

STUDY ON THE RANGE OF DRUGS AUTHORIZED IN ROMANIA – A DETERMINANT ELEMENT FOR THE ACCESSIBILITY AND AVAILABILITY OF DRUGS

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Abstract

As a fact of drugs availability of the drugs in the pharmaceutical assistance of the population, the range of pharmaceutical products authorized to be used in therapeutics represents the main material resource [1].

In the national system of health, the drugs for human use are approved by Order of Ministry of Health and they are registered into the classified list published every year.

The number of products varies from one year to another, depending on the necessities of therapeutics. The products therapeutically superannuated are taken out of the classified list, introducing other new ones, in terms of offer and therapeutical needs.

The products taken out of the classified list can be prescribed and used till the exhaustion of the stock with the condition of maintaining the quality parameters.

In the paper we present a study upon the palette of the authorized medicines in Romania, for years 2003, 2004, 2007, 2008.

Rezumat

Ca factor al disponibilității medicamentelor în asistența farmaceutică a populației, gama de produse farmaceutice autorizate pentru utilizare în terapeutică reprezintă principala resursă materială [1].

În sistemul național de sănătate, medicamentele de uz uman se aprobă prin Ordin al Ministrului Sănătății și se înscriu în nomenclatorul publicat anual.

Numărul de produse variază de la un an la altul, în funcție de necesitățile terapeuticii. Produsele depășite din punct de vedere terapeutic se elimină din nomenclator, introducându-se altele noi, funcție de ofertă și nevoile terapeuticii.

Produsele scoase din nomenclator pot fi prescrise și folosite până la epuizarea stocurilor, cu condiția menținerii parametrilor de calitate.

În lucrare prezentăm un studiu asupra gamei de medicamente autorizate în România, pentru anii 2003, 2004, 2007, 2008.

Keywords: range of drugs, availability, tendencies

Introduction

Analyzing many factors that influence the accessibility and availability of medicines, we considered first the palette of the medicines, on a scale of these factors, among which the quantity and the quality of the human resources (pharmacists), the existence of the sanitary units that assure medicines for people.

In order to have an image of the pharmaceutical products distributed in Romania we studied the drugs considering some classification criteria that are:

- their prescription and issuing from pharmacy;
- autochthonous drugs and import drugs.

The increased interest for the drugs given without a prescription determined us to make a study about the palette of drugs from Romania, according to the way of prescription and giving into pharmacies.

The list of drugs allowed to be delivered without prescription is different for each country, depending on the system of health protection and socio-economic elements. The criteria of selecting the preparations are the same for all countries and are based on the veridical information about the drug, price, and therapeutic effect. The responsibility recognition for own health and the fact that seeing a doctor for an ordinary disease is not rational and sometimes not wished, brought an important contribution in developing the conception of self treatment. World Health Organization (WHO) clearly defines the notion of self treatment: *“The self treatment represents the administration of the drugs by consumer to treat the symptoms and the health disorders recognized by them”*. In practice, this also includes the treatment of the family members or of acquaintances, especially in the case of children treatment.

The researches of the European Regional Bureau of WHO under the name of “Self treatment in Europe” present a unique study concerning this problem. There is evident the tendency of European governments to reduce the reimbursement of the prices of the drugs given only with prescription, and also to stipulate and to approve the transfer of some drugs from the category of those given with prescription to the category of those without prescription. The problem is reflected in the increased interest of the population for its own health, including information accessibility regarding efficient and inoffensive drugs.

The doctors and chemists find out into the actual classified list of the drugs, useful information for their practice:

- the drugs list in alphabetical order after INN (International Non-proprietary Name);

- the drugs list in alphabetical order considering the name of the products given by the producer;
- classification of drugs in anatomical, therapeutic and chemical (ATC) groups and sub-groups; the code of each product according to ATC codification;
- the producer and origin country.

The knowledge importance of general classification by the sanitary professionals consists in:

- the quick orientation of the doctor and chemist to some product, registered in some chapter;
- assuming the suppliers' responsibility in obtaining the products range requested by the market;
- offering the complete information for the range of pharmaceutical products approved for therapeutic use, and also about the size of this palette. This information is necessary for the producers and also for the distributors.

The doctor may prescribe, and the chemist may supply the pharmaceutical unit and may issue only the products from the annual classified list of drugs, list approved by the Ministry of Health. To these are added the products registered after the approval of the classified list.

The classified list of the medical products for human use is the instrument that informs the doctors and the chemists about the medicinal products that can be prescribed by doctors and issued by chemists.

Any research in the sanitary field focused on some elements or on the activities management in this field, has as objective the study of the public health parameters, and, in the end, the increase of life quality.

The aim of our research is joining in the same line, respectively the improvement of the assistance of population with drugs and, finally the increase of life quality.

Materials and methods

Taking into account the specificity of the research field approached in our studies, we used as **materials**, in projecting the research, the collection of the data of the classified list of pharmaceutical products annually approved for the use in therapeutics, in 2003, 2004, 2007, 2008.

For achieving the research objectives, we used **the statistic method**. This method is based on collecting, processing and capitalizing some data concerning the elements considered into the study.

Results and discussion

In this study we analyzed the drugs palette for 2003, 2004, 2007, 2008, the drug being an element of accessibility and availability into the pharmaceutical assistance of the population.

In order to synthetically express the evolution of the number of national and imported drugs, for the period considered into the study, we centered the number of drugs in absolute numbers and percentages into the table.

From the results of our studies concerning the range of drugs presented in Table I and Fig 1 and 2, it can be observed the percentage of drugs given by prescription, compared to the OTC (over the counter) drugs (given on request) for the studied year.

Another element studied, concerning the drugs range, is referring to the share of autochthon drugs compared to the share of import drugs, authorized for therapeutic use in Romania for the studied years.

In the last years, the number of pharmaceutical products authorized and registered into the annual classified list increased from 7683 products in 2003 to almost 12700 in 2007, reaching 17600 products (denominations of the producers) in 2008. (Table I).

Table I
The share of the drugs in Romania in 2003, 2004, 2007, 2008

YEAR	2003		2004		2007		2008	
	CA*	%	CA*	%	CA*	%	CA*	%
TOTAL of MEDICINES	7683		8996		12739		17608	
OTC	1106	14.4	1132	12.6	1494	11.72	1550	8.8
WITH PRESCRIPTION	6577	85.6	7864	87.4	11245	88.28	16058	91.2
AUTOCHTHON	1906	24.8	2236	24.85	2123	16.66	2565	14.56
IMPORT	5777	75.2	6760	75.15	10616	83.34	15043	85.44

CA* - absolute numbers

This tendency presented is valid in the case of import and autochthon drugs, the first significantly increasing not in the favour of the drugs made in Romania.

From the processing of the statistic data obtained during the 2008 classified list analysis, it can be observed that from a total of 17600 products, 14.60 % are made in Romania, and 85.40% are from import.

Through the analysis of the drugs list (fig.1) it can be observed that during 2003-2007 for the import drugs is registered an increase of the number of those imported and a diminution of the indigene ones.

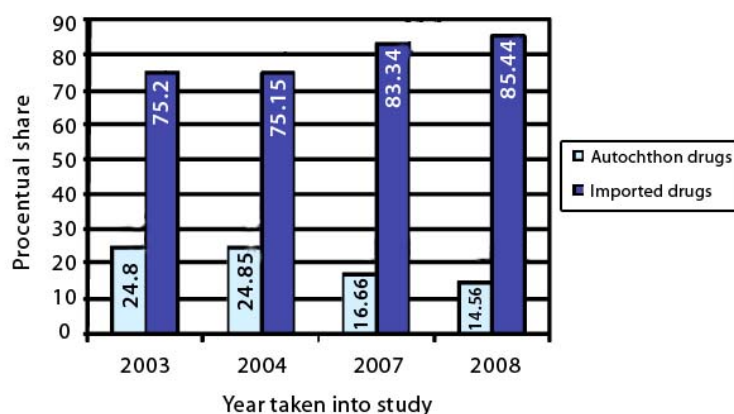


Figure 1

The share of autochthon and import drugs in Romania in 2003 - 2008

As far as it concerns the share of drugs number that needed prescription it can be observed a decrease of OTC medicines number, as follows: for 2003 and 2004 the percentage is 14.4% and 12.6% and for 2007, 2008 the percentage is reduced to 11.72% and 8.8%.

In comparison to the OTC medicines number, the percentage of drugs that need prescription increased in this period as follows: 85.6% in 2003 and 91.2% in 2008.

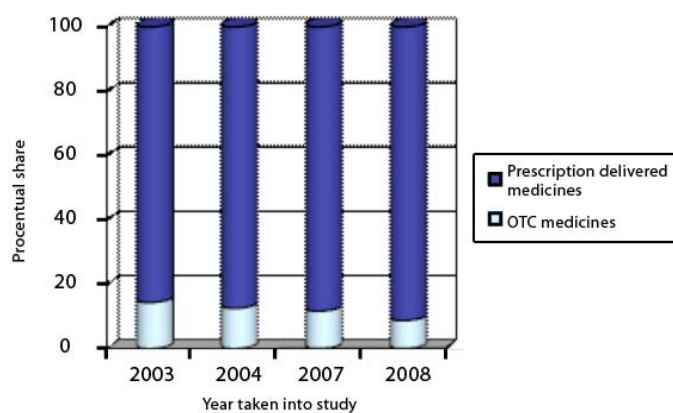


Figure 2

The share of OTC drugs and of those that need prescription in Romania in 2003, 2004, 2007, 2008

Figure 2 shows that the share of the drugs delivered by prescription registered an increased evolution during the 4 studied years, in comparison to the drugs from OTC category that considerably diminished (-6% 2008 vs 2003).

Conclusions

- we analyzed the range of drugs authorized for use in therapeutics in 2003, 2004, 2007, 2008.
- from the study it can be observed an important increase of the drugs offer.
- at the level of the studied years concerning the drugs range, it can be observed an increase tendency of the number of imported drugs compared to the indigene drugs.
- regarding the drugs delivered by prescription and the OTC ones, those needing prescription have the biggest share.
- the classified list proves to be a very useful instrument for the professionals from the medical and pharmaceutical field, because it classifies very strictly the drugs, taking into account the specificity criteria that contribute to a more efficient distribution and prescription.

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