Clinical Pharmacy I

Introduction to community pharmacy

Background

1- Community pharmacists are the most accessible healthcare professional, where no appointment is needed to council a pharmacist and the patient can receive a free advice anywhere without long waiting times at clinics or at other health facilities.

2- Medications include Over-The-Counter medications (OTC) as well as prescription only medications (POM). Nonprescription (or OTC) products are a group of pharmaceuticals considered to be sufficiently safe for use without the intervention of a physician.

Note: in UK. They refer to prescribed medicines as prescription-only medicines (POMs), while medicines provided by a pharmacy without a prescription but under the supervision of pharmacists are under the **"P"** classification. In addition, medicines sold without a pharmacist's supervision (e.g. Paracetamol and ibuprofen) classified as **General Sale List (GSL)** so they can be sold anywhere, such as supermarkets).

3. Because over-the-counter medications are used so frequently. It is important to know the differences between prescription and over-the-counter medications

Table 1: differences between prescription and over-the-counter medications

POM medications	OTC medications
Require a **written order or prescription** from a physician, dentist, or nurse practitioner.	Can be bought **without a prescription.**
Are prescribed for the treatment of a **minor or major** medical problem.	Are intended for relief of **minor ailments.**
Are usually **more powerful** and have more side effects than OTC medications.	Are considered **safe** if warnings and directions are followed.

4-For pharmacists to safely and effectively manage minor ailments requires considerable knowledge **(about the diseases and their clinical signs and symptoms) and skill (mainly communication skills).**

The switch of prescription -only –medicine (POM) to OTC status.

The availability of drugs over the counter varies from country to country. Generally drugs will be accorded OTC status if they fulfill various criteria:

1-The condition for which they are used can be reliably self-diagnosed.

2-Where there is no evidence of irreversible or serious adverse reactions.

3-Where their use does not require medical supervision or monitoring by a doctor.

Year	Table 2: History of switching from POM to OTC Examples
1983	Oral ibuprofen, **Loperamide**.
1991	Nicotine gum.
1992	Vaginal imidazoles, Nicotine patches.
1994	H2 antagonists , Minoxidil , Beclomethasone nasal spray.
2001	Emergency hormonal contraceptive.
2004	Omeprazole, **Simvastatin***.
2005	Chloramphenicol eye drop.
2006	Sumatriptan.
2010	**Tamsulosin**.
2013	FDA approved Oxybutynin transdermal patch for women with **of** overactive bladder (OAB).
2014	Nexium 24 HR (esomeprazole magnesium)
2014	The FDA has approved **adapalene** (a **retinoid-like drug**) (Differin® Gel 0.1%) for OTC use. It is the first **retinoid-based acne** treatment to be made available OTC.

***Simvastatin** represents a milestone in the deregulation of drugs to OTC status, in that it is the first drug licensed to prevent serious chronic condition

Note: when certain drug being OTC, not means that it is OTC in all strengths, in all dosage forms, for all indications, for all ages, in all countries, and in the same maximum dose or duration as when it is use by Rx (as POM) **(table 3)**

	Examples
Not in all **strengths**	Omeprazole 10 and 20 mg are OTC while 40 mg is POM
Not in all **dosage forms**	Omeprazole tablet and capsule are OTC while injection is POM
Not for all **indications**	Omeprazole is OTC for gastro-esophageal reflux disease (GERD) while for ulcer it is POM
Not for all **ages**	Omeprazole is OTC for adults over 18 years. However, it can be used by Rx (as POM) below this age.
Not in all **countries**	Simvastatin (10 mg tablet) is OTC in UK but not in USA, Canada…
The **maximum dose** and **duration** of the drug may be lower than that allowed with its POM use	The max. Daily dose for OTC Omeprazole is 20 mg for max. 4 weeks. However, larger doses for longer duration are allowed with its POM use.

Note: the process of switching may occur in reverse way (i.e. from OTC to POM). The UK has had two reclassifications return to POM (domperidone and oral diclofenac) due to cardiac risks.

Drug	**Year of reverse switching**	**Reason**
Domperidone (Motilium)	Reclassified from OTC to POM in 2014 in **UK**	Studies found that domperidone was associated with a small increased risk of serious cardiac side effects including QT-prolongation, **arrhythmia** and sudden death.
Diclofenac tablets	Reclassified from OTC to POM in 2015 in **UK**	In 2013, a Europe-wide review concluded that systemic diclofenac is associated with a small increased risk of arterial **thromboembolic events**, similar to that of COX-2 inhibitors particularly if used **at high doses** and for **long- term** treatment. [Cyclo-oxygenase-2 selective inhibitors, Diclofenac (150 mg daily) and ibuprofen (2.4 g daily) are associated with an increased risk of thrombotic events]

Note: Trials in UK to switch some oral antibiotics to OTC (Trimethoprim and Nitrofurantoin to treat uncomplicated cystitis in women) were ultimately withdrawn due to concerns over increasing antibiotic resistance.

Responding to symptoms in Community pharmacy

Responding to symptoms is a major activity for the community pharmacist. Many customers visit the community pharmacies each day with various symptoms for which they are seeking advice. This requires a **greater focus from the pharmacists on illness management, rather than on product selling**.

Pharmacists will consider 1 of 3 recommendations during each encounter involving symptom presentation:

1. Provide assurance that drug therapy is unnecessary.
2. Suggest **treatment with non-drug measures, OTCs, or both.**
3. **Refer the patient to appropriate medical personnel.**

As a general rule, the following indicate a higher risk of a serious condition and should make the pharmacist consider referring the patient to the doctor:

1-Long duration of symptoms.

2-Recurring or worsening problems.

3-Severe symptoms.

4-Failed medication (one or more appropriate medicines used already, without improvement).

5-Suspected adverse drug reactions (to prescription or OTC medicine).

6-Danger symptoms (Blood in the sputum, vomit, urine or faeces would be examples of such symptoms, as would unexplained weight loss).

Getting information from the patient:

The following steps highlight the key considerations you should think about when someone asks for your advice (as a pharmacist) about a particular symptom or condition they have.

1-Picking up on non-verbal cues:

Assessment of the patient begins the moment the patient enters the pharmacy and this 'first impression' can be very helpful in giving you clues to their state of health. For example, does the patient look well or poorly? For people who appear in discomfort or look visibly poorly, this might influence your decision to treat or refer.

2-Questioning:

Arriving at a diagnosis is a complex process. In medicine it is based on three kinds of information: patient history; physical examination; and the results of investigations. Currently, physical examination and using diagnostic tests are rarely used in community pharmacy practice. Pharmacists rely almost exclusively on questioning patients when deciding whether to offer treatment or perhaps refer the patient for further evaluation.

Studies have shown that an accurate patient history (gained from asking questions alone) is a powerful diagnostic tool. The ability to ask good questions to gain the appropriate information is therefore critical.

Acronyms

Acronyms have been developed to help pharmacists remember which questions should be asked. **WHAM** is the best known and simplest acronym to remember and has been advocated by many as a useful tool in gaining information from patients.

W–Who is the patient and **What** are the symptoms?

H–How long have the symptoms been present?

A–Action taken? (Any action taken by the patient should be established, including the use of any medication to treat the symptoms).

M – Medication being taken? There are four obvious reasons for this:

A medicine may **be causing** the symptoms

A medicine may **indicate a disease state the patients have.**

The patient may already be taking a medicine the pharmacist is about to recommend and which is **not providing relief.**

Medications that are recommended may **interact** with existing treatment

1. **Outcomes from the consultation:**

The final step in prescribing for minor ailments is telling the patient what course of action you feel is most appropriate. This could be **referral** to another healthcare professional, giving **advice** or supplying a **product**.

A-Treatment and advice:

For many therapeutic groups there is a wide variety of products available, often in various combinations. The pharmacist should take into account the efficacy, potential side-effects, interactions, cautions and contraindications.

When selecting a product, **the patient's needs** should be borne in mind. Factors such as prior use, formulation and dosage regimens should be considered. For example, antacids are available in both tablets and liquid form. Liquids tend to have a quicker onset of action than tablets but can be inconvenient for a patient to carry around with them or take to work.

Non-drug treatment should also be offered where appropriate. For example, advice on increasing dietary fiber and fluids is an essential part of the management of conditions such as constipation and hemorrhoids.

B-Timescales:

One of the key things is telling the patient what **action to take if the symptoms do not improve.** Here, a defined treatment timescale should be used **(this is the length of time for which the problem might be treated before the patient sees the doctor).**

The timescales given to each condition can vary.(The patient should seek medical attention if the cough does not improve in 7-10 days. While adult patient with diarrhea seek medical attention if the diarrhea does not improve in 2 days).

Children and the elderly

These two patient groups have the highest usage of medicines per person compared with anyone else. Care is needed in assessing the severity of their symptoms as both groups can suffer from complications. For example, the risk of dehydration is greater in children with fever or the elderly with diarrhea.

Children should be offered sugar-free formulations to minimize dental decay and elderly people often have difficulty in swallowing solid dose formulations. It is also likely that the majority of elderly patients will be taking other medications for chronic disease and the possibility of OTC-POM interactions should be considered.

Pregnancy

The potential for OTC medicines to cause teratogenetic effects is real. The safest option is to avoid taking medication during pregnancy, especially in the first trimester. Many OTC medicines are not licensed for use in pregnancy and breastfeeding because the manufacturer has no safety data or it is a restriction on their availability OTC.

Table 4: examples of some OTC Medicines to be avoided during pregnancy

Medicines	Advice in pregnancy
Antihistamines - non-sedating	Manufacturers advise avoidance as limited human trial data, but animal data suggest low risk
Fluconazole	Avoid
Systemic sympathomimetics	Avoid in first trimester as mild fetal malformations have been reported
Minoxidil (e.g. Regaine)	Avoid
Selenium (e.g. Selsun)	Manufacturers advise avoidance

Interactions of OTC medicines with other drugs: Medicines that are available for sale to the public are relatively safe. However, there are some important drug-drug interactions to be aware of when recommending OTC medicines. These are listed in Table 5.

Table 5: Some examples of interactions of OTC drugs

Medicine	Possible interactions	Outcome
Antihistamines – sedating	Opioid analgesics,anxiolytics, hypnotics and antidepressants	Increased sedation
Antacids (containing Ca, Mg, and AL)	Tetracyclines, quinolones, ACE inhibitors	Decreased absorption
Fluconazole	Anticoagulants Rifampicin Atorvastatin	Enhanced anticoagulant effect Decreases fluconazole levels Increased atorvastatin levels that can lead to muscle pain/myopathy .
Systemic sympathomimetics	Beta-blockers	Antagonism of antihypertensive effect

- **Evidence-based medicine (EBM) and over-the-counter (OTC) drugs**

1. Evidence-based medicine (EBM) emphasizes the use of evidence from well designed and conducted research in healthcare decision-making.
2. Although evidence-based medicine (EBM) is widely used for prescribed drugs**, it is not currently utilized for OTC medicines in community pharmacies.**
3. With regard to efficacy, pharmacists should be aware that **many OTC medicines have little or no evidence base**. **Therefore, products with proven efficacy should constitute first-line treatment.** Community pharmacists should stop selling over-the-counter (OTC) medicines that have little evidence of efficacy if they want to ensure the best treatment for patients.
4. The OTC products sold in pharmacies can be split into three categories.

A-The products for which **scientific evidence is lacking** like:

اللاصقة السحرية, سوار ابن سينا

B-The second category is OTC medicines with a basis in science but which lack clear evidence of effectiveness. One example is the use of cough medicines (drug combinations can be illogical such as an expectorant with a cough suppressant).

Systematic reviews of **cough medicines show a lack of effectiveness**. Although products in the second category may often be requested by the public, certainly, the lack of evidence of effectiveness must be communicated clearly to patients.

Cyproheptadine has been widely used as an appetite stimulant, but in **the long-term appears to have little value in producing weight gain and such use is no longer generally recommended**. There has been concern that cyproheptadine was being promoted and used inappropriately as an appetite stimulant in some developing countries

C-In the third group are OTC medicines for **which there is clear evidence of effectiveness**, and which can be sold with confidence. Many of these have been used for many years and have data to support their use, such as antifungal creams, painkillers, triptans, and chloramphenicol eye drops.

Current situation in Iraq:

- In many countries including Iraq (**which contain a huge number of community pharmacy)** it was found that in many cases the Iraqi pharmacist was **not asking enough or appropriate questions** and therefore had **insufficient information t**o advice optimally the patient about their symptoms.
- It was also found that the pharmacists do not employ a safe and structured approach when responding to patients' symptoms and they **fail to differentiate between a symptom that might suggest a more serious pathology or one which can be easily managed with an OTC product.**