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TOPIC
**OPTIMIZATION OF PHARMACEUTICAL PROVISION OF THE
POPULATION IN THE DISPENSING OF OTC MEDICATIONS.**

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ABSTRACT

The master's thesis analyzes the current scientific literature concerning the role of OTC medications as the basis for the concept of self-medication, highlighting their importance in managing minor conditions, reducing economic burden on healthcare systems, and promoting responsible self-medication.

A comparative analysis of OTC antihistamines market in Ukraine and Morocco is conducted to underline market differences, drivers of drug choices, and the future of the Moroccan and Ukrainian pharmaceutical industries. Also, the study emphasizes the impact of marketing and advertising strategies on the promotion and use of OTC medicines. Additionally, to optimization strategies for OTC antihistamines dispensing process, such as, Optimization guide that consists of 3 main stages which aim to improve the use of OTC medicines and reduces the risks of self-medication, Integrated artificial intelligence AI into pharmacy practice, and the impact of automated dispensing. Besides, the study provides the Standard Operating procedure for dispensing OTC medicines in retail pharmacies, they are organized by national health care policies, and regulatory authorities. Each country has its own specific standards for dispensing OTC medicines according to current laws and regulations. These standards aim to ensure the safe, effective, and Good dispensing practice of OTC medicines to the public, while improving appropriate self-medication and minimizing risks or adverse effects.

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LIST OF ABBREVIATIONS

OTC- Over the counter drugs

Rx- prescription drug

WHO- world health organization

FDA- food and drug administration

ATC- Anatomical Therapeutic chemical

CAGR- compound annual growth rate

AD- atopic dermatitis

AR- allergic rhinitis

CMSP- chronic musculoskeletal pain

ASPR- age standardized prevalence rate

INN- international non-propriety name

GDP- good dispensing process

Introduction

Relevance of the topic: Over the counter medications are playing an increasingly crucial role in modern healthcare by promoting self-care, managing a broad spectrum of minor illnesses, and reducing the burden on healthcare systems. Since they are safe, effective, and suitable for use without medical prescription or health professional's intervention, World health organization associates closely their use with the concept of self-medication and highlights the importance of responsible self-medication as one of the self-care interventions [6]. Among the wide range of OTC medications used in self-medication, antihistamines are noted as the most commonly used medicines in the treatment of seasonal allergies and related conditions. They are the largest class of medications which consist of more than 44 different varieties of antihistamines used Worldwide [44].

The frequent use of this class of drug emphasizes the importance of optimizing the dispensing process to improve accessibility, ensure appropriate use, and reduce the risks of self-medication.

The goal of research was to study the pharmaceutical provision of OTC antihistamines to patients with allergy in both countries Ukraine and Morocco.

To achieve this goal, the following tasks were formulated:

- To study statistical data literature concerning allergic diseases, and the use of antihistamines
- To conduct a comparative analysis of the OTC antihistamines market in both countries
- To study the current dispensing processes and suggest strategies for optimizing the pharmaceutical provision of OTC medicines

Research methods: comparison and systematic analysis, statistical, generalized and theoretical analysis of scientific literature.

Object of research were the following: relevant scientific literature, the State Register of Medicinal products of Ukraine, the Moroccan agency for medicines and health products (AMMPS).

Practical significance of the research: By analyzing the regulatory approaches and market characteristics of OTC antihistamines in Ukraine and Morocco, the study provides best practices that can be adapted to optimize the dispensing process. The findings may be useful for pharmacists aiming to improve the self-medication process and ensure the appropriate use of OTC drugs. Moreover, the provided optimization strategies can lead to better patient results, and good pharmaceutical service quality.

Approbation of work results.

CHAPTER1: REGULATION OF OTC MEDICATION DISPENSING ON THE NATIONAL LEVEL (literature review)

1-1 OTC Medications as the basis for the concept of responsible self-Medication

Responsible self-medication is a process by which individuals treat their minor illnesses and conditions that are either self-diagnosable or have been previously diagnosed by a physician using nonprescription, safe, high quality medications [1]. World health organization sets 3 basic criteria that should a medicinal product fulfills to be intended for self-medication [2]. Firstly, the active ingredient at recommended dose should have low toxicity, it should present no risks like genotoxic and carcinogenic properties or other risks related to human use unless these risks can be clearly addressed through labelling.

Secondly, the intended use of the medicinal product should be suitable for self-medication and doesn't defer diagnosis or treatment of a condition needing doctor's intervention[2].

Thirdly, the medicine should not have characteristics that make it unacceptable, or undesirable meaning it would therefore not be one that carries severe adverse effects and high risks of dependence and abuse, or present other limitations such as interactions with commonly used medicines or food that could lead to serious outcomes. Also, it must be used under the supervision of a health professional [2].

In developed countries, the concept of responsible self-medication is being further developed. Thus, in the United States, telemedicine allows receiving consultations and monitoring of patients remotely, especially for chronic diseases. A variety of applications and communication technologies encourage self-medication and facilitate health controlling, integrated with electronic health records [3].

In Canada , telemedicine has a potential effect to improve the health care system and ease of access to care by creating technology platforms, mobile devices which

allow patients to perform medical tests and communicate with health care professionals their conditions and self-medicate themselves effectively [4]. In its turn, the European Union has taken efforts to increase the use of telemedicine in Europe and make it accessible to every European as well as creating online resources for self-medication and investing more than € 500 million in research funding on e-health tools development [5].

WHO points out self-medication as one of the self-care interventions which aim to encourage individuals and communities to manage their health and well-being. And it associates the self-medication with the use of Over the counter (OTC) drugs since they are sold directly to the patient without prescription and they are generally considered safe and suitable for use without a health professional's intervention [6]. According to the Who Anatomical Therapeutic chemical (ATC) classification OTC drugs are categorized into ten groups: analgesics, laxatives, anti-thrombotic agents, antacids, cough and cold preparations, antihistamines, dermatological products, throat preparations, nasal preparations, and antidiarrheal [7].

Over the counter medicines are characterized by efficacy and safety. Medicines can be available over the counter if they are effective and safe for use. Many medicines have side effects but in the case of OTC the potential benefit must exceed the potential risk [8]. They are known for their rapid accessibility, cost effectiveness and availability, the patient can treat minor conditions (e.g. sharp headache, asthma attack or allergic rhinitis ..) only by getting an OTC drug from the pharmacy that can improve his condition .OTC medicines are at a lower price than prescription medicines as well as the consumer saves money from fewer doctor visits. Also, they are available for each patient who can self-diagnose his minor ailments for example in case of allergic rhinitis, the patient can treat the symptoms by OTC antihistamines without a medical consultation [8].

OTC medications are commonly used in our society by all age groups. In Morocco, a cross-sectional observational study was conducted by M. Oirdi [9] shows that Self-medication by gender: 64.3% females and 35.6% males. By age group 68% between 20 to 60 years, 17% over 60 years of age, and 15% under 20 years old. As for the intended user of the medication, 79% was for the patient themselves, 16% for their children, and 5% for others. And, the most common therapeutic classes used in self-medication included mucolytic, analgesics/antipyretics, antibiotics, contraceptives, and anti-inflammatory drugs. In the United States, consumers spend almost \$2billion per year on cough and cold remedies alone [10]. These studies show that OTC drugs are very consumed by all the age groups and the consumers assume the responsibility of self-medication . Several Studies conducted worldwide have shown a large use of OTC analgesics, with 20% and 30% of patients reporting pain, depending on the countries [11]. In a university in south Africa, a study was performed reveals the high prevalence of analgesic use. 80% of the respondents reported self-medicating with analgesics to manage their chronic musculoskeletal pain (CMSP), and the point prevalence was 57%. A larger proportion of females, 86%, self-medicated with analgesics but males only 69%. The most used analgesics were found to be nonsteroidal anti-inflammatory drugs (NSAIDS) 70%, followed by paracetamol 58%, and combination analgesics [12]. Pain is the most common condition associated with self-medication.

In many European countries, the sale of OTC medicines is permitted only in community pharmacies under the supervision of a pharmacist (pharmacy only medicines), or they are sold in both pharmacies and non-pharmacy retail outlets such as supermarkets, gas stations...In some cases, OTC medicines are available for sale only in retail outlets [13]. Therefore, the availability of pharmacists to evaluate patient's condition, help select the appropriate OTC medication makes the pharmacy more attractive to consumers for choosing their medications, which

is a powerful marketing tool. Since they are widely available and often contain multiple active ingredients in various combinations, it is necessary to use them safely [14].

The misuse and abuse of OTC medicines in self-medication

The U.S. Food and Drug Administration (FDA) explains the importance of reading the label of all non-prescription medicines before using them because it includes important directions and information that the patient must follow to benefit from the medical product in a safe, effective way and prevent all the risks associated with self-medication [15]. FDA regulations ensure that the labels on all OTC medicines, from sunscreen to cough syrup-are in a similar format. This includes presenting information in the same order in a similar style and in language that is easily understood [15].

The misuse and abuse in self-medication relate to not respecting and following these instructions written on the label or the directions of a health professional. When a medicine is used for medicinal purposes but in an improper way, such as for an extended length of time, or at increased dosage it is regarded as misuse [16]. However, some drugs can be abused because of continuous or intermittent excessive drug use or for purposes other than indications of the medicine [17], some antihistamines may be abused to feel their mind-altering effect and laxatives to achieve weight loss [16]. Certain anabolic steroids are taken for a long period of time to develop muscle mass. For example, Dextromethorphan is widely used in many countries of the world. It's found that the abuse of this medication or the increase of dosage may cause toxicity, psychosis as well as withdrawal syndrome. Also, Diphenhydramine, OTC analgesics, and OTC hypnotics are drugs that can be abused and may cause serious side effects [18].

Self-medication with OTC has great benefits to individuals as well as community [2,19]. From a societal standpoint, patient can choose the suitable medicines for their symptoms or conditions which do not need doctor's consultation, help to

develop autonomy in preventing or alleviating minor symptoms and give them the opportunity to take responsibility of managing their health conditions as a basis of self-care encouragement [20].

From a financial standpoint, self-medication saves scarce medical resources from being wasted on minor conditions, public health expenditure may then be redirected for treating more serious conditions (María Esperanza Drug Safety, 2010) in addition, it helps reducing or avoiding medical consultations and lowers the costs of health care programs. A study was conducted in 2010 in the USA shows that consumers and taxpayers will save nearly \$5.2 billion a year if they use over-the-counter medications more frequently and managed their health care better [21]. However, the self-medication has several risks as a result of the incorrect self-diagnosis, or choice of therapy, lack of knowledge of some specific characteristics of the medicine used, (e.g. route of administration, food and drug interactions, the adequate dose ,side effects). Also, failure to recognize that the same active substance is present in different trademarks product and if the patient takes 2 different trademark medicines with the same active ingredient it may lead to exceed the therapeutic dose. Moreover, the inappropriate storage conditions. At the community level, improper self-medication could lead to an increase in drug induced disease and public health spending [2].

In this case, self-medication with medicines may lead to serious conditions that are unnecessary. The pharmacist must explain to the patient when self-medication is possible and at what time the medical advice is needed. He should clearly advise the patient that he should immediately consult a doctor in the following cases: 1) if symptoms during self-medication do not disappear after 2-3 days; 2) if there are "threatening" symptoms. The pharmacist must warn the patient about it as part of his professional duty when dispensing medicines [86].

Role of pharmacists and national organizations in self-medication [1].

Role of pharmacists in self-medication :

The pharmacist can improve the self-medication by providing these services [1]:

As a communicator:

Through a clear communication with the patients, pharmacists can collect information about their patients' medical histories, guide them on how to take medicines and self-medicate safely, they must provide accurate information about medications and maintain patient confidentiality regarding their conditions [1].

As a quality drug supplier:

The pharmacist should ensure that the products sold are of the best quality [1].

A pharmacist as a trainee and a supervisor:

He should maintain a continuous process of learning and knowledge development. And, since they often work with non-pharmacist staff, they must ensure that the services provided by these assistants meet established practice standards[1] .

As collaborator

Pharmacists should build solid, high-quality working connections with different stakeholders such as, other health professionals, National professional organizations, the pharmaceutical industry Government agencies at both the local and national levels, Patients and the public [1].

As a member of the healthcare team:

The pharmacist should Participate in health screenings to identify health needs and individuals at risk within the community, assist with health promotion programs that focus on illness prevention and health issues. Provide counseling to patients to make appropriate choices concerning their health status [1].

The role of national organizations.

For effective health care services, self-medication protocols, reference materials, and training exercises must be adapted to domestic needs. It means adapting the

existing resources to the community's health infrastructure, cultural context, and local health concerns. At the same time, training and support activities for organizational members ensure that they possess the knowledge and skills necessary to provide quality care. Also, engagement in the process of curriculum development is necessary to ensure that the learning material indicates current best practices and meets the needs of future healthcare professionals. Additionally, encouraging all members to actively participate in teaching, both in academic and practice settings, a continuous learning and sharing of knowledge is essential, it benefits not only the people but also the greater healthcare system [1].

Monitoring safe self-medication and the future approaches:

The demand for self-care as well as the participation in healthcare decision-making has increased due to a variety of factors. These factors include socioeconomic considerations which are manifested in higher educational levels and easier access to information, that promote public awareness and then the increase of self-medication. Also, accessibility is important because consumers are choosing the ease of access to medications without having to wait in long lines at clinics or other healthcare facilities. In addition to other factors such as demographic, public health and environmental considerations [1].

Self-medication offers many benefits, but it also carries risks that could potentially result in death. To prevent the patient from these risks or minimize them, this requires a variety of approaches that are reflected in monitoring the products and patients.

A-Monitoring medicine:

OTC products are susceptible to abuse and misuse, as was previously mentioned. Patients must be guided regarding the proper dosage, the duration of treatment,

and any side effects of the medicine after a diagnosis. This will decrease any product's misuse.

The CSM in the UK and other like organizations throughout the world have received reports which indicate that ventricular arrhythmias, related to High dosages of these antihistamine medications administered either as a single treatment or in combination with other medications like erythromycin or ketoconazole, have led to death [22]. So, informing the patient about the adequate product's use is important.

However, in many countries, controlling drug abuse remains a challenge. As discussed previously, drug abuse is associated with inappropriate, excessive, or continued use of drugs. In the UK, drug abuse is a difficult problem to control because a pharmacy can regulate the quantity sold of a certain product to a particular patient, but this patient may go to the next pharmacies and purchase the same product [23]. To solve this problem and observe patterns of product abuse in their respective communities, some pharmacists operate a communication network whereby they share information about suspected abusers [16].

B-Monitoring patient:

Monitoring patient groups, especially the elderly because they are more susceptible to adverse medication events, according to a structured interview conducted in community pharmacies. Patients over 65 years old use frequently non-prescription drugs and the most used products were laxatives (11.5%), cough preparations (14.8%), and oral analgesics (17.5%) [24]. Pharmacists should focus on these patient groups, their medical history, and OTC medicines they take to avoid all kinds of drug interactions and overdoses of drugs and improve safe self-medication. Also, patients must ask questions about medicines, especially those sold in non-pharmacy stores, and share essential information with health care professionals to guarantee good self-medication [23]

The increase in the prevalence of self-medication depends primarily on the attitudes, actions of health care professionals toward the self-medication and consumer's knowledge of non-prescription drugs and how to use it [25].

Doctors must provide the patients by all the necessary information that will allow him to use the drug in a good way, he must discuss with his patient the indications, therapeutic dose, adverse reactions of the drug and advise him on self-medication and drug interactions. He must be a good listener to his patient and encourage him about the prior self-medication if it is done appropriately. Some patients are uncomfortable sharing their self-medication's details with their doctors because they think that many doctors are not excited about self-medication. So, doctors must change their attitudes and be receptive, accept new ideas and work together with patients to manage their health issues [25].

On the other hand, the increasing use of self-medication presents new difficulties for pharmacists. Increased sales offer greater profits, but over time, dispensing fees and the associated professional allowance will reduce. So, this could lower revenue and affect the survival of some pharmacies. More significantly, the role of professionals in guiding patients' choice of medication could be diminished unless a system is developed which rewards professional advice, instead of just dispensing of medications [25].

If doctors fail to respond to the challenges presented by large use of self-medication, patients may directly ask pharmacists for guidance instead. Which may lead to deterioration of the relation between the two professions.

So, the health care professionals must collaborate and help each other to guarantee that patients receive the best guidance concerning the diagnosis and the medication by increasing number of programs in which physicians and pharmacists collaborate to enhance patients' medication [25].

1-2 COMPARATIVE ANALYSIS OF OTC MEDICATION TURNOVER IN UKRAINE AND MOROCCO

1-2-1 The Transfer from (Rx) to the OTC drugs: The impact on circulation and dispensation of medicines

The concept of OTC is strongly embedded in social factors, and through this, it is connected to the broader concept of accessibility.

The transfer or "switch" of a product from the prescription (Rx) to the OTC category is primarily to make the product more accessible to consumers. Such transition requires clear evidence to support drug's safety and efficacy for use outside the supervision of a healthcare professional [26].

In the USA, such transfers are typical, and certain countries promote them since they benefit both consumers and manufacturers by expanding the choice of drugs for self-medication. For example, in the USA, the rate at which patients suffering from allergies and use over the counter (OTC) drugs increased to 75%, confirming the growing availability of affordable and convenient medicines to patients. The replacement of nicotine products into the category of OTC products shows an increase in sales of 150–200% in the first year alone. This transfer allowed hundreds of thousands of smokers to use products that would lead them to become healthier, and the social benefit was estimated at \$2 billion. Similarly, the transfer of heartburn drugs into over-the-counter medicines reduces doctor visits for prescription authorization, saves an average of \$174 per patient annually [27].

OTC drugs are one of the most profitable components of pharmaceutical production and sales, because the transfer of one prescription drug to the OTC category brings a significant amount of profit to a pharmaceutical company annually due to an increase in sales volumes [87]. But this transfer is done according to some rules established by the FDA.

The FDA points out the need to provide complete data that confirms the drug's efficacy and safety for self-medication without a medical prescription from a healthcare professional. To support an Rx-to-OTC switch, the company must submit data from randomized, controlled clinical trials submitted in the original New Drug Application (NDA) for the prescription drug, and the new trials to offer more verification of the safety and efficacy of the drug for over-the-counter use [28].

This process of transferring a drug from one category to another takes a long time, years of clinical and post-marketing surveillance [27].

Over the counter (OTC) medications are one of the primary reasons behind the transfer in healthcare responsibility. The state transfers a part of its financial burden and responsibility concerning the cost of healthcare to the drug manufacturers' shoulders. So, it allows manufacturers to take on the responsibility of dealing with some charges that initially were on the shoulders of the state or the healthcare professionals. These roles consist of determining appropriate drugs for conditions and patients whom they can treat, and ensuring that consumers have sufficient, reliable information concerning the safe and effective use of these products [26].

In Ukraine, the pharmaceutical market is divided equally between prescription and over the counter (OTC) medicines in value terms. However, in terms of volume, OTC medicines account for a share of nearly 70%, according to (Proxima Research's analytical research system Pharm standard/Pharm Xplorer). Physical availability and affordability of OTC medicines have enabled them to achieve such a high share, apart from performing a significant social function [26].

Ukraine remains the only country in Europe without a system of drug reimbursement, and therefore the responsibility to fund the drugs is on the patient's responsibility. Affordability of basic, essential medicines is one of the

most important criteria for the population, especially when there is no support from the state in the form of financing [26].

The dispensing process of drugs in Ukraine is entirely different. Patients are suffering from the lack of the reimbursement system. They must pay out of pocket for OTC and prescription medications which creates a financial burden on them [26].

On the other hand, Morocco has an established system of reimbursement that allows people to get paid for individual expenses. This system reduces the financial burden on people and promotes, facilitates the access to necessary services.

Medicines are reimbursed by the Mandatory Health Insurance and the supplementary coverage provided by Mutual Insurance Companies, as long as they are present in the list of reimbursed medicines as determined by the Minister of Health decree [29].

According to the first article of Decree 2.05-736, the reimbursement rate for medications varies between: 70% of the Public Sale Price (PPV) for all outpatient medications based on the generic drug price, if applicable (supplementary coverage adds another 16% to 20% supplement). Or, 100% based on the price of the generic medication where applicable, for medications associated with a chronic or expensive ailment reported to the CNOPS and for which the beneficiary has obtained an exemption from the co-payment [29].

1-2-2 Analysis of OTC sales in Ukraine and Morocco:

The OTC market is developing dynamically since every year new medicines are presented to the market. According to estimates, for the period 2021-2026. the market for OTC drugs in Europe will increase annually by an average of 4.19% and by 2026 will amount to USD 55.2 billion. against USD 41.5 billion [88]. And it is expected that the growth rate increases gradually until it achieves 8,5%

between 2022-2027 for so many reasons such as the introduction of new medicines, high level of market penetration in developing country, suitable regulatory framework and the switch from prescription drugs to OTC segment.

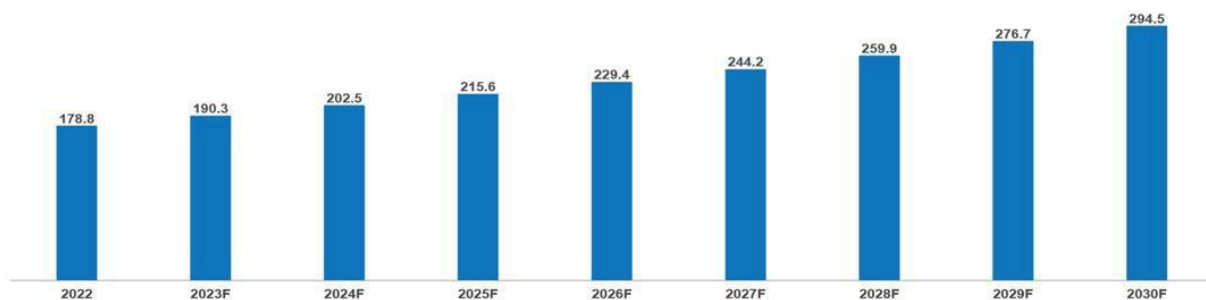
During the last several years, despite the unstable socio-economic situation in Ukraine, the domestic market's average annual growth is still 15-20%. In 2022, the consumption of over-the-counter drugs accounted for 57.3% in physical and 38.9% in monetary terms of the share of the pharmaceutical market in comparison with 63.2% and 42.5%, respectively, in 2016 [88].

According to Statista, OTC market in Ukraine will record a revenue of US\$1.51 billion in 2025 with a growth rate of 3.89% per year (CAGR) from the period 2025 to 2029. The leading category in the OTC pharma market is Analgesics, which is predicted to reach a market volume of US\$490.30 million in 2025. Further, online sales must account for 1.17% of the total revenue in the OTC medicine market by 2025. Growing awareness of self-medication as well as greater availability of various products are increasing in Ukraine, driving the higher demand for over-the-counter medicine [30].

In Morocco ,According to the Ministry of Industry and Trade, Morocco invests every year about 700 billion DHS, with a turnover of 14 to 15 billion DHS in 2022. Added to that, it has one of the most dynamic pharmaceutical industries in Africa and is ranked second on the continent after South Africa, sixth in the MENA area. 80% of the drug needs are covered locally. This is a market with great development potential including the OTC market [31].

The Morocco OTC drugs market was valued at US\$178.8 million in 2022 and is expected to grow at an annual growth rate CAGR of 6.44% during the forecast period of 2022-2030, reaching US\$294.5 million [32].

Morocco OTC Pharmaceuticals Market, 2022-2030 (\$Mn)
Market forecast to grow at a CAGR of 6.44%



The data presented is tentative & subject to change in final report.

insights 10

Fig1:Morocco OTC Pharmaceuticals Market,2022-2030

Source: Market research report (OTC) Pharmaceuticals Market Analysis. https://www.insights10.com/report/morocco-over-the-counter-otc-pharmaceuticals-market-analysis/?srsltid=AfmBOorvXQOw7zdfdwKap6dpJoK-xQEY3ZhGeV8TBITtzwzeP__FTz5O

Over the counter (OTC) drug markets are projected to grow during the forecast period due to a growing trend of individuals consuming such drugs for minor ailments and growing public awareness of general health issues and advancements in the pharmaceutical and healthcare industries are driving market demand for these medications.

Morocco is located at the crossroads of Europe and Africa, Therefore offering a favorable place for international companies to establish a platform for their North African operations. Giants in the pharmaceutical and over-the-counter industries like Pfizer, Mylan, ..have made significant investments in the country in recent years. Morocco's pharmaceutical and consumer healthcare industry is one of the fastest-growing industries in the Middle East and Africa, with a projected Compound Annual Growth Rate (CAGR) of 7.37% from 2025 to 2035, which would have it worth USD 5,99 billion by then [33].

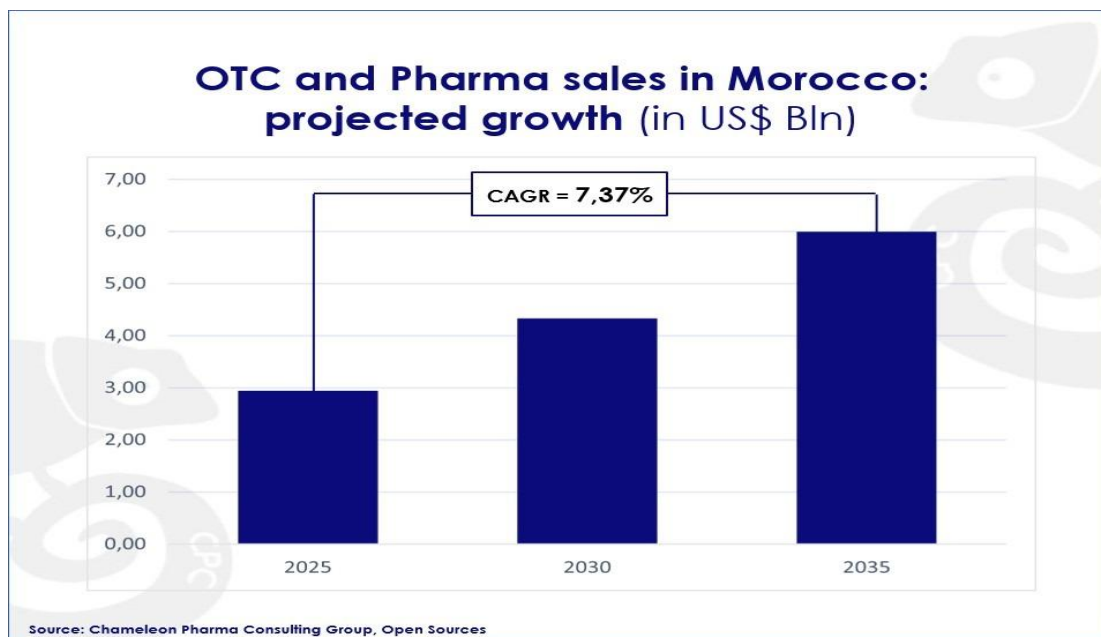


Fig2 : OTC and Pharma sales in Morocco

Source: Chameleon pharma consulting. <https://www.chameleon-pharma.com/exploring-moroccos-booming-otc-and-pharma-sector-trends-growth-and-potential>

The government has been actively optimizing the development of the pharmaceutical sector. The most important among the initiatives provided was the implementation of mandatory health insurance (AMO) for 22 million individuals by December 2022—approximately 75% of the nation's working-age adult population. In addition, the sector has also been making large investments in digital health to increase healthcare service availability, especially in rural areas [33].

1-3 Marketing and advertising OTC medicines

The increase in OTC turnover and sales requires a rise in OTC practice and demand. The large demand of over-the-counter products is due to the awareness of patients about self-medication, cost-effectiveness, large accessibility [34], marketing and advertising [35].

As we mentioned before the high prevalence in self-medication in some countries lead to the increase of demand for OTC products and consequently the increase in OTC turnover. Ease access to these products and their availability from non-

pharmacy retail outlets, like supermarket, gas stations in some countries lead to faster, convenient, less expensive access to these products for the rural population and the general community.

Marketing and advertising are among the driving factors for increasing the sales of OTC. Consumers can make decisions about the choice of their non-prescription medicines so, they are the focus of over-the-counter marketers [36].

The pharmaceutical marketers advertise and market otc products using digital marketing tool which is based on two components the marketing related to E commerce that is established under the activities of online pharmacies and the marketing associated with promotional and advertising goals that is conducted through digital platforms [34]. The marketing department remains as one of the main pillars due to its capacity to promote the sustainability of a company and produce short-and long-term sales [35].The pharmaceutical sector is among the highest sectors that spend on marketing, some pharmaceutical firms spend 30% on marketing [37].

In the United States, the Federal Trade Commission (FTC) is an agency that is responsible for regulating over the counter (OTC) drug advertising. United States federal law appealed that all advertising of such drugs must be reliable, and free from any false information. The FTC depends on three main principles to regulate advertisements and ensure compliance with the requirements. The advertiser must first prove that the information presented in the advertisements is valid and evident. Secondly, the FTC controls how the consumers perceive the advertisements to avoid any mistakes, falsification, or manipulation of information that would mislead the public. Thirdly, the FTC acts against anticompetitive or deceptive advertising practices that might harm consumers [27].

In addition, drug advertising is also controlled by a non-regulatory agency called the National Advertising Division (NAD). The NAD receives and reviews

complaints regarding advertising procedure and, based on review, determines whether the advertisement was done in good faith. If the NAD finds that the advertisement is misleading or includes any falsification, it transfers the case to the FTC or other concerned authorities. This also occurs when the advertiser fails to act on the NAD's recommendations for promoting the advertisement. Besides that, the NAD also carefully supervises the media to ensure that the claims presented about the medicinal products and services in ads are in accordance with the regulations, being accurate and protecting consumers from misinformation [27].

In Ukraine, the Ministry of Health of Ukraine established a law concerning advertising restrictions for medicines. The list of medicinal products prohibited for advertising, was created according to data from the State Register of Ukraine as of May 30, 2023 [38].

The new list includes 513 drugs, which is more than double the 240 drugs in the old one from 2012. Out of the 513 products, 270 medicines are listed because their INN or trade name and dosage form are the same as other medicines that have already been prohibited from advertising. The old list contains each medicine provided by a prescription's doctor, narcotics, precursors and psychotropic drugs, medicines that can lead to withdrawal syndrome after stopping the intake, drugs used for the treatment of a woman during pregnancy, lactation and for a child under 12 years, also, medicines that treat severe diseases such as cancers, insomnia, diabetes... are all prohibited for advertising [38].

The new list contains a column reporting the reasons why each drug cannot be advertised, but it lacks information about the registration certificate numbers or dates of registration of such drugs. However, it includes two issues:

Some of the banned drugs for advertising are also on the list of drugs allowed in the State Register. This is confusing to manufacturers of drugs, who do not know whether to follow the State Register or the new list. And the list, approved in July,

may be outdated, since the State Register is constantly updated with new registrations of drugs on a regular basis, but the list is updated only once a year [38].

This undermines the usefulness and validity of the list, especially since it is not always aligned with the current information held in the State Register. In addition, a new list of non-prescription medications permitted to be sold in Ukraine without a prescription was introduced in June 2023, but only those registered before April 10, 2023, are covered. This decreases the use of the list for those registered later than this date [38].

Morocco regulates the promotion of medicines, according to the law No.17.04. It establishes conditions for advertising. Pharmaceutical promotion must be truthful and not misleading to consumers as well as not impacting human health protection. Secondly, the drug must be presented clearly in the advertisement and marketed for its intended use, in the line with the approved marketing authorization file, also only approved drugs can be promoted. Concerning public advertising, it is permitted only for non-prescription drugs, non-reimbursable, or where advertising is not prohibited under the marketing authorization because of the potential harm to public health. Any public advertising for a product must, in advance, obtain an "advertising visa" from the concerned authority [39]. The visa is one-year valid and renewable as long as the approval to sell the product continues. The visa has a unique serial number that is associated with one or more media for advertising. In addition, any public Ad should be followed by a warning message and a call for consultation with a health professional in case of persistent symptoms [39].

Regarding, health professionals, who prescribe, dispense medicines, advertising is under specific regulations. They must submit a file containing information about the drug and anticipated promotional content to the concerned authority at least 15 days prior to distribution. The authority studies the files and makes

remarks. Any deficient or non-conforming information could lead to the suspension or withdrawal of advertising permits.

To ensure the promotion of drugs, drug companies may use the services of medical and pharmaceutical information agencies, representatives. Individuals involved in advertising activities need to have good scientific knowledge and this should be certified through diploma, title, or certificate approved by the administration through regulatory activities [39].

CONCLUSION 1

1-Self-medication with over the counter (OTC) drugs has increased in society, the primary reason being the numerous benefits offered by such activity. These benefits are minimal cost, cost-effectiveness in terms of affordability, and the easily accessible nature of OTC drugs. More individuals prefer easily accessible and quick solutions to health issues, with OTC drugs being a favorable option, as they allow patients to deal with their main care problems without doctor's intervention.

2-People tend to self-medicate and treat their minor illnesses with OTC medicines but it must be noted that even if the OTC medicines are safe and effective they must be used with caution and follow what is written in the package or label to avoid risks and achieve the desired function of the medication..

3-Individuals should prevent any misuse and abuse of these kind of drugs to benefit from a safe self-medication, and ask help for the health care professional for any information's misunderstanding because they play a substantial role for a good, safe self-medication.

4- Morocco and Ukraine have an increased growth of OTC drug turnover each year. This growth can be explained by various factors that include the prevalence of self-medication in both countries, and the increased level of awareness about OTC practice. Also, marketing strategy has been a stimulating factor in the increase of OTC sales, allowing pharmaceutical companies to expand their market share. Such strategies assure the continued success of the pharmaceutical firms as they respond to growing demand for accessible and cheap treatment.

CHAPTER 2: Analysis of the Moderns pharmaceutical market of antihistamines drugs in Morocco and Ukraine

2-1 Allergic Diseases and Antihistamine Use: A Comparative Study Between Morocco and Ukraine

Allergic diseases remain a significant worldwide concern today. Every person may experience an allergic condition that would be caused by food, drug, immune system dysfunction or other environmental factors. According to the World Health Organization (WHO), allergic diseases are reported as one of the main disorders that must be controlled in the 21st centuries [40].

Allergy is a hypersensitivity reaction which can be antibody-mediated known as IgE antibodies and cell-mediated. Antibody-mediated allergy is the most common hypersensitivity disease affecting more than 30% of the population [41].

When a foreign substance enters the body, the immune system is activated, so allergies are created. We refer to such substances as allergens. They consist of pet dander, pollen, bee stings, some foods, and medicines [42].

The immunologic mechanisms of allergy are similar, even though allergen molecules can be encountered by different routes, e.g., food allergy or allergy to an insect sting. The same symptoms may present in the nose, eyes, lungs, skin, or GI tract, depending on the method of exposure [42]. Patients who suffer from allergies experience some negative symptoms whenever they are exposed to the allergen. These symptoms are primarily caused by the release of histamine which is a crucial inflammatory mediator responsible for immunological cascade allergy diseases. Living with these symptoms, it may affect unfavorably patient's quality of life, energy, mental health even if he tries to avoid allergen exposure [42].

Allergic diseases are diagnosed through skin tests or blood tests that identify specific allergens that cause allergic reactions [43]. Once diagnosed, allergies are

controlled through avoidance of allergens, medications that inhibit the effect of histamine release from basophils and mast cells [43].

Antihistamines are medicines that treat allergic conditions. They are the largest class of medications for the treatment of these diseases and consists of more than 45 different varieties of antihistamines which are used Worldwide [44]. Antihistamines are classified into 2 generations: first generation and second generation. Each generation has its specific mechanism of action, pharmacology, and chemical structure [44].

Medicines of the first generation are hydrophobic substances, non-selective, they can cross the blood brain barrier (BBB), act on the central nervous system provoking a sedative effect. They have different indications such as allergy treatment, insomnia, motion sickness, nausea, vomiting. And they are administered orally and parenterally. However, the antihistamines of the 2nd generation show a good safety profile since they do not act on the central nervous system and treat allergic diseases. They are hydrophilic, selective, and only for oral administration. As first-generation Antihistamines can cross the blood-brain barrier and affect a variety of receptors, they must not be used for a long term for the reason of tachyphylaxis. So, second-generation is more effective in such situations [45].

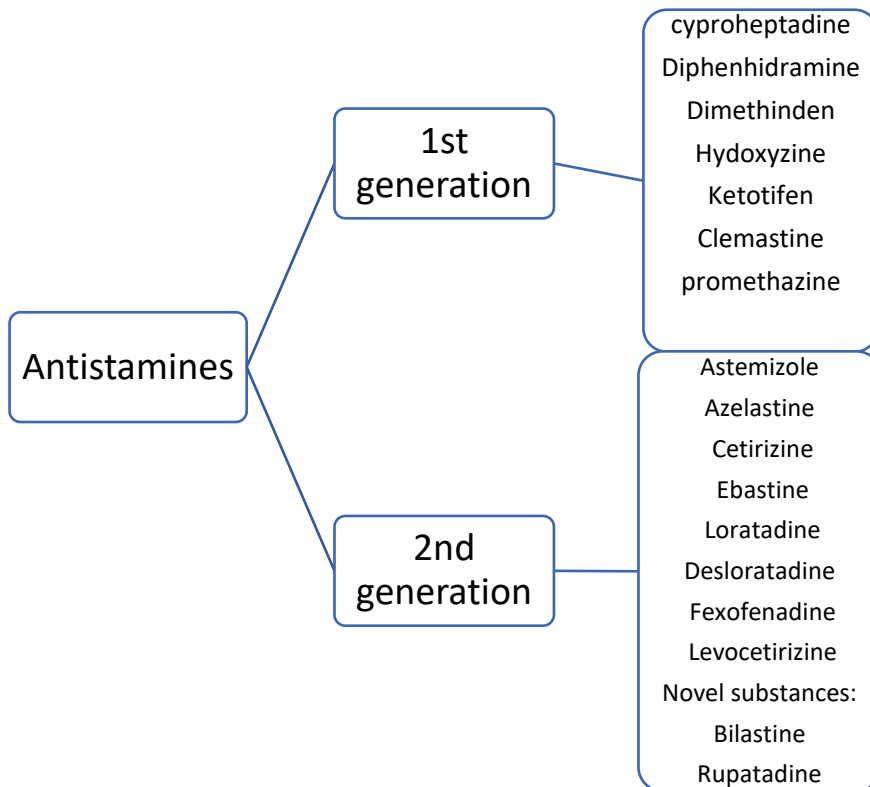


Fig3: Classification of antihistamines

Source of the fig: Terlikowska-Brzósko A, Rustecka A: Histamine and antihistamines. *Pediatr Med Rodz* 2024; 20 (3): 274–279

According to the anatomical therapeutic and chemical classification by the system ATC we analyzed the group of drugs belonging to the group R “Drugs ACTING ON THE RESPIRATORY SYSTEM” subgroup R06–Antihistamines for systemic use [46].

To illustrate the findings of the study, it was established that one of the most frequent clinical signs of allergic rhinitis were repetitive paroxysmal sneezing, rhinorrhea, and breathing discomfort through the nose known as nasal congestion in case of atopic dermatitis the symptoms vary from person to person but the most common ones are dry skin, itching and red rashes on the skin. in case of food allergy, the patient may experience different symptoms such as swelling of the face, hives, itching, redness. Antihistamines are the main group of drugs that treat the allergic conditions and relieve symptoms.

Every year, the prevalence of allergic reactions increases in Ukraine, which consequently leads to an increase in demand for over-the-counter medicines and drugs of antiallergic action [89], which may represent a burden to society. But it's necessary to provide highly efficient, safe, affordable treatment regimens of allergic diseases with the use of antihistamine drugs.

During the study, we used methods of information search, comparison, and systematic analysis. The objects of the study are the State Register of Medicinal Products of Ukraine [47], and The Moroccan Agency for Medicines and Health Products (AMMPS) [48].

Epidemiological aspects of some allergic diseases

The first phase we analyzed the epidemiological aspects of allergy in Ukraine, Morocco and abroad.

The increasing prevalence of allergy disease, now reaching pandemic levels and growing rapidly, explains the present worldwide interest in studying these diseases' epidemiology in the 20th and 21st centuries. The prevalence of allergies is increasing worldwide for example, allergic rhinitis whose prevalence ranged between 3.6% to 22.8% in Africa, from 3.5% to 54.5% in America, from 1.0% to 47.9% in Asia, from 1.0% to 43.9% in Europe, and from 19.2% to 47.5% in Oceania [49]. Children have been the most impacted group by allergy over the past 20 years; their increased prevalence is more evident [50].

According to National Health Interview Survey (2021), the USA has registered 25.7% of adults' cases with a seasonal allergy, 7.3% with eczema, and 6.2% suffer from food allergy [51].

Around 95.7 million cases of pediatric asthma were reported worldwide in 2021. Between 1990 and 2021, the global age-standardized prevalence rate (ASPR) decreased significantly by 30.4%. The worldwide childhood atopic dermatitis

(AD) burden was quite constant between 1990 and 2021, in comparison to asthma, as the ASPR fell slightly from 3889.74 per 100,000 population in 1990 to 3600.45 per 100,000 population in 2021[14]. As in 2021, childhood AD prevalence differed geographically. The prevalence is highest in the Western Europe region, then high-income North America and Australasia regions [52]. In addition, it turned out that in many regions of the globe, there have been differences in the occurrence of allergic diseases between rural and urban areas. Previous studies from Africa have demonstrated a rather low prevalence of disease allergy among members of rural societies, in which they were not exposed to the undesirable consequences of an urban/western way of life. Parasitic infections and the typical rural way of living were investigated as potential protecting factors. Numerous studies across Asia replicated the urban-rural gradient and investigated how food, exposure to other allergens, and air pollution are each contributing to the development of allergy [53].

In Ukraine, among all the allergies in dermatological practice, atopic dermatitis (AD) is the most prevalent. The annual increase in AD incidence worldwide proves this fact. Atopic dermatitis can develop in people of any age and gender. Its incidence in children ranges from 10% to 20%, and in adults from 2% to 6% as per different estimates. Depending on the division of allergic diseases, the disease is most common among children (50–60%) [90].

On the other hand, there were marked that over the last 24 years, in Ukraine the prevalence of allergic rhinitis rose by 48.3% and for atopic dermatitis 43.9% [91].

Epidemiological research indicates that between 10 to 40% of the population suffers from allergic rhinitis [92]. The prevalence of doctor-diagnosed AR was 33.4 per 1000 persons and the prevalence of self-reported AR symptoms was 44.7per 1000 persons [54].

In Morocco, Various studies have focused on the etiology of allergic disorders in people, including drug and food allergies, and olive pollens allergy, because of

the widespread presence of olive trees in Morocco. For instance, Marrakech region is well known for its high productivity of olive trees, it has been reported in 2021 that 32,7% of 432 people are allergic to olive pollen and experience different allergic symptoms including rhinitis (92.1%), conjunctivitis (65.4%), asthma (59%) and urticaria (22.3%) [55].

It was presented that, here are various factors that cause the development of allergies:

Genetic predisposition (if both parents are allergic, the risk to the child is 70%, if one parent is allergic, then the risk is 40%); environment (number and diversity of allergens, climate, geography, and environmental conditions); imbalanced diet; concomitant disease; general health; and stress are some of the causes that lead to allergies. People are facing it more frequently these days [92].

Comorbidity

The currently developed comorbidity accounting system is primarily based on the study of coexistence of two or more diseases in a patient at the same time.

Comorbidity refers to a condition where the patient suffers from two or more diseases simultaneously. They could be related or independent from each other. Comorbidities complicate the treatment and management of the primary condition; they can influence the progression of a patient's condition and may worsen the outcome of the primary disease. Financially, comorbidities are a financial burden on the patient and healthcare system because they lead to expensive hospitalizations [56].

Several studies show that patients with allergic rhinitis suffer simultaneously from other diseases. In the United States, Allergic rhinitis affects 15% of the population and is associated with asthma, eczema, chronic or recurrent sinusitis, cough, and tension and migraine headache [57].

In Ukraine, a study shows that people with AR are at greater risk of suffering from chronic health conditions compared to the non-AR population for an estimation of 100 versus 42%. In addition to hypertension, cardiovascular disease, pneumonia, and anxiety were more frequently observed in the AR patients compared to the non-AR [54].

In Morocco, A study revealed that 36,4 % of patients with asthma suffer from allergic rhinitis and 8% from conjunctivitis [58].

A study found that patients diagnosed with allergic conjunctivitis approximately 88,4% of them had rhinitis, 38,2% asthma, 8,3% food allergy, and 3,5% atopic dermatitis. In allergic respiratory diseases, the severity and duration of AC are connected to those of allergic rhinitis and asthma [59].

Overall, allergic diseases are related to each other in many cases, which aggravate the patient's condition and complicate his treatment.

Analyzing, Comparing the domestic market's structure of Morocco and Ukraine, and identifying its development trend for antihistamines used to treat allergic diseases, such as allergic rhinitis, conjunctivitis, food allergies or used to alleviate some symptoms in case of atopic dermatitis were the goals of this study.

2-2 Comparative Analysis of OTC antihistamines market for allergic diseases in Ukraine and Morocco .

According to the Moroccan Agency of Medicines and the State Register of Medicinal Products of Ukraine, 138 and 121 trade names of antihistamine drugs are registered in Morocco and Ukraine, respectively. (Table.1). In Ukraine drugs with INN Bilastine, Ebastine have 7 trade names, levocetirizine is presented by 32 trade names, Desloratadine – 42 trade names, cetirizine 12 trade names, loratadine 16 trade names, ketotifen 4 trade names and cyproheptadine 1 trade name. However, In Morocco, drugs with INN Bilastine, Ebastine have 3 trade names, Levocetirizine -25 trade names, Desloratadine -45 trade names, Cetirizine

is presented by 30 trade names, Loratadine 19 trade names, Ketotifen 6 trade names and Cyproheptadine 7 trade names.

Table1: Comparative analysis of the registered antihistamines drugs as to INN in Ukraine and Morocco.

ATC CODE	INN	Number of trade names (UKRAINE)	Number of trade names (MOROCCO)	Relative Share (%) (UKRAINE)	Relative Share (%) (MOROCCO)
R06AX27	Desloratadine	42	45	34,71	32,60
R06AE07	Cetirizine	12	30	9,91	21,73
R06AX22	Ebastine	7	3	5,8	2,2
R06AX13	Loratadine	16	19	13,22	13,76
R06AX29	Bilastine	7	3	5,8	2,2
R06AX17	Ketotifen	4	6	3,30	4,34
R06AX02	Cyproheptadine	1	7	0,82	5,07
R06AE09	Levocetirizine	32	25	26,44	18,1
	Total	121	138	100	100

The table shows the availability and market share of various antihistamines in Ukraine and Morocco with variations in drug preference across the two countries. The most often promoted antihistamine in both markets is Desloratadine, which is available in 42 trade names in Ukraine and 45 trade names in Morocco with market shares of 34,71% and 32,60%, respectively. Levocetirizine comes in second place with a share of 26,44% in Ukraine and 18,1% in Morocco.

However, drug with INN Cetirizine reflects a significant disparity in prevalence, with greater popularity in Morocco (30 trade names, 21,73% market share) than

in Ukraine (12 trade names, 9,91% market share), which enables it to be in the 3rd position among the antihistamines in Morocco.

Cyproheptadine, on the other hand has a greater market position in Morocco with 5,07% share than Ukraine with 0,82%.

Drugs Ebastine and Bilastine represent 5,8% and 2,2% of shares, respectively. They share a similar market position in both countries.

Loratadine has almost similar shares in both countries, but it ranks the 3rd position in Ukraine among the antihistamine medicines with a share of 13,76%.

Ketotifen is more common in Morocco (6 trade names, 4,34% market share) than in Ukraine (4 trade names, 3,30% market share), is more preferred in the Moroccan market.

These differences indicate that Desloratadine is still the favorite antihistamine drug in both markets and ranks the first position on the most popular antihistamine medicine, Morocco shows a preference for Cetirizine and Levocetirizine. Whereas Ukraine favors Levocetirizine and Loratadine. (Fig1)

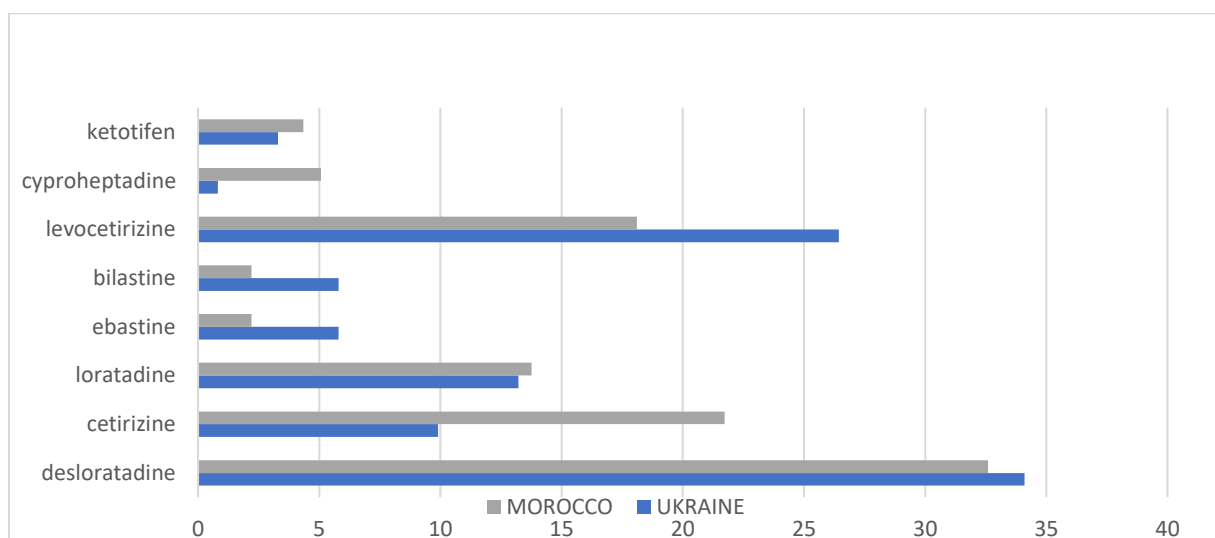


Fig4: Distribution of antihistamine drugs of ATC group R06A in Ukrainian and Moroccan market

Based on the quantity of registered trade names in the two countries, we analyzed the number of dosage forms of these antihistamines (R06A). We found that in

Ukraine, the most frequent dosage forms among this class of drugs are tablets. 87 tablets which are divided into (film coated tablets, orodispersible tablets),13 oral solutions, 7 oral drops, and 14 syrups. Also, in Morocco, the market includes different dosage forms which are tablets 104 (film coated tablets, effervescent tablets, and orodispersible tablets), 15 oral solutions, 1oral drops, 2capsules, 2 suspensions and14 syrups. We present these results in percentage in the (Tab2).

Table 2: The proportion of dosage forms among antihistamines

Dosage form	Ukraine %	Morocco %
Tablets	71,90	75,36
Oral solutions	10,74	10,9
Oral drops	5,8	0,72
Syrups	11,56	10,14
Others (capsules and suspensions)	-	2,88
	100	100

The share of dosage forms within antihistamines in Morocco (fig2) and Ukraine show both similarities and differences. Both share the same most common dosage form **tablets**. Oral solutions are also as popular in Ukraine and Morocco. However, a striking imbalance is evident in the use of oral drops, which represent 5,8% of the market in Ukraine and only 0,72% in Morocco, suggesting a broader utilization of this form in Ukraine. Syrups have relatively close distributions, in both countries. Additionally, 2,88% of other forms of antihistamines are found in Morocco but not in Ukraine, suggesting a slightly wider range of forms in the Moroccan market.

We studied the manufacturing companies of these antihistamines we found that the Moroccan pharmaceutical market includes 23 manufactures. Twenty-two domestic manufacturing enterprises and one foreign company «MSD» represent them. Among the companies that produce the most medications, Genpharma leads with the highest number of products, followed by Lapropharm and Sothema in third place. However, In Ukraine, these antihistamines are presented by 53 manufactures ,41 (77,36%) are foreign manufactures from different countries and 12 (22,64%) domestic manufactures (fig3)

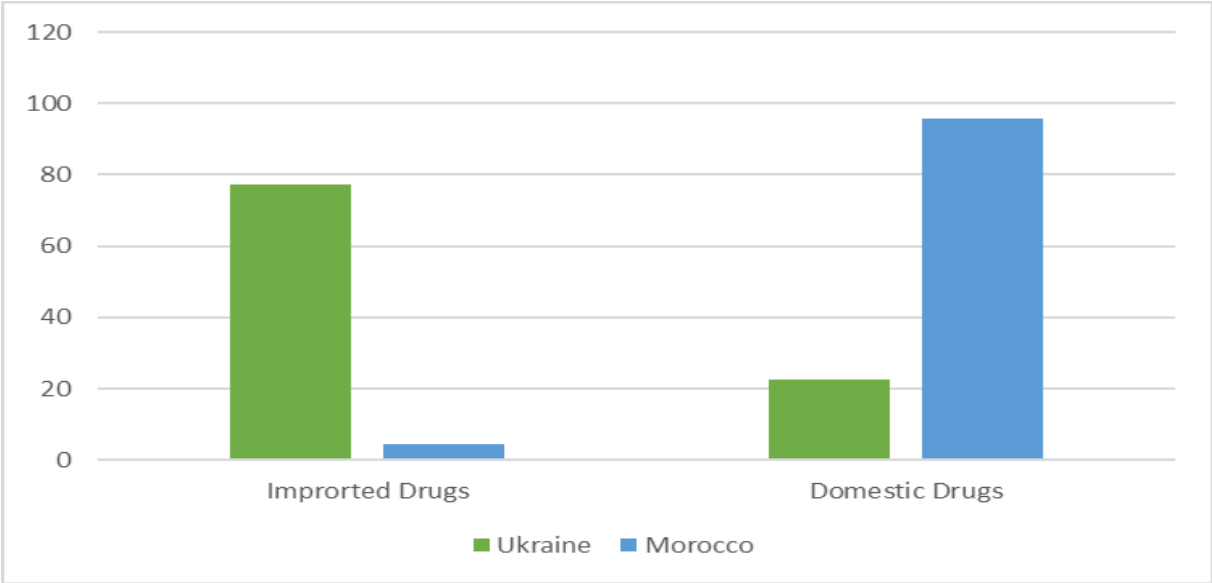


Fig5: Representation of pharmaceutical market of antihistamines in Morocco and Ukraine (%)

In Ukraine, Foreign antihistamines drugs in the pharmaceutical market are presented by 12 countries. The share of supply from these countries and the others are presented in the histogram as follow:

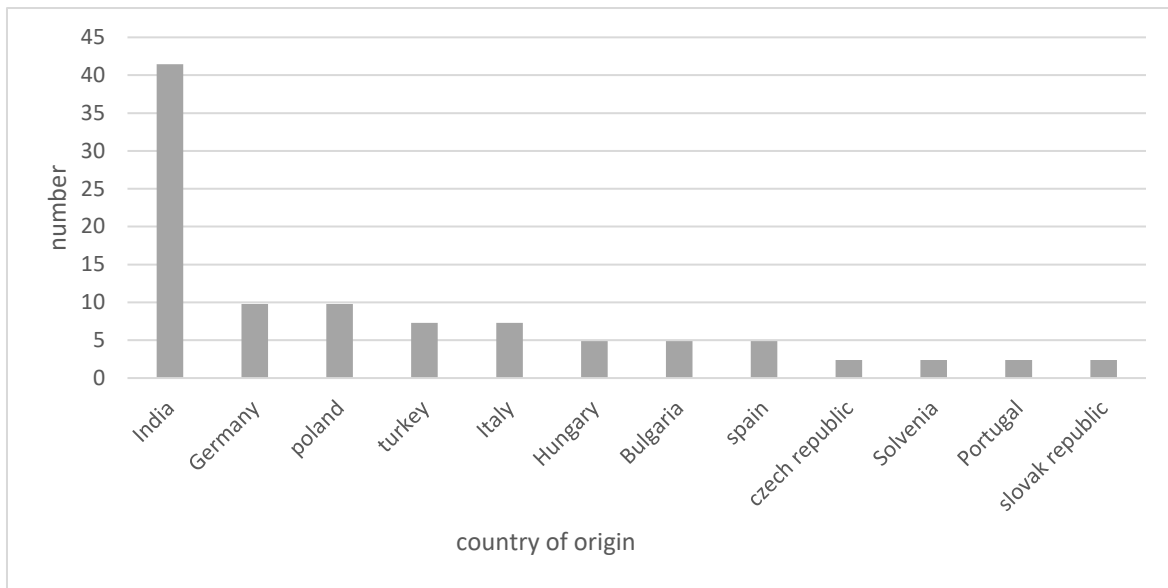


Fig6: The share of supply of antihistamines from foreign countries

The histogram shows an obvious difference in the quantity of supply of antihistamines to Ukraine by 12 countries. The data is presented in the descending order starting with India, the leading country which supply high quantity followed by Germany and Poland and many countries supplying small quantities.

CONCLUSION 2

The contrast between the antihistamines markets in Morocco and Ukraine points to some key findings that can be employed in determining the drivers of drug choices, market forces, and the future of the Moroccan and Ukrainian pharmaceutical industries.

1-One of the major findings is that both countries rely significantly on drug with INN Desloratadine as the most widely used antihistamine, the differences between the other antihistamines market shares reflect varying healthcare habits, patients' demand, and even national treatment norms. The reason cetirizine has a much larger market share in Morocco (21,73% with 30 trade names) compared to Ukraine (9,91% with 12 trade names) is that there is more preference for this antihistamine in Morocco, as it has a balanced efficacy and safety profile. This would suggest that Moroccan patients and doctors would choose cetirizine in allergy treatment, perhaps because it is known to have a good reputation and more product indications. Conversely, popularity of loratadine in Ukraine (13,76 % market share) reflects the fact that Ukrainian doctors or patients favor a more targeted product to manage allergy, such as rhinitis, conjunctivitis.

2-The dosage form comparison also shows additional levels of divergence between the two countries. Both markets use tablets as the most used dosage form since they are so convenient and simple to administer. The relative use of syrups and oral solutions in both markets reflects the significance of liquid forms in both countries. Perhaps because they have special medical requirements, for example to treat children or older patients who might find drugs in liquid form easier to take.

3-The comparative domestic manufacturing capacity of both countries shows that Morocco's stronger local manufacturing base, as seen by the higher share of domestically sourced antihistamines, provides the country with several advantages. However, the study of the pharmaceutical market of Ukraine has

confirmed the necessity of developing domestic antihistamine medicines by encouraging the growth of local industry, Ukraine can enhance its own domestic autonomy and strength in its pharmaceutical market.

CHAPTER 3: Dispensation of OTC antihistamines in Ukraine and Morocco.

3-1 The dispensing process in pharmacy practice.

The pharmacy provides many services to patients within the framework of healthcare improvement. One of the main tasks of pharmacy practice is to help patient with the choice of a suitable, convenient drug to his medical condition. Within this goal, the pharmacist should be responsible and aware of their role which primarily consists of easing access to medicines, providing their patients with all necessary medical information such as the indications, the dosage, frequency, and some common adverse effects that may occur. Dispensing process is organized to help patients with understanding the medication use, what is expected from a particular drug and how to prevent drug-related issues. particularly medication errors such as those occurring in prescribing, dispensing, administration [60].

The pharmacist 's duties are multiple, starting with their responsibility to prepare and check the quality of medications, ensure that the supply chain of medicines comply regulatory standards, store and dispense medications. In addition to some services provided in his pharmacy such as blood pressure monitoring, smoking cessation services and various vaccinations [61].

In assessing patients' knowledge of dispensed medications, some of the most principal factors needed to provide safe and effective use: the name of the medication, dose, route of administration, frequency of administration, duration of treatment, side effects, and storage requirements. Lack of these informations, lead the patients to misuse medicines and do not show improvement with the treatment [62].

The dispensing process has an impact on patient's health outcomes. According to The World Health Organization (WHO) medication errors occur during various stages of medication use process such as prescribing, dispensing, administration

and monitoring practices and others [63]. So dispensing medicines is one of the main factors of a good pharmacy practice that may prevent the patients from harm or any serious condition.

In community pharmacies, drug dispensing is accessible, and helpful to many patients who need prescription or OTC medications. Drug dispensing is a clinical pharmacy service aimed at ensuring that drugs and other health products are safe for use by analyzing the aspects of prescriptions, reviewing each patient's unique health needs, and carrying out interventions during the treatment process, such as pharmaceutical counseling [64].

In this context, pharmacists play a significant part in ensuring the rational use of drugs, since the patients more often consult them so they must closely monitor the use of medicines, and medication adherence. Studies have shown that good dispensing process affects positively patient's health outcomes such as patient satisfaction and quality of life improvement due to the right management of his issues [64].

All the services provided by a pharmacist from obtaining the prescription to giving the patient prescription or over-the-counter drugs are included in the medication dispensing procedure. The pharmacist must follow the good dispensing practice (GDP) to ensure patient safety. Good dispensing reduces the chances of drug errors, which can have severe consequences such as side effects, treatment failure, or even death in some cases. GDP practices also help avoid incorrect dosing, drug interaction, or misunderstanding patient instructions. Accurate dispensing is essential to the realization of the desired treatment outcomes because incorrect dosage, substitution, or drug interaction can affect the effectiveness of treatment, patient recovery and health. Additionally, preventing errors saves healthcare costs, as medication-related complications can lead to expensive hospitalizations, more treatments, and prolonged patient care [65].

Over-the-counter (OTC) drugs are medications that can be sold without a medical prescription. Their sale is regulated by two primary elements: the monopoly of the pharmacy in medicine distribution and the classification of OTC drugs into risk classes and other national considerations.

In countries such as Belgium, Germany, Romania, and France, all medicines, including OTC medicines, are available only in pharmacies. While in other countries, OTC medicines are available also in non-pharmacy outlets, and online stores [66].

When there is a monopoly on dispensing of medicines by pharmacies, OTC medicines are classified into 3 classes. Some medicines are freely available for customers to buy, while others are dispensed only after a consultation with a pharmacy employee. Additionally, there are OTC medicines that cannot be displayed in pharmacy's sales area and must be supplied by a pharmacy employee, only after giving advice on their use (pharmacist-only medicines).

In countries where pharmacies lack a monopoly to dispense medication, regulators would limit where OTC medicines can be sold. For example, the medicines are available for purchase in some premises or by certain individuals, such as drug experts, with the permission of the authorities. The sale of some OTC medicines is restricted to consumers of a certain age group, for example, individuals 18 years and older. [66]

Classification of OTC medicines is based on some considerations including scientific evidence, local characteristics of the health system, medication awareness, and culture that influence the extent of misuse and rational use of these drugs [66].

The dispensation of OTC antihistamines in Ukraine and Morocco

In Ukraine, the ministry of health approved a list of medicinal products without a doctor's prescription to regulate the dispensing of medicinal products from pharmacies and their structural units.

The list includes 3, 191 items of over-the-counter drugs including their trade names, international nonproprietary name (INN), release form, applicant data and producer's information. A research revealed that 26% of pharmaceutical workers periodically use this List but 60% do not use it in their work, they rely on the pharmacy software or the instructions for medical use of the drug to dispense medications [67].

Pharmacies in Ukraine offer a wide range of antihistamines especially for systemic use R06A, 21% of antihistamine sales are prescription drugs, and the remaining 79% are over the counter, which significantly increases the role of the pharmacist in recommending and dispensing these drugs [68]. The dispensing of antihistamines in Ukraine differs from European countries some antihistamines are available only by prescription in Ukraine but over the counter in other countries. For example, in Germany, drugs with the INN Clemastine and Diphenhydramine are OTC medicines while in Ukraine they are available only with a prescription, in Switzerland, Doxylamine drug is available without prescription, unlike in Ukraine [69].

In Ukraine, the Pharmacist follows a protocol when dispensing over the counter medicines for the treatment of allergy.

Firstly, the pharmacist collects information about the patients, such as when the illness first appeared, what measures the patient has already taken before visiting the pharmacy, the symptoms he has experienced, and what medications he has used to relieve these symptoms. Secondly, the pharmacist asks his patient to consult a doctor if the symptoms worsen or if medical attention is needed, for example, in cases of severe shortness of breath, edema, allergic rhinitis accompanied by nasal bleeding, or the disappearance of allergy symptoms even

after treatment with medications. Thirdly, the pharmacist provides the patient with the necessary information for an adequate self-medication process, explain the use of the drug, route of administration, duration of the treatment, storage conditions and some precautions (e.g. side effects, influence on diet..) Also informs the patient about the secondary effects of antihistamines of first generations that they can cause drowsiness, fatigue, decreased attention therefore should be taken with caution by individuals whose jobs require focus and increased attention, the pharmacist must warn his patient about drugs interactions, antihistamines of the first generation should not be combined with alcohol or drugs that act on the central nervous system like sedatives, hypnotics, tranquilizers to prevent any drug interactions [70].

Pharmaceutical care for allergies:

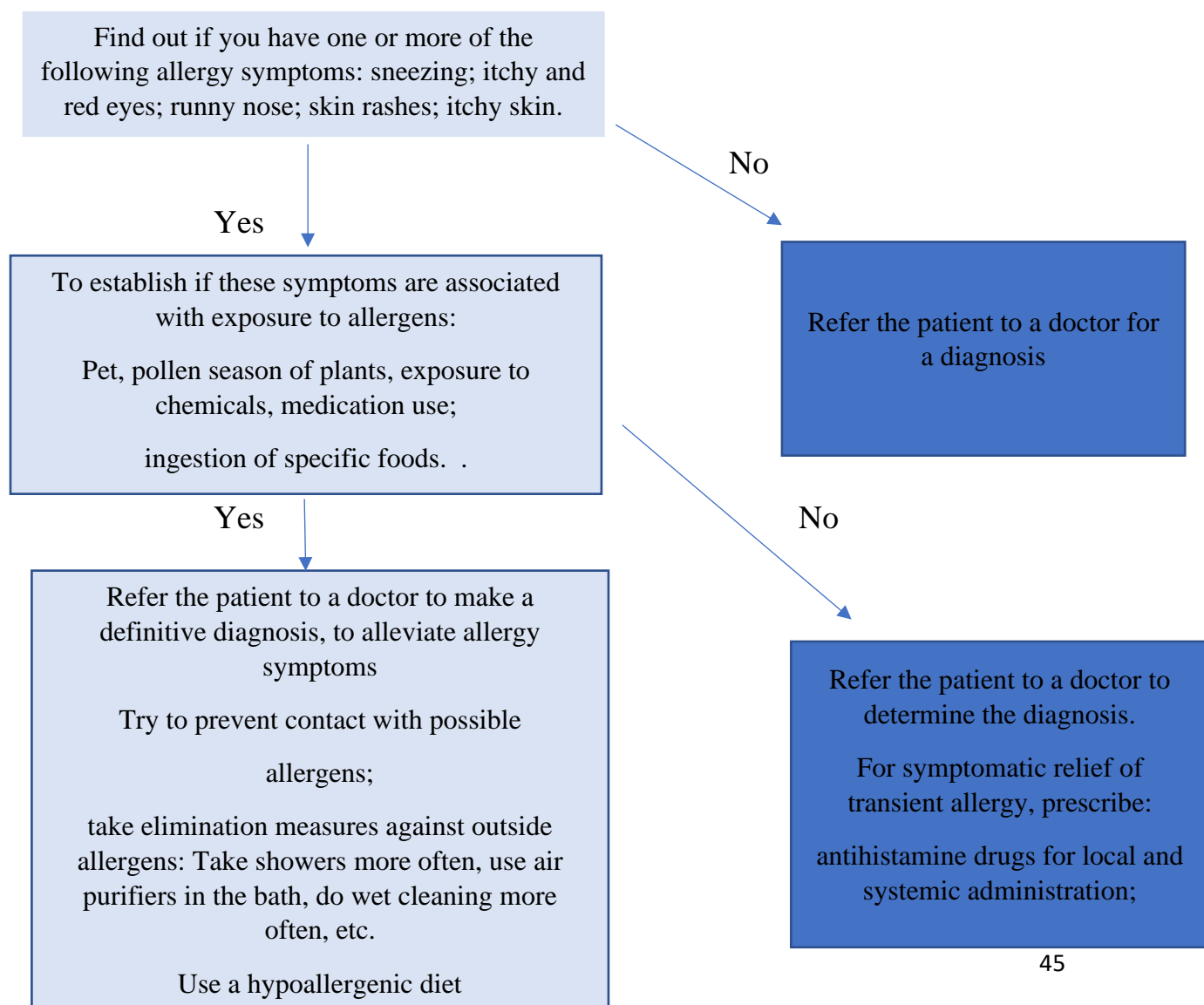


Fig7: Pharmacist's protocol when dispensing OTC medicines for allergy

Source: PHARMACIST'S PROTOCOL WHEN DISPENSING OVER-THE-COUNTER MEDICINES "SYMPTOMATIC TREATMENT OF ALLERGY" from the Order of the Ministry of Health of Ukraine dated January 5, 2022 No. 7

Retail dispensing of non-prescription medications is a duty of community pharmacists due to their scientific knowledge and must follow the current legislative and regulatory circumstances .

According to the law n°17- 04, During dispensing, the pharmacist counsels and informs the patient to ensure the proper use of treatment according to current laws and regulations. The pharmacist has a greater responsibility to provide advice on antihistamines that do not need a mandatory medical prescription [71].

The pharmacist must first identify the patient (e.g. who is ill —whether it is the person visiting the pharmacy or a member of their family). Then, he identifies and analyzes the symptoms. Following that, the pharmacist decides whether a treatment can be recommended or if the patient needs a medical consultation.

If treatment without a doctor's intervention is possible, the pharmacist must collect information about the patient's medical history of drug allergies or the medications they are currently taking. Based on this, the pharmacist can provide a suitable antihistamine, and clearly explain the drug's indications, duration of treatment, side effects, and contraindications [72].

Additionally, the pharmacist should advise the patient on lifestyle and dietary measures to relieve some symptoms and optimize the treatment, point out the importance of treatment adherence, and provide warnings related to self-medication [72].

Some OTC antihistamines can be dangerous if they are misused, One of the most examples of this misuse in Morocco is the extensive use of cyproheptadine as an appetite stimulator [73].

Morocco Poison Control and Pharmacovigilance Center (CAPM) has registered 734 cases of poisoning and 28 cases of adverse reactions with cyproheptadine-

based drugs. Based on these results, and following a decision issued in August 2019 by the National Consultative Pharmacovigilance Commission the Directorate of Medicines and Pharmacy has once more reminded health care professionals of the need to respect the indications of Cyproheptadine. The misuse of such substances tends to increase over time, and monitoring their use is a duty of the pharmacist because the abuse or misuse of sedating antihistamines or any OTC drugs can be life threatening [73].

3-2 Optimization of the dispensing process of OTC antihistamines.

A Study shows that, pharmacists can optimize the use of OTC antihistamines first generation by encouraging patients switch to less-sedating antihistamines or minimizing the use of sedating antihistamines based on a medication optimization guide [74].

This guide includes 3 steps to deprescribing which is an indispensable component of MOH Pharmaceutical care services guidelines 2019 [75], and a crucial part of medication optimization process. Deprescribing is an organized, controlled process of dose reduction, substitution, or drug cessation that might be causing harm, or no longer providing any benefit [76].

The stages to deprescribing are: Patient assessment, Management and recommendation, and monitoring. The first stage outlines a series of steps taken to counsel the patient whether he could stop or change his current antihistamine based on the study of the indications of the medicine, the antihistamines of 2nd generation that was used previously, any allergic conditions experienced by the patient, also drug interactions and contraindications [74].

The second stage provides some suggestions about treatment's management, such as switching to a less-sedating antihistamine or trying non-pharmacological therapies, depending on the patient's case. The table below explains the management process of each condition [74].

Scenario	Management
Allergic conditions without prior trial of non sedating antihistamines	<ul style="list-style-type: none"> • Raise awareness of the side effects of the medication • Ask if the customer/patient has ever experienced any side effects associated with the use of the medication • Suggest replacement with non-sedating antihistamines such as fexofenadine, desloratidine or levocetirizine
Chronic itch due to dry skin	<ul style="list-style-type: none"> • Consider non-pharmacological therapy such as: • Eliminating/minimising contact with allergen or irritating material • Using topical therapies like moisturisers, anti-inflammatory and local anaesthetics • Bathing with cool water and applying moisturisers within 10mins after
Experience adverse effects	<ul style="list-style-type: none"> • Provide advice to customer/patient or caregiver on what to do if symptoms recur based on own professional judgement and discretion
Inappropriate, no current indication or non-evidence-based usage For example, use as a sedative, hypnotic, neuropathic itch or itch due to medical conditions or medications	<ul style="list-style-type: none"> • Cease the sedating antihistamine and recommend proper treatment. Referral to a physician may be necessary

Table3: Optimization guide, the 2nd stage, Management process

Source of the fig : International Journal of Pharmacy Practice, 2021, Vol 29, 451–457

The last stage provides the monitoring parameters, during patient’s counseling and when to refer the patient for a medical consultation.

The optimization guide aims to improve the use of OTC sedating antihistamines and reduces the risk of self-medication with this class of drug [74].

On the other hand, Integrating artificial intelligence AI into pharmacy practice plays a huge role in optimizing the dispensing of antihistamines through the introduction of advanced techniques that improve the efficiency, and patient care. Integrating this innovative technology into dispensing medicines performs pharmacy work, ensures accuracy and efficiency. Automated dispensing has an impact on the optimization of medication use, it allows pharmacists to focus more on counselling the patient, medication reviews to avoid any errors, and responding to patient’s concerns [77]. It helps pharmacists to analyze patient data such as

medical history, allergies, and current medications, to identify drug interactions and determine the appropriate dose. This analysis promotes medication safety, and lowers the chance of severe side effects [78].

To optimize dispensing process of medicines, the pharmacist must organize the inventory, keep a balancing stock to avoid shortages or surplus and to meet the customers need whenever they visit the pharmacy. Cooperating with trusted suppliers who provide the pharmacy with reliable OTC medicines, it reduces the chances of mistakes, promotes treatment outcomes, and helps gain the trust of patients. In addition, pharmacy dispensing equipment help patients to understand their medication such as comprehensive labels, clear instructions, dispensing bags [79].

Pharmacies must be compliant with regulatory standards, and the pharmacy staff must continue the learning and training process, and develop their communication skills to exchange information with patients effectively to avoid mistakes, and ensure safe medication use [79].

3- 3 The Standard Operating Procedure in the dispensing (sale) of over-the-counter drugs

The standard operating procedure for retail pharmacies is a set of activities that take place at the pharmacy. It is established to guide , explain how to perform specific tasks in a retail pharmacy, and minimize errors in pharmacy practice.

SOPs are guidelines for organizing the work at the pharmacy starting by receiving, and storing medications to dispensing, counseling patients and finally dealing with customer complaints [80].

Each pharmacy should follow a standard operating procedure (SOP) in dispensing over the counter drugs that includes: purchase of medicine and monitor its quality, selling of medicines, preservation and quality control, and handling any complaints [80]. Each country, has its own specific standards and

regulations for dispensing OTC drugs, for example, Ukraine has formal pharmacists protocols that include patient assessment, medicine recommendation, and counselling [70]. On the other hand, Morocco follows current laws and regulations and has a list of OTC medications allowed for sale without prescription [71].

The standard operating procedure “Sale of over-the-counter drugs online” in Morocco:

In Morocco, the dispensing of prescription and OTC medicines online is forbidden by the current legislation. According to the law n° 17-04, Article 112, It's illegal to sell OTC medicines on the street, in markets or in stores that is not dedicated to the pharmaceutical profession, only pharmacies are allowed to sell medicines or health-related products to protect public health and ensure safe access to medications. Also, the Article 107 makes it illegal to sell medicines outside pharmacies, or in unauthorized places [81].

In addition, Morocco signed the Medicrime Convention, which was adopted by the Council of Europe in 2022 to combat the illegal production and trade of medicines, protect public health by punishing those who manufacture or sell counterfeit medicines, and to encourage countries to cooperate to stop this illegal act [82]. Drug and Pharmacy Code law n17-04 forbids the sale of medicines online regardless of the category of the drug. The Minister of Health and Social Protection points out that only licensed pharmacies, pharmaceutical establishments, and public or private healthcare institutions are authorized to sell medicines, indicating that this sector was managed by strict laws which regulate the medicine sector from manufacturing to distribution [83].

The increasing spread of online drug sales is becoming serious concerns among authorities. Although various measures have been taken to stop this illegal activity, the phenomenon continues to expand. Unauthorized individuals are

using social media platforms and networks to sell pharmaceutical products with unknown origin and unverified quality which is a danger to citizens' health.

To deal with the rise of this issue, the Moroccan Confederation of Pharmacists' Unions (CSPM) proposes two actions:

1-Create a specialized website where people can report illegal online drug advertisements or sales.

2- Work more closely with authorities dealing with cybercrime (internet crimes) to better monitor and stop these illegal activities [84].

In addition to other measures proposed to prosecutors, such as Coordination with health authorities, which means the judicial police must collaborate with the Moroccan Agency for Medicines and Health Products to identify illegal sales channels. Impose severe criminal penalties to every person sells medicines online. In some cases, involving international networks, judicial cooperation must allow extradition procedures and the seizure of illegal profits. Moreover, systematic appeals must be pursued when judicial decisions are not strict, ensuring penalties are related to the seriousness of the offenses. These actions are essential to protect public health [85].

CONCLUSION 3

The dispensing of OTC antihistamines medicines is a critical process that is based primarily on the pharmacist's responsibility. Since these medications are used without medical consultation they rely on the role of the pharmacist. The pharmacist assesses the patient's symptoms, chooses the appropriate medication, gives the guidance on proper dosage, way of administration, side effects and contraindications as well as informs about drug interactions and when the medical consultation is necessary. This interaction minimizes or prevents the risk of self-medication such as the abuse and misuse of medication which is the case for some OTC antihistamines first generation that act on the central nervous system and cause a sedative effect. To dispense OTC antihistamines safely, pharmacists must follow national regulations, which require accurate labeling, proper storage.

Despite OTC antihistamines are available without prescription the pharmacist's involvement remains crucial to minimize the risks and promote responsible use.

The Ministries of Health in both countries Ukraine and Morocco set national protocols and requirements for pharmacists concerning the dispensing of OTC antihistamines and the promotion of safe self-medication in case of allergy. Cyproheptadine and other OTC antihistamines have the potential for misuse, so pharmacists must control the use of such medicines and provide patients with all necessary information and guidance.

To Optimize the dispensing process of antihistamines, many tools have been suggested, starting with the optimization guide which consists of 3 mandatory stages of deprescribing, and including the integration of artificial intelligence and new technologies such as automated dispensing system. Also, the organization of work inside the pharmacy (e.g. managing stock levels, supply chain,..) impact the optimization of antihistamines use.

Conclusions

1- Self-medication with over the counter (OTC) drugs has increased in society, the primary reason being the numerous benefits offered by such activity. These benefits are minimal cost, cost-effectiveness in terms of affordability, and the easily accessible nature of OTC drugs. More individuals prefer easily accessible and quick solutions to health issues, with OTC drugs being a favorable option, as they allow patients to deal with their main care problems without doctor's intervention.

2- Morocco and Ukraine have an increased growth of OTC drug turnover each year. This growth can be explained by various factors that include the prevalence of self-medication in both countries, and the increased level of awareness about OTC practice. Also, marketing strategy has been a stimulating factor in the increase of OTC sales, allowing pharmaceutical companies to expand their market share. Such strategies assure the continued success of the pharmaceutical firms as they respond to growing demand for accessible and cheap treatment.

3- The contrast between the antihistamines markets in Morocco and Ukraine points to some key findings that can be employed in determining the drivers of drug choices, market forces, and the future of the Moroccan and Ukrainian pharmaceutical industries.

4- The dispensing of OTC antihistamines medicines is a critical process that is based primarily on the pharmacist's responsibility. Since these medications are used without medical consultation they rely on the role of the pharmacist. The pharmacist assesses the patient's symptoms, chooses the appropriate medication, gives the guidance on proper dosage, way of administration, side effects and contraindications as well as informs about drug interactions and when the medical consultation is necessary.

5- Optimization strategies of the dispensing process of antihistamines include many tools that have been suggested, starting with the optimization guide which consists of 3 mandatory stages of deprescribing, and including the integration of artificial intelligence and new technologies such as automated dispensing system. Also, the organization of work inside the pharmacy (e.g. managing stock levels, supply chain,..) impact the optimization of antihistamines use.

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88. АНАЛІЗ ДИНАМІКИ РОЗВИТКУ РИНКУ БЕЗРЕЦЕПТУРНИХ ЛІКАРСЬКИХ ЗАСОБІВ У СВІТІ ТА В УКРАЇНІ Гала Л.О. Національний медичний університет імені О.О. Богомольця, Київ, Україна ЛО Гала 2023 Формування Національної лікарської політики за умов впровадження медичного страхування: питання освіти, теорії та практики: матер. VI Всеукр. наук.-практ. конф., м. Харків, 14-15 березня 2023 р. / ред. кол.: А.С. Немченко та ін. – Х. : Вид-во НФаУ, 2023. – 384 с. <http://ir.library.nmu.com/bitstream/123456789/7229/1/6-nlp-oef-sbirnyk-2023-248-250.pdf>
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