

MIRACLE Academy

قال تعالى (يَرْفَعُ اللَّهُ الَّذِينَ آمَنُوا مِنْكُمْ وَالَّذِينَ أُوتُوا الْعِلْمَ دَرَجَاتٍ)

تفريغ OTC
زميلتكم أنفال النعيمات



لجان الدفعات

OTC medications & The Practitioner's Role in Self Care

Non-Prescription Drugs and Parapharmaceuticals

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أي شيء عنده **X** يكون مو مطلوب حفظه
T/F: true/false question

Brief History

- In 1906^x, 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

مضام الأروية
كانت تنهرف
بدون وصفة
طبية.

هاب المواد كانت موجودة
في بعض الأروية القى تباع
بدون وصفة طبية بدون علم
المرضى بوجودها.



Brief History

- **Durham-Humphrey Amendment** ^{تعديل} of 1951^x
- 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.

القانون
الذي يميز
بين
الأدوية التي
بوصفة والأدوية
التي بدون وصفة.



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.

* في كثير أدوية خائفة برا الأردن
تتباع أونلاين زي ال Herbal products
مابدها و هنته ، بعض ال vitamins, supplements ,
minerals كلها هتعب (OTC)

* سألت سؤال : ليه بنشوف زياد ال Consumption على ال Self-medication شو بتوقعوا ؟

* زيادة ال population .

* كمان زيادة ال Elderly population

مع معظم كبار السن ياخدوا Chronic medications للعنقد ، للسكرب ، للقلب لكن برهنوا استعمالهم لـ OTC products كمسكنات عم بزيد .

* وبعنوف فئه ما عندهم تأمين طبي بشوفوا انه بدهم يوفروا فلوسهم بدل ما يروحوا على دكانة (واملات روحة ورجعة ، كسفية ، اشترى الدواء) لا ، بوفرهم وبيع على هيدلثي بستشير .

* كمان من ناحية توفير وقت
(اروح على مستشفى ، وأخيل واقف على الدور) لا ، بروح على هيدلثي .

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.

كبار السن

الأطباء أو مقدمي الرعاية الصحية

بعض مشاهد
شعبية ومعدودية
الوصول إلى الأطباء
كثيرا ما صارت تعتمد
على الحالات ومنهج
الأدوية

نفس المعنى

(ناس ما عندهم تأمين)



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.

← حب یہ جو لانا؟!
لأنه متأكدین انه آمن - safe
وفعال - effective.



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

لازم أسأل حالي (3) أسئلة

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?
هل المريض بقدر يستخبر حاله أولاً، وحقق لو بقدر انتخذ واعطى معه بالأسئلة ممكن تشخيصه لنفسه يكون غلط.
2. Can the clinically abnormal condition be successfully **self-treated**?
Because it's a minor element (Not severe Not complicated) like dandruff (قشرة), mouth ulcer ...
3. Is the self-treatment product **safe and effective** for consumer use under conditions of actual use?
هل هو آمن وفعال

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

* هاي السلايد بتحكى عن ليه
زاد استهلاك ال OTC وال Rx
عنا بالذريعت.

- OTC consumption is estimated to have reached USD77.8 million in 2018, increasing by a CAGR of 7.8% from USD53.5 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.

"Rx"

- Jordan's prescribed consumption is estimated at USD181.5 million in 2018, representing 70% of overall consumption⁵¹. This high percentage is due to 87% of the Jordanian population holding health insurance⁵² and a significant proportion of those have multiple insurances^{1, 21, 11}

Jordanian population awareness about OTC medications

دراسة قامت بها دكتورة هيدلانية في جامعة الازراء بال 2020 عن وعي الشعب الأردني عن منتجات ال OTC وما هي أكثر المنتجات المستخدمة شهوياً.

Most commonly used OTC product (N (%))



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

1

- **Safety** + the drug is safe in that it has a wide therapeutic index → (For ex: we cannot switch digoxin, or warfarin from Rx to OTC)
 - Which is a Relative matter.
 - benefits outweigh risks.
 - the potential for misuse and abuse is low.

(Reading) * I want the medication to be used as an OTC Product so it should have the same indication as the prescribed drug before, to be used for an easily diagnosed conditions & for easily self-treated, controlled conditions

2

- **Ease of diagnosis and treatment.**

3

- **Proper Labeling.**

↔ However, not all patients read the labels, even when the drug is properly labeled like when the patient chooses what he wants to read → مثلاً ما يقرأ الاستخدام وبقراءة الآثار الجانبية (1)

The likelihood of improper non-prescription drug use is due to misreading of the product label (By the patient)

Sometimes due to language barrier (2) or (3)

+ some people do not care → مثلاً هيك اجنا لادزم نساألهم إذا كندهم فحسن مثلك أو لا