Duration of study: 3 months.

Inclusion criteria:

Undergraduates and postgraduate medical students, medical officers, specialist, super-specialist, nursing students, staff nurse who were willing to participate voluntarily in study are included.

Study method:

Online google form (structured questionnaire) was circulated among study population through social media after approval by institutional ethics committee. Questionnaire comprised 14 questions. 212 responses were received and entered into Microsoft office excel & statistical analysis was done.

RESULT

In present study, 212 responses were received. Out of which 120 (56.6%) were male and 92 (43.4%) were female. Out of 212 responses, 74 (34.9%) Undergraduate medical students, 44 (20.8%) Postgraduate medical students, 31 (14.6%) Medical officer, 21 (9.9%) Specialist, 6 (2.8%) Nursing students, 36 (17%) Staff nurses gave response in this study.

Out of 212 respondents 190 (89.6%) respondents knew that OTC drugs are sold directly without prescription. (Figure 1)

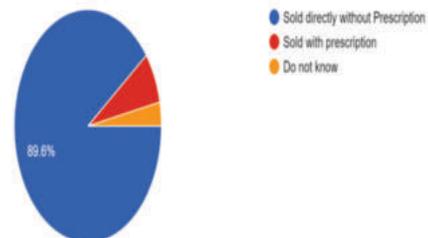


Figure 1: OTC drugs are

Most respondents (n=144, 67.9%) believed that 'OTC/Non-prescription drug' are mentioned in Drug and cosmetics act, which is not true. 111(52.4%) knew that there is committee for OTC/Non-prescription

drugs in India. 104 (49.1%) respondents believed that in India OTC/Non-prescription drugs are included in a separate category of drugs and have established regulations for their use, which is not true. (Figure 2)

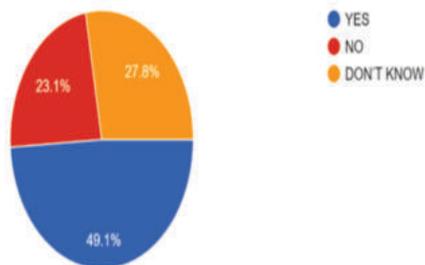


Figure 2: OTC/Non-prescription drugs as a separate category of drugs and have established regulations for their use in India

Table 1: Knowledge regarding over-the-counter drugs

Si. NO	Questions	Correct response	Participants providing correct response N (%)
1	OTC drugs are	Sold directly without Prescription	190 (89.6)
2	Is OTC/Non-prescription drug mentioned in Drug and cosmetics act?	NO	27 (12.7)
3	Is there any committee for OTC/Non prescription drugs in India?	YES	111 (52.4)
4	In India, is there any OTC/Non-prescription drugs as a separate category of drugs and have established regulations for their use?	NO	49 (23.1)
5	According to 'THE DRUGS AND COSMETICS ACT AND RULES' which Schedule includes drugs which does not require license for sale?	Schedule K	48 (22.6)
6	According to 'THE DRUGS AND COSMETICS ACT AND RULES' Aspirin is under which schedule?	Schedule K	22 (10.4)
7	As per USFDA, drugs under OTC list are all except	Antibiotics	130 (61.3)
8	According to the US FDA, OTC drugs should fulfil the following criteria:	All of the above	185 (87.3)
9	In the US, OTC medicines are marketed under regulations referred to as "OTC monographs."	True	110 (51.9)

Only 48 (22.6%) respondents knew that according to 'The drugs and cosmetics act and rules' schedule K includes drugs which does not require license for sale. Only 22(10.4%) respondents knew that according to Drugs and cosmetics Act and Rules, Aspirin is under schedule K. 61.3% (130) participants aware that as per USFDA, drugs under OTC list does not include antibiotics. According to the US FDA, OTC drugs should fulfil the following criteria: favourable benefit-risk ratio, low potential for misuse and abuse, adequate labelling. 87.3% (185) give all of the above response.

In the US, OTC medicines are marketed under regulations referred to as "OTC monographs." 51.9% (110) knew this. 123 (58%) respondents update their knowledge about OTC/Non-prescription drugs. 173

(81.6%) respondents have used OTC/non-prescription drugs and figure 3 showing sources of information.

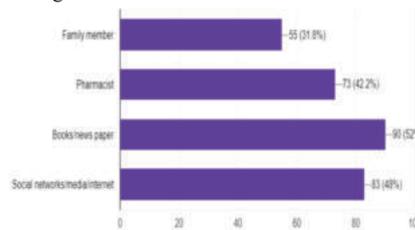


Figure 3: Source of information for OTC/Non-prescription drugs

Figure 4 showing common illnesses for which OTC drugs are use. Most common indications are fever, headache, cough, common cold, diarrhoea, vomiting and gastritis.

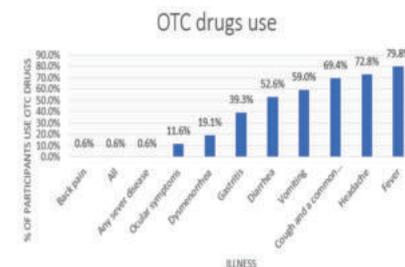


Figure 4: Common illnesses for which OTC drugs are use by participants.

DISCUSSION

'The Drugs and Cosmetics act,1940(amended up to 2016)) and rules, 1945 (amended up to 2020) classify drugs into different schedules like Schedule H, H1, G, K, and X. Schedule K includes "household remedies", sold only in a village having population of not more than one thousand persons and no license or prescription is required for sale or dispensing of drugs. On 25th May, 2022, Ministry of health and family welfare has published a draft to amend schedule-K (25 May, 2022)¹⁵. Serial no. 40 has been added- containing 16 drugs- Povidone Iodine 5% w/v, Chlorhexidine Mouth wash, Clotrimazole 1% w/w cream, Clotrimazole 1%w/w dusting powder, Dextromethorphan Hydrobromide Lozenges (5mg) , Diclofenac ointment/cream/gel, Sodium Chloride Nasal spray – 0.9% , Oxymetazoline nasal solution 0.05% , Ketoconazole shampoo 2% w/v, Lactulose solution 10gm/15ml, Benzoyl peroxide 2.5 w/w, Calamine Lotion, Xylometazoline hydrochloride 0.05% w/v Diphenhydramine Capsules 25 mg, Paracetamol tabs 500 mg, Bisacodyl tablets 5mg, which can be sold Over-The-Counter (OTC) by retail under the valid licence. These drugs can be sold by retail Over-The-Counter without prescription of a Registered Medical Practitioner (RMP) if duration of treatment is less than 5 days and indication should be already approved by the Licensing Authority. In our study only 22(10.4%) respondents knew that in 'The drugs and cosmetics act and rules', Aspirin is under schedule K. Aspirin and quinine like drugs are under 'household remedies' and they are not included in schedule H which contain prescription drugs. In present study, 27(12.7%) respondents were aware that, 'The Drugs and Cosmetics Act 1940' till date does not mention OTC/Non-prescription drugs. Whereas, 23.1% (49) respondents gave correct response for information with regard to separate category and no established regulations for their use. 111(52.4%) were aware about committee for OTC/Nonprescription drugs and regulations are still being formulated⁸.

The USA, UK, Australia, and Japan have well defined guidelines regarding classification and uses of OTC.⁴ In the US, OTC medicines are marketed under regulations referred to as "OTC drug monographs" (1972). 110 (51.9%) respondents give correct response. An OTC drug monograph establishes conditions, such as active ingredients, uses (indications), doses, routes of administration, labelling, and testing, under which an OTC drug in a given therapeutic category (e.g., sunscreen, antacid) is generally recognized as safe and effective (GRASE) for its intended use. Final OTC drug monographs (final monographs) were codified in regulations under Title 21 of the CFR part 330. CARES Act was introduced in March 27,2020. The CARES Act-2022 replaces the rulemaking process with an administrative order process for issuing, revising, and amending OTC monographs.

The CARES Act added section 505G to the Federal Food, Drug and Cosmetic (FD&C) Act. Section 505G reforms and modernizes the framework for the regulation of OTC monograph drugs.⁹

According to the US FDA, OTC drugs should fulfil the following criteria: favourable benefit-risk ratio, low potential for misuse and abuse, and adequate labelling.¹⁰ In our study, 185(87.3%) respondents gave correct response. Some of the accepted OTC Drug Categories as per USFDA are antacids, anti-diarrheal products, antiemetic, cough and cold products, ophthalmic products, and analgesics. It does not include antibiotics¹¹, in our study 130 (61.3%) respondents knew this.

In our study, 173 (81.6%) respondents have used OTC/non-prescription drugs and 123 (58%) respondents update their knowledge about OTC/Non-prescription drugs. In Subramanian S. et al study¹² among medical students, 84% were aware about the OTC drugs are sold without prescription, in our study 89.6% aware about that. In our study 81.6% have used OTC drugs. Whereas in Subramanian et al and Agrawal et al study¹³ 86% students and 88.57% have used OTC drugs respectively. Main source of information; In Subramanian S. et al study¹², reading material (56.3%) followed by advice from seniors/pharmacist (43.7%); In Agrawal et al study¹³, previous prescription 107 (61.14%), text book 15 (8.57%), in our study books/newspaper 52%, Social networks/media/internet 48%. Most common conditions for taking self-medication with OTC drugs in Subramanian S. et al study¹², fever (89%), cough and cold (75%); in Agrawal et al study¹³, cough and cold (69.14%) and fever (69.14%); in our study most, common conditions were Fever 79.8%, headache 72.8%, cough and cold 69.4%. Self-medication is widely used in India. Self-medication is risky and can prove to be fatal. Indiscriminate use can lead to antimicrobial resistance. OTC drugs can also have potential for their misuse and abuse such as codeine-based medicines, cold and cough medications, sedative antihistamines, decongestants and laxatives.¹⁴ So, there should be guideline regarding use and sale of over the counter or non-prescription drugs and also there should be a list of these drugs.

CONCLUSION

General awareness and knowledge of OTC is very good but few are aware about rules with regard to OTC/Non-Prescription/Household remedies drugs in India. In India, there is a committee for OTC/Nonprescription drugs and regulations are still being formulated.

Ethical approval: Taken.

Conflict of interest: Authors declare no conflict of interest.

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