

## RESEARCH STUDIES

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### Pharmacists' role in managing food supplements

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#### Abstract

**Background:** Every year, the value of the world market of Food Supplements (FS) increases considerably, especially following the accepting the role of nutrition in maintaining health. The share of official importers of medicinal products on FS market is not significant and the procedure for placing food supplements on the market is not sufficiently regulated. All these conditions create major health risks for FS consumers.

**Material and methods:** In order to study the complexity of the field of food supplements and to highlight the existing problems in this field at the national level, and also to determine the pharmacist's role in releasing food supplements and counseling patients, was used comparative method for registering the dietary supplements in Romania and the Republic of Moldova.

**Results:** The complex assessment of food supplements in the Republic of Moldova and Romania and elucidation of the pharmacist's role in dispensing of food supplements were carried out in order to prevent the abuse and non-rational use of the FS. For this reason it was carried out a comparative analysis of the legal framework for FS in both mentioned countries and the study of the national food supplements market was performed according to the criteria of the producers and importers that are present on the market.

**Conclusions:** Legislation on food supplements in the Republic of Moldova is incomplete and unsatisfactory formulated. The value of the food supplements market is constantly increasing making this area attractive. The prevalence of economic interests over the medical interests may have adverse consequences for the health of the population. The pharmacist has the primary role both in implementing the necessary legislative changes and in counseling patients to prevent the non-conforming use of food supplements.

**Key words:** food supplement, legislation, food supplements market, risk, population health.

#### Introduction

As early as in 90s, the food supplements market (FS) was almost non-existent in the Republic of Moldova and as well, in its neighboring countries, which is a total difference from the current situation. Excessive consumption of food supplements (FS) is becoming more and more current issue, taking into consideration the concern of modern people about healthy living and eating, as the environment becomes more unfriendly and the life more stressful.

Along with the benefits that population has through the technology in the most areas of life, this is also a prerequisite for the environmental degradation of the environment.

The ecological issue has been worldwide discussed and considered one of the main global problems faced by people. There are a lot of studies carried out all around the world, demonstrating the damage caused by the ecological status of the environment and its effects on the quality of life. According to WHO data till 2050 around 25% of the European population will be over 65, a large number of countries face demographic challenges, the aging of the population, etc. Under these conditions, an increased attention is paid to healthy lifestyle: reducing stress, physical activity and, last but not least, an appropriate nutrition regime. Due to this reason, a favorable condition for the develop-

ment of the FS market has been created [1]. FS have begun to extend their coverage area in the EU due to the widespread recognition of the role of nutrition in maintaining health. FS consumption, as well as consumer confidence in their effects increases each year, constituting an easy solution to the problem of maintaining health in the accelerated pace of contemporary life.

The global market value of the FS has exceeded \$ 80 billion USD, on the background of modern people concern for a proper health status and quality of the life [2].

Based on the Directive 2002/46 / EC of the European Parliament and of the Council of 10<sup>th</sup> of June 2002 on the harmonization of the legislation of the Member States relating to food supplements, "food supplements" means food stuffs intended to supplement the nutrition and which are concentrated nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed via different forms of issue, such as capsules, pills, tablets, powders, liquid in vials, other similar forms of liquids and powders intended to be taken in small measured unit quantities. In the "Dietary Supplement Health and Education Act of 1994" it is foreseen that FS are food products and not medication.

The phenomenon of the increase of FS consumption is

obvious also in the Republic of Moldova, having, in principle the same premises as in the rest of the countries with a different level of development. However, despite this, regulating the registration and circulation of FS on the Moldovan market, controlling the consumption of the FS, monitoring the adverse reactions and advising the consumer on FS – need to be improved [3, 4, 5]. The incomplete legislation of the Republic of Moldova and the lack of a set of 7 good practices in the management of the circulation of the FS, the advertising that may suggest to the consumer erroneous ideas about the effects of the FS, may consequently lead to the inappropriate and uncontrolled consumption of FS and, as a result, compromising the consumer health [6]. The possibility of purchasing FS without a prescription, not only in pharmacies, but also in other ways (online shops, tele-shopping, drugstores, supermarket, natural products' shops, etc.), deprive the consumer of getting any professional advice and the often inconsistent advertisement becomes the sole source of information for the population.

In this context, we intend to evaluate the complexity of factors that have contributed to the current situation in the food supplements market in the Republic of Moldova.

### Material and methods

The research was conducted to study the complexity of the field of food supplements and highlight the existing problems in this field at national level, as well as to determine the role of the pharmacist as the main specialist in the field of dispensing food supplements and counseling the population to prevent abuse and non-adequate use of food supplements.

The study, analysis and synthesis of literature data regarding the circulation of food supplements on Romanian and Moldovan markets by using the interpretative and comparative method of the legislation and procedures for registration and placing of food supplements on the market have been carried out with the purpose to propose different ways to improve the regulation and monitoring of FS circulation on the national market.

The comparative method involves comparing the procedures of registering food supplements in Romania and the Republic of Moldova, comparing the content of the food supplements dossiers and assessing the differences in order to determine some possibilities for improving the procedure of registering food supplements.

The interpretative method involves performing statistical surveys of the national food supplements market based on the criteria of FS manufacturers, importers and distributors and interpreting the results obtained.

### Results and discussion

According to the legislation of Romania and the Republic of Moldova, food supplements are not included in the category of medicines, therefore the procedure for their registration and placing on the market differs from the one for medicinal products.

In Romania, the procedure for registering food supplements differs depending on their composition. Food supplements (vitamins and minerals) are registered directly in the Ministry of Health, and the FS containing other substances for nutritional and physiological purposes are registered at the Institute of Food Bioresources within the Ministry of Agriculture and Rural Development or at the Regional Centers of Public Health in Cluj-Napoca, Timisoara or Iasi, belonging to the Ministry of Health.

In the Republic of Moldova, the registration and notification procedure is carried out at the National Public Health Center (NPHC), food supplements, containing nutrients are subject to the registration procedure and those containing other substances for nutritional and physical purposes are the subject of notification procedure.

According to the legislation, the food supplement manufacturer or the person responsible for placing the food supplement on the market fulfills a registration form to which the product label is enclosed in the folio and the food supplement dossier is going to be registered.

The content of the file attached to the request for notification is different in both countries (tab. 1). The legislation of the Republic of Moldova on the procedure for registration and notification of FS is incomplete and is incorrectly formulated. General notions are used, without clarifications, which make it possible to avoid the necessary rules. (e.g.: «documents and information ....», «statements ...», «evidences ...», etc.). It is not mentioned the nature of the document by whom they should be issued and confirmed.

Table 1

The comparative content of the FS dossier in Romania and the Republic of Moldova

No	Republic of Moldova	Romania
1.	Information about the applicant's name and his legal address	Application for Product Notification
2.	Identification data of manufacturer and importer (if applicable)	Certificate of registration at the Trade Register, its copy
3.	Place of production, trade name of the product	Product Presentation Format for Import Products - Certificate of Conformity and Country of Origin
4.	Original label design and the one with its translation into the state language	List of product ingredients (quantitative and qualitative)
5.	Documents and information certifying that the components of the product are legally manufactured and marketed in the country of origin	Physico-chemical and microbiological analysis bulletin issued by a laboratory accredited by a third party
6.	Evidence of the components of the product	Product label in Romanian
7.	Declaration/Statement that the product is not registered as a medicine in the country of origin	Packaging certificate, issued in accordance with the legislation in force

In 2013, in order to improve the regulations in the field of food supplements in the Republic of Moldova, a draft Government Decision on the notification of food supplements was developed, representing a transposition of:

- Directive 2002/46 / EC of the European Parliament and of the Council of 10<sup>th</sup> of June 2002 on the approximation of the laws of the Member States relating to food supplements.
- Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements.
- Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20<sup>th</sup> of December 2006 on nutrition and health claims made on foods.
- Commission Regulation (EU) No 432/2012 of 16<sup>th</sup> of May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health.

Recent data on national market values of food supplements are not visible in the information flow.

In this paper we conducted the statistical analysis of the market by producers, importers and distributors of FS on the Moldovan market.

As a database served the Register of Food Supplements of the National Centre of Public Health, which includes the following lists:

- The list of registered food supplements – 813 trade names
- The list of food supplements notified – 1696 trade names
- The list of nutritionally and physiologically registered substances – 3 trade names
- The list of food supplements which have been refused for the registration – 1 trade name

The market share of the producers of food supplements registered and notified in the Republic of Moldova is demonstrated in figure 1.

According to the results, almost 30% represents the group of importers holding less than 1% on the national market of the FS. The other 70% constitute 20 importers, from which six are official medicine distributors: Tetis International, Prosanitas Farm – 1%; Esculap-Farm, Farmina SRL – 3%, Dita EstFarm – 4%, IM Becor SRL – 8%. The leader is the “Sibimport” importer with 9% (tab. 2).

Table 2

Share of (%) of FS importers registered in the Republic of Moldova by 01.10.16

No	Importer	Market share, %
1.	Tetis International	1
2.	Prosanitas Farm	1
3.	Vainstein Sanatate	1
4.	SC Farmaco Social	2
5.	Moebius SRL	2
6.	Darurile Vietii	2
7.	Virim Impex	2
8.	Vivasan	2
9.	PVR Stil SRL	3
10.	Farmina SRL	3
11.	Esculap-Farm	3
12.	Forever	3
13.	Maiac-Farm	3
14.	Ocean Resourse	4
15.	Zezifora	4
16.	Dita EstFarm	4
17.	Coral Club	6
18.	Cosmovis	7
19.	ÎM Becor SRL	8
20.	Sibimport	9
21.	Others (importers with quota < 1%)	30

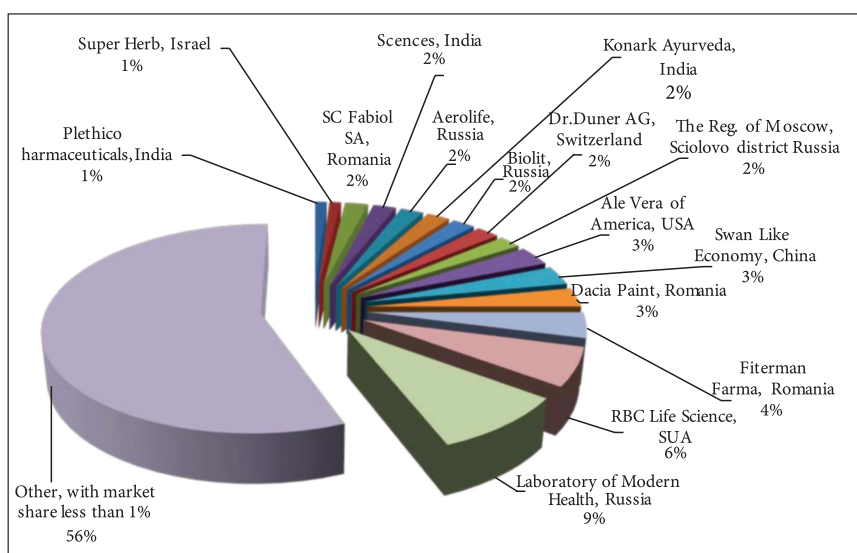


Fig. 1. The market share (%) of the producers of food supplements registered in the Republic of Moldova by 01.10.16

At the last stage of the statistical study of the national food supplements market we identified the share of the notified importers of the FS on the national market (tab. 3).

Table 3

**Share of (%) of FS importers notified in the Republic of Moldova by 09.04.17**

No	Importer	Market share, %
1.	IM Becor SRL	5
2.	Foralux	7
3.	DitaEstFarm	22
4.	Importers with quota 0 -0,5%	10
5.	Importers with quota 0,51 -1%	5
6.	Importers with quota 1.1-5%	41

Since the mandatory implementation of GMP compliance for medicinal products, more and more manufacturers choose to register their products as food supplements. Even after the expiring date of the Certificate of Registration of a medicine, the manufacturer chooses for the following registration to register their product as a food supplement.

This fact generated the so-called phenomenon of double registration of the same active substance on the national market. Thus, the chemical or plant substance with the same dose is found to be registered both, as a medicinal product and as a food supplement at the same time (tab. 4).

Table 4

**Active substances with double registration status on the Republic of Moldova market**

No	Name of the active substance	Presentation	Name of the medicine	Name of FS
1.	Silymarinum	140 mg	Lagosa	SameLive
2.	Pancreatinum	10000 IU	Kreon	DIGEX
3.	L- carnitinum	100 mg	Cartan	Proefect
4.	Glicinum	100 mg	Glicised	Glicin – Эвалар
5.	Carbo activatum	250 mg	Carbune activat	Toxinol

The substances listed in the table are just a few examples demonstrating the presence of this phenomenon on the national medicines and food supplements market. Operating with the Food Supplements Register it is very difficult to perform an analysis and statistical study in this area for the following reasons:

- The list is made in the format of a Microsoft Word file, which significantly complicates the statistical analysis.
- The same manufacturer or importer is registered in different cases under different names, eg., the same producer is registered as: “Laboratorul Sanatatii Moderne” (Modern Health Laboratory), “Laboratorul Sănătății Contemporane” (Contemporary Health Laboratory) and “Лаборатория

Современного Здоровья” (Laboratory of Contemporary Health).

- The composition of food supplements included in the list of notified FS is specified in a superficial manner and without specifying doses. The composition is completely missing in the registered FS list. This is an obstacle in comparing the composition of food supplements and medicines.

Changing the status of their product from the medicine to a food supplement, the manufacturer pursues certain purposes, all of them having more or less an economic nature:

1. Avoiding the state control of different levels which is mandatory for the medicines – thus, avoiding additional costs and obtaining the possibility of saving on the quality of raw materials and finished products.

2. Avoiding the rigorous requirements imposed on medicinal products in the registration procedure and the presence of a detailed dossier including all the characteristics of the medicinal product. The lack of the requirement to declare sources of raw material, the technological process, the lack of the need to justify the validity - which again is done by producers in order to save and get financial benefits.

3. Possibility to make active and aggressive promotion of the product through the media, online space, through communication with medical personnel and pharmacists.

4. Including of food supplements in OTC list, which makes possible to sell them without a prescription, but only at the recommendation of the pharmacist or based on the advertising information.

5. Lack of vigilance and monitoring of the circulation of these products on the market, and the considerable decrease in the likelihood that the adverse reactions of these products will be considered or studied by the pharmacovigilance authorities.

6. Avoiding the need for post-marketing trials.

7. Mandatory implementation of GMP rules for medicines manufacturers.

These and many other factors influence the decision of manufacturers to change the status of their medicinal products in food supplements.

Inappropriate and abusive use of food supplements can lead to adverse health consequences for the population. Nonrational use of food supplements can also cause various side effects on all organ systems, generated both by the intrinsic effect of the food supplement and their association with medicines. Considering the fact that some food supplements are recommended to children and pregnant women and the elderly with chronic diseases, there is absolutely obvious need to regulate this area and monitor the circulation and consumption of these products by the population.

The pharmacist, being a major specialist in medicines, has the primary role both in implementing the necessary legislative changes and in counseling patients to prevent non-compliant use of food supplements.



### Conclusions

1. Legislation on food supplements in the Republic of Moldova is incomplete and unsatisfactory formulated, which could be a prerequisite for the irrational use of food supplements with all subsequent consequences.
2. The value of the food supplements market is constantly increasing, making this area attractive from the economic point of view for both producers and distributors. The prevalence of economic interests over the medical interests may have adverse consequences for the health of the population.
3. The quality of food supplements on the national market is compromised once the most important market segments are held by manufacturers and importers for whom food supplements market is an auxiliary branch.
4. Frequent and obvious violations of the legislation provisions on the composition and labeling of food supplements are observed, and any provisions or reporting protocols on such breaches are missing.
5. The pharmacist has the primary role both in implementing the necessary legislative changes and in counseling patients to prevent the non-conformed use of food supplements.

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