

# Abuse of over-the-counter medicines: a pharmacist's perspective

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**Abstract:** Self-care and self-medication practices are essential components of any health care systems. The use of over-the-counter (OTC) medications is a part of the self-medication process. The popularity of OTC medication use among patients may increase the abuse potential of OTC medications. With pharmacists being as accessible as they are, they are often the first line of contact for patients, and have the opportunity to educate and counsel patients on appropriate OTC medication use. The presence of a pharmacist ensures safe and effective use of OTC medications. Pharmacists can liaise with other health care providers in the management of self-care practices by patients. However, a pharmacist has traditionally been underutilized in this role. This article provides a brief review on OTC medications with abuse potential and the effect of self-medication on OTC medication abuse. This review further describes the barriers faced by pharmacists in OTC medication abuse management, given the increased potential of prescription-to-OTC switch in recent years. In addition, the potential for a behind-the-counter drug category to boost patient-pharmacist interaction was discussed. The current review supports the positive role played by pharmacists in the management of OTC medication abuse. This review adds to the knowledge base of the barriers faced by pharmacists to prevent OTC medication abuse while developing appropriate intervention strategies. By expanding the role of pharmacists, OTC medication abuse may be controlled more effectively, thereby providing better patient medication therapy management and outcomes.

**Keywords:** non-prescription, behind-the-counter, medication, self-medication

## Introduction

Medications obtained by patients for treatment of common ailments, without a prescription from a physician, are known as over-the-counter (OTC) or non-prescription medications. OTC medications provide prevention and treatment for a wide range of conditions, including but not limited to headaches, common cold, musculoskeletal pain, allergies, tobacco dependence, and heartburn.<sup>1</sup> However, there is always a risk involved in using OTC medications.<sup>1,2</sup> These include improper self-diagnosis, inappropriate dosage, addiction issues upon prolonged use, adverse drug reactions, and drug interactions.<sup>3,4</sup> As most patients do not discuss their OTC medications with a physician, they are unaware of the risks associated with OTC medications.<sup>5</sup> In addition, direct-to-patient advertising increases the exposure of medications to patients.<sup>5</sup> As a result, there is increased product use in the absence of professional help.<sup>4,6</sup> OTC medication abuse for the purpose of this review is defined as the use of non-prescription medications for non-medical purposes.<sup>7</sup> Abuse is often intentional, unlike OTC medication misuse, which may be medication used for medical purposes but used incorrectly, for example, incorrect dosage, lack of interactions knowledge, inappropriate medication use, and incorrect duration of use.<sup>8</sup>

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However, there is a growing concern of the potential harm associated with these medications. The objective of this article is to provide a brief review of the OTC medication abuse, extent of the OTC medication abuse, the role of pharmacists to address this issue, the concept of behind-the-counter (BTC) medications, and needed future steps that must be taken by pharmacists and the pharmacy profession to curb the issue with nationwide impact. While there have been articles studying the OTC medications and abuse, very few have reviewed the barriers faced by pharmacists and the steps to prevent abuse from a pharmacy-based approach. This review will provide pharmacists and researchers a perspective to consider the possible role played by pharmacist in reducing OTC medication abuse and how strategies can be implemented to reduce it further.

## OTC medication abuse

### OTC medications with most potential for 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>9–11</sup> Laxatives are abused for weight loss and high antihistamines doses are used for euphoria.<sup>12</sup> 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>7,13,14</sup> Codeine is not available as OTC in the US. However, it is a primary medicine with abuse potential in other countries.<sup>15</sup> Numerous studies have recorded OTC codeine analgesics as the most commonly abused medication.<sup>6,16,17</sup> Table 1 highlights the OTC medications with high abuse potential.

One of the probable reasons for OTC abuse is increased access to medications. This is because medications for common illnesses are made accessible by prescription (Rx)-to-OTC switch.<sup>16</sup> Most switches are driven by firm's patent expiration. However, in case of prescription antihistamines like Claritin, Zyrtec, and Allegra, Blue Cross and their parent company petitioned the switch to the US Food and Drug Administration (FDA).<sup>17</sup> Providing patients with autonomy, diagnosis of the condition on the patient's judgment and the

**Table 1** List of over-the-counter medications abused

Class/therapeutic group	Medication example
Antihistamines <sup>40,41</sup>	Diphenhydramine and coricidin
Cough medicines <sup>42</sup>	Cough medicines containing dextromethorphan
Codeine-containing products <sup>7</sup>	Compound analgesics (codeine with ibuprofen or paracetamol) and cough medicines
Analgesics <sup>43</sup>	Aspirin and acetaminophen
Hypnotics <sup>40</sup>	Sominex and nytol
Laxatives (oral and rectal) <sup>7,44</sup>	Sodium phosphate laxatives and laxatives containing bisacodyl
Decongestants <sup>45</sup>	Pseudoephedrine

absence of a physician may lead to inaccurate self-diagnosis.<sup>5</sup> For example, the availability of treatment for dyspepsia masks the presence of a severe gastrointestinal disease, which may not be diagnosed by patients.<sup>16</sup> Lack of pharmacist vigilance may lead to long-term inappropriate use of OTC medications and hamper the health of patients.<sup>5</sup>

Switching of drugs increases patient autonomy while encouraging them to make their health care decisions.<sup>16</sup> About \$12.9 billion savings were recorded for the switch of cold/allergy, analgesics, and dermal products.<sup>18</sup> However, this increasing number of medications being switched to OTC status increased the spectrum of medications available for abuse.<sup>19</sup> For example, the switch of acetaminophen from prescription to OTC has led to increased cases of severe liver hepatotoxicity.<sup>20</sup> If abused, acetaminophen leads to withdrawal symptoms, in addition to suicidal thoughts and liver failure.

### Role of pharmacist in OTC medications

Patients have easy and free access toward seeking advice from a pharmacist. Many issues faced by a patient can be easily solved by pharmacists, including product selection, OTC brand name confusion, appropriate product use, and when to take medications. Thus, pharmacists exercise a strong influence on OTC medication purchase and product selection.

Many patients find product selection confusing due to marketing strategies by manufacturers. A common marketing technique by pharmaceutical manufacturers is line extension.<sup>5</sup> A large percent of revenue is spent on OTC medication advertisements and line extensions. Once a manufacturer has an established brand name, other products are sold under the extension of the same brand. For example, the primary brand Tylenol® has many line extensions including Tylenol PM®, and Tylenol Cold and Cough®. This often leads to confusion among the minds of patients. Many times these line extensions have multiple ingredients causing more confusion.

A patient–pharmacist interaction would help patients in their decision-making process during these instances.

OTC advertisements are often the driving factor in OTC medication selection by the patients. If the advertisements are misleading, a patient may be misinformed.<sup>21</sup> The advertisements focus upon the beneficial effects of the medication with bare information on the contraindications and safety concerns. With this regard, a pharmacist can also provide insight into all aspects of the drug, as well as information on the safe use of OTC medications.<sup>19,22</sup>

## Pharmacy-based efforts to address OTC medication abuse

### Pharmacist's role in OTC medication abuse

Historically, pharmacists focused on the medication distribution system. Over the past years, with the rising incidence of chronic illness, increased need for preventive services, and complex use of medications, both pharmacists and pharmacy technicians are expected to provide broader services. They assume more clinically patient-oriented roles.<sup>14</sup> Within a hospital setting, certified pharmacy technicians have demonstrated positive impacts by obtaining medication history and conducting medication reconciliation for patients.<sup>7,15,23–25</sup> Furthermore, pharmacy technicians help with care transitions from the hospital setting to the home and community settings.<sup>26</sup> The dynamic environment of the health care system demands to expand the role of a pharmacist and pharmacy technician.

Pharmacists are the first point of contact during the purchase of OTC medications. They are required to monitor OTC medication use among a specific population.<sup>7</sup> For example, in the case of elderly patients, who take multiple medications, pharmacists should be more vigilant. Also, patients who come in with request for frequent refills must be monitored as well including OTC medications used.<sup>27</sup> Pharmacists can be more proactive in managing OTC medication abuse by utilizing their clinical skills, by providing oral and written medication information, and by developing trust among patients.<sup>23,28</sup> Programs like prescription drug monitoring log information about a patient upon refills of prescription drugs. While if a similar program were set up for OTC medications, the person would have to visit the same pharmacy always. Hence, implementation of such a program may not be pragmatic.

Several methods employed by pharmacists to reduce OTC medication abuse have been suggested in the past.<sup>28</sup> The top three methods used by pharmacists to control OTC medication abuse were keeping the implicated products out of sight, questioning on the purchase of these products by

pharmacists, and refusal to sell the implicated product.<sup>3,29</sup> It was demonstrated that 62% of pharmacists reported certain measures being taken to curb OTC medication abuse, for instance, not displaying medicines, refusing sales, and associated policies including pharmacist's conducting an interview of the patient. The interview may include asking additional questions to patients at the time of purchase and providing advice to patients as necessary to reduce abuse of potential products.<sup>24</sup> Some other techniques used and reported by pharmacists to reduce OTC medication abuse were referral to a physician, referral to a drug and alcohol abuse team, and/or involvement of pharmacists in harm reduction programs.<sup>17</sup> Table 2 lists the strategies that can be adopted in different locations and scenarios to curb OTC abuse.

## Barriers for pharmacists to prevent OTC medication abuse

There are multiple challenges faced by pharmacists and their pharmacies in monitoring OTC abuse. Due to lack of consistent data with OTC medications, identification of drug-related problems may become difficult. Pharmacists usually never keep any record or monitor patient medication profiles for OTC medication use, which creates a vacuum in the information necessary to make appropriate counseling decisions.<sup>30</sup>

An individual seeking to abuse an OTC medication could probably obtain it from the same pharmacy at different times or visit different pharmacies for the same medication. However, considering this potential to abuse medications,

**Table 2** Common strategies used by pharmacists to control over-the-counter medication abuse

Target locations	Pharmacist-initiated strategies
In a pharmacy	Refusing sales Contacting other pharmacies to warn them of the suspicions of a customer who may be abusing a product Claiming products were not in stock Prevent supplies by hiding medicines Supplying only limited amounts
Patient involvement	Counseling customers about the abuse potential of products Raising awareness of Internet-based support groups among patients by advising them Providing information leaflets
Physician involvement and other services	Working on general practitioner engagement/consultation Providing referral to doctors Using private clinic services Using specialist drug services and drug and alcohol treatment services

**Note:** Data from Cooper<sup>7</sup> and Paulose-Ram et al.<sup>46</sup>

specifically pseudoephedrine, US federal government passed the Combat Methamphetamine Epidemic Act of 2005 (CMEA). This act was passed to monitor the amount of pseudoephedrine which an individual can purchase in a pharmacy in the US.<sup>31</sup> The aim of this act was to curb illegal consumption of methamphetamine which can be bulk produced using drugs like ephedrine and pseudoephedrine that are commonly found in OTC cough and cold medications. The CMEA has placed a purchase limit of no more than 9 g of pseudoephedrine in a 30-day period.<sup>31</sup> Although this act has successfully helped reduce the issue of OTC medication abuse of pseudoephedrine-containing products, adaptation of this process for other medications proactively by pharmacists has been non-existent in the US.

In addition, the lack of pharmacist's proactive initiatives to monitor patient's OTC medication use has led to many abuse opportunities. Pharmacists are usually overworked and the continuous high stress prescription processing workload also reduces the potential opportunities to be pharmaco-vigilant. Further, the legal requirements associated with medication distribution have not kept up with the abuse potential nor are the laws for the practice of pharmacy revised or kept up with patient or pharmacist needs.<sup>30</sup>

For example, a study conducted in a community pharmacy indicated that pharmacists were overworked.<sup>32</sup> The lack of workforce in a pharmacy led to reduced attention and problem identification among the patient's OTC decisions.<sup>32</sup> Further, the role of pharmacy technicians has not been adequately utilized to improve the practice of pharmacy. Due to limited number of pharmacists, pharmacy technicians are an important aspect in preventing OTC medication abuse as well. Pharmacy technicians provide an extra layer for patient safety. They can help pharmacists with roles like drug dispensing, obtaining patient information, and processing order entry. Their vigilance during these processes may further help in reducing OTC medication abuse.<sup>32</sup>

There are several programs in place to counter prescription drug abuse; OTC medication abuse has been overlooked. Pharmacy take back programs, drug monitoring programs as well as vigilance of professional pharmacy programs like the American Pharmacists Association (APHA) have been notable in the past few years and little focus has been provided for OTC medication abuse.

### BTC medications: a promising third class

BTC medications are defined as "a third category of drugs available without a prescription; placed BTC, they are available only after consultation with a pharmacist."<sup>33</sup> BTC

medications are widely adopted in many countries including the UK, Ireland, Canada, New Zealand, France, and Australia.<sup>34-36</sup>

The need for a BTC category was first assessed in 1995 by the Government Accountability Office (GAO) in the US while it was rejected by the FDA at that time. In 2007, the idea was re-proposed by the FDA and then reevaluated by GAO in 2009, without any conclusive statement. The FDA requested comprehensive evidence about the role that a potential BTC category would play in the US since 2007.

To distinguish from OTC medications, the characteristics of BTC medications are dispensing only with professional supervision. This ensures the safety, appropriateness, effectiveness of the dispensed medication, and increased control over medications with high clinical risk.<sup>37</sup> However, implementation of BTC medication requires pharmacists and technicians to be qualified to perform initial assessments and screenings, medication reviews, patient counseling, and medication monitoring.

Some of the medications potential for transition to BTC category include those used for high blood pressure, high cholesterol, asthma, gastrointestinal reflux, allergies, and pain.<sup>37</sup> To name a few as examples, aspirin/hydrocodone and nabilone (antiemetic) are listed as schedule II drugs in Canada, the counterpart of a BTC category, and children's cough and cold medications were recommended to be included into BTC by pharmacists for safety consideration.<sup>38</sup> A similar class is required within the US. The current OTC medications with high abuse potential should be included under this medication class. Table 3 provides a list of medications that could be moved to BTC.

Despite the seemingly attractive prospects of BTC medication, including the potential to reduce medication abuse, the implementation of BTC medication category is controversial among primary stakeholders. Considering the safety and effectiveness of BTC medications, the Consum-

**Table 3** Medications potential for transition to behind-the-counter category

Indication of medication	Example
High cholesterol	Statins <sup>47,48</sup>
Blood sugar level maintaining	Insulin <sup>49</sup>
Cold remedies	Pseudoephedrine and ephedrine <sup>48-50</sup>
Schedule V cough syrups	Certain codeine-containing products <sup>49,50</sup>
Emergency contraceptives	Plan B <sup>48,49</sup>
Painkillers	Painkillers with small amounts of codeine (up to 12.8 mg per tablet) and aspirin <sup>51,52</sup>
Sleep aid/allergy	Diphenhydramine <sup>52</sup>

ers Union and the National Consumers League argued for supportive evidence to make a national move to develop a third category, while the Consumers Healthcare Products Association (CHPA) opposed it. Physician organizations questioned the adequacy of pharmacists to provide clinical services, with a primary concern about the impact of BTC on physician–patient relationship. However, majority of pharmacy organizations provided a strong backing to the implementation of BTC medication.<sup>39</sup>

To facilitate the implementation of BTC medication category, the following recommendations were made: demonstration of benefits outweighing the risks, evidence for positive outcomes, financial savings to society, sufficient allocation of resources, and appropriate compensation systems.<sup>37</sup> The BTC medication class provides adequate opportunities for pharmacists to reduce OTC medication abuse. The FDA should consider the BTC medication category to reduce OTC medication abuse.

## Role of pharmacists in BTC medications

The presence of a pharmacist would be essential to purchase a BTC medication. These medications should be provided only upon a pharmacist's recommendation. Upon performing the necessary tests, initial screenings and appropriate counseling a BTC medication can be dispensed. Some of the potential candidates could be patients with high blood pressure, gastrointestinal reflux, asthma, severe allergies, and pain.<sup>5,37</sup> All current OTC medications with high abuse potential can be included as BTC medications. If the pharmacists work collaboratively with their patients, it will lead to informed decision making and safer use of medications. Once a pharmacist disapproves a particular medication, they should refuse to dispense it. BTC medication is a bridge between OTC and prescription medications, with a potential to increase access of health care while efficiently using the knowledge and expertise of a pharmacist.

## Conclusion

This review concludes that pharmacists need to be well informed of the OTC medications which have an abuse potential. Better communication strategies between pharmacists and patients may help pharmacists understand the issues of OTC medication abuse. OTC medicine abuse was identified in many countries. The implementation of a new class of BTC medications will help improve patient monitoring while curbing potential OTC medication abuse.

Pharmacists do play an essential role in counseling patients. Pharmacist vigilance can help reduce OTC

medication abuse. The current health care system calls for more regulation on OTC medications, especially those with identified abuse potential. We need to strike a balance between providing the required access to medications and at the same time managing the risk of OTC medication abuse. Finally, the data collection and reporting for OTC medication abuse can be standardized with distinctive reporting for medication misuse, abuse, and addiction.

## Disclosure

The authors report no conflicts of interest in this work.

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