

OTC medications & The Practitioner's Role in Self Care

Non-Prescription Drugs and Parapharmaceuticals

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Brief History

- In 1906, the FDA was established
- Before this, most drugs were available without prescription
- Cocaine, marijuana, and opium were included in some OTC products without notification to the users



Brief History

- **Durham-Humphrey Amendment of 1951**
- In the US, the term OTC drugs was legalized in 1951 via Durham-Humphrey Amendment.
- The law distinguished between legend (prescription) drugs and over-the-counter (OTC) (non-prescription) drugs.
- OTC drugs were required to be both safe and effective.



Definitions

- Over-the-counter (OTC) medications are defined as **safe and effective drugs available to use by the general public without a doctor's prescription(FDA).**
- They play an increasingly vital role in our health care system and are the most prevalent means of treating the majority of common health problems in the United States.



The Self-Care Revolution

- >100,000 OTC products are available to consumers in the US to treat > 400 ailments.
- OTC drugs account for ~ 60% of all the medications in the US.
- In 2016, the American public spent approximately \$34 billion on OTC products to self-manage a wide variety of acute and chronic medical conditions

Self-care, Self-medication

Factors that drive reliance on self-medication include:

- The increase in size of the aging population.
- Restricted access to prescribers through health management organizations.
- The increasing cost of health care.
- The high proportion of underinsured or uninsured population.



Rx-to-OTC switch

- An Rx-to OTC switch is defined as over-the counter (OTC) marketing of a drug product that was once a prescription (Rx) drug for the **same indication, with the same strength, dose, duration of use, dosage form, and route of administration.**

Selected agents switched from prescription to over-the-counter status by the US Food and Drug Administration (2006–2017).

Ingredient	Indication (Pharmacologic Category)	Year Ingredient First Switched	Single-Ingredient Product Examples
Adapalene	Acne (topical retinoid)	2016	Differin Gel
Budesonide	Allergic rhinitis (topical glucocorticoid)	2015	Rhinocort Allergy Spray
Cetirizine	Hay fever/upper respiratory allergies (antihistamine)	2007	Zyrtec
Esomeprazole	Acid reducer (proton-pump inhibitor)	2014	Nexium 24 hour
Fexofenadine	Hay fever/upper respiratory allergies (antihistamine)	2011	Allegra 12 hour, Allegra 24 hour
Fluticasone	Allergic rhinitis (topical glucocorticoid)	2014	Flonase Allergy Relief, Flonase Sensimist Allergy-Relief
Ketotifen	Itchy eyes (ophthalmic antihistamine)	2006	Alaway, Zaditor
Lansoprazole	Acid reducer (proton-pump inhibitor)	2009	Prevacid 24 hour
Levocetirizine	Hay fever/upper respiratory allergies (antihistamine)	2017	Xyzal
Levonorgestrel	Emergency contraceptive (progestin)	2006	Plan B One-Step
Orlistat	Weight loss aid (lipase inhibitor)	2007	Alli
Oxybutynin	Overactive bladder (transdermal anticholinergic)	2013	Oxytrol for Women
Polyethylene glycol	Constipation (osmotic laxative)	2006	MiraLAX
Triamcinolone	Allergic rhinitis (topical glucocorticoid)	2013	Nasacort Allergy 24 hour

Rx-to-OTC switch

Rx to OTC switch is considered if the following questions can be answered in the affirmative

1. Can the patient adequately **self-diagnosed** the clinical abnormality?
2. Can the clinically abnormal condition be successfully **self-treated**?
3. Is the self-treatment product **safe and effective** for consumer use under conditions of actual use?

Rx-to-OTC switch

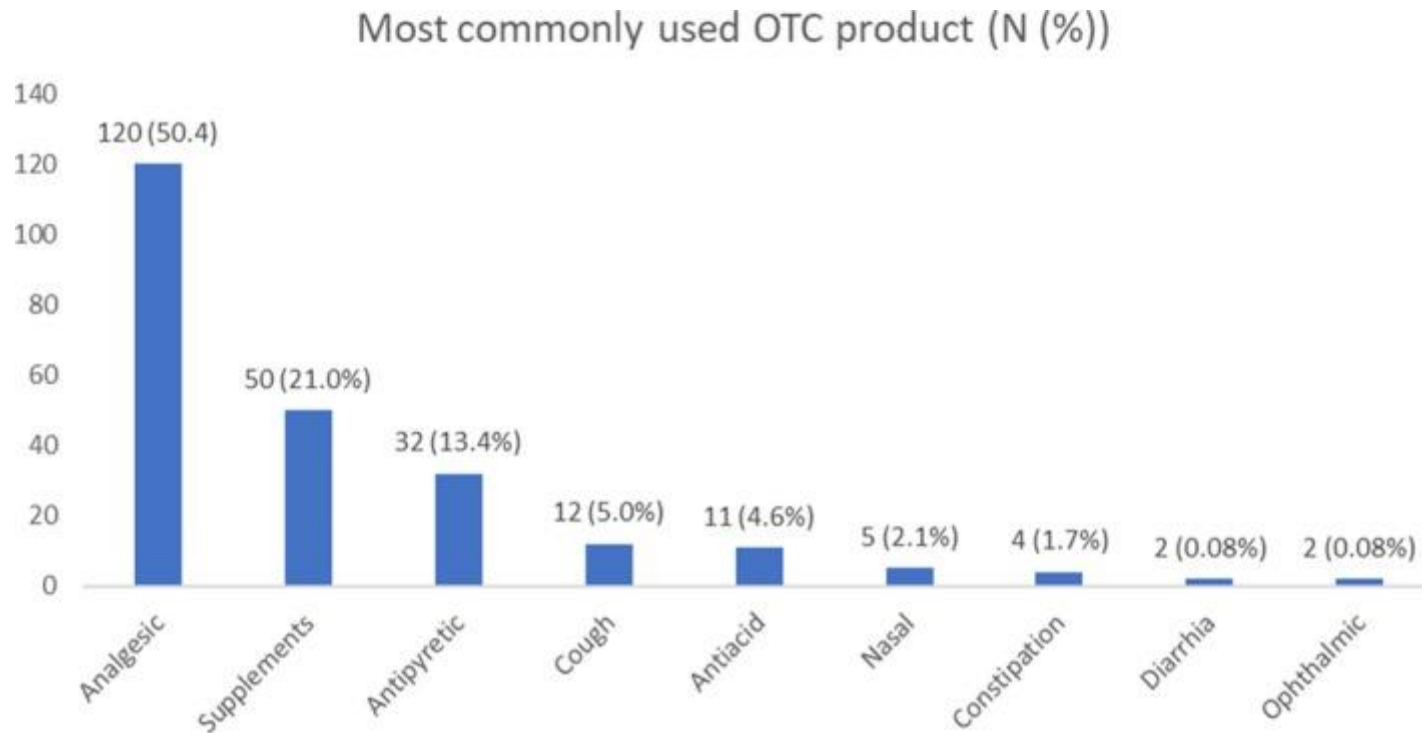
Reclassification Criteria:

- The indication(s) for which the drug to be used on an OTC basis should be similar to those on Rx and must permit easy diagnosis and monitoring by the patient.
- A favorable adverse-event and drug interaction profiles, relatively low toxicity and a low potential for abuse.
- The drug should not have properties that make it impractical for OTC use, e.g. narrow therapeutic index.

OTC drugs in Jordan

- OTC consumption is estimated to have reached USD77.8 million in 2018, increasing by a CAGR of 7.8% from USD 53.5 million in 2013. This significant increase is due to the influx of Syrian refugees, who demand OTC to attend to basic health needs, especially at point of arrival¹.
- Jordan's prescribed consumption is estimated at USD181.5 million in 2018, representing 70% of overall consumption. This high percentage is due to 87% of the Jordanian population holding health insurance and a significant proportion of those have multiple insurances¹.

Jordanian population awareness about OTC medications



Analgesics were the most commonly used OTC products among the participants (50.4%) followed by supplements (like vitamins and minerals) and antipyretics. Other categories of OTC products used were cough syrups, anti-acids, nasal drops and sprays to reduce nasal congestion and a runny nose, constipation medications, diarrheal medications, and ophthalmic drops and ointment²

2.Taybeh, E., Al-Alami, Z., Alsous, M., Rizik, M., & Alkhateeb, Z. (2020). The awareness of the Jordanian population about OTC medications: A cross-sectional study. *Pharmacology research & perspectives*, 8(1), e00553.

Considerations in Reclassifying a Drug as OTC

- Safety
 - Which is a Relative matter.
 - benefits outweigh risks.
 - the potential for misuse and abuse is low.
- Ease of diagnosis and treatment.
- Adequately labeled

Nonprescription drug labeling

- The law requires all over the-counter drug labels to have information in a standard format designed to give the user easy-to-find information.

Drug Facts

Active ingredients/Purposes

- Make sure the *Active Ingredients* aren't the same as those in another medicine already being used.
- If the medicine contains more than one *Active Ingredient*, read the *Purposes* of each active ingredient to make sure all of the active ingredients are needed for the problem(s) or symptom(s) to be treated.

Uses

- Find medicine that **treats only** the problem(s) or symptom(s) to be treated.

Warnings

- Is there any reason this medicine shouldn't be used?
- Is there any reason to talk to a doctor or pharmacist before using this medicine?

Directions

- Find the correct dose on the package.
- Make sure liquid medicine comes with a measuring tool (such as dosing or measuring cup). If not, ask for one at the pharmacy. Spoons made for eating and cooking may give the wrong dose and **shouldn't be used**.

They read the label..NOT !

- 90% to 95% of consumers read the Drug Facts label. However,
 - most read the label selectively
 - often pay insufficient attention to the active ingredients and the safety information.
 - Even if patients read the label, they may not comprehend it.
- 50% of respondents who reported taking an OTC pain reliever in 2009 were not concerned about potential side effects.
- Only 16% of consumers read the whole label !

Nonprescription drug labeling

- However, the likelihood of inappropriate nonprescription drug use resulting from misreading of product labels increases when patients have limited reading skills or language barrier.
- Pharmacists can take prominent role in ensuring the safe use of nonprescription drugs.

The benefits of over-the-counter availability

- Direct, rapid access to effective medicines
- Wide availability
- Decreased health care system utilization (fewer physician visits, lower health care system costs)
- Allowing individuals to be in charge of their own health.
- OTC drugs are cheaper

Risks associated with OTC use

- Incorrect self-diagnosis, delaying diagnosis and treatment of serious illnesses (delay in seeking advice from a health care professional)
- Increased risk of drug-drug interactions.
- Increased risk of adverse events when not used appropriately.
- Potential for misuse and abuse

Examples of drug abuse : cough relievers (Codeine) & Cold medicines

- 5% of teens have abused cough medicines in 2009, they look for Codeine ..
- Pseudoephedrine is commonly found in OTC cold drugs, It is abused by sport players.



Drug interactions



- The risk for drug interactions increases as consumers use more nonprescription medications.
- In addition, diet and lifestyle can affect medications' ability to work in the body.
- Certain food, beverages (grapefruit juice), alcohol, caffeine and even cigarette smoking can interact with medications.
- To avoid drug interactions, patients should consult pharmacists when first selecting nonprescription medications.



Drug–Food/Beverage Interaction		
OTC Drug	Food/Beverage	Potential Adverse Effect
Acetaminophen	Garlic	Delayed acetaminophen absorption
Aspirin	Garlic	Increased risk of bleeding
Calcium	Oxalic acid foods (spinach, rhubarb); phytic acid foods (bran/whole-grain cereal)	Altered calcium absorption
Zinc	Caffeine; dairy products (milk)	Decreased zinc absorption
Drug–Disease Interactions		
OTC Drug	Condition	Mechanism
Aspirin	Hyperuricemia	Decreased renal excretion of uric acid
Doxylamine succinate, phenylephrine HCl	Glaucoma	Obstructed aqueous outflow
Naproxen, ketoprofen	Peptic ulcer disease	Altered gastric mucosal barrier
Pheniramine maleate, naphazoline HCl, nicotine	Hypertension	Increased vascular resistance
Drug–Alcohol Interactions		
OTC Drug	Potential Adverse Effect	Mechanism
Aspirin	Increased gastrointestinal blood loss	Prolongs bleeding time
Diphenhydramine HCl	Increased sedation	Depresses central nervous system
Insulin	Increased hypoglycemia	Decreases hepatic gluconeogenesis

Allergies to active or inactive ingredients

- Although the likelihood is low, any medicine can cause allergic reaction.
- Patients should always be counseled about the signs and symptoms of an allergic reaction (Itching, hives, and trouble breathing) and instructed to seek medical care immediately.
- Therefore, for safety reasons, FDA requires inactive ingredients to be listed in the label.

Infants and Children

- For most products, FDA recommends against self-medication in children younger than 2 years, especially using cough and cold products.
- Pharmacists can provide recommendations regarding medications with which they are familiar and for which dosage guidelines are readily available (e.g. pediatric acetaminophen products).

Pharmaceutical care for high-risk and special groups

Infants and Children

- It is important to differentiate among relatively distinctive pediatric ages as follow:
 - *Premature*: gestation of less than 36 weeks
 - *Neonate*: first postnatal month of life
 - *Infant (baby)*: ages 1 to 12 months
 - *Toddler*: ages 1 to 3 years
 - *Preschool or early childhood*: ages 3 to 6 years
 - *Middle childhood*: ages 6 to 12 years
 - *Adolescence*: ages 13 to 18 years

Infants and Children

TABLE 2-1 Selected Medication Administration Guidelines for Oral Medications

Infants

- Use a calibrated dropper or oral syringe.
- Support the infant's head while holding the infant in the lap.
- Give small amounts of medication to prevent choking.
- If desired, crush non-enteric-coated or non-sustained-release tablets into a powder and sprinkle them on small amounts of food.
- Provide physical comfort while administering medications to help calm the infant.

Toddlers

- Allow the toddler to choose a position in which to take the medication.
- If necessary, disguise the taste of the medication with a small volume of flavored drink or small amounts of food. A rinse with a flavored drink or water will help remove an unpleasant aftertaste.
- Use simple commands in the toddler's jargon to obtain cooperation.

- Allow the toddler to choose which of the medications (if multiple) to take first.
- Provide verbal and tactile responses to promote cooperative taking of medication.
- Allow the toddler to become familiar with the oral dosing device.

Preschool Children

- If possible, place a tablet or capsule near the back of the tongue; then provide water or a flavored liquid to aid the swallowing of the medication.
- If the child's teeth are loose, do not use chewable tablets.
- Use a straw to administer medications that could stain teeth.
- Use a follow-up rinse with a flavored drink to help minimize any unpleasant medication aftertaste.
- Allow the child to help make decisions about dosage formulation, place of administration, medication to take first, and type of flavored drink to use.

Pharmaceutical care for high-risk and special groups-Pregnant women

- Most self-medication products state “ if pregnant or breast-feeding, ask a health care professional before use”
- **Pharmacists** are trained to assess whether a nonprescription medication is safe for use during pregnancy (A, B, C, D, X system).
- The decision to suggest a medication must be based on up-to-date knowledge of the literature and a critical risk-benefit evaluation.
- Pharmacists should consult a reference such as the *Drugs in Pregnancy and Lactation* by Briggs and others to check for the safety of medication in this population.
- The pharmacist must be alert to the possibility of pregnancy in any women of childbearing age who has certain symptoms of early pregnancy (nausea, vomiting and frequent urination)

Pharmaceutical care for high-risk and special groups-Nursing Mothers

- Breast-feeding mothers are also faced with difficult choices when selecting nonprescription medications.
- **Pharmacists** can provide the following recommendations to help avoid problems in women who are breast-feeding:
 1. Use nonpharmacologic therapy if possible.
 2. Take medications immediately after nursing or before the infant's longest sleep period.
 3. Avoid recommending any medications that are extra-strength, maximum-strength or long-acting.
 4. Avoid recommending combination products.
 5. Counsel about potential side effects that could occur in the child.

Nursing Mothers

Nonprescription medications that are usually considered compatible with breast-feeding include the following^{46,50}:

- Analgesics: acetaminophen, ibuprofen, naproxen, and ketoprofen
- Antacids
- Antidiarrheals: kaolin-pectin, attapulgite, and loperamide
- Antihistamines: brompheniramine, chlorpheniramine, diphenhydramine, and triprolidine
- Antisecretory agents: cimetidine, famotidine, ranitidine, and nizatidine
- Cough preparations: dextromethorphan
- Cromolyn sodium
- Decongestants: phenylephrine and pseudoephedrine
- Fluoride
- Laxatives: bran type, bulk-forming type, docusate, glycerin suppositories, magnesium hydroxide, and senna
- Vitamins

Managing minor ailments in the community pharmacy



Patient presentation

- Members of the public present to pharmacists and their staff in a number of ways, which include:
 1. Requesting advice about symptoms and appropriate treatment.
 2. Asking to purchase a named medicine.
 3. Requiring general health advice (e.g. about dietary supplements).
 4. Asking about effects/symptoms perceived to relate to prescribed medicines.

Role and responsibility of pharmacist

1. Differentiation between minor and more serious symptoms
2. Effective communication: Listening skills & Questioning skills
3. Treatment choices based on evidence of effectiveness
4. Role model & educator: the ability to pass these skills on by acting as a role model for other pharmacy staff

Working in partnership with patients

- Any person seeking advice about symptoms is considered as patient.
- Pharmacists are skilled and knowledgeable about medicines and about the likely causes of illness but **patients are not blank sheets:**
 1. May have experienced the **same or a similar condition in the past**
 2. May have **tried different treatments already**
 3. Will have **their own ideas about possible causes**
 4. May **have preferences for certain treatment approaches**
 5. Will **have views about different sorts of treatments**

Responding to a request of a named product

- Consider if the person making the request might be an expert?!
 - Expert user is someone who has used the medicine before for the same or a similar condition and is familiar with it.
- While pharmacists and their staff need to ensure that the requested medicine is appropriate, they also need to bear in mind the previous knowledge and experience of the purchaser. So:
 - Briefly explain why questions are needed?
 - Fewer questions are normally needed when customers request a named medicine that they have used before.

Responding to a request for help with symptoms

**Information
gathering**

**Decision
making**

Treatment

Outcome

1- Information gathering

- Information gathering is to develop rapport, listen and question to obtain information
- The process should start with questions and perhaps an explanation of why it is necessary to ask personal questions.

2- Decision making

- Community pharmacists have developed procedures for information gathering when responding to requests for advice that identify when the presenting problem can be managed within the pharmacy and when referral for medical advice is needed.
- **Referral?**

The possible reasons for referral for further advice include the following:

- Unknown cause for symptoms
- Incomplete information (e.g. an ear condition where the ear has not been examined)
- Duration or recurrence of symptoms
- Potential need for a prescription-only medicine

As a general rule, pharmacist should consider referring the patient to the doctor:

- Long duration of symptoms
- Recurring or worsening problems
- Failed medication (one or more appropriate medicines used already, without improvement)
- Suspected adverse drug reactions (to prescription or OTC medicine)
- Red flag signs and symptoms

Examples of Red flag symptoms

- Bleeding
- Signs and symptoms of infection (fever, pus, swelling)
- Loss of appetite or weight without reason
- Severe pain

3- Treatment

- The pharmacist's background in pharmacology, therapeutics and pharmaceuticals gives a sound base on which to make logical treatment choices based on the individual patient's need.
- In addition to the effectiveness of the active ingredients included in the product, the pharmacist will need to consider potential interactions, cautions, contraindications and adverse reaction profile of each constituent.

Pharmacists should be aware of!!

- Drug interactions:
 - OTC drugs may **worsen existing medical conditions or interact** with prescription medications.
- Abuse or misuse of OTC drugs
- Hidden ingredients in OTC drugs

4- Outcome

- Pharmacist should advise the patient what action to take if the symptoms do not improve
- **TIMESCALE!!**

PATIENT CONSULTATION



Structuring the consultation

- It is very useful to adopt a framework to help structure the consultation.
- Pharmacists need to develop a method of information seeking that works for them.
- 1st build rapport!!

W – Who is the patient and what are the symptoms?

H – How long have the symptoms been present?

A – Action taken?

M – Medication being taken?

Patient

- Confirm identity

Drug

- Name
- Strength
- Indication

Directions

- Route
- Frequency
- Duration
- Missed doses
- Storage

Precautions

- Adverse effects
- Food & drug interactions
- Contraindications
- Steps to take if any of the above are encountered

Monitoring

- How to monitor response to therapy
- Expected therapeutic outcomes
- When to seek medical attention
- Refill information
- Any other information specific to drug/patient

Pharmacist's role in nonprescription drug therapy

- In the initial encounter with a patient who is seeking assistance with nonprescription drug, the pharmacist should:
 1. **Assess**, by interview and observation, the patient's physical complaint/ symptoms.
 2. **Differentiate** self-treatable conditions from those requiring a physician's intervention.
 3. **Advise** and counsel on **the proper course of action** (no drug treatment, self-treatment with nonprescription medications, or referral to a physician).
 4. **Advise** the patient on the **outcome** of the selected course of action.
 5. **Assure** the patient that the desired **therapeutic outcome can be achieved if nonprescription medications are taken as directed** on the label.