

# HOLISTIC COMMUNITY PHARMACY: SELF-MEDICATION & SELF- TREATMENT

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**HOLISTIC COMMUNITY PHARMACY: SELF-MEDICATION & SELF-TREATMENT**  
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Authors: Martina Puc, Nina Strah, Matija Centrih, Azra Uzunović, Irma-Hermina Klemenc, Mojca Slodej Kušlan, Katja Hleb

Editor: Martina Puc

Technical editor: Špela Vozelj

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## TABLE OF CONTENTS

HOLISTIC COMMUNITY PHARMACY® ROLE IN SELF-MEDICATION AND SELF-HEALING .....	2
EVALUATION OF THE FINANCIAL IMPACT OF HOLISTIC COMMUNITY PHARMACIST ON PUBLIC HEALTHCARE EXPENDITURE.....	6
LESSONS LEARNED ON VISITORS' ACCEPTANCE OF HOLISTIC COMMUNITY PHARMACY® APPROACH ON SELF- MEDICATION .....	14
FOOD SUPPLEMENTS DEFINITION VARIATION IN EUROPE IMPACTS THE ROLE OF COMMUNITY PHARMACIST IN SELF-MEDICATION & SELF-TREATMENT.....	17
THE ROLE OF HOLISITC COMMUNITY PHARMACIST IN THE TREATMENT OF AN IRON LOW INTAKE .....	48
THE ROLE OF COMMUNITY PHARMACIST IN THE SELF-TREATMENT WITH SCHUESSLER SALTS .....	57
HEALTH PROFESSIONALS BETWEEN THE CARE FOR OTHERS AND THE CARE FOR SELF.....	65

## TABLE OF FIGURES

Figure 1: The percentage of visitors picking up the prescribed medicine without knowledge on specified issue evaluated by IRRK methodology. The evaluation was carried out in the years 2017 and 2018 in Lekarna Dobrova. In one year time we observed a significant drop in absence of knowledge on specified knowledge. ....	8
Figure 2: The difference in negative findings between years 2017 and 2018 evaluated by IRRK methodology in Lekarna Dobrova.....	9
Figure 3: The scheme of calculating process. Numbers were calculated for each year and each question separately. ....	10
Figure 4: The difference in % of direct costs due to structured holistic consultancy from the year 2017 to the year 2018.....	12
Figure 5: Presentation of European countries' national food supplements definitions alignment with the referent one (EU Directive 46/2002).....	19

Figure 6: Model of human mind development, developing in six different directions  
(Kegan, 2020) ..... 68

## TABLE OF PICTURES

Picture 1 Deeply sunkien eyes into their sockets - No 11 .....	61
Picture 2 Brownish colouring – No 1 .....	61
Picture 3 Waxy like ear.....	61
Picture 4 Large pores - No 8.....	62
Picture 5 Milky bluish reddish Colouring - No 4 .....	62
Picture 6 Impure skin, blackheads, acne No - 9.....	62
Picture 7 Olive greenish discolouring around eyes, mouth, chin or entire face - No 10 ...	62
Picture 8 Thick, compacted wrinkles - No 12 .....	63
Picture 9 Facial signs indicating the need for Nr. 7.....	63

## TABLE OF TABLES

Table 1: The rough evaluation of direct and indirect cost as a consequence of lack of knowledge regarding specified issues No. 1.....	10
Table 2: The rough evaluation of direct and indirect cost as a consequence of lack of knowledge regarding specified issues No. 2.....	11
Table 3: The rough evaluation of direct cost as a consequence of lack of knowledge regarding specified issues No. 3. * Indirect costs were not calculated due to lack of information.....	11
Table 4: The rough evaluation of direct and indirect cost as a consequence of lack of knowledge regarding specified issues No. 4.....	12
Table 5: European countries covered by the review on food supplements definition .....	19

# FOREWORD

Community Pharmacies are developing in different directions, many of them losing their own identity. Think about it. What is the identity of a professional who is performing vaccination? What is the identity of a professional who is producing products? What the identity of a professional who is selling products by price promotion? And who are you without your own identity? Do you have tomorrow?

The identity of a Holistic Community Pharmacy© is on the other hand very clear, helping its visitors to maintain or improve their health with health products. However clear, it does not mean easy. It is obvious from all the effort of PGEU and other professional organizations they are putting in promotion of a patient oriented care. But the goal of healthcare systems, Community Pharmacies being a gate keeper to the doctor's offices and hospitals as it obviously has risen during this year, is not reachable through selection of patients like in Pharmaceutical Care programs. The systematic approach to all visitors of a Holistic Community Pharmacy© with the structured consultancy is giving actual and measurable results.

The amazing results of the structured consultancy and other parts of a Holistic Community Pharmacy© approach on compliance are now known for couple of years, so are financial results for the Community Pharmacy. The time to evaluate an effect on public health expenditure came. And with the publication of results the question, is a profession mature enough to embrace the new approach regardless of the sweat involved, or it will need a push from outside, is more evident.

The impact of a Holistic Community Pharmacy© approach on a compliance in the case of prescribed medicines is evaluated, this year we are sharing the experience with the structured consultancy on non-prescription medicines. It is becoming more evident what alternatives people see and use in a daily life not just for products but also for services of consultancy. And they are choosing.

Time is running faster and faster. Will we all survive changes on the way? The future for a Holistic Community Pharmacy© looks bright through results. Will you embrace it? It depends on your values, convictions, broad knowledge and awareness.

Editor

mag. sci. Martina Puc, MPharm, spec., MBA

# HOLISTIC COMMUNITY PHARMACY<sup>®</sup> ROLE IN SELF-MEDICATION AND SELF-HEALING

Mag. sci. Martina Puc, mag. farm. spec., MBA

The Holistic Community Pharmacy<sup>®</sup> concept differentiation from other approaches in Community Pharmacies is based on the added value to visitor's health. Some of the most important characteristics include also the following:

- People coming in are treated as visitors. It means we are speaking about people centered approach. Furthermore the communication is among equally valid persons, two adults as defined in Transactional analyses of E. Berne. A pharmacist is not above the visitor and the visitor is not above the pharmacist, there are no kings or queens.
- Selection of people (patients or visitors) for a detailed consultancy is considered as discrimination. Every visitor should be treated in the same manner and be given the highly possible care.
- Structured consultancy is designed to improve the consultancy process itself, to improve compliance and to follow the quality principles of ISO 9001 standard.

The Holistic Community Pharmacy<sup>®</sup> concept differentiation demands different grounds then for other approaches, among them the consultants identity, organisation and communication stand out. Holistic Community Pharmacists<sup>®</sup> embrace consultants identity. Besides relevant knowledge and competences it means that relevant personal values and level of awareness are keys to success and satisfaction of visitors and pharmacists themselves. Organisation should support the purpose and that means process oriented organization, not functional one. There should be risk management included in all processes top down, quality management system of services and appropriate space design, including sitting consultant tables. Structured communication should be planned, performed and evaluated not just with visitors, but also with employees and with business partners.

To implement the Holistic Community Pharmacy<sup>®</sup> concept approximately 5 years are needed for a main transition. For implementation big success factors are owner's and manager's commitment to purpose. The organizational culture is changed during a transition along with a decision making process and leadership, common values and rituals. Complexity of change is a hurdle and should be overcome, since there are a lot of interconnections. Nevertheless the speed of change is a crucial success factor. A manager is required to manage a number of different parameters at the same time.

The Holistic Community Pharmacy<sup>®</sup> concept add value to visitor's health in general and in self-medication and in self-treatment, too. Visitor's health is a central focus point in a Holistic Community Pharmacy<sup>®</sup>. Process wise the following steps should be followed:

- Identification of factors with an impact on individual's health
- Evaluation of information
- Decision should be made, if it necessary to visit a doctor
- Selection of appropriate substances
- Selection of appropriate products
- Instructions and advice

Besides the content of these steps the Holistic Community Pharmacy<sup>®</sup> approach address also the communication and adjustment to the community pharmacy identity timewise and space wise.

With the question, what is your role in the process of self-medication and self-healing, the community pharmacist at this point do not doubt their desirable identity and process itself. They doubt profitability. On the other hand community pharmacy services users realize at this point there is more depth in self-medication than a proper use of medicines. They expect the same approach for different healing systems. But the most important is their doubt, who can I trust?

If we want to answer the question, is the Holistic Community Pharmacy<sup>®</sup> approach paying off, we have to consider to whom. Visitors are in a good position, since they are advised just when it is necessary what is necessary. A Community Pharmacy itself gains higher profitability, however complete guidance and speed of implementation should be followed. Employees get fulfilment and come to a higher salary quicker. For public finances it is important to notice less misuse and higher compliance with a huge impact on healthcare costs. In that context justified doctor's visits should not be omitted. For health product industry there is also higher profitability with sometimes necessary adjustment of the relationship and portfolio quality.

Trustworthiness of a Community Pharmacy depends on its responsibility, integrity and visitors expectations. For a Community Pharmacy it is important to re-evaluate the answers on questions like:

- When a Community Pharmacy is taking responsibility, for what?
- When a Community Pharmacist is taking responsibility, for what?

Visitor's expectations correlate to their previous long term experiences and messages they received from Community Pharmacies. If they see just a merchant with a diploma in a pharmacist, from which experiences they came with that conclusion? If a pharmacist recommends the cheapest products, visitors learn no complex knowledge is needed for a choice. On the other hand visitors more and more expect products, advice and consultancy from different healing systems. And still they take various responsibilities for their own health, self-medication and self-healing. It can be also correlated with a perception of a Community Pharmacy integrity, especially since many Community Pharmacies do not differentiate their identity from the identity of a Pharmaceutical



Industry. For a Community Pharmacy it is important to re-evaluate the answers on questions like:

- What is traded with vendors?
- What ethical and moral dilemmas you have?

Based on above written positions the answer to the question, what is your role in the process of self-medication and self-healing, is bringing in the picture of identity and process questions like, what is your message to visitors when you are promoting certain products and brands or when you are writing articles and giving advices in different media.

Community Pharmacy identity depends strongly on Owner's and Manager's understanding of an added value of the Community Pharmacy and in which value chain they position themselves. If anyone of them does not understand the term value chain or do not actively choose one, it is a bad news for that Community Pharmacy. The same is valid for the design of their service.

Process of self-medication implies complex thinking and decisions, like for example:

- What are the health issues of the visitor?
- What are the reasons?
- What should be the best goal for visitor's health?
- Which products can help and how?
- What products really do?
- How long should they be taken?

How an individual understand health, context of symptoms, an illness, has an influence and impact on the behaviour during self-medication and self-healing. If a person just want to get rid of the annoying symptoms, it is more difficult to approach them then if the person is coming with a question, what is causing the symptoms they notice.

At the end of the day, the consultancy depends on the chosen identity, since the actual behaviour of a Community Pharmacy follows it.

If a Community Pharmacy chooses to be just a distributor of health products, it ends up as an ordinary retail business, where one can expect as much automation as possible, together with an on-line shop. They advertise a lot of products and their brands. Employees are trained just to a level which is legally required and checked and that training is sponsored by the industry.

If a Community Pharmacy chooses to add value to a product, one can expect the central role of pharmaceutical technicians. A Community Pharmacy arranges for them so much sponsored trainings on certain products as possible. Tight relationship with the industry is a highly appreciated value.

If a Community Pharmacy chooses to improve and/or maintain visitor's health, a pharmacist is a consultant. A Community Pharmacy is organizing independent in- depth

training for them. They are setting and implementing professional criteria for selection of products.

In every one of those three choices the question is, is the added value big enough to ensure a sustainable business.

If a Community Pharmacy is in a business of health products distribution of products, it is almost a common knowledge, retail chains are more effective. Profit margins are low and without big enough scale you are nothing. And competition is global. Look at the Amazon and European on-line pharmacies.

If a Community Pharmacy is in a business of adding value to the product, there are more and more alternative enthusiasts. They have many advantages, like less legal restrictions for example.

If a Community Pharmacy choose to improve and/or maintain visitors health, i.e. a Holistic Community Pharmacy<sup>®</sup>, change needs a commitment.

In reality a Community Pharmacy identity varies and they are more and more segmented in one of the above mentioned approaches. To get their real value tomorrow, they should answer the question, how much would they earn without a monopole.

However the questions leading to the brighter future includes also new cooperation like:

- Do health insurance companies recognise the added value of different community pharmacies?
- Is the approach to different healing systems different?

A different added value of a Community Pharmacy in self-medication is a consequence of the source of theirs self-confidence. It could be:

- structured consultancy
- promotion of product brands including house brands or
- performance of nurse's tasks

With financial evaluation we are coming to the core of existence of Community Pharmacies as a business, consisted of proficiency and values, which are comprised in the answers of the following questions:

- How do you implement moral and ethical principals in your daily work?
- What kind of competences do you have for structured consultancy?
- What kind of knowledge do you have about structured consultancy?

# EVALUATION ON THE FINANCIAL IMPACT OF HOLISTIC COMMUNITY PHARMACIST ON PUBLIC HEALTHCARE EXPENDITURE

Dr. Nina Strah, mag. farm.

Mag. sci. Martina Puc, mag. farm. spec., MBA

Matija Centrih, mag. farm.

## INTRODUCTION

The financial evaluation system of community pharmacy services in Slovenia was established in 1982 and since then has not been changed. The measuring unit is the average time needed for different stages of expediting the medicine. The evaluation unit named "The Point" is proportionally divided regarding the pharmacist's profile and education (1).

The current system has many cons. The first one is the way medicines in Slovenia are prescribed. Three-month-long monotherapy is usually prescribed with a single prescription. They result in the same size of a financial payment for prescription processing, whether a community pharmacist expedites one or three boxes. However, the expedition is still charged per box. The second issue is time, which is paid. Community pharmacist has, on average 3 minutes and 41 seconds paid for one prescription. Of this, 1 minute and 57 seconds are paid by obligatory health insurance, the remaining 1 minute and 44 seconds are paid by voluntary health insurance or by the patient himself. Legal obligations of a Community Pharmacist that need to be done in less than 4 minutes are:

- proper community pharmacy operation prior patient visit, ordering and receiving the boxes of medicine
- to check the patient's insurance and accept the prescription (paper or electronic),
- to confirm the congruity of the prescription with regulations
- to check the prescribed dosage and instructions for the patient,
- to make an administrative control of the prescription,
- to coordinate issues with the patient due to groups of interchangeable medicines and therapeutic groups of medicines (official grouping is made by state health insurance and it has direct impact on the financial refund),
- to prepare the medicine (place it from stock on the work surface),

- to process the box or boxes of the medicine and prescription, which includes computer work,
- to mark the medicine with all legally prescribed signatures,
- to re-check the medicine, prescription, and signatures,
- to give orally or in writing all the necessary information about the correct use and storage of the medicine, possible side effects, and all other necessary professional instructions,
- issue an invoice and receive patient surcharge if it occurred (1).

Therefore, community pharmacist has two options. Either does everything required without enough payment or reduce the amount of work required (only possibility is communication with patient and signatures) to stay within the paid time frame.

## HOLISTIC COMMUNITY PHARMACY<sup>©</sup> APPROACH

M. Puc developed the structured approach to holistic consultancy with recording of pharmacy cases and supervision. The measurement of the system's success is the evaluation of the impact on patient's compliance. In this case, the visitor receives consultancy, including advice and explanation needed for effective and safe use of a medicine (2).

As a compliance evaluation method, we used the IRRK method, which was initially developed to evaluate service quality (2). We checked whether this methodology could be used as a base for evaluation of the holistic community pharmacy<sup>©</sup> approach's financial impact according to prescribed medicines. The key question however is, do direct and indirect public healthcare costs with the holistic community pharmacy<sup>©</sup> approach decrease enough to be financially supported by public finances. On the way to answer that question, we made a rough evaluation first, to decide if more detailed analyses are reasonable.

We expected the holistic structured consultancy improves people's compliance to prescription medicines by more than 5% and that the holistic structured consultancy reduces public costs caused by medicine misuse by more than 5%.

## DATA ANALYSIS

From the IRRK methodology for evaluation of Community Pharmacy impact on patient compliance we have chosen 4 issues for our rough evaluation of financial impact, namely:

- Q1: The knowledge on purpose of the prescribed and dispensed medicine
- Q2: The knowledge on frequency of usage
- Q3: The knowledge on consequences of overdose
- Q4: The knowledge on consequences of omitting the medicine

The year 2017 was the entering year when Community Pharmacy Lekarna Dobrova started with introduction of a structured holistic community consultancy. The evaluation of impact on visitor's<sup>1</sup> knowledge on specified issues was done prior to the start of implementation in 2017 and one year later in 2018. Figure 1 shows the share of negative findings on above specified issues. Therefore, in the year 2017, 15% of visitors did not know the purpose of prescribed medicine, 8% did not know how often they should take medicine, 69% of visitors were not aware of the consequences of overdose, and 36% of visitors were not familiar with the consequences of not taking the medicine.

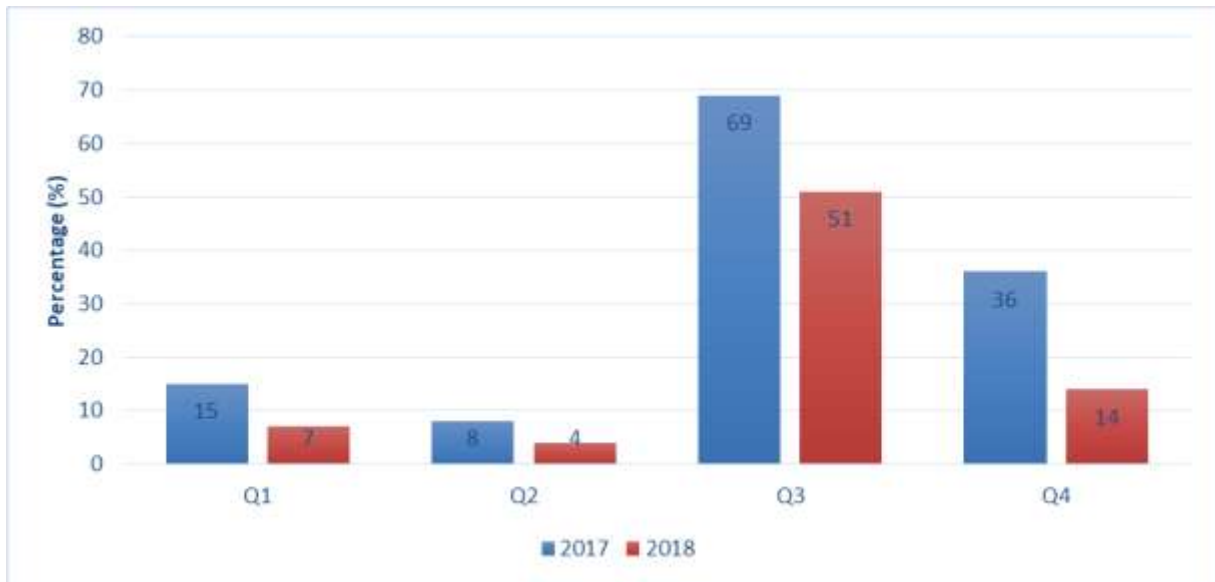


Figure 1: The percentage of visitors picking up the prescribed medicine without knowledge on specified issue evaluated by IRRK methodology. The evaluation was carried out in the years 2017 and 2018 in Lekarna Dobrova. In one year time we observed a significant drop in absence of knowledge on specified knowledge.

A year later (2018), the shares were significantly lower. There were only 7% negative answers for question 1, 4% for question 2, question number 3 was negatively answered in 51% of cases, and question number 4 in 14% of cases visitors did not know any of the consequences of not taking medicine.

<sup>1</sup> With Holistic Community Pharmacy concept<sup>©</sup> the person visiting is a visitor, who could be a patient or not. Within IRRK methodology a visitor is checked, is it a patient for whom the prescription is named to, or not in more detail.

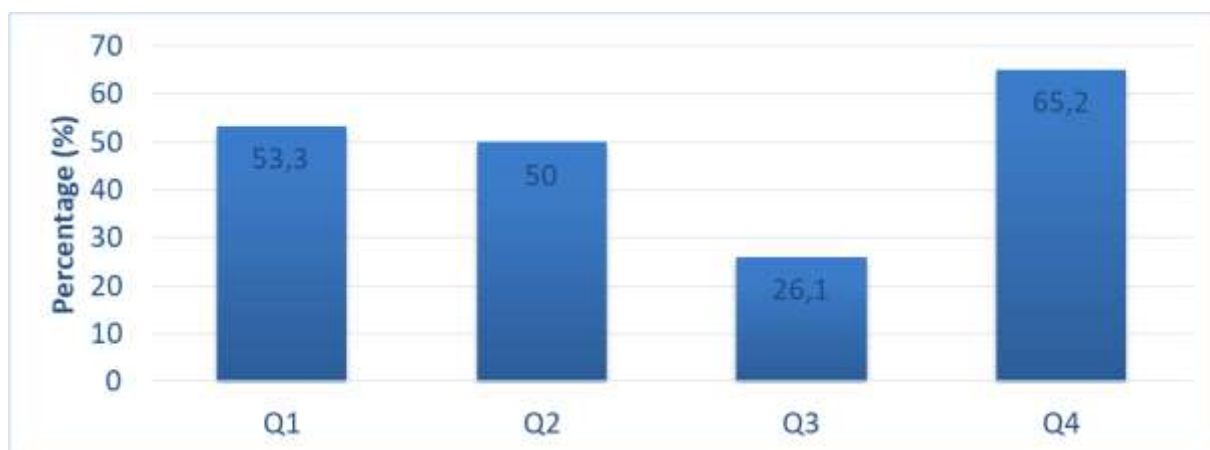


Figure 2: The difference in negative findings between years 2017 and 2018 evaluated by IRRK methodology in Lekarna Dobrova.

The drop of % of negative findings between the year 2017 and the year 2018 is depicted in Figure 2. Apart from knowledge in issue number 3, one can appreciate at least 50% improvement in only one year of practicing the holistic structured consultancy (2).

## FINANCIAL IMPACT EVALUATION ON ASPIRIN PROTECT AS A WORKING STANDARD

Aspirin Protect was in the years 2017 and 2018 among ten the most prescribed medicines in Slovenia. We used it as a working standard, since it is not the most expensive medicine (effect on direct cost), and it is relatively easy to evaluate the consequences (effect on indirect costs). The results are therefore just the first estimation for a decision, should more detailed calculation follow.

It is registered for prevention of cardiovascular complications (H/92/00220/005, H/92/00220/006, (3)). The daily dose of acetylsalicylic acid (ASA) as an active ingredient ranges from 100 mg to 300 mg. The benefits of regular use of 100 mg ASA per day were analyzed in meta analysis (4), where it was recorded a significant reduction in non-fatal myocardial infarction (OR 0.81) and a significant reduction in ischemic stroke (OR 0.88). However, there was also a significant increment in the rates of major bleeding (OR 1.45) and significant gastrointestinal bleeding (OR 1.55) (4).

In case of overdose, chronic salicylism can occur when doses are higher than recommended for a more extended period. It has unspecific symptoms - nausea, dizziness, ringing in the ears, deafness, sweating, nausea, vomiting, headache, confusion. Ringing in the ears occurs at plasma concentrations of 150 to 300 micrograms/ml. Severe side effects occur at plasma concentrations above 300 micrograms/ml. The second hazard is an acute intoxication, which is shown as severe acid-base imbalance (max dose is 3 g of ASA/day) (5).

For an initial rough estimation of costs, we used statistical data and values available for both years. In the year 2017, 16.781.808 prescriptions were prescribed in total. Among them, 500.838 prescriptions were prescribing Aspirin Protect. For more straightforward

calculations, we normalized everything over 100.000 prescriptions, which sum up to 2984 prescriptions/100.000 prescriptions. The total cost of prescriptions for Aspirin Protect was 2.783.625,98€, the cost for one prescription was 5,56€, and the cost for 2984 prescriptions was 16.591,04€ (6).

The total number of prescriptions in 2018 was 17.511.628. Among them, Aspirin Protect was prescribed 501.404-times, which sums up to 2863 prescriptions /100.000 prescriptions. The total cost of prescriptions for Aspirin protection was 2.880.661,81€, and the cost of one prescription was 5,76€. The cost for 2863 prescriptions was 16.448,48€ (6).

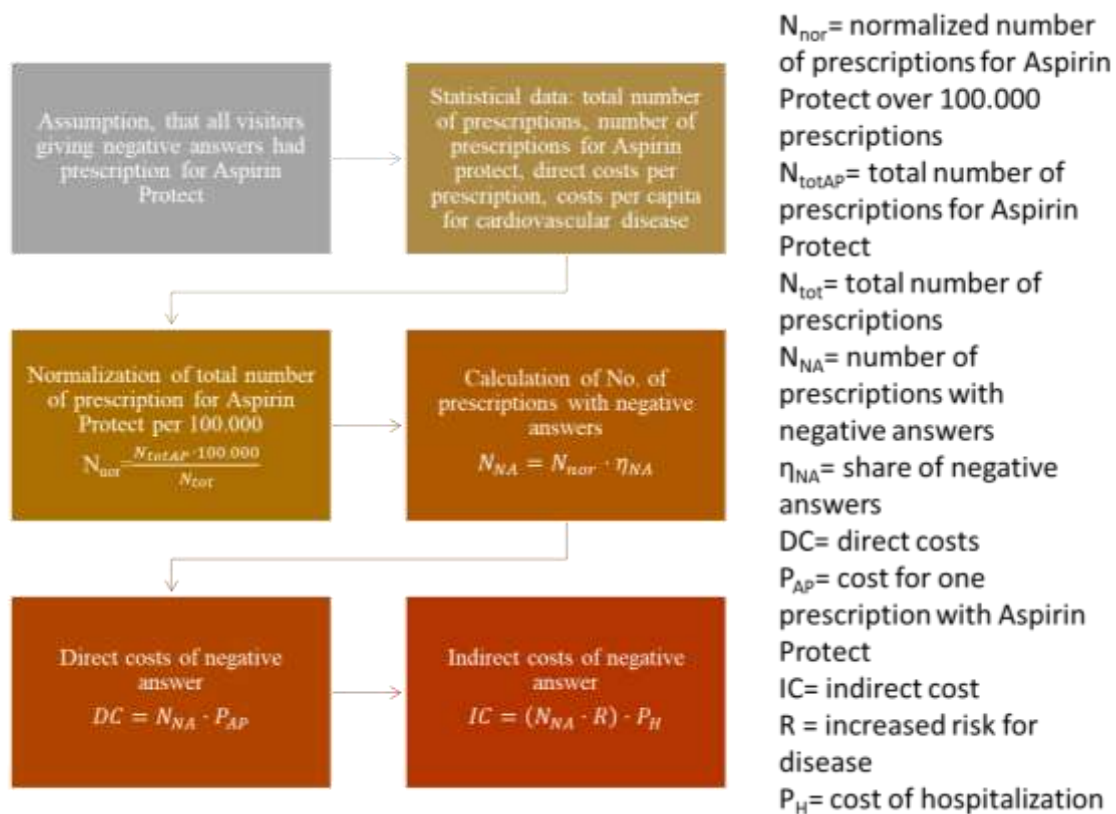


Figure 3: The scheme of calculating process. Numbers were calculated for each year and each question separately.

The calculations were all done in the same way (

Figure 3). We assumed that all visitors with negative answers to questions 1, 2, 3, and 4 had prescribed and dispensed Aspirin Protect. The direct costs were calculated as the multiplication of the number of negative answers and one prescription's cost. The indirect costs were calculated using meta-analysis data (3) and the health care costs for cardiovascular diseases recorded in Bulgaria, Croatia, Romania, Latvia, Lithuania, and Cyprus. Costs per capita were around 100 000 € (7).

Table 1: The rough evaluation of direct and indirect cost as a consequence of lack of knowledge regarding specified issues No. 1

	No. of prescriptions	Direct cost	Indirect cost
2017	448	2491 €	8.500.000 € (MI) + 5.300.000 € (IS)
2018	200	1154 €	3.800.000 € (MI) + 2.400.000 € (IS)
difference	55,4%	53,7%	55%

Table 2: The rough evaluation of direct and indirect cost as a consequence of lack of knowledge regarding specified issues No. 2

	No. of prescriptions	Direct cost	Indirect cost
2017	239	1327 €	4.500.000 € (MI) + 2.800.000 € (IS)
2018	115	660 €	2.100.000 € (MI) + 1.300.000 € (IS)
difference	51,9%	50,3%	53,4%

Table 3: The rough evaluation of direct costs as a consequence of a lack of knowledge regarding specified issues No. 3. \* Indirect costs were not calculated due to lack of information.

	No. of prescriptions	Direct cost	Indirect cost*
2017	2059	11.448 €	/
2018	1460	8410 €	/
difference	29,1%	26,5%	/



Table 4: The rough evaluation of direct and indirect costs as a consequence of a lack of knowledge regarding specified issues No. 4.

	No. of prescriptions	Direct cost	Indirect cost
2017	1074	5973 €	MI (20.400.000 €) + IS (12.800.000 €)
2018	401	2309 €	MI (7.600.000 €) + IS (4.800.000 €)
difference	62,7%	61,3%	62,7%

We came to a rough estimation that structured holistic consultancy saved up to 60% of direct and indirect costs (The calculations were all done in the same way (

Figure 3). We assumed that all visitors with negative answers to questions 1, 2, 3, and 4 had prescribed and dispensed Aspirin Protect. The direct costs were calculated as the multiplication of the number of negative answers and one prescription's cost. The indirect costs were calculated using meta-analysis data (3) and the health care costs for cardiovascular diseases recorded in Bulgaria, Croatia, Romania, Latvia, Lithuania, and Cyprus. Costs per capita were around 100 000 € (7).

Table 1,

Table 2,

Table 3, Table 4, Figure 4). As one can appreciate, indirect costs are more crucial, and the savings could pay more working force, who would strive to ensure correct information and quality services.

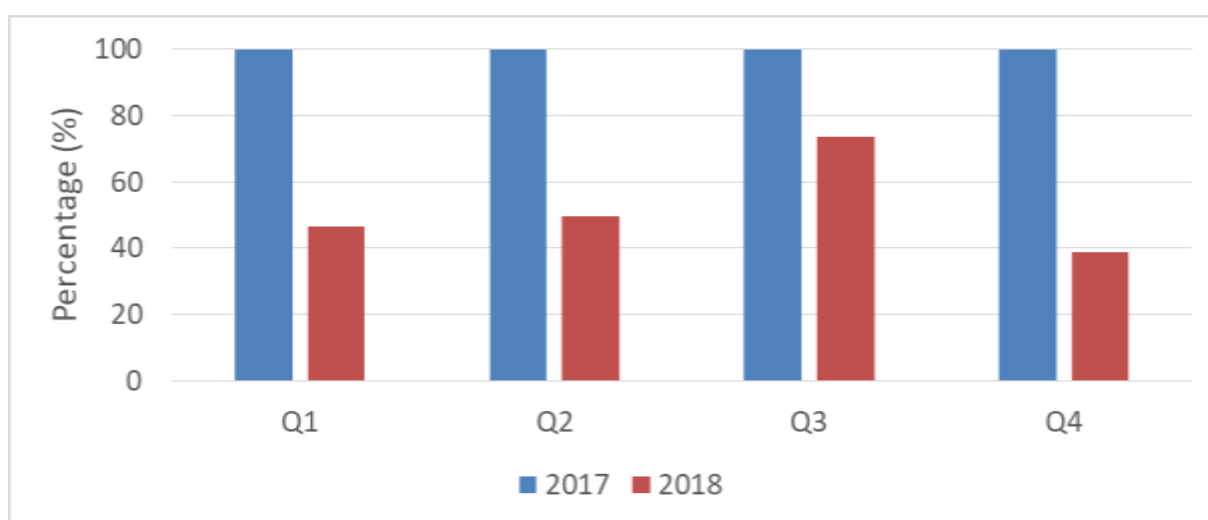


Figure 4: The difference in % of direct costs due to structured holistic consultancy from the year 2017 to the year 2018.

## CONCLUSIONS

With this evaluation, we showed that the HCP approach improves people's compliance by much more than 5% and that the HCP approach reduces public costs caused by medicine misuse by more than 5%. The results are showing 60% improvement in compliance and in savings of public health expenditure.

A preliminary financial impact assessment is worth further evaluation. We expect insurance companies to invest in community pharmacies, which will introduce the holistic community pharmacy© concept.

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# LESSONS LEARNED ON VISITORS' ACCEPTANCE OF HOLISTIC COMMUNITY PHARMACY<sup>©</sup> APPROACH ON SELF- MEDICATION

Matija Centrih, mag. farm.

In Slovenia the role of Community Pharmacist in Self-medication is regulated with laws on medicines, law on pharmacies, policies that are directly under this laws and Good practice guidelines of Slovene Chamber of Pharmacies. By all this documents, Community Pharmacist are obligated to counseling when they are dispensing prescription and nonprescription medicines or OTC medicines. When dispensing OTC medicines, we are also obliged to do triage for medical problems. We must refer the patient to a doctor when medically justified or advised on proper self-medication. Self-medication counseling includes not only counseling on the proper use of over-the-counter medications, but also the use of other products that could make a significant contribution to improving or maintaining a patient's health. These can be medical devices, nutritional supplements, cosmetics and other care products and, of course, advice on the right way of living for certain problems.

The rules are written, but the question is, how they are implemented in individual pharmacies in everyday practice. Virtually all pharmacies leave individual pharmacists to decide for themselves how to implement these requirements.

Currently, in all pharmacies, we are meeting an increasing number of patients who themselves know best what is right for their problem. Let them read this from the print media, here we should mention the so-called PR articles or just ordinary advertisements that promise miracles. Of course, they also learn a lot on television and radio, and all off the mentioned is quickly overtaking the Internet. If at one time pharmacists were most annoyed that people came to the pharmacy for something because a neighbor said it was the best, now the all-knowing neighbor is persistently being replaced by the all-knowing internet.

The reaction of pharmacists to such explanations by pharmacy visitors is usually inappropriate. Instead of trying to focus on the problem that such a pharmacy visitor has and trying to explain to them what they have chosen for such a problem in their selection of pharmacy products with professional criteria, pharmacists usually focus on the product the visitor is asking about. The result of such action is everything but satisfactory in means of solving visitors problem and also of pharmacies financial benefit.

A great tool for systematically focusing on the patient's problem and properly advising all pharmacists in the pharmacy is the concept of Holistic Community Pharmacy<sup>®</sup>. With the help of this concept, we can prepare an appropriate selection of products for the pharmacy; prepare pharmacists to know how to respond properly to all the challenges posed by one way self-educated or, on the other hand, completely uneducated visitors. It is essential that pharmacists make a shift in their head that the pharmacy is not the house of fairies that fulfill all wishes for all kind of products and that pharmacists are not goldfish that fulfill every wish. With the concept of HCP<sup>®</sup>, pharmacists in the pharmacy can once again take control of solving a problem for pharmacy visitors and improve the health of just about every visitor. It is possible to say this in theory, but in practice, a lot of work is needed to make the shift, to maintain the different way of counseling and it is also necessary to change the traditional view of pharmacy premises. Of course, there may be concerns about how this will be received by pharmacy visitors, who have to get used to the new approach used by pharmacists. Above all, it is foreign to them, that the pharmacist is interested manly in purpose of their visit to the pharmacy and not that much in what they want to buy. There was a lot of fear that visitors would no longer want to come to the pharmacy and that this would result in a drop in pharmacy income.

First, let's get rid of the fear of financial loss. In 2016, our pharmacy issued just a little under 3.5% more cash invoices than in 2015, and we detected just a little under 8.5% less earnings compared to 2015. In 2017, we began to introduce the HCP<sup>®</sup> concept. In 2017, compared to 2016, we issued 0.3% fewer cash invoices, but the value of these invoices increased by so much, that our earnings increased by more than 12%. In 2018, compared to 2017, we issued almost 6.5% more invoices and the profit increased by almost 7% compared to 2017. In total, from the beginning of 2017 to the end of 2018, our profit on self-paying accounts increased by 18.19%, whereas we previously perceived a pronounced negative trend.

Now that we have shaken off the fear of financial loss, we can look at other more important aspect of HCP<sup>®</sup> concept. Visitors to the pharmacy had different responses to the fact that we were not willing to sell them the product they wanted or demanded, but they were actually thoroughly questioned about the problem and purpose of their visit. Of course, there were some dissatisfied visitors because they didn't get exactly what they envisioned and here and there the accusation fell that we were a very poorly stocked pharmacy. But these few are negligibly little in contrast of satisfied visitors and a lot of praise that we really try to explain, that we take the time and above all, that after our intervention their health is significantly better. People thanked me on the road or in the market store and praised me for my pharmacy and most of all the team that really makes an effort to alleviate or eliminate their health problems. I have also heard many times that in the pharmacy we are really interested in people's health and we pay attention to each visitor individually. Because the pharmacy was already before physically too small for the area it covers, and because we don't have the option of expanding or relocating, sometimes a queue is made in front the pharmacy. However, people quickly realized that they should not be upset about this, because we will also pay

as much attention to them when it is their turn as we did to the visitor before them, which results that everybody needs to wait a little longer.

Usually, people naturally remember and emphasize negative experiences more than positive ones, which is specially typical for Slovenes. However, we had so many good experiences with the HCP<sup>®</sup> concept that it would be hard to say that it was something so wrong that it would have stuck in my memory.

We had gained enough experience that I can with certainty say this. If a pharmacy wants to greatly contribute to the health of pharmacy visitors, adequate space and ambient is needed, professional selection of products with criteria is a must and all pharmacists must prepare and reconcile in advance their answers to different health problems. All this and more is included in the concept of Holistic Community Pharmacy<sup>®</sup>. But change with this concept is so profound and hard, that it is essential to stay focused on positive feedback of pharmacy visitors that greatly surpass some initial disapproval that we had with few a visitors.

# FOOD SUPPLEMENTS DEFINITION VARIATION IN EUROPE IMPACTS THE ROLE OF COMMUNITY PHARMACIST IN SELF- MEDICATION & SELF-TREATMENT

Azra Uzunović, mag. farm.

## THE DEFINITION OF A TERM DETERMINES THE REACH, SCOPE AND THE CONTENT OF THE TERM

As the definition is defined as a condition of being definite, distinct or clearly outlined (1), the term definition sets the reach, scope and the content of the specific term. The way the specific term is defined will affect its further perception and usage in processes that include that term.

In order to make a correct approach to counseling and advising food supplements during the self-medication and self-treatment practice the community pharmacists should approach to the same from a true understanding of the food supplements definition. The community pharmacist must be aligned with the national law provisions, but also to take a true role in promoting human's health and thus preserving community pharmacy's identity and integrity in the society.

The perception and implementation of every further processes that involve food supplements, including self-medication and self-treatment, depends on fundamental perception of the food supplements definition. In other words, how we perceive the meaning of a term, we will set the term in every other relationship according to that perception. Every possible misunderstanding can affect further processes and approaches. Community Pharmacist's perception of the food supplements definition can affect their approach to self-medication and self-treatment. Especially if the fundamental definition is not set as accurate and if it is not excluding all misleads and misunderstandings that could affect community pharmacist's approach to counseling.

In the following we will see how variations in the European countries' national definitions of food supplements affect the roles of community pharmacists in counseling practice of self-medication and self-treatment.

## THE IMPORTANCE OF CORRECT FOOD SUPPLEMENTS DEFINITION PERCEPTION

According to the EU Directive 46/2002 food supplements definition, which has been taken for the purposes of this review as a referent one, »food supplements« means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities:

(b) "nutrients" means the following substances:

(i) vitamins,

(ii) minerals. (2)

The definition sets the food supplements as foodstuffs, not medicines. Food supplements supplement the normal diet. Those are nutrients or other substances with physiological or nutritional effect. Not pharmacological. These facts of the food supplements definition community pharmacists should have in mind when approaching to counseling food supplements.

What does this mean in practice?

In general, correct and accurate food supplements definition should assure correct approaches in further processes.

For the pharmacy profession it means that correct perception of food supplements definition should lead to correct counseling and advising and the correct approach in adding value to the community pharmacy visitors' health.

For the future, it means the worth recognition of community pharmacy's added value by the visitors and end users which leads to preservation and continuation of pharmacy profession identity and integrity. Having in mind that food supplements definition doesn't put food supplements strictly in community pharmacies, as their sole right to market, sell and counsel, the community pharmacies should not act like common retail stores in the relation to the food supplements in order to have hope for the future that will last. Community pharmacies should have the right approach in counseling food supplements as food supplements, and not considering them as medicines in processes of self-treatment and self-medication. Food supplements should be counseled with right approach, an integrative holistic approach aligned with the purpose and food supplements definition.

**THE REVIEW OF EUROPEAN COUNTRIES' NATIONAL FOOD SUPPLEMENTS DEFINITIONS**

The review of food supplements definition covered 40 European countries, including both: EU member countries and non-member countries (Table 5).

EU member countries covered by review			Non-EU member countries covered by review	
<b>AUSTRIA</b>	FRANCE	MALTA	ALBANIA	SERBIA
<b>BELGIUM</b>	GERMANY	NETHERLANDS	BOSNIA AND HERZEGOVINA	SWITZERLAND
<b>BULGARIA</b>	GREECE	POLAND	ENGLAND	UKRAINE
<b>CROATIA</b>	HUNGARY	PORTUGAL	KOSOVO	WALES
<b>CYPRUS</b>	IRELAND	ROMANIA	MONTENEGRO	
<b>CZECH REPUBLIC</b>	ITALY	SLOVAKIA	NORTH MACEDONIA	
<b>DENMARK</b>	LATVIA	SLOVENIA	NORTHERN IRELAND	
<b>ESTONIA</b>	LITHUANIA	SPAIN	NORWAY	
<b>FINLAND</b>	LUXEMBOURG	SWEDEN	SCOTLAND	

Table 5: European countries covered by the review on food supplements definition

The definitions were compared to the EU Directive 46/2002 food supplements definition which was taken as the referent one. The review resulted as 90% alignment with the EU Directive 46/2002 food supplements definition (Figure 5).

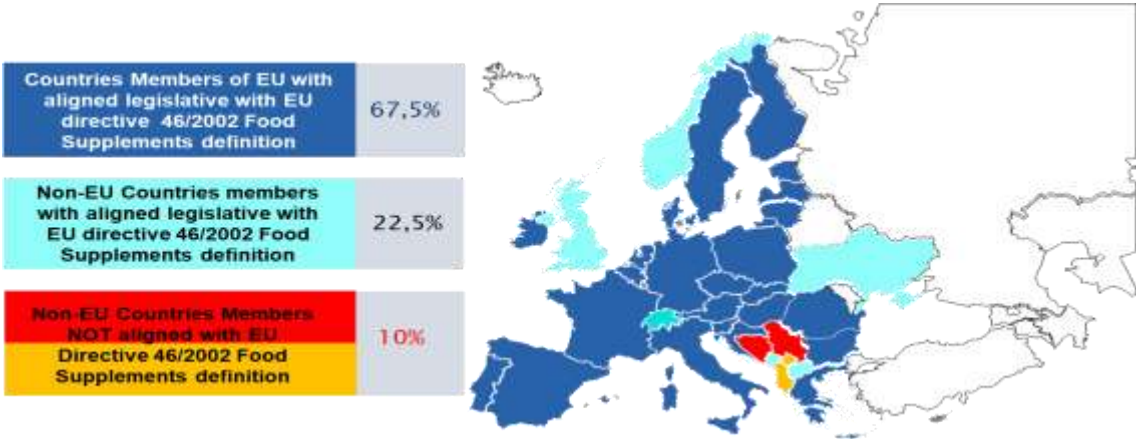


Figure 5: Presentation of European countries' national food supplements definitions alignment with the referent one (EU Directive 46/2002)

The food supplements definitions resulted in review are presented in Appendix 1 (EU member countries with aligned food supplements definition with the referent one), Appendix 2 (non-EU member countries with aligned food supplements definition with



the referent one) and Appendix 3 (non-EU member countries with not aligned food supplements definition with the referent one). Bosnia and Herzegovina and Serbia, Kosovo and Albania are grouped into pairs due to a similar legislative structure.

## EXAMPLE OF LEGISLATIVE NON-COMPLIANT COUNTRY: BOSNIA AND HERZEGOVINA

As can be seen in Bosnian legislative in Appendix 3 and according to the defined purpose for use, food supplements term has been replaced with another term – dietary supplements.

### FOOD SUPPLEMENTS ≠ DIETARY SUPPLEMENTS

The Federal Food, Drug, and Cosmetic Act in USA defines a dietary ingredient as a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to **supplement the diet by increasing the total dietary intake**; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. (3)

So when we talk about diet supplementation in Bosnia and Herzegovina we have to use term dietary supplements as a part of the large group of foodstuffs intended for use in special nutritional needs. (4)

Bosnia and Herzegovina consists of two entities and a district. Each of state constituents has it's own legislative in the field of food supplements with the existing differences. Federation of Bosnia and Herzegovina has older version of legislative and not aligned version with the EU Directive 46/2002 while Republic of Srpska has been aligned with the EU Directive 46/2002 due to food supplements definition.

These differences in food supplements legislation can be obstacles for further processes not only in Bosnia and Herzegovina, but also in the near and far environment. This seemingly small difference in the meaning and semantic, conjoined with the wrong perceptions, affected with community pharmacists' obligation to fulfill all legislation provisions affects further approaches to counseling food supplements including self-medication and self-treatment.

According to the results of IRRK© survey conducted in April 2020. and presented during 5th annual COVIRIAS© symposium on food supplements in June 2020. attitudes and behaviors related to the dietary supplements in Bosnia and Herzegovina showed:

- More than half of the respondents (community pharmacists) consider dietary supplements as medicine;
- 31% of community pharmacists consider medicine-dietary supplements difference in usage purpose;
- 75% counsel dietary supplements according to the previous diagnose, symptoms and existing therapy;

- 21% consider most important factor for selection of dietary supplements is the amount of main ingredient;
- 51% of community pharmacies are shelving the dietary supplements by mode of action. (5)

All these results indicate the existence of wrong perception of food supplements definition implemented in practice also. The shown approach puts Bosnian community pharmacies more into alignment with the US approach than the European. If the community pharmacy's aim is to consult every visitor what is best for them, then this is not a correct approach.

When we take a look what are the provisions, the community pharmacists in Bosnia and Herzegovina have to be compliant with, these are:

- Medicine and Medicinal Product Act (6) defining all community pharmacists' obligations related to medicines and medicinal products;
- Pharmacy Act (7) defining among community pharmacy's activities also a supply of baby food and baby equipment, as well as dietary products, counseling regarding the proper use of medicines, medical devices, herbal and homeopathic medicines, cosmetics and dietary products. (7)
- Good Pharmacy Practice (GPP) (8) demanding from community pharmacists: the well-being of the patient/visitor as the first community pharmacist's interest and each element of community pharmacy practice should be relevant to the individual patient/visitor, to provide clear information and effective communication. (8)

All these provisions must be refined with the high respect of moral and ethical code. The primary community pharmacy's aim should be to consult the visitors what is the best for them respecting all these above provisions. Moral and ethical code presence in community pharmacies is the precious line dividing community pharmacies from common retail stores. The community pharmacists have to apply these provisions equally to the processes related to dispensing medicines and counseling food supplements, but it has to be done from totally different perspectives respecting the correct perceptions of food supplements and medicines definitions.

#### EXAMPLE OF LEGISLATIVE COMPLIANT COUNTRIES: SLOVENIA, FINLAND AND MONTENEGRO

As seen in Appendix 1 and 2, Slovenia, Finland and Montenegro are countries compliant with the referent food supplements definition in their legislations.

IRRK© conducts regular annual surveys related to the community pharmacies' attitudes towards food supplements in Slovenia. According to the annual survey from 2017:

- 8% of community pharmacists consider the purpose of food supplements is to support treatment;
- 16% advise food supplements for milder symptoms and ailments. (9)

According to Puc and these annual surveys »the community pharmacies' attitude towards food supplements is slowly but steadily changing in various ways«.(9)

Montenegro and Finland stood out with even more caution and willingness to exclude all misleads and misunderstandings. Montenegro's article (10) related to the food supplements definition (aligned with the referent one) adds one more paragraph that excludes any associations with medicines and treatment related to medicines. Finland's article (11) on food supplements definition is also supplemented by an additional warning sentence, excluding also misleads and misunderstandings. Caution is never enough in order to provide us the best service outcomes.

But, no matter the caution, it is high recommendable to conduct IRRK's© survey on food supplements in Finland and Montenegro as well in order to gain the complete and broader picture in the field of food supplements.

## CONCLUSIONS

The distinction line between counseling medicines and food supplements approaches is very thin, but must be respected in order to maintain community pharmacies' integrity to diverse from common retail stores in the future as community pharmacies have no exclusive right to market food supplements. Correct approach to counseling and the knowledge with the high respect of moral and ethics can assure the advantages for the community pharmacies. The following conclusions stood out of this review:

- Food supplements definition variation in Europe impacts the role of community pharmacist on self-medication and self-treatment;
- Correct perceptions of food supplements definition should be followed by correct approaches in community pharmacy practice (aligned with the national GPP and Pharmacy Activity Law);
- Community pharmacists would have to make a difference in counseling approaches related to the medicines and food supplements;
- These different, but correctly applied approaches in counseling, are qualities and a part of a HCP© approach to counseling;
- In order to maintain the integrity of the profession and it's future, European community pharmacies should not act like common retail stores.

APPENDIX 1

	COUNTRY	ORIGINAL TEXT OF NATIONAL LEGISLATION	ENGLISH TRANSLATION BY GOOGLE TRANSLATE
EU MEMBER COUNTRIES COMPLIANT WITH EU DIRECTIVE 46/2002 FOOD SUPPLEMENTS DEFINITION	AUSTRIA	Nahrungsergänzungsmittel: Lebensmittel, die dazu bestimmt sind, die normale Ernährung zu ergänzen und die aus Einfach- oder Mehrfachkonzentraten von Nährstoffen oder sonstigen Stoffen mit ernährungsspezifischer oder physiologischer Wirkung bestehen und in dosierter Form in Verkehr gebracht werden, d.h. in Form von zB Kapseln, Pastillen, Tabletten, Pillen und anderen ähnlichen Darreichungsformen, Pulverbeuteln, Flüssigampullen, Flaschen mit Tropfeinsätzen und ähnlichen Darreichungsformen von Flüssigkeiten und Pulvern zur Aufnahme in abgemessenen kleinen Mengen. (12)	Food supplements: Foodstuffs which are intended to supplement normal nutrition and which consist of single or multiple concentrates of nutrients or other substances with nutritional or physiological effects and which are placed on the market in dosed form, i.e. in the form of, for example, capsules, troches, tablets, pills and other similar dosage forms, powder bags, liquid ampoules, bottles with dropper inserts and similar dosage forms of liquids and powders for absorption in measured small quantities.
	BELGIUM	[6. Nahrungsergänzungsmittel: vordosierte Nahrungsmittel, die die Ergänzung der normalen Ernährung bezwecken und aus einem oder mehreren Nährstoffen, Pflanzen, Pflanzenpräparaten oder anderen Stoffen mit ernährungsspezifischer oder physiologischer Wirkung bestehen.] [Art. 1 einziger Absatz Nr. 1 einziger Absatz Buchstabe a) und b) ersetzt durch Art. 1 Buchstabe a) des K.E. vom 19. September 2017 (B.S. vom 31. Oktober 2017); einziger Absatz Nr. 2 ersetzt durch Art. 1 Nr. 1 des K.E. vom 15. Mai 2003 (B.S. vom 8. Juli 2003); einziger Absatz Nr. 3 ersetzt durch Art. 1 Buchstabe b) des K.E. vom 19. (13)	[6. Food supplements: pre-dosed foods that are intended to supplement normal nutrition and consist of one or more nutrients, plants, plant preparations or other substances with a nutritional or physiological effect.] [Art. 1 single paragraph no. 1 single paragraph letters a) and b) replaced by Art. 1 letter a) of the K.E. of September 19, 2017 (B.S. of October 31, 2017); only paragraph no. 2 replaced by Art. 1 no. 1 of the K.E. dated May 15, 2003 (B.S. dated July 8, 2003); only paragraph no. 3 replaced by Art. 1 letter b) of the K.E. from 19.
	BULGARIA	"Хранителни добавки" са храни, предназначени да допълнят нормалната диета и които представляват концентрирани източници на витамини и минерали или други вещества с хранителен или физиологичен ефект, използвани самостоятелно или в комбинация, които се пускат на пазара в дозирани форми, като капсули, таблетки, хапчета и други подобни, на прах, ампули с течност и други подобни течни или прахообразни форми, предназначени да бъдат приемани в предварително дозирани малки количества. (14)	"Food supplements" are foods designed to supplement a normal diet and which are concentrated sources of vitamins and minerals or others substances having a nutritional or physiological effect, used alone or in combination that are marketed in dosage forms such as capsules, tablets, pills and the like, in powder, liquid ampoules and the like, in liquid or powder form forms intended to be administered in pre-dosed small amounts.

	COUNTRY	ORIGINAL TEXT OF NATIONAL LEGISLATION	ENGLISH TRANSLATION BY GOOGLE TRANSLATE
EU MEMBER COUNTRIES COMPLIANT WITH EU DIRECTIVE 46/2002 FOOD SUPPLEMENTS DEFINITION	CROATIA	<p>Članak 3.</p> <p>(1) U smislu ovoga Pravilnika dodacima prehrani smatraju se pripravci proizvedeni iz koncentriranih izvora hranjivih tvari ili drugih tvari s hranjivim ili fiziološkim učinkom koji imaju svrhu dodatno obogatiti uobičajenu prehranu u cilju održavanja zdravlja.</p> <p>(2) Hranjivim tvarima u smislu stavka 1. ovoga članka smatraju se vitamini i minerali.</p> <p>(3) Druge tvari u smislu stavka 1. ovoga članka smatraju se: aminokiseline, esencijalne masne kiseline, vlakna, organi i ekstrakti biljnih vrsta, mikroorganizmi, jestive gljive, alge, pčelinji proizvodi i druge tvari s hranjivim ili fiziološkim učinkom.</p> <p>Članak 4.</p> <p>(1) Dodaci prehrani mogu se stavljati na tržište krajnjem potrošaču isključivo zapakirani i to pojedinačno ili u kombinaciji.</p> <p>(2) Oblici dodataka prehrani su:</p> <p>1. dozirani oblici: kapsule, pastile, tablete i slično,</p> <p>2. prah, granule, tekućine, te ostali oblici koji su pripremljeni da se uzimaju u odmjerenim količinama i/ili posebnim načinom primjene. (15)</p>	<p>Article 3</p> <p>(1) For the purposes of this Ordinance, food supplements are preparations prepared from concentrated sources of nutrients or other substances with a nutritional or physiological effect which have the purpose of further enriching the usual diet in order to maintain health.</p> <p>(2) Vitamins and minerals shall be considered nutrients in the sense of paragraph 1 of this Article.</p> <p>(3) Other substances within the meaning of paragraph 1 of this Article are considered: amino acids, essential fatty acids, fibers, organs and extracts of plant species, microorganisms, edible fungi, algae, bee products and other substances with nutritional or physiological effect.</p> <p>Article 4</p> <p>(1) Food supplements may be placed on the market to the final consumer only in packages, individually or in combination.</p> <p>(2) Forms of food supplements are:</p> <p>1. dosage forms: capsules, lozenges, tablets and the like,</p> <p>2. powders, granules, liquids, and other forms prepared for administration in metered amounts and / or by special route of administration.</p>
	CYPRUS	<p>The term 'food supplements' means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities. (16)</p>	

	COUNTRY	ORIGINAL TEXT OF NATIONAL LEGISLATION	ENGLISH TRANSLATION BY GOOGLE TRANSLATE
EU MEMBER COUNTRIES COMPLIANT WITH EU DIRECTIVE 46/2002 FOOD SUPPLEMENTS DEFINITION	<b>CZECH REPUBLIC</b>	g) doplňkem stravy potravina, jejímž účelem je doplňovat běžnou stravu a která je koncentrovaným zdrojem vitaminů a minerálních látek nebo dalších látek s nutričním nebo fyziologickým účinkem, obsažených v potravine samostatně nebo v kombinaci, určená k přímé spotřebě v malých odměřených množstvích; (17)	g) food supplement means a food intended for the purpose of supplementing a normal diet and which is a concentrated source of vitamins and minerals or other substances with a nutritional or physiological effect, contained in the food alone or in combination, intended for direct consumption in small measured quantities;
	<b>DENMARK</b>	<p>Definitioner</p> <p>§ 1. Ved kosttilskud forstås i denne bekendtgørelse fødevarer, der</p> <p>1) har til formål at supplere den normale kost,</p> <p>2) er koncentrerede kilder til næringsstoffer eller andre stoffer med en ernæringsmæssig eller fysiologisk virkning, alene eller kombinerede, og</p> <p>3) markedsføres i dosisform, fx kapsler, pastiller, tabletter, piller og andre lignende former, pulverbreve, væskeampuller, dråbedispenseringsflasker og andre lignende former for væsker og pulvere beregnet til at blive indtaget i mindre afmålte mængder.</p> <p>Stk. 2. Ved næringsstoffer forstås i denne bekendtgørelse følgende stoffer: Vitaminer og mineraler. (18)</p>	<p>Definitions</p> <p>§ 1. For the purposes of this Executive Order, food supplements are understood to mean foods that</p> <p>1) aims to supplement the normal diet,</p> <p>2) are concentrated sources of nutrients or other substances having a nutritional or physiological effect, alone or in combination; and</p> <p>3) marketed in dosage form, e.g. capsules, lozenges, tablets, pills and other similar forms, powder letters, liquid ampoules, droplet dispensing bottles and other similar types of liquids and powders intended to be ingested in smaller quantities.</p> <p>PCS. 2. For the purposes of this Executive Order, nutrients shall mean the following substances: Vitamins and minerals.</p>
	<b>ESTONIA</b>	<p>§ 2. Toit ja toidulisand</p> <p>(3) Toidulisand on toitaine või toitainete segu, mis ei kuulu ravimite ega ravimisarnaste ainete hulka ning mida lisaks toidule kasutatakse organismi toitainevajaduse rahuldamiseks. Toidulisandid on vitamiinid, mineraalained ja nende segud, taimsed ja loomsed ekstraktid ning teised sedalaadi ained. (19)</p>	<p>§ 2. Food and food supplement</p> <p>(3) A food supplement is a nutrient or mixture of nutrients which does not belong to medicinal products or drug-like substances and which is used in addition to food to satisfy the nutrient needs of the organism. Food supplements include vitamins, minerals and their mixtures, plant and animal extracts and other such substances.</p>

	COUNTRY	ORIGINAL TEXT OF NATIONAL LEGISLATION	ENGLISH TRANSLATION BY GOOGLE TRANSLATE
	<b>FINLAND</b>	<p>2 §</p> <p>Määritelmät</p> <p>Tässä asetuksessa tarkoitetaan</p> <p>1) ravintolisällä puristeena, kapselina, pastillina, tablettina, pillerinä, jauheena, tiivisteenä, uutteenä, nesteenä tai muussa vastaavassa annosmuodossa myytävää valmiiksi pakattua valmistetta, jota pidetään kaupan elintarvikkeena, jota nautitaan pieninä mitta-annoksina ja josta saatavalla energiamäärällä ei ole merkitystä ruokavalion kannalta. Ravintolisän tarkoitus on sille ominaisten ravintoaineiden tai muiden aineiden vuoksi täydentää ruokavaliota tai muulla tavalla vaikuttaa ihmisen ravitsemuksellisiin tai fysiologisiin toimintoihin. Ravintolisällä ei tarkoiteta valmistetta, joka lääkelain (395/1987) nojalla luokitellaan lääkkeeksi.</p> <p>2) ravintolisälle ominaisella aineella ravintoainetta, kuten vitamiinit ja kivennäisaineet, tai muuta ainetta, jolla on ravitsemuksellinen tai fysiologinen vaikutus. (11)</p>	<p>§ 2</p> <p>Definitions</p> <p>For the purposes of this Regulation:</p> <p>1) a food supplement is a pre-packaged preparation sold as a compress, capsule, lozenge, tablet, pill, powder, concentrate, extract, liquid or other similar dosage form, marketed as a food consumed in small measured doses and the amount of energy obtained is not relevant to the diet. The purpose of a food supplement is to supplement the diet or otherwise affect a person's nutritional or physiological functions due to its specific nutrients or other substances. A food supplement does not mean a preparation that is classified as a medicinal product under the Medicines Act (395/1987).</p> <p>2) a substance specific to a food supplement means a nutrient, such as vitamins and minerals, or another substance that has a nutritional or physiological effect.</p>
	<b>FRANCE</b>	<p>Article 2</p> <p>Aux fins du présent décret, on entend par :</p> <p>1° " Compléments alimentaires ", les denrées alimentaires dont le but est de compléter le régime alimentaire normal et qui constituent une source concentrée de nutriments ou d'autres substances ayant un effet nutritionnel ou physiologique seuls ou combinés, commercialisés sous forme de doses, à savoir les formes de présentation telles que les gélules, les pastilles, les comprimés, les pilules et autres formes similaires, ainsi que les sachets de poudre, les ampoules de liquide, les flacons munis d'un compte-gouttes et les autres formes analogues de préparations liquides ou en poudre destinées à être prises en unités mesurées de faible quantité ;</p> <p>2° " Nutriments ", les substances suivantes: a) Vitamines; b) Minéraux; (20)</p>	<p>Article 2</p> <p>For the purposes of this decree, the following mean:</p> <p>1 ° "Food supplements", foodstuffs the aim of which is to supplement the normal diet and which constitute a concentrated source of nutrients or other substances having a nutritional or physiological effect, alone or in combination, marketed in the form of doses, at namely forms of presentation such as capsules, lozenges, tablets, pills and other similar forms, as well as sachets of powder, ampoules of liquid, bottles fitted with a dropper and other similar forms of liquid or powder preparations intended to be taken in measured units of small quantities;</p> <p>2 ° "Nutrients", the following substances: a) Vitamins; b) Minerals;</p>

	COUNTRY	ORIGINAL TEXT OF NATIONAL LEGISLATION	ENGLISH TRANSLATION BY GOOGLE TRANSLATE
EU MEMBER COUNTRIES COMPLIANT WITH EU DIRECTIVE 46/2002 FOOD SUPPLEMENTS DEFINITION	GERMANY	<p>§ 1 Anwendungsbereich</p> <p>(1) Nahrungsergänzungsmittel im Sinne dieser Verordnung ist ein Lebensmittel, das</p> <ol style="list-style-type: none"> <li>1. dazu bestimmt ist, die allgemeine Ernährung zu ergänzen,</li> <li>2. ein Konzentrat von Nährstoffen oder sonstigen Stoffen mit ernährungsspezifischer oder physiologischer Wirkung allein oder in Zusammensetzung darstellt und</li> <li>3. in dosierter Form, insbesondere in Form von Kapseln, Pastillen, Tabletten, Pillen und anderen ähnlichen Darreichungsformen, Pulverbeuteln, Flüssigampullen, Flaschen mit Tropfeinsätzen und ähnlichen Darreichungsformen von Flüssigkeiten und Pulvern zur Aufnahme in abgemessenen kleinen Mengen, in den Verkehr gebracht wird.</li> </ol> <p>(2) Nährstoffe im Sinne dieser Verordnung sind Vitamine und Mineralstoffe, einschließlich Spurenelemente. (21)</p>	<p>§ 1 Scope</p> <p>(1) Food supplements within the meaning of this Ordinance are foods that</p> <ol style="list-style-type: none"> <li>1. is intended to supplement the general diet,</li> <li>2. a concentrate of nutrients or other substances with nutritional or physiological Represents effect alone or in combination and</li> <li>3. in dosed form, especially in the form of capsules, lozenges, tablets, pills and other similar Dosage forms, powder bags, liquid ampoules, bottles with dropper inserts and the like</li> </ol> <p>Dosage forms of liquids and powders for absorption in measured small amounts in the</p> <p>Is brought into circulation.</p> <p>(2) Nutrients within the meaning of this Ordinance are vitamins and minerals, including trace elements.</p>
	GREECE	<p>Ως συμπληρώματα διατροφής ορίζονται:</p> <p>«τα τρόφιμα με σκοπό τη συμπλήρωση της συνήθους διαίτας, τα οποία αποτελούν συμπυκνωμένες πηγές θρεπτικών συστατικών ή άλλων ουσιών με θρεπτικές ή φυσιολογικές επιδράσεις, μεμονωμένων ή σε συνδυασμό, και τα οποία διατίθενται στο εμπόριο σε δοσιμετρικές μορφές, ήτοι μορφές παρουσίασης όπως, κάψουλες, παστίλιες, δισκία, χάπια και άλλες παρόμοιες μορφές, καθώς και φακελάκια σκόνης, φύσιγγες υγρού προϊόντος, φιαλίδια με σταγονόμετρο, και άλλες παρόμοιες μορφές υγρών και κόνεων που προορίζονται να ληφθούν σε προμετρημένες μικρές μοναδιαίες ποσότητες» (Ορισμός ΣΔ, βάσει ΟΔ46/2002) (22)</p>	<p>Food Supplements are defined as: "Foods supplementing the standard diet, which are concentrated sources of nutrients or other substances with nutritional or physiological effects, individually or in combination, and which are commercially available in dosage forms, ie presentation forms such as capsules, pastes , tablets, pills and other similar forms, as well as powder sachets, liquid product cartridges, dropper vials, and other similar forms of liquids and powders intended to be taken in pre-measured small unit quantities' (SD definition, based on OD46 / 2002)</p>



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EU MEMBER COUNTRIES COMPLIANT WITH EU DIRECTIVE 46/2002 FOOD SUPPLEMENTS DEFINITION	HUNGARY	<p>2. § E rendelet alkalmazásában:</p> <p>a) étrend-kiegészítő: a hagyományos étrend kiegészítését szolgáló olyan élelmiszer, amely koncentrált formában tartalmaz tápanyagokat vagy egyéb táplálkozási vagy élettani hatással rendelkező anyagokat, egyenként vagy kombináltan; adagolt vagy adagolható formában kerül forgalomba (például kapszula, pasztilla, tableta, port tartalmazó tasak, adagolható por, ampulla, csepegtető üveg vagy más hasonló por-, illetve folyadékforma, amely alkalmas kis mennyiség adagolására).</p> <p>b) tápanyag:</p> <p>ba) a vitaminok, és</p> <p>bb) az ásványi anyagok. (23)</p>	<p>§ 2 For the purposes of this Decree:</p> <p>(a) food supplement: a food intended to supplement a traditional diet, containing in concentrated form nutrients or other substances having a nutritional or physiological effect, singly or in combination; it is marketed in a dosed or administrable form (for example, a capsule, lozenge, tablet, sachet containing a powder, a dispensable powder, an ampoule, a dropper bottle or other similar powder or liquid form suitable for administration in small quantities).</p> <p>(b) nutrient:</p> <p>(ba) vitamins, and</p> <p>(bb) minerals.</p>
	IRELAND	<p>“food supplements” means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities;</p> <p>“nutrients” means the following substances—</p> <p>(a) vitamins,</p> <p>(b) minerals; (24)</p>	

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EU MEMBER COUNTRIES COMPLIANT WITH EU DIRECTIVE 46/2002 FOOD SUPPLEMENTS DEFINITION	ITALY	<p>Art. 2.</p> <p>Definizione</p> <p>1. Ai fini del presente decreto si intendono per «integratori alimentari» i prodotti alimentari destinati ad integrare la comune dieta e che costituiscono una fonte concentrata di sostanze nutritive, quali le vitamine e i minerali, o di altre sostanze aventi un effetto nutritivo o fisiologico, in particolare ma non in via esclusiva aminoacidi, acidi grassi essenziali, fibre ed estratti di origine vegetale, sia monocomposti che pluricomposti, in forme predosate.</p> <p>2. I termini: «complemento alimentare» o: «supplemento alimentare» sono da intendersi come sinonimi di: «integratore alimentare».</p> <p>3. Si intendono per predosate le forme di commercializzazione quali capsule, pastiglie, compresse, pillole, gomme da masticare e simili, polveri in bustina, liquidi contenuti in fiale, flaconi a contagocce e altre forme simili di liquidi e di polveri destinati ad essere assunti in piccoli quantitativi unitari. (25)</p>	<p>Art. 2.</p> <p>Definition</p> <p>1. For the purposes of this decree, "food supplements" are understood to be food products intended to supplement the common diet and which constitute a concentrated source of nutrients, such as vitamins and minerals, or of other substances having a nutritional or physiological effect, in particular but not exclusively amino acids, essential fatty acids, fibers and extracts of vegetable origin, both single and multi-compound, in pre-dosed forms.</p> <p>2. The terms: "complement alimentare" or: "supplemento" are to be understood as synonyms of: "integratore alimentare".</p> <p>3. Pre-dosed forms of marketing such as capsules, tablets, tablets, pills, chewing gum and the like, powders in sachets, liquids contained in vials, dropper bottles and other similar forms of liquids and powders intended to be taken in small unit quantities.</p>
	LATVIA	<p>Uztura bagātinātāji ir pārtikas produkti parastā uztura papildināšanai koncentrētu uzturvielu (vitamīnu un minerālvielu) veidā vai citas vielas, kurām ir uzturvērtība vai fizioloģiska ietekme, atsevišķi vai kombinācijās. Uztura bagātinātājus realizē noteiktās devās kapsulās, pastilās, tabletēs, dražejās un citos līdzīgos veidos, pulvera maisiņos, ampulās, pilināmās pudelītēs un citā līdzīgā šķidrums un pulvera veidā, kas paredzēts lietošanai mazā un nomērītā daudzumā. (26)</p>	<p>Food supplements are foods to supplement the normal diet in the form of concentrated nutrients (vitamins and minerals) or other substances that have a nutritional or physiological effect, alone or in combination. Food supplements are marketed in fixed doses in capsules, lozenges, tablets, dragees and other similar forms, powder sachets, ampoules, dropper bottles and other similar liquid and powder forms intended for use in small and measured quantities.</p>

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	LITHUANIA	<p>4. Šioje higienos normoje vartojamos sąvokos ir jų apibrėžimai:</p> <p>maisto papildas – maisto produktas, skirtas papildyti įprastą maisto racioną ir kuris vienas arba derinyje su kitomis medžiagomis yra koncentruotas maistinių ar kitų medžiagų, turinčių mitybinį arba fiziologinį poveikį, šaltinis. Maisto papildai rinkai tiekiami dozuotomis formomis – kapsulėmis, pastilėmis, piliulėmis, tabletėmis, kitomis panašiomis formomis bei miltelių maišeliais, ampulėmis, buteliukais su lašų dozatoriais bei kitomis panašiomis skysčių ir miltelių, skirtų vartoti mažais dozuotais kiekiais, formomis:</p> <p>maistinės medžiagos – vitaminai ir mineralinės medžiagos. (27)</p>	<p>4. Terms used in this hygiene standard and their definitions:</p> <p>"food supplement" means a food intended to be added to the normal diet and which is one or which is contained in another substance which contains a source of concentrated nutrients or other substances with a nutritional or physiological effect. Food supplements are supplied to the market in dosage forms - capsules, lozenges, pills, tablets, other similar forms and powder bags, ampoules, bottles with drop dispensers and other similar forms of liquids and powders, skirts for small doses;</p> <p>nutrients - vitamins and minerals.</p>
	LUXEMBOURG	<p>Art. 2.</p> <p>Aux fins du présent règlement, on entend par:</p> <p>a) «compléments alimentaires», les denrées alimentaires dont le but est de compléter le régime alimentaire normal, et qui constituent une source concentrée de nutriments ayant un effet nutritionnel ou physiologique seuls ou combinés, commercialisés sous forme de doses, à savoir les formes de présentation telles que les gélules, les pastilles, les comprimés, les pilules et autres formes similaires, ainsi que les sachets de poudre, les ampoules de liquide, les flacons munis d'un compte-gouttes et les autres formes analogues de préparations liquides ou en poudre destinées à être prises en unités mesurées de faible quantité;</p> <p>b) «nutriments», les substances suivantes:</p> <ul style="list-style-type: none"> <li>• vitamines;</li> <li>• minéraux. (28)</li> </ul>	<p>Art. 2.</p> <p>For the purposes of this Regulation:</p> <p>(a) 'food supplements' means foodstuffs the purpose of which is to supplement the normal diet, and which constitute a concentrated source of nutrients having a nutritional or physiological effect, alone or in combination, marketed in the form of doses, namely the forms of presentation such as capsules, lozenges, tablets, pills and other similar forms, as well as sachets of powder, ampoules of liquid, bottles fitted with a dropper and other similar forms of liquid or powder intended to be taken in measured units of small quantity;</p> <p>(b) 'nutrients' means the following substances:</p> <ul style="list-style-type: none"> <li>• vitamins;</li> <li>• minerals</li> </ul>

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EU MEMBER COUNTRIES COMPLIANT WITH EU DIRECTIVE 46/2002 FOOD SUPPLEMENTS DEFINITION	MALTA	<p>3.1. In these regulations, unless the context otherwise requires, the following definitions shall apply: (a) 'food supplements' means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities; (b) 'nutrients' means the following substances: (i) vitamins, (ii) minerals; (c) 'other substances', in the context of paragraph (a), shall mean any substances falling within one of the categories listed in the Fourth Schedule. General provisions. (29)</p>	
	NETHERLANDS	<p>Artikel 1</p> <p>1. In dit besluit en de daarop berustende bepalingen wordt verstaan onder:</p> <p>a. microvoedingsstoffen: vitaminen en mineralen;</p> <p>b. voedings supplementen: eet- of drinkwaren die:</p> <p>1° bedoeld zijn als aanvulling op de normale voeding;</p> <p>2° een geconcentreerde bron vormen van één of meer microvoedingsstoffen of van andere stoffen met een voedingskundig of fysiologisch effect; en</p> <p>3° verhandeld worden in voor inname bestemde afgemeten kleine eenheidshoeveelheden; (30)</p>	<p>Art. 2.</p> <p>For the purposes of this Regulation:</p> <p>(a) 'food supplements' means foodstuffs the purpose of which is to supplement the normal diet, and which constitute a concentrated source of nutrients having a nutritional or physiological effect, alone or in combination, marketed in the form of doses, namely the forms of presentation such as capsules, lozenges, tablets, pills and other similar forms, as well as sachets of powder, ampoules of liquid, bottles fitted with a dropper and other similar forms of liquid or powder intended to be taken in measured units of small quantity;</p> <p>(b) 'nutrients' means the following substances:</p> <ul style="list-style-type: none"> <li>• vitamins;</li> <li>• minerals</li> </ul>

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	POLAND	<p>39) suplement diety – środek spożywczy, którego celem jest uzupełnienie normalnej diety, będący skoncentrowanym źródłem witamin lub składników mineralnych lub innych substancji wykazujących efekt odżywczy lub inny fizjologiczny, pojedynczych lub złożonych, wprowadzany do obrotu w formie umożliwiającej dawkowanie, w postaci: kapsulek, tabletek, drażetek i w innych podobnych postaciach, saszetek z proszkiem, ampulek z płynem, butelek z kroplomierzem i w innych podobnych postaciach płynów i proszków przeznaczonych do spożywania w małych, odmierzonych ilościach jednostkowych, z wyłączeniem produktów posiadających właściwości produktu leczniczego w rozumieniu przepisów prawa farmaceutycznego; (31)</p>	<p>39) Food supplement - a foodstuff aimed at supplementing a normal diet, being a concentrated source of vitamins or ingredients</p> <p>minerals or other substances with a nutritional or other effect</p> <p>physiological, single or combined, marketed in a dosage form, in the form of capsules, tablets, dragées and</p> <p>other similar forms, powder sachets, liquid ampoules, dropper bottles and other similar forms, liquids and powders</p> <p>intended for consumption in small, measured unit quantities, excluding products with product properties</p> <p>medicinal products within the meaning of the pharmaceutical law;</p>
	PORTUGAL	<p>Artigo 3.o Definições Para efeitos do presente diploma, entende-se por: a) «Suplementos alimentares», os géneros alimentícios que se destinam a complementar e ou suplementar o regime alimentar normal e que constituem fontes concentradas de determinadas substâncias nutrientes ou outras com efeito nutricional ou fisiológico, estremes ou combinadas, comercializadas em forma doseada, tais como cápsulas, pastilhas, comprimidos, pílulas e outras formas semelhantes, saquetas de pó, ampolas de líquido, frascos com conta-gotas e outras formas similares de líquidos ou pós que se destinam a ser tomados em unidades medidas de quantidade reduzida; b) «Substâncias nutrientes ou nutrimentos», as vitaminas e os minerais; c) «Autoridade competente», a Agência para a Qualidade e Segurança Alimentar, organismo responsável pela avaliação dos riscos dos géneros alimentícios e que, nessa matéria, colabora</p> <p>com a Autoridade Europeia para a Segurança</p> <p>dos Alimentos. (32)</p>	<p>Article 3 Definitions For the purposes of this law, the following definitions apply: (a) 'food supplements' means foodstuffs that are intended to complement and or supplement the normal diet and that constitute concentrated sources of certain nutrient substances or others with effective nutritional or physiological, individually or in combination, sold in dosage form, such as such as capsules, lozenges, tablets, pills and other similar forms, powder sachets, liquid ampoules, flasks with droppers and other similar forms of liquids or powders that are intended to be taken in units measured reduced quantity; (b) 'nutrient substances or nutrients' means vitamins and minerals; (c) 'competent authority' means the Agency for the Food Quality and Safety, body responsible for the risk assessment of foodstuffs and, in that regard, collaborates with the European Security Authority Food.</p>

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	ROMANIA	<p>ART. 2</p> <p>În sensul prezentelor norme, termenii folosiți se definesc după cum urmează:</p> <p>a) suplimente alimentare - produsele alimentare al căror scop este să completeze dieta normală și care sunt surse concentrate de nutrienți sau alte substanțe cu efect nutrițional ori fiziologic, separat sau în combinație, comercializate sub formă de doză, cum ar fi: capsule, pastile, tablete, pilule și alte forme similare, pachete de pulbere, fiole cu lichid, sticle cu picurător și alte forme asemănătoare de preparate lichide sau pulberi destinate consumului în cantități mici, măsurabile;</p> <p>b) nutrienți - următoarele substanțe:</p> <p>(i) vitamine;</p> <p>(ii) minerale. (33)</p>	<p>ARTICLE 2</p> <p>For the purposes of these rules, the terms used are defined as follows:</p> <p>a) food supplements - food products whose purpose is to supplement normal diet and which are concentrated sources of nutrients or other substances with effect nutritional or physiological, separately or in combination, marketed in the form of dose, such as: capsules, pills, tablets, pills and other similar forms, packs of powder, liquid ampoules, dropper bottles and other similar forms of preparations liquids or powders intended for consumption in small, measurable quantities;</p> <p>b) nutrients - the following substances:</p> <p>(i) vitamins;</p> <p>(ii) minerals.</p>
	SLOVAKIA	<p>e) výživovým doplnkom potravina na doplnenie prirodzenej stravy, ktorá je koncentrovanými zdrojmi živín, ako sú vitamíny a minerálne látky alebo iných látok s výživovým alebo fyziologickým účinkom, jednotlivo alebo v kombinácii; umiestňuje sa na trh v dávkovanej forme, ako sú kapsuly, pastilky, tablety, piluly a ostatné podobné formy, vrecúška s práškom, ampulky s tekutinami, fľašky s dávkovačom kvapiek a ostatné podobné formy tekutín a práškov navrhnuté tak, aby ich bolo možné brať v odmeraných malých jednotkových množstvách, (34)</p>	<p>e) Food supplement is a food to supplement the natural diet, which is a concentrated source of nutrients such as vitamins and minerals or other substances with a nutritional or physiological effect, individually or in combination; it is placed on the market in dosage form such as capsules, lozenges, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, bottles with a drop dispenser and other similar forms of liquids and powders designed to be taken in measured small unit quantities,</p>

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EU MEMBER COUNTRIES COMPLIANT WITH EU DIRECTIVE 46/2002 FOOD SUPPLEMENTS DEFINITION	SLOVENIA	<p>2. člen</p> <p>Posamezni pojmi v tem pravilniku imajo naslednji pomen: (a) "prehranska dopolnila" so živila, katerih namen je dopolnjevati običajno prehrano. So koncentrirani viri posameznih ali kombiniranih hranil ali drugih snovi s hranilnim ali fiziološkim učinkom, ki se dajejo v promet v obliki kapsul, pastil, tablet in drugih podobnih oblikah, v vrečkah s praškom, v ampulah s tekočino, v kapalnih stekleničkah in v drugih podobnih oblikah s tekočino in praškom, ki so oblikovane tako, da se jih lahko uživa v odmerjenih majhnih količinskih enotah;</p> <p>(b) "hranila" so vitamini in minerali. (35)</p>	<p>Article 2</p> <p>Individual terms in this policy have the following meanings:</p> <p>(a) 'food supplements' means foods intended to supplement the normal diet. They are concentrated sources of individual or combined nutrients or other substances with a nutritional or physiological effect, which are placed on the market in the form of capsules, lozenges, tablets and other similar forms, in powder bags, in ampoules with liquid, in droppers and in other similar liquid and powder forms which are designed in such a way that they can be consumed in metered small quantities;</p> <p>(b) 'nutrients' means vitamins and minerals.</p>
	SPAIN	<p>Artículo 2. Definiciones.</p> <p>A los efectos de este real decreto, se entenderá por:</p> <p>1. Complementos alimenticios: Los productos alimenticios cuyo fin sea complementar la dieta normal y consistentes en fuentes concentradas de nutrientes o de otras sustancias que tengan un efecto nutricional o fisiológico, en forma simple o combinada, comercializados en forma dosificada, es decir cápsulas, pastillas, tabletas, píldoras y otras formas similares, bolsitas de polvos, ampollas de líquido, botellas con cuentagotas y otras formas similares de líquidos y polvos que deben tomarse en pequeñas cantidades unitarias.</p> <p>2. Nutrientes: Las sustancias siguientes:</p> <p>a) Vitaminas.</p> <p>b) Minerales. (36)</p>	<p>Article 2. Definitions.</p> <p>For the purposes of this royal decree, it shall be understood as:</p> <p>1. Food supplements: Food products whose purpose is to complement the normal diet and consisting of concentrated sources of nutrients or other substances that have a nutritional or physiological effect, in simple or combined form, commercialized in dosed form, i.e. capsules, pills, tablets, pills and other similar forms, powder sachets, liquid ampoules, dropper bottles, and other similar shapes of liquids and powders to be taken in small unit quantities.</p> <p>2. Nutrients: The following substances:</p> <p>a) Vitamins.</p> <p>b) Minerals.</p>

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EU MEMBER COUNTRIES COMPLIANT WITH EU DIRECTIVE 46/2002 FOOD SUPPLEMENTS DEFINITION	SWEDEN	<p>2 § Med kosttillskott avses livsmedel</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> som är avsedda att komplettera en normal kost,</li> <li><input type="checkbox"/> som utgör koncentrerade källor för näringsämnen eller andra ämnen</li> </ul> <p>med näringsmässig eller fysiologisk verkan, var för sig eller tillsammans, och</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> som tillhandahålls i avdelade doser, dvs. i form av kapslar, pastiller, tabletter, piller eller liknande, portionspåsar med pulver, ampuller med vätska, droppflaskor eller andra liknande former av vätskor eller pulver som är avsedda att intas i små uppmätta mängder.</li> </ul> <p>Med näringsämnen avses vitaminer och mineralämnen. (37)</p>	<p>Section 2 Food supplements refer to food</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> which are intended to supplement a normal diet,</li> <li><input type="checkbox"/> which are concentrated sources of nutrients or other substances</li> </ul> <p>with nutritional or physiological effects, individually or together, and</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> provided in divided doses, ie. in the form of capsules, lozenges, tablets, pills or similar, sachets with powder, ampoules with liquid, dropper bottles or other similar forms of liquids or powders which are intended to be ingested in small measured amounts.</li> </ul> <p>Nutrients refer to vitamins and minerals.</p>



APPENDIX 2

	COUNTRY	ORIGINAL TEXT OF NATIONAL LEGISLATION	ENGLISH TRANSLATION BY GOOGLE TRANSLATE
NON-EU MEMBER COUNTRIES COMPLIANT WITH EU DIRECTIVE 46/2002 FOOD SUPPLEMENTS DEFINITION	ENGLAND	<p>“food supplement” means any food the purpose of which is to supplement the normal diet and which—</p> <p>(a) is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination; and</p> <p>(b) is sold in dose form; (38)</p>	
	MONTENEGRO	<p>Član 63</p> <p>(1) Suplement je hrana čija je svrha dopuna uobičajene ishrane, a koji predstavlja koncentrovani izvor hranljivih materija ili druge materije prehrambenog ili fiziološkog dejstva, pojedinačno ili u kombinaciji, koji se stavlja na tržište u doziranom obliku (kapsule, pastile, tablete, pilule, vrećice praha, ampule tečnosti, bočice na kapaljku i drugim sličnim oblicima za tečnost i prah za korišćenje u odmjerenim malim količinama).</p> <p>(2) Zabranjeno je stavljati na tržište suplemente koji ne ispunjavaju zahtjeve utvrđene ovim zakonom.</p> <p>(3) Zabranjeno je prilikom označavanja, prezentacije i reklamiranja ukazivati da suplementi imaju svojstva prevencije, liječenja ili izlječenja bolesti ljudi i upućivati na takva svojstva.</p> <p>(4) Suplementi se mogu stavljati na tržište pod nazivom "dodatak ishrani" ili "suplement" u originalnom pakovanju u odgovarajućem obliku, ukoliko ispunjavaju propisane zahtjeve.</p> <p>(5) Vrste i oblici vitamina i minerala koji se smiju koristiti u proizvodnji suplemenata i zahtjevi koje moraju ispunjavati vitamini, minerali, suplementi i druge supstance, kao i način i uslovi označavanja i stavljanja na tržište utvrđuju se propisom Vlade. (10)</p>	<p>Article 63</p> <p>(1) A supplement is a food whose purpose is to supplement the usual diet, and which represents a concentrated source of nutrients or other substances nutritional or physiological action, singly or in combination, which is put on the market in dosage form (capsules, lozenges, tablets, pills, sachets of powder, liquid ampoules, dropper bottles and other similar forms for liquid and powder use in measured small quantities).</p> <p>(2) It is prohibited to place on the market supplements that do not meet the requirements determined by this law.</p> <p>(3) It is prohibited to indicate that during marking, presentation and advertising Supplements have the properties of preventing, treating or curing human diseases and referring of such properties.</p> <p>(4) Supplements may be placed on the market under the name "food supplement" or "supplement" in the original packaging in the appropriate form, if meet the prescribed requirements.</p> <p>(5) Types and forms of vitamins and minerals that may be used in production supplements and the requirements that vitamins, minerals, supplements and must meet other substances, as well as the manner and conditions of labeling and placing on the market shall be determined by a regulation of the Government.</p>

	COUNTRY	ORIGINAL TEXT OF NATIONAL LEGISLATION	ENGLISH TRANSLATION BY GOOGLE TRANSLATE
NON-EU MEMBER COUNTRIES COMPLIANT WITH EU DIRECTIVE 46/2002 FOOD SUPPLEMENTS DEFINITION	NORTH MACEDONIA	66. "Додатоци на исхрана" е храна чија цел е да ја дополнуваат нормалната исхрана и кои се концентрирани извори на хранливи состојки или други супстанции со прехранбен или физиолошки ефект, сами или во комбинација, произведени во вид на капсули, пастили, таблети, кеси со прашкаста супстанца, ампули со течност и други слични форми на течни или прашкасти супстанции дизајнирани да можат да бидат употребени во малимерливи единечни количини; (39)	66. "Food supplements" are foods whose purpose is to supplement a normal diet and which are concentrated sources of nutrients or other nutrients or physiological effect, alone or in combination, produced in the form of capsules, lozenges, tablets, powder bags, liquid ampoules and other similar forms of liquid or powdered substances designed to be used in small quantities measurable unit quantities;
	NORTHERN IRELAND	<p>"food supplement" means any food the purpose of which is to supplement the normal diet and which—</p> <p>(a) is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination; and</p> <p>(b) is sold in dose form; (40)</p>	
	NORWAY	<p>§ 3. Definisjoner</p> <p>I denne forskriften forstås med:</p> <p>1. kosttilskudd: Næringsmidler som</p> <p>a) er beregnet til å supplere kosten, og</p> <p>b) er konsentrerte kilder av vitaminer og mineraler eller andre stoffer med en ernæringsmessig eller fysiologisk effekt, alene eller i kombinasjon, og</p> <p>c) omsettes i ferdigpakket og dosert form beregnet til å inntas i små oppmålte mengder; som for eksempel kapsler, pastiller, tabletter, piller, pulverposer, ampuller, dråpeflasker og lignende former for væsker og pulver.</p> <p>2. omsetning: Besittelse med sikte på salg, utbud for salg, distribusjon, samt selve salget og enhver annen form for overdragelse med eller uten vederlag. (41)</p>	<p>§ 3. Definitions</p> <p>For the purposes of this Regulation:</p> <p>1st supplements: Foods such as</p> <p>a) is intended to supplement the diet, and</p> <p>b) are concentrated sources of vitamins and minerals or other substances with a nutritional or physiological effect, alone or in combination, and</p> <p>c) sold in pre-packaged and dosed form intended to be ingested in small measured quantities; such as capsules, lozenges, tablets, pills, powder bags, ampoules, dropper bottles and similar liquids and powders.</p> <p>2nd turnover: Possession with a view to sale, offer for sale, distribution, as well as the sale itself and any other form of transfer with or without consideration.</p>

	COUNTRY	ORIGINAL TEXT OF NATIONAL LEGISLATION	ENGLISH TRANSLATION BY GOOGLE TRANSLATE
NON-EU MEMBER COUNTRIES COMPLIANT WITH EU DIRECTIVE 46/2002 FOOD SUPPLEMENTS DEFINITION	SCOTLAND	<p>“food supplement” means any food the purpose of which is to supplement the normal diet and which—</p> <p>(a) is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination; and</p> <p>(b) is sold in dose form; (42)</p>	
	SWITZERLAND	<p>Art. 1 Nahrungsergänzungsmittel</p> <p>Nahrungsergänzungsmittel sind Lebensmittel, die dazu bestimmt sind, die normale Ernährung zu ergänzen. Sie bestehen aus Einfach- oder Mehrfachkonzentraten von Vitaminen, Mineralstoffen oder sonstigen Stoffen mit ernährungsspezifischer oder physiologischer Wirkung und werden in dosierter Form in Verkehr gebracht.</p> <p>Art. 2 Anforderungen</p> <p>1 Nahrungsergänzungsmittel dürfen nur vorverpackt in Verkehr gebracht werden, ausser sie werden an Konsumentinnen und Konsumenten zum direkten Verzehr abgegeben.</p> <p>2 Sie müssen zur Aufnahme in abgemessenen kleinen Mengen, in Form von Kapseln, Pastillen, Tabletten, Pillen oder anderen ähnlichen Darreichungsformen oder in Form von Pulverbeuteln, Flüssigampullen, Flaschen mit Tropfeinsätzen oder ähnlichen Darreichungsformen von Flüssigkeiten und Pulvern, angeboten werden. (43)</p>	<p>Art. 1 Food supplements</p> <p>Food supplements are foods that are designed to complement a normal diet. They consist of single or multiple concentrates of vitamins, minerals or other substances with nutritional or physiological effects and are put on the market in dosed form.</p> <p>Art. 2 Requirements</p> <p>1 Food supplements may only be placed on the market in prepackaged form, unless they are made available to consumers for direct consumption.</p> <p>2 They must be offered for absorption in measured small quantities, in the form of capsules, troches, tablets, pills or other similar dosage forms or in the form of powder bags, liquid ampoules, bottles with dropper inserts or similar dosage forms of liquids and powders.</p>
	UKRAINE	<p>20) дієтична добавка – харчовий продукт, що споживається у невеликих визначених кількостях додатково до звичайного харчового раціону, який є концентрованим джерелом поживних речовин, у тому числі білків, жирів, вуглеводів, вітамінів, мінеральних речовин (цей перелік не є виключним), і виготовлений у вигляді таблеток, капсул, драже, порошків, рідин або інших формах; (44)</p>	<p>20) food supplement - a food product consumed in small quantities in addition to the usual diet, which is a concentrated source of nutrients, including proteins, fats, carbohydrates, vitamins, minerals (this list is not exclusive), and made in the form of tablets, capsules, pills, powders, liquids or other forms;</p>

	<b>COUNTRY</b>	<b>ORIGINAL TEXT OF NATIONAL LEGISLATION</b>	<b>ENGLISH TRANSLATION BY GOOGLE TRANSLATE</b>
<b>NON-EU MEMBER COUNTRIES COMPLIANT WITH EU DIRECTIVE 46/2002 FOOD SUPPLEMENTS DEFINITION</b>	<b>WALES</b>	<p>“food supplement” means any food the purpose of which is to supplement the normal diet and which—</p> <p>(a) is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination; and</p> <p>(b) is sold in dose form; (45)</p>	

APPENDIX 3

	COUNTRY	ORIGINAL TEXT OF NATIONAL LEGISLATION	ENGLISH TRANSLATION BY GOOGLE TRANSLATE
NON-EU MEMBER COUNTRIES NON-COMPLIANT WITH EU DIRECTIVE 46/2002 FOOD SUPPLEMENTS DEFINITION	<b>BOSNIA AND HERZEGOVINA</b>  <b>FBIH</b>	<p>„Član 2. Dijetetske namirnice, usmislu ovog pravilnika, su namirnice za posebne prehrambene potrebe, a koje se zbog svog posebnog sastava ili procesa proizvodnje razlikuju od namirnica uobičajenog sastava. Dijetetske namirnice iz stava 1. ovog člana namijenjene su: prehrani zdrave dojenčadi i male djece; b) licima kod kojih je poremećen proces probave ili metabolizma; c) licima koja se nalaze u posebnim fiziološkim stanjima i kod kojih je potrebno postići posebno djelovanje kontroliranim unosom određenih sastojaka namirnica “ Dijetetske namirnice prema članu 1. ovoga pravilnika su:</p> <ol style="list-style-type: none"> <li>(1) Dječija hrana</li> <li>(2) Namirnice sa smanjenom količinom laktoze i namirnice bez laktoze</li> <li>(3) Namirnice sa smanjenom količinom ili vrlo smanjenom količinom natrija, uključujući i dijetetsku sol sa smanjenom količinom natrija ili bez natrija</li> <li>(4) Namirnice sa smanjenom ili povećanom količinom bjelančevina i/ili izmijenjenim sastavom bjelančevina</li> <li>(5) Namirnice bez gluteina</li> <li>(6) Namirnice sa smanjenom ili povećanom količinom ugljikohidrata i/ili izmijenjenim sastavom ugljikohidrata</li> <li>(7) Namirnice obogaćene vitaminima, mineralnim tvarima i ostalim biološki vrijednim tvarima</li> <li>(8) Osvežavajuća bezalkoholna pića sa povećanom količinom kofeina i drugim dodacima i aditivima</li> <li>(9) Namirnice sa smanjenom ili povećanom energetsom vrijednosti</li> <li>(10) Namirnice obogaćene dijetalnim vlaknima</li> <li>(11) Namirnice sa smanjenom i/ili izmijenjenom količinom masnoća posebno holesterola</li> <li>(12) Namirnice za posebnu medicinsku namjenu</li> <li>(13) Namirnice namijenjene licima oboljelim od šećerne bolesti</li> <li>(14) Zamjene za šećer (saharozu) i umjetna sladila</li> <li>(15) <b>Nadomjesci i dodaci prehrani</b></li> </ol>	<p>"Article 2 Dietary foods, in the sense of this ordinance, are foods for special nutritional needs, which due to their special composition or production process differ from foods of normal composition. Dietary foods referred to in paragraph 1 of this Article are intended for: a) nutrition of healthy infants and young children; b) persons in whom the process of digestion or metabolism is disturbed; (c) persons who are in special physiological conditions and in whom special action is required by the controlled intake of certain food ingredients. " Dietary foods according to Article 1 of this Ordinance are: 1. Baby food 2. Foods with reduced amount of lactose and foods without lactose 3. Foods with reduced or very low sodium, including dietary salt with or without sodium 4. Foods with reduced or increased protein content and / or altered protein composition 5. Gluten-free foods 6. Foods with reduced or increased carbohydrate content and / or altered carbohydrate composition 7. Foods enriched with vitamins, minerals and other biologically valuable substances 8. Refreshing soft drinks with increased amount of caffeine and other additives 9. Foods with reduced or increased energy value 10. Foods enriched with dietary fiber 11. Foods with reduced and / or altered fat, especially cholesterol 12. Foodstuffs for special medical purposes 13. Foods intended for persons suffering from diabetes 14. Substitutes for sugar (sucrose) and artificial sweeteners 15. Supplements and dietary supplements 16. Athlete dietary supplements Other dietary foods in terms of Article 2 of this Ordinance. Nutritional supplements are individual forms or mixtures of nutrients, which serve as a food supplement in terms of its enrichment or are taken directly in</p>

		<p>(16) Dodaci prehrani sportaša Ostale dijetetske namirnice u smislu člana 2. ovoga pravilnika. Pod <b>prehrambenim dodacima</b> podrazumijevaju se pojedinačni oblici ili mješavine hranjivih tvari, koje služe kao <b>dodatak prehrani u smislu njenog obogaćivanja</b> ili se uzimaju direktno u koncentriranom obliku (vitamini, mineralne tvari, bjelančevine, aminokiseline, masne kiseline). Sadržaj pojedinog sastojka u proizvodu koji se prema preporuci proizvođača koristi tokom dana, ne može biti viši od 3 puta od preporučene dnevne količine, osim vitamina A i D koji se mogu koristiti samo u količinama do 1 RDA. Pod prehrambenim dodacima podrazumijevaju se i zaštitna sredstva biljnog porijekla (bioflavonoidi, karotenoidi, izoflavoni, glukozinolati) mliječno kisele bakterije (laktobacili i/ili bifidobakterije), prirodni enzimi i koenzimi. Pod prehrambenim dodacima podrazumijevaju se i pripravci proizvedeni iz sirovina biljnog porijekla, mješavine pčelinjih proizvoda i pčelinji proizvodi sa dodacima ljekovitog bilja, uz uvjet da ne utiču na zdravstvenu ispravnost gotovog proizvoda. (4)</p>	<p>concentrated form (vitamins, minerals, proteins, amino acids, fatty acids). The content of an individual ingredient in a product that is used during the day according to the manufacturer's recommendation, cannot be higher than 3 times the recommended daily amount, except for vitamins A and D, which can only be used in amounts up to 1 RDA. Dietary supplements also include plant protection products (bioflavonoids, carotenoids, isoflavones, glucosinolates), lactic acid bacteria (lactobacilli and / or bifidobacteria), natural enzymes and coenzymes. Dietary supplements also include preparations produced from raw materials of plant origin, mixtures of bee products and bee products with the addition of medicinal herbs, provided that they do not affect the health of the finished product.</p>
	<p><b>BOSNIA AND HERZEGOVINA</b>  <b>RS</b></p>	<p>Član 2.  Dodaci ishrani su prehrambeni proizvodi čija je svrha dopuna uobičajene ishrane, a koji predstavljaju koncentrovani izvor hranjivih materija ili drugih materija prehrambenog ili fiziološkog dejstva, pojedinačno ili u kombinaciji, koji se stavlja na tržište u doziranom obliku kao što su kapsule, pastile, tablete, pilule, vrećice praha, ampule tečnosti, bočice na kapaljku i u drugim sličnim oblicima za korištenje u odmjerenim malim količinama u skladu sa zakonom. (46)</p>	<p>Article 2  Food supplements are food products whose purpose is to supplement the usual diet, and which are a concentrated source of nutrients or other substances of nutritional or physiological action, individually or in combination, placed on the market in dosage form such as capsules, lozenges, tablets, pills, powder bags, liquid ampoules, dropper bottles and other similar forms for use in measured small quantities in accordance with the law.</p>

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NON-EU MEMBER COUNTRIES COMPLIANT WITH EU DIRECTIVE 46/2002 FOOD SUPPLEMENTS DEFINITION	<b>SERBIA</b>	<p>Члан 3.</p> <p>Дијететски производи намењени су да задовоље посебне нутритивне захтеве и то:</p> <ol style="list-style-type: none"> <li>1) здраве одојчади и мале деце;</li> <li>2) одређене категорије особа код којих је поремећен процес пробаве или метаболизма;</li> <li>3) одређене категорије особа које се налазе у посебним физиолошким стањима и код којих је потребно постићи посебно деловање контролисаним уносом одређених састојака хране;</li> </ol> <p>Дијететски производи зависно од састава и намене, стављају се у промет као:</p> <ol style="list-style-type: none"> <li>1) формуле за одојчад;</li> <li>2) храна за одојчад и малу децу;</li> <li>3) храна за особе на дијети за мршављење;</li> <li>4) храна за посебне медицинске намене;</li> <li>5) храна за особе интолерантне на глутен;</li> <li>6) замене за со за људску исхрану, и</li> <li>7) додаци исхрани (дијететски суплементи).</li> </ol> <p>Дијететски производи се стављају у промет само као упаковани производи.</p> <p>На сваком паковању дијететског производа мора бити наведена ознака „дијететски производ”, а за додатке исхрани из става 2. тачке 7) овог члана мора бити наведена ознака „додатак исхрани”.</p> <p>Члан 77.</p> <p>У смислу овога правилника поједини изрази употребљени у овом поглављу имају следеће значење:</p> <p>Супстанце са хранљивим или физиолошким ефектом су витамини и минералне супстанце наведене у Прилогу бр. 24. овог правилника, као и друге супстанце са хранљивим или физиолошким ефектом као што су: протеини, аминокиселине, масне киселине, лецитини, влакна, квасац, биљке, биљне сировине, препарати биљних сировина, састојци изоловани из биљног материјала (нпр. биофлавоноиди, каротеноиди, изофлавоноиди, глукозинолати), ензими и коензими, живе културе микроорганизама, одређени пчелињи производи и друге супстанце.</p> <p>Биљна сировина је цео или уситњен, сиров или осушен део биљке, алге, гљиве или лишћаја.</p> <p>Препарати биљних сировина су производи који се добијају из биљних сировина применом специфичних поступака као што су: дестилација, цеђење, екстракција, фракционисање, пречишћавање, концентрисање, ферментација и др. (47)</p>	<p>Article 3</p> <p>Dietary products are intended to meet special nutritional requirements, as follows:</p> <ol style="list-style-type: none"> <li>1) healthy infants and young children;</li> <li>2) certain categories of persons in whom the process of digestion or metabolism is disturbed;</li> <li>3) certain categories of persons who are in special physiological conditions and in whom it is necessary to achieve special action by controlled intake of certain food ingredients;</li> </ol> <p>Dietary products, depending on the composition and purpose, are placed on the market as:</p> <ol style="list-style-type: none"> <li>1) infant formulas;</li> <li>2) food for infants and young children;</li> <li>3) food for people on a weight loss diet;</li> <li>4) food for special medical purposes;</li> <li>5) food for people intolerant to gluten;</li> <li>6) substitutes for salt for human consumption, and</li> <li>7) dietary supplements (dietary supplements).</li> </ol> <p>Dietary products are placed on the market only as packaged products. Each package of a dietary product must bear the label "dietary product", and for dietary supplements referred to in paragraph 2, item 7) of this Article, the label "dietary supplement" must be indicated. For the purposes of this Ordinance, certain terms used in this Chapter have the following meaning: Substances with a nutritional or physiological effect are vitamins and mineral substances listed in Annex no. 24. of this Ordinance, as well as other substances with nutritional or physiological effect such as: proteins, amino acids, fatty acids, lecithins, fibers, yeast, plants, plant raw materials, preparations of plant raw materials, ingredients isolated from plant material (eg bioflavonoids, carotenoids, isoflavones, glucosinolates), enzymes and coenzymes, live cultures of microorganisms, certain bee products and other substances. Plant raw material is a whole or chopped, raw or dried part of a plant, algae, fungus or lichen. Preparations of plant raw materials are products that are obtained from plant raw materials by applying specific procedures such as: distillation, straining, extraction, fractionation, purification, concentration, fermentation, etc.</p>

	COUNTRY	ORIGINAL TEXT OF NATIONAL LEGISLATION	ENGLISH TRANSLATION BY GOOGLE TRANSLATE
NON-EU MEMBER COUNTRIES NON-COMPLIANT WITH EU DIRECTIVE 46/2002 FOOD SUPPLEMENTS DEFINITION	ALBANIA	32.“Ushqim për nevoja të veçanta dietetike” është një ushqim me përbërje të veçantë ose një mënyrë e veçantë prodhimi, i ndryshëm nga ushqimi i zakonshëm, për shkak të karakteristikave ushqimore. Këto ushqime mund të parashikohen për përdorim te fëmijët deri 12 muaj dhe fëmijët e vegjël, te njerëzit me çrregullime të aparatit tretës ose të metabolizmit dhe te personat, të cilët janë në gjendje të veçantë fiziologjike, për të cilët është e nevojshme të arrihen efekte të veçanta nga një marrje e kontrolluar e disa përbërësve ushqimorë. (48)	32. "Food for special dietary needs" is a food with a special composition or a special way of production, different from ordinary food, due to nutritional characteristics. These foods can be prescribed for use in children up to 12 months and young children, in people with digestive or metabolic disorders and in persons who are in a special physiological state, for whom it is necessary to achieve the effects of separate from a controlled intake of certain nutrients.
	KOSOVO	“Ushqimi për nevojat e veçanta - ushqimet dietale”, është ushqim i përbërjes së veçantë ose I prodhimit të veçantë, i ndryshëm nga ushqimi i zakonshëm për shkak të cilësive ushqyese, kurse mund të dedikohet për ushqimin e foshnjave dhe fëmijëve të vegjël, personave të cilëve u është vështirësuar procesi i tretjes ose metabolizmi sikurse edhe personave që janë në gjendje të veçantë fiziologjike, të cilët kanë nevojë për arritjen e veprimit të marrjes së kontrolluar të materieve ushqyese. (49)	"Food for special needs - dietary foods", is food of special composition or special production, different from ordinary food due to nutritional qualities, courses can be dedicated to feeding infants and young children, persons to whom it is  complicate the digestive process or metabolism as well as persons who are able to special physiological, who need to achieve the action of controlled intake of nutrients.



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# THE ROLE OF HOLISTIC COMMUNITY PHARMACIST IN THE TREATMENT OF AN IRON LOW INTAKE

Irma-Hermina Klemenc, mag. farm.

According to WHO one-third of the world population has lower iron intake than recommended. It is suggested that as many as 30% of people have anemia due to prolonged iron deficiency. Around 20% of population with low iron intake develops iron deficiency anemia in the developed countries. The low iron intake is ten times more occurring in female population. Young children and elderly are also individuals with great risk for iron deficiency. In infants and children, requirements were calculated by taking into consideration the needs for growth and absorption from the diet (1, 2, 3).

Iron deficiency anemia occurs in 2-5% of adult men and postmenopausal women in the developed countries. The World Health Organization defines anemia as a haemo-globin (Hb) concentration below 13 g/dl in men over 15 years of age, below 12 g/dl in non-pregnant women over 15 years of age, and below 11 g/dl in pregnant women. In iron depletion, the body's stored iron is reduced, and individuals are at greater risk of anemia in situations of increased demand. (4, 5)

While menstrual blood loss is the most common cause of low body iron in premenopausal women, blood loss from the GI tract is the most common cause in adult men and postmenopausal women. Iron deficiency occurs in 5-12% of otherwise healthy premenopausal women usually due to menstrual loss (6, 7).

Premenopausal women are also the most perceptible for dietary choices which results in lower iron intake than recommended. During menstruation period women lose 12-15 mg of iron daily. Female population is most commonly at risk to develop iron deficiency also due to higher demands in pregnancy and breast feeding, or dietary deficiency (8, 9).

Iron is a component of several proteins including haemoglobin. Haemoglobin is important for transport of oxygen to tissues throughout the body. Iron can exist in a range of oxidation states. Almost two thirds of the body's iron is found in haemoglobin in circulating erythrocytes. A quarter of the body's iron is found in readily metabolised stores as ferritin or haemosiderin in the liver and reticulo-endothelial system. The remaining iron is in the myoglobin of muscle tissue and a variety of enzymes necessary for oxidative metabolism and other cell functions (10).

Red blood cells bring oxygen to the body's tissues. Iron is a key part of red blood cells, and without iron, the blood cannot carry oxygen effectively. Human body normally gets iron through diet. Body also reuses iron from old red blood cells. Iron stores go from

being replete to deplete and finally absent, consequently resulting in iron deficiency anemia. Iron deficiency is a progressive process, in which iron stores fall (11, 12, 13).

Inadequate iron intake can lead to varying degrees of deficiency. It begins with low iron stores as indicated by low serum ferritin and a decrease in iron-binding capacity. Early iron deficiency shows with decreased serum transferrin saturation, increased erythrocyte protoporphyrin concentration and increased serum transferrin receptor. Iron-deficiency anemia results in low haemoglobin and haematocrit as well as reduced mean corpuscular haemoglobin and volume (14, 15, 16, 17).

Fatigue is the most common symptom of iron deficiency. The clinical symptoms of iron deficiency with or without developed anemia are non-specific and cannot be relied on for diagnostic purposes. Early symptoms such as fatigue, nausea, pale skin, dizziness, problematic thermoregulation, dyspnoea, irritability and restless leg, hair loss, must not be overlooked as they are likely to be the early signs of iron deficiency before anemia develop. At first iron deficient anemia can be mild and unnoticed, but symptoms worsen to irregular heartbeats, chest pain, and amenorrhoea, craving for non-food items such as ice and soil and headaches. Altered thyroid metabolism can also occur in iron deficiency anemia (lower thyroid-stimulating hormone and T3 hormone) and contribute to fatigue (16, 17).

EU Commission has authorized based on EFSA opinion through years 2009 and 2010, health claims concerning iron effect on human organism:

- Iron contributes to normal cognitive function.
- Iron contributes to normal energy-yielding metabolism.
- Iron contributes to normal formation of red blood cells and haemoglobin.
- Iron contributes to normal oxygen transport in the body.
- Iron contributes to the normal function of the immune system.
- Iron contributes to the reduction of tiredness and fatigue.
- Iron has a role in the process of cell division.
- Iron contributes to normal cognitive development of children. (18)

There are many possible causes for Iron deficiency. Malabsorption (most commonly from coeliac disease), blood donation, gastrectomy and use of non-steroidal anti-inflammatory drugs (NSAIDs) are some of the most common causes of iron deficiency. Iron deficiency anemia secondary to inadequate dietary iron intake is caused by consuming a diet low in iron-rich foods. Family history of iron deficiency anemia may indicate inherited disorders of iron absorption or haematological and bleeding disorders (17, 18, 19, 20).

The prevalence of anemia in pregnancy remains high. In pregnancy, there is a physiological expansion of plasma volume beginning in the first trimester and plateauing by the third, which exceeds the increased production of red blood cells and haemoglobin. The resulting haemodilution contributes to the fall in Hb during pregnancy. Iron utilization is increased during pregnancy, as iron is required for fetal growth and development, as well as for increased maternal erythropoiesis (20, 21, 22, 23).

Anemia in pregnancy can be caused by including vitamin B12 and folate deficiency. Iron deficiency anemia has been linked to poor health outcomes in the mother, fetus and infant. Iron deficiency with or without anemia, is associated with maternal fatigue and poorer quality of life due to increased risk of postpartum depression. Maternal anemia may also increase the risk of postpartum haemorrhage, as a result of impaired uterine

contractility due to reduced availability of oxygen. Data from the WHO, derived mainly from low and middle-income countries, show that the risk of maternal mortality increases with the severity of anemia (24).

British guidelines on the management of iron deficiency recommend all healthcare professionals to be cautious. Healthcare professionals should be aware that iron deficiency anemia in pregnancy is common and associated with increased risk of maternal morbidity and mortality. Healthcare professionals should be aware that iron deficiency anemia in pregnancy is associated with increased risk of perinatal morbidity and mortality and has important potential implications for the future neuro-development of the infant. Current good practice

guidelines advise testing Hb during pregnancy every 28 weeks (22, 23, 25).

Changes in red cells that accompany iron deficiency are reduced mean cell Hb (MCH) hypochromia, and increased percentage of hypochromic red cells. Reduced mean cell volume (MCV) is called microcytosis. The serum markers of iron deficiency include low ferritin, low transferrin saturation, low iron, raised total iron-binding capacity, raised red cell zinc protoporphyrin, and increased serum transferrin receptor (sTfR). The MCH is probably the most reliable measurement. A trial of parenteral iron may be more reliable, and a significant change in MCH should occur within 7 days when there is iron deficiency anemia present. According to UK guidelines for management of iron deficiency, therapeutic trial of oral iron for 3 weeks may aid diagnosis, but depends on patient's compliance (26, 27, 28, 29)

The concentration of ferritin varies between 12 and 15mg/l. Where there is inflammatory disease, a concentration of 50 mg/l or even more of ferritin, may still be consistent with iron deficiency. An increased red cell distribution width will often indicate coexistent vitamin B12 or folate deficiency (30, 31). Both microcytosis and hypochromia are sensitive indicators of iron deficiency in the absence of chronic disease or coexistent vitamin B12 or folate deficiency. Microcytosis and hypochromia are also present in many haemoglobinopathies, in sideroblastic anemia and in some cases of anemia of chronic disease. When the MCV is often out of proportion to the level of anemia compared with iron deficiency, we are dealing with haemoglobinopathie such as thalassaemia (32, 33, 34).

According to guidelines, the aim of iron deficiency treatment is to restore Hb concentrations and red cell indices to normal. Replenish iron stores and long-term maintenance of which should be recognized as the main goal of the iron deficiency treatment. Treatment of an underlying cause should prevent further iron loss. All recovering people after iron deficiency anemia treatment, should have iron supplementation both to replenish body stores of iron and to prevent anemia from reoccurring (31, 35, 36).

Assuming 10 % absorption the recommended daily iron intake for grown men is 11 mg. Taking

into account menstruation losses, daily iron requirement for premenopausal women is 15 mg, which drops to 8 mg daily in menopause. Recommended daily requirements during pregnancy for iron are 27 mg, during lactation around 10 mg in average. Requirements for infants 7-11 months are 11 mg daily, 7 mg/day in children aged 1-6 years and 11 mg/day in children aged 7-11 years. For girls aged 12-17 years calculated requirements are 13 mg/day taking into consideration PRI for premenopausal women (37, 38).

A dietary history should be taken into consideration to identify poor iron intake. Borderline iron-deficient diets are common, as especially in premenopausal female population.

Management of low iron intake is often suboptimal, with most individuals at higher risk being incompletely investigated or not investigated at all. Groups of people that are prone to iron deficiency should be referred to a dietitian, who can help make sure someone is getting all the necessary vitamins and minerals from preferred foods (35, 39, 40, 41). There are many reasons why people may not be getting enough iron in their diet: vegetarians or vegans who don't replace meat with other iron-rich foods or people with an eating disorder, people who live in urban "food deserts," where healthy food is not available, elderly people who do not eat a complete and diverse diet, people on a weight loss diet or people who eat a diet low in fruits, vegetables, and meat, people who consume excessive amounts of daily caffeine or people who regularly take antacids or NSAID. Both calcium and tannins (found in tea and coffee) reduce iron absorption, therefore tea, coffee, and calcium supplements should be used several hours before a meal that is high in iron (42, 43, 44). Haem iron is the more readily absorbed form of iron. Haem iron makes up about 40% of the iron in meat, poultry and fish. Eggs and many plant foods also contain iron, but it is in the non-haem form, which is less well absorbed. Omnivores gain in average 15% intake of haem iron from animal products that contributes about 50% of all absorbed iron from diet as a result of superior bioavailability. Iron is located in foods in 3+ valent form and has to be reduced in 2+ form in order to become physiologically active, for which antioxidants like ascorbic acid or B-complex vitamins are needed (43, 45, 46). Recommendations for iron intake for vegetarians (including vegans) may be as much as 1.8 times higher than for omnivores. Because vegan diets only contain non-heme iron, vegans should be especially aware of foods that are high in iron and techniques that can promote iron absorption. Since the vegan diet contains a form of iron that is not that well absorbed, they might be prone to developing iron deficiency anemia, if their food choices are poorly attended. Vegetarians and vegans should make sure they are eating enough beans, tofu, dried fruits, spinach, and other dark vegetables. Satisfactory iron status of vegans is possible because vegan diets are based on foods high in vitamin C, which markedly increases absorption of non-heme iron (47, 48). Providing information about early symptoms may facilitate earlier presentation of iron depletion. Recognizing early symptoms of fatigue, irritability, poor concentration and hair loss, may be crucial to prevent anemia development. A recent systematic review of non-anemic iron deficiency found that fatigue improves with early iron replacement (36, 41). In Australia diagnosis and treatment methods for iron deficiency depends on your iron status. If there is iron depletion, doctor will give information about including iron-rich foods in diet and another blood test will be performed in 6 months. When iron deficiency is already present, doctor will give dietary advice and closely monitor patient's diet; encourage to include iron-rich foods and discourage from foods and drinks (such as tea and coffee) that can interfere with iron absorption with meals, also doctor will regularly review patient's iron status and may prescribe dietary supplements. If iron deficiency anemia has been developed, doctor will prescribe medication containing iron. It may take 6 months to a year for body to restock iron stores and iron levels will be regularly reviewed with blood tests.

When there is an underlying problem for cause of patient's iron deficiency, it is doctor's obligation to investigate the possible medical cause (49, 50, 51, 52).

A report in line with a holistic structured case of consultancy concerning iron deficiency of everyday practice from community pharmacy Dravlje in Ljubljana, was presented at the HCP conference 2020. Holistic structure of cases from community pharmacy practice was designed by Mag. Martina Puc, mag. far. Spec., MBA. The presented report



discussed the woman with diagnosed anemia, caused by low iron intake with doctor's prescription of medicine with iron replacement. The woman experienced various side effects with repetition of the prescription.

The most common treatments of iron deficiency include ferrous sulphate 325 mg taken orally once daily. Lower doses may be as effective and better tolerated and should be considered in patients not tolerating traditional doses. Other iron compounds (e.g., ferrous fumarate, ferrous gluconate) or formulations (iron suspensions) may also be tolerated better than ferrous sulphate (53, 54). Ferrous sulphate is commonly known for causing some characteristic side effects. Compliance to standard iron deficiency treatment is in average very low due to commonly occurring side effects. Especially ferrous sulfate is known for possible cause of side effects regarding stomach pain and cramps, nausea, epigastric pain, diarrhea, or constipation, upset stomach and throwing up (55, 57, 58).

Oral iron supplementation should be continued longer than for 3 months after the iron deficiency has been corrected. According to valid medical practice in European countries, once normal, the Hb concentration and red cell indices should be monitored at intervals. Most guidelines for iron deficiency management suggest 3 monthly monitoring for 1 year, then after a further year, and again if characteristic symptoms of anemia develop after that. Iron supplementation should be attended longer after iron deficiency has been corrected in order to replenish iron stores in body (60, 61).

Prescription of iron substitution should be followed by proper advice about therapy routine. According to research ascorbic acid in doses 250 to 500 mg twice daily with the iron preparation enhances iron absorption, on contrary supplements containing calcium, zinc, manganese, or copper decrease iron absorption. Antacids, H<sub>2</sub> blockers, and proton pump inhibitors decrease iron absorption and should not be used within 1 to 2 hours of iron administration. As mentioned coffee, tea, milk, cereal, dietary fiber, and phosphate containing carbonated drinks also decrease iron absorption (55, 56).

Other forms of supplemental iron, such as heme iron polypeptides, carbonyl iron, iron amino-acid chelates, and polysaccharide-iron complexes have fewer gastrointestinal side effects than ferrous or ferric salts. Long term absence of digestion problems gives people an opportunity to continue treatment longer than few months. According to several foreign guidelines on iron deficiency supplementation, iron in prescription medications is not being labeled as better to the one in Food Supplements. Objectively, our organism is unaware of the difference, whether the needed nutrition is packed as prescription medication or labelled as Food Supplements. The difference between iron as a nutrition consumed in form of ordinary food from the one integrated as a form of supplementation is, that the latter is more concentrated. However, our organism is physiologically incapable of recognizing iron gained for prescription medicine as being any different, from the one pack as food supplement. Furthermore, Food Supplements based on iron isolated from herbs and plants are less likely to cause digestion problems. Iron from food supplements in usual practice also contains a fair amount of vitamin C and B-complex that should help with body's absorption, with no need for additional combination with other supplements (31, 49, 50, 57, 58).

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# THE ROLE OF COMMUNITY PHARMACIST IN THE SELF-TREATMENT WITH SCHUESSLER SALTS

MSc. Mojca Slodej Kušlan, mag. farm.

## INTRODUCTION AND OVERVIEW OF THE SITUATION LINKED TO COMPLEMENTARY TREATMENT METHODS

Complementary (alternative) portfolio in Slovene pharmacies consists of homeopathic monoremedies, homeopathic complexes, Schuessler salts (that are currently in the process of registration and that are perceived as a special branch of homeopathy) as well as of Bach flower system. This kind of portfolio has no tradition in Slovenia which is peculiar especially in the light of the fact that this kind of therapy is perceived as »European traditional medicine« all over Europe. Complementary portfolio has been step by step brought onto the market in Slovenia as of last 10 years.

Legislation in Slovenia is not particularly in favour of homeopathy; homeopathic drugs are classified as OTC drugs however they are not allowed to bear indication therefore advertising of homeopathic medicines is not possible. Medicinal doctors with a valid licence are not allowed to practise homeopathy. Only Pharmacists with additional knowledge in homeopathy can dispense homeopathic drugs and advise on homeopathy; certificate that proves additional knowledge is given based on completion of education on homeopathy organised via Pharmaceutical Chamber and comprises 120 educational hours. Pharmacy that offers homeopathy needs to be verified to be able to dispense this kind of products,

ECHAMP (European Coalition on Homeopathic and Anthroposophic Medicinal Products) annual report 2019 reveals several interesting facts:

A European Commission report informs that three out of four Europeans know about homeopathy, and out of these, 29% use it for their health care – that was 100 million European citizens who used homeopathic medicinal products in 1998 in EU. 78% of Germans who use homeopathy do so because it has barely any side effects, 63% say it is well-tolerated and 58% that is well suited to children. 91% of Austrian users believe that homeopathic medicines have fewer side effects. 53% of Italian users do so because it is natural and non-toxic; Italians choose homeopathic medicines for their lack of side effects and contraindications (18%), because they are non-toxic (15%) or because they are

perceived to be particularly suitable for less severe disorders such as anxiety, stress, cystitis and gastritis (12%).

Homeopathy therefore according to ECHAMP report represents a significant opportunity for pharmacies:

Over 60% of Germans think it is important or very important to be given free choice of medicines in the pharmacy, including conventional medicine, natural medicine or homeopathy. An Australian study confirms that consumer expectations on the pharmacist with regards to complementary medicines include expectation on selection of the right product for the right person, they expect product knowledge and a wide range of good quality stock. Three arguments therefore confirm the opportunity for pharmacies to engage in homeopathics:

- this market thrives in the context of a trend towards self-medication and demand for medicines with a high safety profile;
- it offers a field of specialist expertise allowing individual pharmacies to create their own distinct profile;
- HAMPs foster customer loyalty through high level customer contact and individual advice.

ECHAMP report also points on stable or in many cases increased demand for education in complementary therapies in pharmacies, which comprises information about complementary products as well as a knees on related education and trainings. As the general environment for advertising about these products is very restricted, companies are aware of the need to provide the right support for pharmacists so that they can provide quality information to the end users.

## ABOUT SCHUESSLER SALTS

Dr. Schuessler and his theory



Dr. Schuessler (1821 – 1898) was a German MD and homeopath.

His theory, later known as Schuesler theory postulates, that the human body contains 12 essential mineral (cellular) salts. The proper balance of these salts must be maintained to ensure normal cellular function and thus health. Any imbalance leads to the collapse of health (disease). The balance of vital minerals is established by replacing the missing mineral in a very dilute form, which can quickly enter into the bloodstream and thus into the cells. This vital minerals in a diluted form are nowadays known as Schuessler salts.

## What are Schuessler Salts

Schuessler salts are homeopathically diluted mineral salts that are endogenous to the body and allow cells to function normally. Minerals are found in the body as building agents that operate on an extracellular (macro) level (intake as food supplements) as well as functional agents that operate on an intracellular (micro) level (intake as Schuessler salts).

Dilution is important so that mineral salts can enter into the cell where such a functional agent is involved in metabolic processes. There exist a fixed concentration gradient between the intracellular and extracellular value of minerals, therefore the intracellular value of minerals also affects their extracellular value. Lack of cellular mineral salts is common in the time we live due to stress, poor food quality, excessive sport activity ...Lack of intracellular minerals is reflected on the face (facial diagnostics) even before physical and mental problems occur. Schuessler salts replace deficiency of intracellular mineral depots and act as functional agents.

Schuessler salts system comprises Basic Schuessler salts (No 1- No 12) as well as complementary Schuessler Salts (No 13 – 27 (33). EU numbers that are attributed to Schuessler salts differ to the ones in UK or USA; in EU, the Schuessler salt Calcium sulfuricum is named No. 12, whereas in America and the UK Calcium sulfuricum is named No. 3. Therefore all cell salts following No 3 are attributed EU number +1 in UK and USA (e.g. Ferrum phosphoricum has No. 3 in EU and No. 4 in UK and USA).

## Difference between Schuessler salts and Homeopathy

Schuessler salts ARE NOT homeopathic remedies in a classical meaning of homeopathy. They ARE homeopathic remedies in the way they are manufactured, however they ARE NOT homeopathics according to the mechanism of action. According to legislation they are classified as homeopathic remedies and are therefore approved by Drug Agencies (proof for safety, quality and efficacy). Mode of action of Schuessler salts does not follow the principle of similarity (the principle of Similia similibus curentur; similar is treated with similar) that applies to homeopathy. It follows the basis of physiological and chemical processes in the human body. Diagnosis in homeopathy is based the totality of symptoms (physical, emotional, mental) and repertorisation. In case of Schuessler salts we follow the facial diagnostics that determines the signs of mineral salt deficiency in the body. Active substance in homeopathic remedies derive from plants, animals and minerals and include exogeneous substances in several potencies. More than 2000 active ingredients are known so far in homeopathy. Schuessler salts on the other side are made of endogenous minerals and they only appear in one low potency; they are comprised of 12 basic active ingredients.

## Art of administration of Schuessler salts

Schuessler salts can be administered per os or externally.



The tablets can be dissolved in the mouth, preferably under the tongue (rapid absorption through the oral mucosa) or one can sip tablets in a jug (glass) of water and let them disintegrate; only liquid is taken, decomposed lactose is left over in the glass. Externally they can be used as baths (10 - 15 minutes; T under 37; approx. 20 tablets of selected salt are dissolved in the water) or compresses (in acute cases such as bites, injury, burns tablets are dissolved in few drops of water to form a paste and then applied to the skin). Schuessler salts also appear as creams and gels; this kind of application is used when there is a preference for the direct application to the problem area or when per os application is not possible.

Overview of 12 Basic Schuessler Salts along with a main therapeutic area

There are 12 BASIC tissue salts that can be used as single agents or in combinations, to treat a very wide variety of acute and chronic health problems.

- No 1: Calcium fluoratum D12
  - Salt for Connective tissue, the joints and skin.
  - Tissue elasticity restorer.
- No 2: Calcium phosphoricum D6
  - The salt of the bones and teeth.
  - Growth support, osteoporosis.
- No 3: Ferrum phosphoricum D12
  - Salt of Immune System
  - Anti-inflammatory, First Aid agent.
- No 4: Kalium chloratum D6
  - The salt of the mucous membranes.
  - Detoxifying agent
- No 5: Kalium phosphoricum D6
  - The salt of the nerves and psyche.
  - Energy restorer.
- No 6: Kalium sulfuricum D6
  - The salt of purification.
  - Metabolism, pancreas conditioner.
- No 7: Magnesium phosphoricum D6
  - The salt of the muscles and nerves.
  - Pain and cramp killer.
- No 8: Natrium chloratum D6
  - The salt of the fluid balance.
  - Water distributor, allergies, rhinitis.
- No 9: Natrium phosphoricum D6
  - The salt of Acid-base balance
  - Acidity neutraliser.
- No 10: Natrium sulfuricum D6
  - The salt of inner purification.
  - Liver cleanser.
- No 11: Silicea D12
  - The salt of the hair, skin and connective tissue.

- Skin and connective tissue conditioner.
- No 12: Calcium sulfuric D6
  - Purulent agent, excretion.

### Facial diagnostics revealing the need for Schuessler Salts

Lack of intracellular minerals is reflected on the face (facial diagnostics) even before physical and mental problems occur. The face clearly shows the condition and inner state of a human, because facial skin poses excellent blood perfusion and because it is exposed to all external factors. While performing facial diagnostics we observe: face colour and glow, structure and losses, signs on ears, tongue, teeth, eyes and nails, colour of the secretions...

Some facial signs indicating deficiency of selected Schuessler salt can be seen on the photos below:



Picture 1 Deeply sunken eyes into their sockets - No 11



Picture 2 Brownish colouring – No 1



Picture 3 Waxy like ear



Picture 4 Large pores - No 8



Picture 5 Milky bluish reddish Colouring - No 4



Picture 6 Impure skin, blackheads, acne No - 9



Picture 7 Olive greenish discolouring around eyes, mouth, chin or entire face - No 10



Picture 8 Thick, compacted wrinkles - No 12

Food craving as diagnostic help in searching for an appropriate Schuessler Salt  
Experience in biochemistry according to Dr. Schuessler shows that there is always a need for a certain salt behind these needs; if the need for salt is met, unhealthy habits disappear: need for smoked or ketch up (children) - No. 2; need for nuts or chocolate with nuts - No. 5; need for dark chocolate - No. 7; need for sweets - No 9; need for salt - No. 8; need for milk - No. 2

Example of a need for and area of use for Schuessler salt No 7 Magnesium phosphoricum  
Schuessler salt No 7 is known as a pain and cramp killer. This is a main tissue salt to be considered for cramps and spasms in the muscles or nerves. Nerve pains are typically sharp and may shoot along the nerve (like migraine). Relaxation effect makes this salt “a sleeping agent”. This tissue salt acts more quickly when taken dissolved in some hot water and taken in small sips as hot as possible. This kind of administration is known as “Hot 7”



Picture 9 Facial signs indicating the need for Nr. 7

Marked flushing, vibrant red spots, frantic blush, red flush after a meal or drinking alcohol, red cheeks, craving for dark chocolate

*Helpful questions indicating possible need for No 7:*

Menstrual cramps? Migraine? Sleeping problems? Do you like chocolate? Especially dark chocolate? Do you blush quickly?

## CONCLUSION AND TAKE AWAY MESSAGE

Decreased intracellular level of minerals as seen on the face of the customer and as proven with some additional questions can be easily diagnosed by the pharmacist.

Holistic Community Pharmacy approach in self-medication and self-treatment with Schuessler salts is a valuable additional option for maintaining and ensuring health of

the population. Treatment with Schuessler salts is a safe, effective and simple natural method of health care prevention with a long tradition (140 years) in the EU region. Schuessler Salts portfolio available in the Pharmacy offers an added value for the Pharmacy in the light of expertise. A personal holistic approach in the treatment with Schuessler salts builds a long lasting relationship with a customer and gains his / her loyalty.

# HEALTH PROFESSIONALS BETWEEN THE CARE FOR OTHERS AND THE CARE FOR SELF

Katja Hleb, MSc. Psych., Prof. Kin.

## ABSTRACT

Health is a personal value number one for vast majority of people and among the first three personal values for nearly every human on the planet. Therefore, we as a humanity place much emphasis on preserving personal and communal health. The perspective on where the health comes from is changing. The responsibility for its preservation gradually switches from others, like medical professionals, to ourselves and people are becoming more willing to respond actively to the issues of health.

With personal development of an adult, and the humanity as a whole, the terms like self-awareness are becoming coined in our consciousness. For health professionals this means the shift of focus from “one up” status that is also the carrier of all the decisions and related consequences, towards the status of “equals partners”, where the health professional needs to cultivate cutting edge expertise and well exercised competences and the patient needs to ask well informed questions and needs to be willing to actively participate in both; health preservation and the carrying of the responsibility in case of a lesser outcome.

**Key words:** values, anxiety, awareness, orders of consciousness, the development of adult mind

## INTRODUCTION

In this article we will discuss some psychological properties in the relationship between community pharmacist and a visitor. We will describe some common hallmarks that form a daily operational psychological makeup and will further elaborate on how these hallmarks differ at different stages of consciousness development, in community pharmacist. We will tackle upon the human values, fear and anxiety management, ego states, the properties of leadership and supervision and the model of adult development of the mind (Kegan, 2020).

## HUMAN VALUES

Health is one of the top three values in an average human being. Values are a very stable psychological category. They are formed in our closest and earliest environments like home, school, the country of origin and are not a subject of easy change later in life. Individuals and collectives regard values as a very sensitive issue and are willing to risk or invest much for their preservation. Traditionally, health is placed high in most values systems across cultures, collective and individual alike. Lack of health is a complementary value of a similar potency, that most of us want to abide. When a personal value is affirmed, the connection between the two communicators has much bigger probability to succeed. The opposite is also true.

When a visitor steps into a contact with community pharmacist, he/she filters all the received information (visual, aural, kinaesthetic) through the value of health (gaining or preserving). We can contribute to successfully sharing the psychological space with our visitor through the active affirmations of this value. Verbally, we can emphasise, that we all value health or that their health is important to us. Audibly, we can repeat visitors words as to affirm, we have not only heard what the visitor has expressed, but also understood the meaning. Kinaesthetically, holding the upper arm or a hand would be an example, however not culturally acceptable or protocol allowed in most situations.

## FEAR, ANXIETY AND CHILDLIKE STATE

When an individual or a group of people is in the state of malady, this usually triggers fear and consequently a psychological defence mechanism of regression manifests. In such situations, people go into a vulnerable and often childlike state or leaning towards it. Such is very possibly a state of a visitor when meeting a community pharmacist.

A visitor consciously or subconsciously looks for a restored feeling of safety and comfort in an expert consulting community pharmacist. The community pharmacist's task, besides best possible expert advice for the health issue a visitor is experiencing, is the provision of anxiety management in a visitor and possibly bringing him/her back to calm. Visitor, that has regressed to a less than adult ego state due to fear triggered by ailment, is in need of a specific mental state from the side of a community pharmacist, one that comprises of soft, calm, slow and explaining.

When facing adversity, what is perceived as an expertise and care is not only associated with safety, but can also temporarily enhance the internal feeling of self worth in a visitor. The logic applied is something similar to the following; if someone with this level of knowledge attends to me, I must be a worthy person. The opposite is, unfortunately, also true. When a visitor in a regressed, fearful state is vis-a-vis with a mindless pharmacist, he/she might consciously or subconsciously translate the treatment received into perceived lack of self worth. While one act of advisory from one pharmacist can in no way be responsible for a perceived self worth of an individual (visitor), the little acts of calm kindness in such cases cannot and shall not be underestimated as a cumulative function of health preservation in population.

Kind attitude also helps the pharmacist him/herself. As a single act it seems countless, but when practiced diligently from visitor to visitor and day-by-day, it effects the nervous system and the self perception of the community pharmacist. As such, it affirms the positive self-image of a regularly caring, attentive community pharmacist.

## LEADERSHIP PRACTICE

Community pharmacist practices leadership through his/her daily contact with visitors. Perceived as an authority, a community pharmacist sets an example and guides/leads through his/her behaviour and advice.

Being very aware of our own humanness internally, we sometimes fail to observe that our surroundings might perceive us through much different lens than we usually see ourselves.

What may seem a little, daily, routine, professional deed to us, may shape the many years of life of a visitor, whom we have had the chance to have made an impact on. Such acts, even less their cumulative power, shall never be underestimated.

## SUPERVISION - A COMMON PRACTICE IN PSYCHOLOGY AND HOW TO APPLY IT IN COMMUNITY PHARMACY

In psychology, where the direct work with the patient can easily and regularly does trigger the internal dynamics in a psychotherapist, we apply a regular practice of supervision. Supervision represents a chain of caring for the caring, so that the practicing psychologist can be at all times aware of and secure in the fact that he/she is not alone in his/her expert pursuits. The system is designed in a way of regular peer to peer conversation, where another colleague, usually senior in years and status, will listen, exercise compassionate attitude, give a peer advice and also a peer critique. This way, knowledge building and agreed procedures are being preserved and regulated in real time and the practitioners can share a burden of professional responsibility, knowing they will be able to talk out all their dilemmas with senior colleagues in a psychologically safe environment.

As all the caring professions are very taxing on a caregiver, it probably is a wise idea for the practice of supervision to be applied in all such settings. Communal pharmacy as a place, built by caring top class experts, is a place that presumably does benefit from such practice in a long and short term.



## KEGAN'S MODEL OF ADULT DEVELOPMENT OF THE MIND AND ITS APPLICATION TO THE PROFESSION OF A COMMUNITY PHARMACIST

Kegan (1982) in his Cognitive Developmental Theory (CDT) demonstrated how the human mind develops over the course of all life, contrary to the prior belief, that this development ends with early adulthood around the age of 25 (Piaget, 1954; Kohlberg, 1969). In his theory, Kegan describes the five stages of the development of human mind, levels three to five being the stages of the development in adulthood. Most adults never surpass the third level in his model, 20% plus reach the fourth stage and up to 5% reach the fifth level of the development of mind.

In his latest model, Kegan (2020) elaborated the five levels as five layers raying in six different directions (1) compassion, empathy, (2) complexity awareness, (3) contextual awareness, (4) perspectival awareness, (5) self insight, (6) relational awareness. Figure 1 charts the model of five levels of the development of human mind, represented as five layers raying in six different directions. In this article, I will elaborate on possible meanings of all the proposed categories in the case of community pharmacy and community pharmacist.

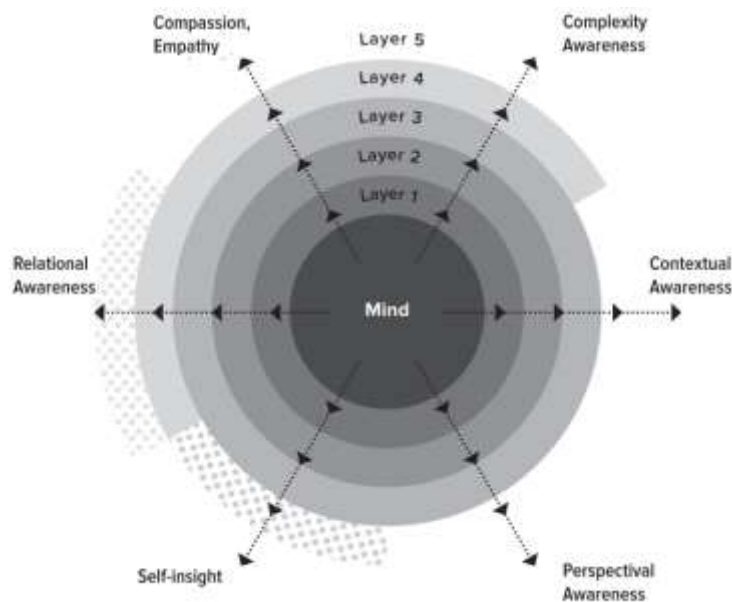


Figure 6: Model of human mind development, developing in six different directions (Kegan, 2020)

- (1) **compassion, empathy**; in theory we distinguish among the three sorts of empathy; the behavioural - “You cry, therefore I will bring the handkerchief”, the emotional - “I feel what you feel; as you are sad, I cry with you”, and the cognitive - “I understand how you feel”. The more the human mind is developed, the more empathy one feels, in quantity, in spectrum, in granulation, in depth and the more appropriate type one applies for the occasion. For example, in community pharmacy cognitive and behavioural empathies are very proper and emotional empathy is proper to some degree.
- (2) **complexity awareness**; describes the capability of the comprehension of the scope of the phenomenon. In case of a community pharmacist, at layer 3 the phenomenon would be internally comprehended as “I come to work and hand out prescriptive drugs in line with regulation.” At layer 4 the phenomenon would be internally

comprehended as “I manage my own business, I choose what I put on my shelves and how I conduct the relation with my visitor.” At layer 5 the phenomenon would be internally comprehended as “I previewed the developmental span of the field, have my own thinking about how it should be shaped and I act accordingly.”

- (3) **contextual awareness**; is the awareness of the surrounded factors framing the reality. It also shapes the relation towards meta issues like morals and ethics. At layer 3 the common context is a “home-work-home” context, the moral/ethical stand evolves around being a good citizen as one earns the living, pays the bills, goes to church etc. At layer 4 the context is framed by the regulators and the regulations, the moral/ethical stand evolves around the law. At layer 5 the context is the contribution to the overall level of how the pharmaceutical science (and art) is practiced. Ethical/moral stand evolves around serving as a health preserving agent of people and humanity and serving as an integrity guardian for the best practice of the profession.
- (4) **perspectival awareness**; is the awareness of the scope of personal attention. At layer 3 the perspective is short and narrow and constitutes of “my world, my tribe, my job” and aims to short term goals, like a month. At layer 4 the perspective is wider and longer; the scope of the attention is “my visitor, my career, the peer group” and time perspective can cover a couple of decades. At layer 5 the perspective is even wider and longer, the scope of attention is humanity, the concerned is the personal purpose, historical perspectives that can shape long projected futures are understood. We are aware of our capability to shape reality and operate through a strong force like agape (gr. love for all the life).
- (5) **self insight**; is the level of awareness about our inner world. At layer 3 we have a very basic insight, that sheds some light on our internal world, at layer 4 we have a complex and comprehensive self insight, possibly with the help of a coach, therapist, friend or a regular habit of self-reflection, but we still live most of our lives on the outside. At level 5 we are aware that the leverage to shape our outside world is inside of us.
- (6) **relational awareness**; describes the inherent quality of our relatedness. At layer 3 the relations are transactional, we give in order to get. At layer 4 the relationships are “adult”, professional, we both stick to who we are and strive for a common goal, being reciprocally industrious. At layer 5 the relationships between sovereign entities are synergic and strive to the a common good in broad spectrum of this word.

## CONCLUSION

The development of human mind is a continuous process throughout human life. It shapes our lives but also the lives of the people we interact with. Even though the development of mind can not be accelerated, educating ourselves in basic psychological principles and exposing ourselves to a regular practice of inner development, contributes to our capability of reaching advanced stages of maturity in more eloquent manner.

Highly responsible professions like community pharmacist encounter all sorts of psychological phenomena in themselves and in the visitor, on a daily basis. In order to serve both interests to the highest degree, deliberate psychological development of a community pharmacist may be considered as a valid regular routine, easing daily pressures, but even more giving community pharmacist the mandate to grow into the core purpose of this

fascinating profession. Surpassing the tests of ill appetites in time, towards the ancient, everlasting wisdom of healing.

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