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## OTC drug trend and its social impact – A Review

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### Introduction

Over-the-counter medicines (OTC), also known as nonprescription medicines (NPMs), are medicines that can be obtained or supplied without a prescription from registered medical practitioners. OTC medicines are frequently used to manage various minor ailments. They are conveniently obtained from community pharmacies and other retail outlets such as petrol stations, supermarkets and are now increasingly purchased on the internet<sup>1</sup>. OTC medicines promote self-care, benefiting both individuals and the health care systems by reducing the burden on other health care settings<sup>2</sup>.

Self-medication also has advantages for health care systems as it facilitates better use of clinical skills of pharmacists, increases access to medication and may contribute to reducing prescribed drug costs associated with publicly funded health programmes.<sup>3</sup> However, increasing availability of non-prescription medicines may encourage patients to believe that there is a drug treatment for every ailment. Furthermore, the use of such products may delay/mask the diagnosis of serious illness, with increased risks of interactions and adverse reactions and of self-treatment being undertaken when medical aid should have been sought.<sup>4</sup> There is also the potential for misuse and abuse of such products.<sup>5</sup>

### Use of OTC medicines:

#### Global perspective

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. 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.<sup>6</sup>

#### India perspective

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. A study by Phalke et al. reported prevalence of self-medication in rural population of state of Maharashtra in India to be 81.5%.<sup>7</sup> 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.<sup>8</sup>

### Public opinion towards OTC drugs

One of the major problems of using OTC is that the public may be influenced by information received from family and friends that affect their medication selection. The public may also have perceptions that these medications are safe and don't cause any harmful effects. Previous reports show that the individuals who use OTC non-steroidal anti-inflammatory drugs were in general unaware of the potential side-effects of these medications.<sup>9</sup> Further, consumers usually had a lack of awareness of the potential interactions of OTC drugs with other drugs.

### General attitudes towards the use of OTC medicines

The main reason for the OTC drug use among the public are included low cost, easy accessibility, safe and well tolerable. Due to high cost of medical consultation, the patients are finding easy ways of getting the treatment, which they find through medical shop or through some known person. People are happy to spend the same high consultation money in procuring OTC drug. Public consider that they prefer OTC medicines mainly for the treatment of minor illness such as headache, cough, and fever and analgesics, antipyretics and anti-diarrhoeals were most commonly used drugs.<sup>10</sup>

In a study conducted in Saudi Arabia, majority of the public had positive attitudes towards OTC medication use. Further, the patients had the attitude of reading the pamphlet and they also believe that buying medication without prescription is not safe practice. Meanwhile, the consumers did not have the attitude to inform the pharmacist regarding the medications they use at home time of buying medications without prescription.<sup>11</sup>

### Patient contact with pharmacies

OTC medicines allow greater access to treatment of people at large at lower cost for minor or self-limiting illnesses. Moreover, General Practitioners (GP) 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.<sup>12</sup> For ensuring optimum use of OTC medicines, pharmacists can provide a valuable interface by using their professional knowledge to guide patients. Patients usually

tend to visit the same pharmacy for the main reason to acquire a prescription medicine. The patients might seek advice from pharmacist rather than from GP, when the condition was not serious enough to visit the doctor. Further, the consumers would seek a pharmacist's advice if they had no time to wait for a GP appointment.<sup>13</sup>

**Benefits on the safety, potency and effectiveness of using approved OTC medicines**

Most of the OTC consumers are tend to follow the directions on the OTC drug package. The US-FDA states that the OTC manufacturers generally use tamper-evident packaging for their products to guard the consumers against criminal tampering.<sup>14</sup> Further, the OTC medicine labels have detailed usage and warning information so consumers can properly choose and use the products. In a study conducted in Sweden, 7% of the respondents agreed completely or to a large extent with the statement that OTCs are completely harmless regardless of how they are being used, while 71% agreed to a small extent or not at

all.<sup>15</sup> Meanwhile in another study, the majority of the consumers were not aware of the pharmaceuticals composition, it can be assumed that they did not understand leaflet information correctly.<sup>16</sup>

Regarding potency or effectiveness of the OTC medicines, the consumers views are they would prefer GP when the OTC medicines are not responsive within the specific period of time. Meanwhile, some consumers tend to return the OTC medicine to pharmacy when it is not effective. Further, consumers also believe to reduce the dose and stop taking the OTC medicines when it is not effective. In contrast, some consumers believed that increasing the doses and long term use of OTC might be effective. Further, the consumers also strongly agreed' or 'agreed' that they knew non-prescription medicine was effective because it had been tested by scientists and was shown to be effective.<sup>17</sup> The various consumers view on the safety, potency, and effectiveness of OTC drugs are displayed in table 1

**Table 1: The consumer's social view on the safety, potency, and effectiveness of OTC drugs**

The public purchase OTC medicines during the first sign of disease
The consumers prefer OTC medicines only during the severe illness
The public consider that OTC medicines are completely safe to
Public believe that OTC medicines can have serious adverse effects
Improper use of OTC medicines might be serious as compared to prescription drugs
The consumers believe that OTC might mask the serious clinical conditions
The consumers also believe that some OTC medicines might affect the natural healing process of the human system
Routine use of OTC medicine might loss the potency

**Common concerns about OTC medications: Inappropriate use and adverse effects**

The main concerns of OTC medication among the consumers were due to the chance of misuse, side effect, dependence, drug resistance and misdiagnosis of present condition due to OTC medicine use. According to the National survey data reported by Substance Abuse and Mental Health Services administration in USA, 3.1 million consumers with age more than 12 years had misused the OTC drugs at least once in their lifetime.<sup>18</sup> In India, reports regarding to OTC medicine abuse is very limited. Previous reports show that the cough syrups and antihistamines products are most prevalent OTC medication with highest chance of drug abuse.<sup>5</sup> An UK study which evaluated the use of OTC ibuprofen on 555 patients and on follow up they used for more than 8 weeks. Among these patients, 4% had peptic ulcer disease and 7% showed the sign of asthma.<sup>19</sup>

**Scale of OTC medicine abuse**

The terms 'misuse' and 'abuse' are frequently used to describe the problematic use of OTC medicines reciprocally, but each term has a definite meaning. Previous literature defined misuse as using the OTC

medicine for a legitimate medical reason, but improperly, such as taking a higher dose than recommended or using it for a longer duration. On the other hand, abuse is known as using the medicine for an illegitimate medical reason, such as achieving a mind-altering effect or losing weight. Dependence and addiction have also been defined as the frequent use of the medicine with the desire to continue using it regardless of its harm and the struggle to voluntarily quitting or changing its use. Of note, misusing OTC medicines such as opiates can progress to dependence as a result of both legitimate (misuse) and illegitimate (abuse) purposes.<sup>20</sup> Also, an association have been reported in some individuals between the abuse of OTC medicines and the use of illicit substances. The evidence shows that the problematic use of OTC medicines can lead to harms that range from physical, psychological to socioeconomic harm to the users and their families.<sup>21</sup> The physical harms, for instance, of long term misuse of codeine-based analgesics containing ibuprofen and paracetamol, involved chronic headache, gastrointestinal haemorrhage, nephrotoxicity and hypokalaemia.

### Prevalence, knowledge and opinion on misuse and abuse of OTC medicines

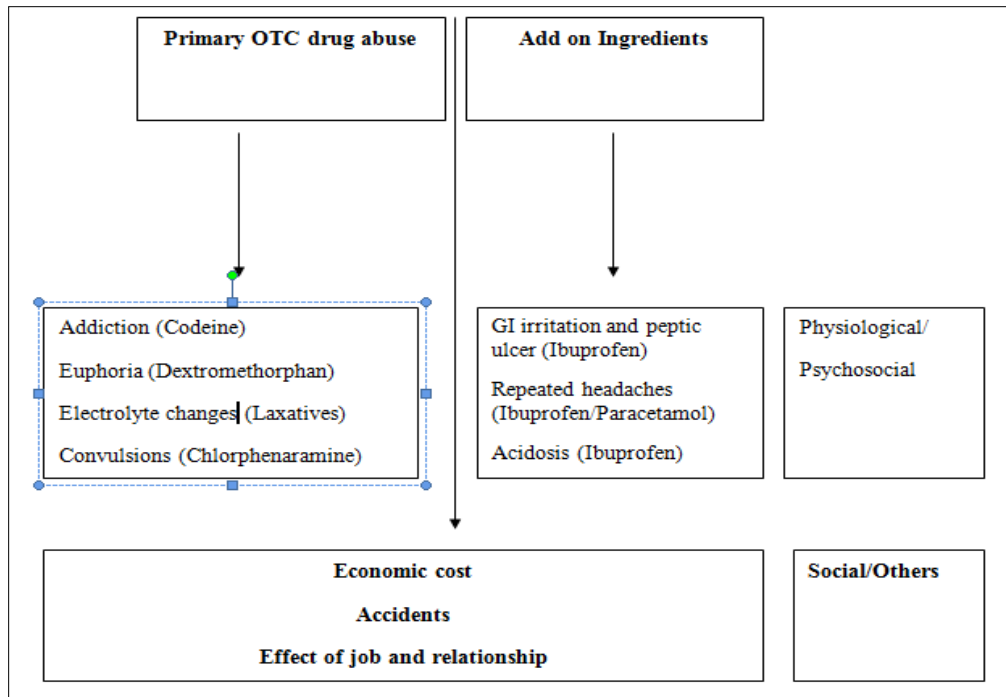
In a recent systematic review, based on the outcome of the 14 studies, the prevalence reported via survey questionnaires with pharmacy customers and the general public ranged from 3.1 to 59% for misuse, 0.8 to 4.1% for abuse and 4.2 to 17.8% for dependence. The pooled prevalence was 16.2% for misuse, 2.0% for abuse and 7.2% for dependence.<sup>22</sup> In a study, the prevalence of misuse of OTC analgesics containing codeine and sedative antihistamine in pharmacy customers was 39.45%.<sup>23</sup> Individuals suffering from regular headaches and presenting for self-medication in community pharmacies in Belgium were estimated to misuse analgesics at a total rate of 24%, of whom 58.2% misused caffeine-combined analgesics.<sup>24</sup>

Acute and chronic pain management was the leading medical reason for individuals misusing OTC analgesics such as paracetamol, nonsteroidal anti-inflammatory drugs (NSAIDs) and other combination analgesics. On the other hand, abuse of OTC medicines for non-medical reasons was frequently reported with codeine-based analgesics, dextromethorphan, sedative antihistamines and loperamide.<sup>25</sup> Individuals who were dependent on codeine-based analgesics and loperamide attributed their dependence to the avoidance of acute opioid withdrawal symptoms and, in some cases, to harm themselves or commit suicide.<sup>25</sup> Other risk factors implicated in OTC medicines problematic use collectively involved behavioural, cultural, socioeconomic and health factors. For instance, socioeconomic factors such as personal and relationship problems, living alone, childhood experiences of a negative divorce process, unemployment and low self-esteem, low educational level and occupation were correlated to dextromethorphan abuse and codeine dependence.<sup>26</sup>

### Harms related to OTC medicine abuse

Harms resulting from misuse, abuse, and dependence on OTC medicines generally included; physical, psychological, social and financial harm, decreased health-related quality of life (HRQoL), hospitalization, and death. Harms related to codeine-based analgesics' abuse and dependence were more frequently reported than other OTC medicines in the reviewed studies. Physical harms reported by codeine abusers and dependents were either acute side effects such as urticarial itching, distorted vision and respiratory depression or chronic side effects such as nausea, constipation, liver, bowel kidney failure, anaemia, seizures, ulcers and swollen stomach.<sup>25</sup> Also, codeine dependents reported psychological harms such as depressive mood, anxiety, tiredness, inattention, nervousness and feeling sleepy.<sup>25</sup> Rebound insomnia was reported as a withdrawal symptom by individuals who were dependents on the sedative antihistamine doxylamine.<sup>25</sup> Cough mixtures containing promethazine, ephedrine, pseudoephedrine, codeine, hydrocodone were reported to cause psychotic disorder, schizophrenia, depressive disorder, and dysthymia in abusers admitted for treatment in specialized abuse clinics in Hong Kong.<sup>26</sup>

Cardiovascular events such as QTc-prolongation, ventricular dysrhythmias were distinctive of loperamide abuse and dependence in patients presented in hospital with toxicity symptoms.<sup>27</sup> Harms related to dextromethorphan abuse included balance disorders, psychomotor retardation and agitation in individuals admitted to hospital for DXM poisoning.<sup>28</sup> Social harms were mainly experienced by codeine dependents and commonly include; deteriorated family relationships, inability to continue employment, loss of children, spouses and family homes.<sup>29</sup> Misuse of OTC medicines resulted in decreased health-related quality of life in the elderly population. Significantly, it increased the relevant adverse drug events (ADEs) ( $\beta = 0.298$ ).<sup>30</sup> The harms related to OTC drug misuse or abuse is shown in Fig 1.



**Fig 1: Harms related to OTC drug misuse or abuse**

**Medicines implicated in OTC abuse**

Multiple OTC medications have abuse potential. Commonly abused medications include antihistamines, sleep aids, caffeine, ephedrine, pseudoephedrine, antitussives and expectorants, dextromethorphan, laxatives, anabolic steroids, and sildenafil.<sup>31</sup> Laxatives are abused for weight loss and high antihistamines doses are used for euphoria. From the studies done across the world for OTC medication abuse, opiate-based combination products and cough/cold products containing dextromethorphan, sleep aids, antihistamines, analgesic,

hypnotics, and laxatives have been highlighted as having abuse potential. Cough medicines and painkillers are most abused medications. OTC codeine or other opiate-containing products and OTC cough and cold medications are the most commonly implicated medications for abuse.<sup>32</sup> Codeine is not available as OTC in the US. However, it is a primary medicine with abuse potential in other countries. Numerous studies have recorded OTC codeine analgesics as the most commonly abused medication.<sup>33</sup> OTC medicines with high abuse potential are displayed in table 2.

**Table 2: Classification of OTC medicines with high abuse potential**

Pharmacological classification	Drugs name
Anti-histamines	Diphenhydramine and Chlorphenaramine
Cough medicines	Cough medicines containing dextromethorphan
Codeine-containing products	Compound analgesics (codeine with ibuprofen or paracetamol) and cough medicines
Analgesics	Aspirin and acetaminophen
Hypnotics	Estazolam, Flurazepam.
Laxatives (oral and rectal)	Sodium phosphate laxatives and laxatives containing bisacodyl
Decongestants	Pseudoephedrine

**Steps to Optimize use of OTC medicines among the public**

There are the few strategies used globally to streamline the proper use of OTC medications. In India, MOH is also involved in taking effective strops for the safety and misuse of OTC drugs.

**Prescription monitoring programs**

Canada’s “First Do No Harm” programme of 2013 against OTC drug abuse that provided a creative solution to this problem. Prescription monitoring programmes to collect, monitor, and analyse electronically transmitted prescribing and giving pharmacists real-time information

about potential OTC drug abuse at the time of purchase are possible solutions to these problems.<sup>34</sup>

**Spreading awareness through news and electronic media**

In a survey conducted among 1872 viewers of television advertisements in USA, 70% stated that they learned minimal or no information regarding treatment related to diseases and 59% reported that they acquired little information regarding the advertisement related to the drugs.<sup>35</sup> The advertisement may be allowed legally in a condition where the separate category of OTC is recognized. Before, advertizing the content must be approved by respective department as per company norms. In UK, the websites such as overcount.org.uk and codeinefree.me.uk gives the information regarding the appropriate use of OTC analgesia for pain such as back injury or menstrual cramps. Further, the patients also give their opinion about the personal experiences with OTC medicines on these websites.<sup>36</sup>

**Proper 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.”<sup>37</sup> 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. Labeling requirements of OTC were displayed in table 3.

As per FDA	As per drug and cosmetic rules (1945)
Active ingredient in each dosage unit	Generic and trade name
Appropriate precaution for use and special warning	Net contents and content of active ingredient
Dosage instructions	Batch number
Interactions	
Warnings	Name and address of manufacturer including manufacturer license number.
Adverse effects	Manufacture and expiry date.
Directions for use	Maximum retail price

**Distribution and delivery of OTC drugs**

In India, still there is no proper delivery of essential healthcare services to remote and rural sectors. 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.<sup>38,39</sup> Conversely if the drugs are provided in places other than the pharmacy shop, then conditions necessary for proper storage need to be strictly followed.

**Implementation of a subcommittee to categorize OTC drugs**

The Drug consultative committee is the statutory advisory committee set up by Central Government under Section 7 of the D&C Act to advise Central Government, the State Governments and the Drugs Technical Advisory Board on any matter tending towards securing uniformity throughout India in the administration of the D&C Act. The DCC has been in the process of deliberating upon the

creation of specific rules and regulations to govern OTC drugs.

During the 52nd meeting of the DCC, held on September 18, 2017, the DCC deliberated upon the creation of separate provisions for OTC drugs to be sold in retail pharmacies. In this respect, the DCC had recommended the creation of a separate category of OTC drugs. Further, a subcommittee was created to comprehensively examine drugs marketed in India vis-à-vis conditions for sale stipulated under various schedules, i.e. Schedules H, H1, G, X, and K, and recommend the list of drugs that may be considered for marketing as OTC along with conditions to be followed.

During the 55th meeting of the DCC, held on January 31, 2019 and February 1, 2019, the DCC had examined the matter in detail and submitted its report, which inter alia contained its recommendations on the following aspects of OTC drug.

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. 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. There needs to be clarity

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in instructions about contents and uses on the label and, hence, labeling norms will have to be developed.<sup>40</sup>

### Conclusion

There exists a significant challenge in regulating the level of misuse and abuse of OTC among the public to ensure of safety in some consumers and allowing the access of OTC drug to consumers who use them safely. It is recommended that by monitoring usage of certain OTC products, in addition to data recording and education, safe and effective use of such medicines can be promoted

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