

## DIFFICULTIES IN THE LIBERALIZATION OF THE MARKET OF OTC MEDICATIONS IN REPUBLIC OF NORTH MACEDONIA AND EXPERIENCES FROM EUROPEAN COUNTRIES

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### Abstract

Amendments to the Law on Medicines and Medical Devices (Official Gazette 27/2014) allow the marketing of OTC drugs outside pharmacies. Despite numerous controversies among the concerned parties, in February 2014, the Ministry of Health announced a list of medicines that can be sold at certain points of sale, namely in supermarkets and gas stations, arguing that the sale of OTC medications outside pharmacies is a practice that has been implemented in several European countries and, in addition, the increased market competition will lead to lower prices for these medicines. Practically, the European countries share different views on this issue. In 10 out of the 28 European countries there is a monopoly in the pharmaceutical sector in terms of the sale of OTC medicines, whereas in the remaining 18 countries, OTC medicines can be sold outside pharmacies. In addition, the range of OTC medicines that can be sold outside pharmacies varies among different countries. In some countries, the list of medications that can be sold outside pharmacies is quite restricted. In the Republic of North Macedonia, this list includes 108 drugs. This approach in the sale of OTC drugs in Republic of North Macedonia has been viewed with a great deal of skepticism by pharmacists. Its implementation in practice remains a challenge for relevant institutions in the country.

*Keywords:* OTC medications, pharmacy, market liberalization

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### INTRODUCTION

Amendments to the pharmaceutical legislation in the national legislation of all European countries and policies undertaken in recent years have primarily aimed at reducing pharmaceutical expenditures. To achieve this objective, the legal changes have mainly attacked the distribution network of medications. The distribution network of medications includes distributors or wholesalers and pharmacies that include open network pharmacies and hospital pharmacies.

The implementation of legal regulations dealing with the interference in the wholesale network has led to the reduction of the number of wholesalers across the entire European territory. In the early 1990s there were about 600 wholesalers in the EU. This large number of wholesalers was greatly reduced and in 2001 there were 346 wholesalers in the EU. (OECD, 2014)

Regarding the legal changes that attacked the retail network or, more specifically, open network pharmacies, it has been ascertained that they referred to liberalization or deregulation. The liberalization of the pharmaceutical market in fact constitutes a "facilitation of rigid and strict rules and regulations", considering it as a mechanism that would increase market competition, which would result in lower costs for patients, but on the other hand they (patients) would have easier access to more quality services.

## RESULTS AND DISCUSSIONS

### *Legal changes aiming at the liberalization of the pharmaceutical market in open network pharmacies*

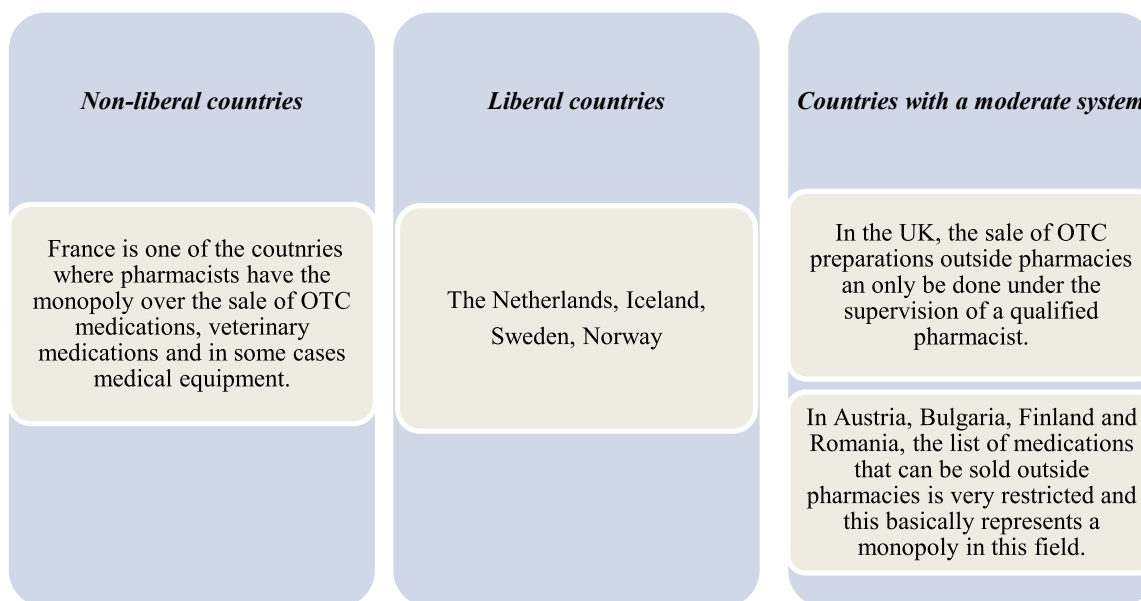
The liberalization of the pharmaceutical market in open network pharmacies implies a modification of several important segments such as:

- Liberalization of regulations regarding the establishment of new pharmacies;
- Liberalization of pharmacy ownership;
- Liberalization of the sale of the OTC medications outside pharmacies. (Report on the Irish retail pharmacy sector, 2014)

In some EU member states, the application of the new rules on liberalization began earlier, whereas in most of the member states the liberalization began after 2000. Legislative rules which imposed strict criteria on the foundation of new pharmacies by applying demographic and geographic criteria began to be abolished in some places. Thus, in Spain, national legislation laid down the criteria for opening new pharmacies that required a minimum distance of 250 meters between pharmacies and a minimum of 2,800 persons to be supplied by that particular pharmacy. These restrictions on the establishment of pharmacies were abolished in 1998. In addition, the rules on the establishment of new pharmacies and the restrictions that existed from these legal regulations were abolished in other EU member states such as Germany, Iceland (1996), Ireland, the Netherlands, Norway (2001) and Sweden (2009). (Vogler et al. 2014)

### *Legal changes on the liberalization of the market for OTC medications in European countries*

Liberalization also envisaged lifting the monopoly from pharmacies regarding OTC medications. However, at this point of market liberalization, the EU states differ quite a lot. France, for example, is one of the EU countries where pharmacists have a monopoly over the marketing of not only prescribed medications but also of OTC products, veterinary drugs and in some cases even of medical equipment. On the other hand, other countries allow the sale of OTC medications even outside pharmacies. A rather liberal country in this regard is the Netherlands where less qualified people are allowed to distribute a wide range of OTC preparations through the so called 'drug stores'. On the other hand, in the United Kingdom, the sale of OTC medications outside pharmacies can only be done under the supervision of a pharmacist. In Norway, the sale of OTC preparations outside pharmacies is also permitted. In 10 out of the 28 European countries, there is a monopoly in the pharmaceutical industry with regard to the sale of OTC medications, while in the remaining 18 other countries, OTC medications can be sold out of the pharmacies. However, the rate of OTC medications that can be sold out of the pharmacies varies among different countries. In Austria, Bulgaria, Finland and Romania there is a very limited list of drugs that can be sold out of the pharmacy and it is almost equal to a monopoly in the pharmaceutical industry. In other countries where the sale of OTC drugs is allowed outside the pharmacy, this is done either by OTC-specific dispensers such as Denmark, Norway and Portugal, or in general stores such as supermarkets, grocery stores, pharmacies or gas stations. (Vogler et al. 2012)



**Figure 1.** Different viewpoints in European countries regarding the liberalization of the OTC medication market

Although there are still no data on the success achieved with the liberalization of the sale of OTC preparations from the EU countries, some reports indicate an increase in annual turnover from OTC preparations in Norway. According to statistical data from 2012 1 billion NOK (Norwegian krona) were collected from the sale of OTC preparations. This represents an increase of almost 23% since 2003 when the free sale of OTC preparations was launched in this country. Statistics show a 1% increase in OTC sales in 2012 compared to 2011. This generates a 12% increase in the total sales of drugs. OTC drugs that have had a sales increase include: Paracetamol with 6 %, Xylometazoline (a medication used to improve nasal congestion and the only one allowed to be sold outside pharmacies) by 7% in 2012 and for nicotine substitutes sales increased by 31-35%. (Report on the Irish retail pharmacy sector, 2014)

#### *Liberalization of market for OTC medications in the Republic of North Macedonia*

Amendments to the Law on Drugs and Medical Aids in the Republic of North Macedonia add some new attitudes. According to these changes:

- Legal persons who are registered and carry out wholesale and retail trade in food products, beverages and tobacco and/or are registered and carry out the retail sale of petroleum derivatives in petrol stations under the Law on Business Organizations may perform wholesale of medicines that are offered without a prescription.
- This specific legal person should engage highly-qualified personnel in the field of pharmacy who should always be available and responsible for the reception, storage, transportation, distribution and delivery of medicines as well as to carry out the supervision of documentation for the Agency of Medicines through which the tracking of these medicines is carried out. (Official Gazette No.27/2014)
- The legal person in question can also perform retail sales of drugs without prescription, only in their own stores.

In February 2014, the Ministry of Health published a list of drugs that can be sold at certain points of sale, namely in supermarkets and gas stations. This list contains 108 preparations such

as: paracetamol, ibuprofen, metamizole; vitamins such as tocopherol, pyridoxin, vitamin C, etc. and can still be viewed on the website of the Ministry of Health. In 2015, various subjects were licensed to sell OTC drugs. (Table 1)

**Table 1.** Licensed subjects for selling OTC medications in the Republic of North Macedonia

<b>Subject</b>	<b>Number of points of sale</b>
„Zhito Market“	21
„Makpetrol“	86
„Tinex“ and „Kosmo“	43

The decision of the Ministry of Health on allowing the sale of OTC drugs outside pharmacies was severely criticized by the Group of Pharmaceutical Companies, wholesalers and pharmacies in the country, arguing that the sale of drugs from unprofessional people poses a risk to the health of the population; however, this law was adopted. The liberalization of drug sale by the Ministry of Health was argued by the fact that selling OTC drugs outside pharmacies is a practice that has been implemented in several European countries and, in addition, increased market competition will lead to lower prices for these medicines.

For a period of several months, the above-mentioned subjects continued selling OTC drugs. However, this way of selling did not last long. The licensed subjects withdrew from this activity, arguing that the interest of the citizens was extremely low and the profit margin as well. In other words, this was a failure of the competent bodies. The law is still in force and commercial entities also have permits to sell OTC drugs, while practically nothing is happening. Pharmacists apparently anticipated all of this, so they were skeptical and long opposed this law. After all this, it is necessary to revisit once again the changes to the law regarding this section.

A review of the law by consulting all parties concerned is indispensable by evaluating one by one all the benefits and risks that might result from the practical implementation of the law in question. Despite the arguments put forward by the Ministry of Health, one should not overlook the risks inherent in this matter. The following table presents some of the arguments for and against the sale of OTC drugs outside pharmacies. Although these drugs are considered as "light" drugs, one should not overlook the fact that they remain drugs and the consequences of their inadvertent intake could be very serious for patients.

**Table 2.** Arguments pro and against the liberalization of the market of OTC drugs

<b>Benefits</b>	<b>Risks</b>
<b>Lower prices</b>	Side effects and complications from the interaction with other medications
<b>Easier and faster access to medications</b>	Consequences from self-diagnosis and self-treatment
<b>Time-saving for healthcare employees</b>	Non-evidencing of undesired reactions caused by the use of OTC drugs.
<b>Faster solution for “lighter treatments”</b>	Uncontrolled usage of medications and lack of necessary information.
<b>Full autonomy in selection</b>	Consequences from addiction and/or intentional abuse.

## CONCLUSIONS

Based on this study as well as on the analysis of the legislation in EU member states regarding this issue as well as going into the details of various different aspects of the implementation of the infamous law in practice and different viewpoints that exist regarding the liberalization of the market of OTC drugs, we can conclude the following:

- The liberalization of the market of OTC drugs is not a general practice implemented in all EU member states;
- There are still no precise data with regard to the achieved success through the liberalization of the OTC sales (in Norway there has been an increase of about 23% since 2003, when the open sale of OTC drugs began in this country);
- The market liberalization remains a well-disputed and debated issue in many EU countries and its effects are yet to be seen in the upcoming years;
- The comparison with EU countries is not real because those countries have a very well-developed and organized surveillance system; the awareness of the population regarding the usage of drugs in those countries varies a lot in terms of cognition and understanding of medications as such compared to the level of awareness at our population;
- The dysfunctionality in practice of the mentioned law speaks for itself and implies that further changes and amendments to the infamous law are more than necessary.

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