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Abstract This study aimed to investigate Romanian physicians' awareness, recommendation practices, and opinions regarding using Foods for Special Medical Purposes (FSMPs) products. A total of ten physicians were interviewed using a structured questionnaire, and their responses were analysed using thematic content analysis. The study found that physicians were aware of FSMPs and recommended them to their patients based on nutritional deficits, weight loss, or deglutition impairments. In addition, disease stage, treatment scheme, taste, affordability, and availability were identified as factors influencing the recommendation and use of FSMPs. While physicians generally did not consult clinical trials, clinical experience was deemed essential for recommending FSMPs to patients. Patients' feedback regarding the usage and sourcing of FSMPs was generally positive, with some expressing concerns about the availability of different flavours and the costs of purchasing the products. The study concludes that physicians play a vital role in recommending FSMPs to patients and ensuring they have the necessary nutritional support during treatment. However, more patient education materials and collaboration with nutritionists may be required to improve patient outcomes and reduce patient financial burden.

Keywords: food for special medical purposes, FSMP, qualitative research, nutritional needs for oncology patients.

I. INTRODUCTION

Food for special medical purposes (FSMPs) are foods designed for people with particular medical disorders and nutritional needs. FSMPs address the dietary requirements of individuals who cannot eat a typical diet because of ailments like malabsorption, metabolic abnormalities, and food allergies. They are often only available with a prescription and are meant to be used under medical supervision.

FSMPs may be used as the sole source of nutrition or as a supplement to a regular diet, depending on the individual's medical needs. These products can

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come in different forms, such as powders, liquids, or semi-solids and can be used in various settings, including hospitals, long-term care facilities, and home settings.

Inborn errors of metabolism, severe food allergies, and gastrointestinal illnesses like Crohn's disease or ulcerative colitis are a few examples of medical conditions that might call for the usage of FSMPs.

To ensure their effectiveness and safety, FSMPs are governed by regulations and are required to adhere to specific standards. The FSMP industry is regulated by various national and international bodies, such as the European Food Safety Authority (EFSA) and the U.S. Food and Drug Administration (FDA), which set standards for the safety, quality, and efficacy of FSMP products [8, 16, 28, 31].

FSMPs are defined according to Article 2(2)(g) of Regulation 609/2013[10]as follows:

"food specially processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone".

Particularly in Romania, Regulation 128/2018 updated the Regulation 609/2013 mentioned above (named within most of the documents as "FSG Regulation"), and the food notification procedure for special medical purposes (FSMP) was set by Order of the Ministry of Health nr.820/2019[19]. Furthermore, specific standards which apply to FSMP are also outlined within Codex Alimentarius by World Health Organisation [8, 31].

The Commission wanted to clarify the distinctions between FSMP and food supplement products and other ideas relevant to the legislative framework that applies to this category of products through the classification of FSMP, which was subject to specific notice [8].

FSMPs are divided into three groups [8]: (a) nutritionally complete foods with a standard nutrient formulation, (b) nutritionally complete foods with a nutrient-adapted formulation unique to a disease, disorder, or medical condition, and (c) nutritionally incomplete foods with either a standard formulation or a nutrient-adapted formulation unique to a disease, disorder, or medical condition. The first two categories can serve as a patient's only source of nutrition, whereas the third can only increase intake to supplement other sources of nutrients. The FSG Regulation and Codex Alimentarius both clearly define the composition of products, which are defined as FSMP that must contain specific nutrients from the List (vitamins, minerals, amino acids, carnitine-*taurine*, nucleotides, and *coline-inositol*) or meet specific requirements (meet food standards, provide scientific support regarding the contribution of ingredients to satisfying nutritional needs and to comply with conditions related to pesticides) [10, 16, 31].

Some writers believe that FSMPs intended for oncology patients may not be adequate for some critical elements such as Zn, Cu, Se, Fe, or Mn, despite the regulatory standards regarding the composition of FSMP implying that the formulations are based on commonly accepted scientific facts [11]. In addition, similar studies indicated sample determination for Se, Zn, K, Mg, and vitamin C differed from (E.U.) 2016/128 requirements for enteral tube feed formulae, raising questions about the bioavailability of synthetic vitamins and minerals in comparison to those from natural sources [23].

Products classified as FSMP should be usable by humans and effectively supply nutritional support to the people they are designed for. Other authors put up a different classification that is more workable and acceptable. This classification explains some product categories that fall under the FSMP range and is being developed by an interdisciplinary group of German industry [10, 29].

All regulatory bodies stress the significance of accurately labelling FSMP products, and there are now clear guidelines and explanations. The labelling should provide information regarding energy value, the content of proteins, carbohydrates and fat (per 100 g or ml), the content of vitamins and minerals (per 100 g or ml), osmolarity and/or acid-base balance and the origin and nature of proteins (animal or plants). The manufacturers should disclose the nature of the product, its purpose, and specific usage instructions in sufficient detail. The material shouldn't mislead people or include any characteristics or qualities that imply these items may cure or treat certain illnesses. Additionally, references to usage guidelines should be made, such as use only under medical supervision, information about how to store or retain a container after it has been opened, not suited for parenteral use, etc. It is important to note that

while general public advertising should be outlawed, providing educational materials and appropriate resources to healthcare professionals is paramount [8, 9, 31].

Stomatitis and oral mucositis are common in oncology patients receiving chemotherapy or radiation therapy for various types of cancer. These conditions significantly negatively impact the duration, complications, and cost of the entire treatment and the toll they take on the patients' and families' quality of life. Several papers and studies support the value of nutrition and its impact on lowering patient stress and oncology treatment expenses.

Medical costs for patients receiving radiotherapy and developing mucositis or pharyngitis during the treatment are much greater than for those without such conditions, according to a study on patients with head and neck cancer (HNC) and non-small cell lung cancer (\$39,313 vs \$20,798) [21]. Another study on HNC patients receiving radiotherapy found that 91 percent of patients experienced oral mucositis, and 66 percent of those cases were severe (>Grade 3). Depending on the severity, oral mucositis was associated with increased expenses of \$1700–\$6000[6]. In addition, the side effects of cancer treatment, such as nausea, vomiting, oral mucositis, and exhaustion, create numerous logistical difficulties and significantly strain the patient and the healthcare system, especially when cancer is treated as a chronic condition [3]. According to a different study, oral or/and G.I. mucositis occurred in 51% of chemotherapy-treated cancer patients with solid tumours or lymphoma. If a patient has oral mucositis or both G.I. and oral mucositis, the projected cost of chemotherapy each cycle is 1.6 times higher and 2.3 times higher, respectively. For patients receiving a hematopoietic cell transplant, an additional point in the peak mucositis score resulted in an additional \$25,000 in hospital expenses [17]. In treating several cancers, surgery, chemotherapy (including immunotherapy or target therapy), and radiotherapy may be employed, and the expenditures involved with all these efforts are substantial [13].

Early nutrition support and prevention of oral mucositis or other radiochemotherapy-related side effects for cancer patients determine benefits on all levels (patient, physician, and cost management) by reducing weight loss, fewer radio/chemotherapy breaks, fewer delays in completing radio/chemo cycles, fewer unplanned hospitalisations or shorter lengths of stay in hospitals, and ultimately a higher rate of treatment completion [7, 17, 22, 24].

National healthcare systems reimburse FSMP products in several countries. The E.U. allows for regional or provincial variations in granting FSMP reimbursement. France, Germany, Italy, Spain, and the U.K. are some nations that reimburse FSMPs. Also,

France and Brazil are the countries that have a formal HTA process for medical nutrition [25]. However, the FSMP type and content may affect the reimbursement criteria and procedure. It's critical to remember that depending on the country and the patient's medical condition, different restrictions may apply for FSMP product reimbursement ([2, 25, 27]. Chinese researchers and authorities place a high value on FSMP and HTA evaluation for products under this category. Several papers have been written about creating rules, clinical trial prerequisites, and HTA evaluation standards [15, 20, 26].

We examined numerous sources to estimate the size of the worldwide FSMP market, and the results are consistent. The market is estimated to be worth \$11.2 billion in 2019 or \$13.48 billion in 2021, depending on the source, and it might reach \$19.67 billion in 2028 or \$19.41 billion in 2030. For the timeframes mentioned above, a CAGR of 5.6 percent to 6.5 percent is anticipated for the growth rate. The key drivers of the growth mentioned by the sourced consulted are the increased awareness of the benefits of this category of products, the increased prevalence of chronic diseases, the increased demand of older adults, the proliferation of new private label manufacturers and the expansion of new distribution channels. More than 65 percent of the market share in the worldwide FSMP market is held by the top 10 companies. Nestle, Danone (Nutricia), Abbott, Bayer, Mead-Johnson, Ajinomoto, Fresenius-Kabi, Lenus Pharma, GFI-Gruppo Farmaimpresa, Galen Limited, BOSSD, and Leskon & EnterNutr are among the companies mentioned. In addition, the 2020 acquisition by Danone of the Murray Goulburn Dairy company in China has indicated a market concentration [5, 18, 30].

An important issue is related to the information regarding the FSMP category. The regulation stipulates that using FSMP needs medical supervision, which is part of this category's definition. Healthcare professionals give medical supervision, and they can help patients with FSMPs. By healthcare professionals (HCPs), the regulatory body means "persons having qualifications in medicine, nutrition, pharmacy or for other healthcare professionals responsible for maternal care and childcare" according to FSG Regulation, art 9. Without the limits typically imposed on communication to the general public, it is crucial that HCPs may receive complete information regarding the product composition, the clinical justification and supporting data, the appropriate usage, preparation, and the intended target group [2, 10]. However, the legal responsibilities of pharmacies and pharmacists for dispensing FSMPs must be investigated within the current legal framework for the entire pharmacy practice, given that the majority of products in this category are obtained from pharmacies, and there are no formal

prescription requirements capable of tracing the recommendation process as a whole [1].

Public outreach efforts should adhere to the aforementioned regulations. Therefore, they are limited to labelling, educational content, and possibly using digital techniques like SEO or SEM. Nevertheless, the digitalisation of healthcare systems is a fact and will significantly impact all future issues. One possible connection between healthcare digitalisation and FSMPs is that digital tools can help monitor, assess, and manage food safety hazards and offer consumers and health professionals information and transparency. Another possible connection is that digital technologies can assist in customising FSMPs based on an individual's needs, preferences, and circumstances [12].

II. MATERIAL AND METHODS

The research technique examined was in-depth interviews with medical professionals with specialities in the sectors that suggest patients with demands for such products - cancer, ENT, radiation, or surgery - to evaluate the factors influencing the recommendation and use of FSMPs. The in-depth interview method allows the researcher to approach the subject with common questions. It enables us to decide which issues, during a quantitative research phase, the participants should be questioned about. Using this strategy, we can get a wealth of descriptive information on people's attitudes, behaviours, and perceptions [14].

The following benefits of in-depth interview methods [13] are beneficial for this study:

- Since respondents are dispersed, bringing them all together for a focus group study would be difficult and expensive.
- While a respondent has approximately 10 minutes in a focus group setting, and the other participants may influence his perspective, in an in-depth interview, only 30 to 45 minutes are set aside for the conversation with one respondent.
- The debate may disclose previously assumed habits since the participants fully engage with the topic and tell the whole tale.
- Since using FSMPs requires specialised expertise, the study process necessitates thorough explanations of some subjects.
- Later on, the research agenda incorporates respondents' viewpoints.

The operators were given instructions on conducting themselves before and during the interview. The logic of the research was emphasised, as well as simple instructions such as the need for a preparatory discussion before the interview, how to conduct the interview itself and to follow the guide as well as how notes should be made and finally, the extraction of answers and the final document for each subject.

The interview's outline contained several subjects for conversation with the issues, including:

- Is the subject recommending any FSMPs? Do they know the category of FSMP? How did they become aware of this category?
- Which factors are influencing the subject's recommendation? Clinical proof, the stage of the disease, correlation with the underlying treatment, relationships with other specialities?
- Which particular names or brands are popular or used? What features should the items that the subject recommends or uses have?
- Does the subject know what laws apply to FSMPs? Did the topic have any thoughts on how to make clarity more precise?
- Price: are FSMPs expensive or affordable? Who covers the cost of the products?
- Which are the suppliers and the channels to procure FSMPs products?
- Patients' feedback about the use of FSMPs
- Subject' feedback, in their medical capacity
- Few data about the subject of the interview to analyse the answers, such as speciality, type of medical unit in which they work, city and age, experience or associations with academic work.

The operators were equipped additionally with the following:

- Script of introductory talk with the subject about the research, a short description of the research aims and a little information about FSMPs.
- A list of the most popular brands/products available to help the subjects put the questions in context.

Three operators conducted in-depth interviews, and answers from 10 interviews were collected. The interviews were done from October 2022 to January 2023.

We expected doctors to evaluate several considerations before recommending Food for Special Medical Purposes (FSMPs), including:

- The patient's medical condition: FSMPs are designed for those with particular medical conditions with unique dietary requirements. Doctors will assess the patient's condition to decide whether an FSMP is necessary.
- Nutrient requirements: FSMPs are created to satisfy the patient's unique nutrient requirements. Doctors will consider the patient's nutritional demands and determine whether an FSMP can fulfil those needs.
- Digestive capabilities: FSMPs are designed for those whose medical circumstances prevent them from following a typical diet. Doctors will assess the patient's digestibility and decide whether an FSMP is necessary.
- Allergies or intolerances: Patients with severe food allergies or intolerances may take FSMPs. If an FSMP is necessary, doctors will assess the patient's allergies or food intolerances.
- Medical history: The doctor's recommendation of an FSMP may also consider the patient's medical background. For instance, to guarantee enough nutrition, a patient with a history of malabsorption may need an FSMP.
- Accessibility: Doctors will also consider the patient's ability to access the FSMP. This encompasses elements like price, accessibility, and usability.

III. RESULTS AND DISCUSSIONS

Ten in-depth interviews were conducted to gather information, and the distribution of specialities and places of residency is shown in the accompanying table:

Table 1: Demographics for the respondents

| Residence | | Specialities | |
|-------------|---|--------------|---|
| Brasov | 2 | ENT's | 1 |
| Cluj Napoca | 2 | Oncology | 4 |
| Constanța | 1 | Pneumology | 1 |
| București | 1 | Radiotherapy | 3 |
| Oradea | 1 | Surgeron | 1 |
| Sibiu | 1 | | |
| Târgu Mures | 2 | | |

Key findings were grouped following this article's interview guidelines and narrative logic.

a) Awareness about the FSMPs category of products

All of the subjects interviewed were aware of FSMPs products.

When asked where they first learned about FSMPs, most respondents (7/10) reported they got their information from the producers' medical personnel, and only one said they found out on their own through an

internet search. Two respondents stated that they knew these items from their training period for their internship or residency more than ten years prior. The other doctors - their colleagues, who learned from medical reps, were an additional source of information. The statement made by one respondent that information about FSMPs is provided at the medical committee's weekly meetings, where medical representatives attend and present various goods, was also noteworthy. Other respondents addressed the distribution of samples to

patients. The Fresibin, Nutridrink, and Nutricia lines were cited in response to brands.

When we inquired about FSMP information sources, the responses were consistent. They all listed the same kind of resources: medical representatives, inserts and pamphlets ordered by the manufacturers, documents found online through searches, and various manufacturing company presentations at medical congresses and events.

b) How are these products recommended?

The conditions surrounding the recommendation of FSMPs were crucial to our study. Respondents mentioned patients with specific illnesses (pancreatic cancer, gastric cancer, oesophageal cancer, bronchopulmonary cancer, and any cancer of ENT kind) are candidates of choice to benefit from the FSMPs use. Due to the prolonged length of combo treatment, nutritional support with FSMPs is especially necessary for cancer of the ENT type (chemotherapy and radiotherapy). According to one respondent's experience, patients who utilised FSMPs during their treatment likely improved the treatment and had greater success. Several responders mentioned nutritional deficits, weight loss, or deglutition impairments (dysphagia or xerostomia). According to that respondent, one responder further links the usage of FSMPs with the clinic's nutritionist, who suggests such products be used. All respondents mentioned they recommended FSMPs products to their patients. Patients were encouraged to use FSMPs after being discharged from the hospital for those who require such indication.

c) Which factors influence the recommendation?

Usually, the doctor makes the recommendation, and the availability of products in the pharmacies in the neighbourhood of the hospital or patient's residence is considered.

Another respondent was more specific, saying that in ENT cancers, the standard is to recommend FSMPs starting with 2nd week of treatment, which takes six weeks and the patient is monitored every week concerning weight and alimentation.

In addition, it was reported that cancer patients and those with Chronic obstructive pulmonary disease (COPD) had difficulty with deglutition or nutrition and appeared cachectic. Therefore, these products are also advised for their use.

Most respondents mentioned that patients with cancers in ENT, oesophagus, bronchopulmonary or patients with widespread metastasis and palliative needs require FSMPs to keep their nutritional status, weight and general condition satisfactory.

d) Are clinical trials available and influence the recommendations?

Most respondents mentioned they did not consult clinical trials, some justifying due to lack of time. However, some respondents emphasise that clinical experience is essential for recommending FSMP products to patients. At the same time, one respondent considers that there is no significant difference between various brands within this category of products. It is worth mentioning that one respondent considers that clinical trials are available and results are good ones and recommend using such products in line with the stage of the disease. However, the same doctor recommends keeping the patient without medicinal products and with ordinary alimentation as long as possible.

e) Does the disease stage influence the choice of the FSMPs?

Respondents generally indicated weight loss and body mass index (BMI) as principal triggers for recommending FSMP to patients under treatment. The primary need is to have the patient well balanced from the nutritional point of view to support chemo or radiotherapy treatment for the whole duration. FSMP products are helping patients to achieve this objective. The appearance of problems with deglutition or food absorption also triggered the recommendation of using these products, as well as certain medical conditions (such as gastrectomy, oesophagectomy, acute pancreatitis or complete dysphagia for solid food).

A subject stressed that, when making a suggestion, the affordability must be addressed alongside medical reasons.

f) Is the recommendation correlated with the treatment scheme?

FSMPs are recommended for cancers like colon cancer or pancreatic cancer with the condition that makes ordinary alimentation challenging to achieve, according to one respondent or the recommendation being linked with BMI or weight loss.

Another respondent considers that the administration has nothing to do with the treatment scheme, but with the comfort or the patient's needs, so the FSMPs might be recommendable to those in need.

The linkage with the treatment is that doctors must ensure that the patient can follow the treatment scheme. Particularly in radiotherapy, postponing or delaying treatment is not an option. Thus FSMPs products may help the patient to cope with the side effects of chemo or radiotherapy and enable him to keep up with and complete the whole treatment scheme successfully.

g) Which products or brands are used or recommended?

The respondents spontaneously mentioned four brands, as per the following table:

Table II: FSMP brands mentioned by respondents (count of mentions)

| Brand | Mentions, out of total |
|------------|------------------------|
| MediDrink | 1/10 |
| Nutridrink | 3/10 |
| Fresubin | 9/10 |
| Nutricia | 1/10 |

In addition to brand names, several respondents cited other requirements for items to be utilised, including hypercaloric or normocaloric content, high protein content, and various tastes and flavours.

h) What features and characteristics of products make them useful?

The taste and flavour are the most significant and commonly cited characteristics. According to the feedback received by the physicians in our panel, some patients claimed that certain products were overly sweet or had a high level of acidity. In contrast, others disapproved of the products that tasted like bananas. Conversely, patients more readily accepted FSMPs when they tasted strawberries and chocolate.

One respondent gave a more detailed description, emphasising the demand for lactose-free, gluten-free products, high in vitamins, minerals, and proteins and hypercaloric.

i) Is the pertinent legal framework known? Are there any necessary changes that need to be made?

With one exception, our respondents were unaware if there is in place specific legislation governing FSMPs and how this product category differs from food supplements. One participant had in-depth knowledge of E.U. regulations, informational requirements, informational requirements for the public and

specialists, classification, quality standards, labelling, indication, and precautions. No change to the current legislation was mentioned as necessary, identified or proposed by participants in this research.

j) Price and affordability

Participants paid careful attention to the concerns regarding the pricing and accessibility of FSMPs, which were identified as an important topic affecting the use and availability of FSMPs for in-need patients.

Three respondents indicated their awareness of prices; one accurately identified the average bottle price as 15 RON, but the other two knew a price range of 30–50 RON. One even brought up the substantial distinction between Nutridrink, an example of a more reasonably priced product with 30 RON/bottle, and Fresubin, an example of an expensive product with 50 RON/bottle. According to respondents' calculations, a patient would require products costing between 30 and 50 RON for every bottle (4-5,000 RON or 800- 1,000 Euro), which is out of reach for many patients, given the overall cost of cancer therapy.

We gathered some pricing for products in this category from online pharmacies or wholesalers and their spot prices to explain the mathematics of the price problem. The following table displays the findings.

Table III: Price information about brands mentioned by respondents and sources of information

| Product | List price per pack | Source of information | bottles per pack | price per bottle | price per 7 weeks treatment (2 bottles/day) |
|---|---------------------|---|------------------|------------------|---|
| Fresubin Protein Energy, 4x200ml | 62.88 RON | https://alimentespeciale.ro/fresubin-protein-energy-drink-fructe-tropicale-x-200ml-fresenuis-kabi/103593.htm | 4 | 15.72 RON | 1,540.53 RON |
| Bautura cu aroma de vanilie Fresubin 2kcal, 4x200ml - hypercaloric | 80.02 RON | https://alimentespeciale.ro/fresubin-2kcal-drink-x-200ml-vanilie-fresenius-kabi/100992.htm | 4 | 20.01 RON | 1,960.49 RON |
| Fresubin Pro Drink Alune de padure 4x200ml- hypercaloric, hyper-proteic | 120.33 RON | https://alimentespeciale.ro/fresubin-pro-drink-alune-de-padure-4x200ml-fresenius-kabi/161630.htm | 4 | 30.08 RON | 2,948.09 RON |

| | | | | | |
|---|-----------|---|---|-----------|--------------|
| Fresubin, 4x200 ml, Fresenius Kabi Germania | 57.50 RON | https://comenzi.farmaciatei.ro/vitamine-si-suplimente/digestie/nutritie-speciala/bautura-energizanta-cu-proteine-aroma-de-vanilie-fresubin-4x200-ml-fresenius-kabi-germania-p323667 | 4 | 14.38 RON | 1,408.75 RON |
| MediDrink plus vanilie x200ml | 17.00 RON | https://www.farmaciienapofarm.ro/nutritie-speciala/medidrink-plus-vanilie-x200ml-39202.html | 1 | 17.00 RON | 1,666.00 RON |
| Nutridrink banane x 200ml Nutricia | 14.62 RON | https://alimentespeciale.ro/nutridrink-banane-x-200ml-nutricia/103021.htm | 1 | 14.62 RON | 1,432.76 RON |

Sources for prices have been accessed on March 2, 2023

Using the price data from the above sources, the cost for a patient using two bottles daily for seven weeks would range from 1,433 to 2,948 RON (i.e. 290-590 Euro). Furthermore, the National Institute of Statistics, cited by Statista, said that the average salary in Romania was 3,416 RON in 2021, which is necessary to make the previous information pertinent.

The responses from the other respondents were less detailed. At the same time, 1/3 of them said that these products are generally accessible and affordable, and the other third claimed that they are far too expensive for patients to afford to be used as they should be.

k) *Who is paying for FSMPs products?*

In Romania, FSMPs are not reimbursed; consequently, the patient, their family, or the hospital covers the expense of these items during hospitalisation. At the same time, most treatments are also administered in an outpatient setting, and most respondents to our survey said that the patient is responsible for purchasing these goods. There were two mentions of the hospital purchasing such products for hospitalised patients, out of the general budget of the

healthcare unit, or it received donations. Respondents also emphasised that for some patients, the cost of purchasing the required quantity of FSMP's products may exceed their financial means.

l) *How do patients source FSMP products?*

As far as our respondents learned from personal experience, buying these products from pharmacies, online pharmacies, or online shops doesn't present any significant problems. However, some stressed the necessity of placing a preorder to guarantee that the required versions will be available. One participant spoke about successfully obtaining Medidrink from the online pharmacy Spring Farma and buying FSMP products online rather than from traditional pharmacies or the neighbour country, ungary, which may be more affordable in some cases. Pharmacy, online shopping, and charity donations were the supply methods highlighted. One participant brought up a hospital-organised tender for the purchase of Fresubin.

Additionally, we examined the market data from the research firm Cegecim [4], which compiles data from hospitals and retail pharmacies in Romania, as shown in the following table.

Table IV: Sales (units and value) for FSMP on pharmacy channel in Romania for the year 2022 (source: Cegecim)

| MANUFACTURER | PRODUCT NAME | Sales 2022 (units) | Value 2022 (PPP, RON) |
|----------------|-------------------|--------------------|-----------------------|
| FRESENIUS-KABI | | 106,178 | 4,807,822 |
| | FRESUBIN | 92,786 | 4,032,172 |
| | DIBEN | 4,692 | 203,146 |
| | SUPPORTAN | 4,220 | 279,809 |
| | SURVIMED | 2,722 | 165,364 |
| | PROVIDEXTRA DRINK | 663 | 44,565 |
| | CALSHAKE | 502 | 19,499 |
| | FREBINI | 453 | 18,469 |
| | KABI GLUTAMINE | 140 | 44,798 |
| NESTLE | | 21,532 | 790,416 |
| | OPTIFIBRE | 20,971 | 749,973 |
| | NUTREN OPTIMUM | 420 | 20,571 |
| | MODULEN | 141 | 19,872 |
| NUTRICIA | | 2,408 | 25,558 |
| | NUTRIDRINK | 2,408 | 25,558 |

For 2022, we identified reports of relatively low sales and only a few brands. Although this is the only source we could find, it is improbable that only 106,178 units were sold through retail pharmacies in Romania. We can only speculate that online pharmacies are not counted and that most online shops did not report sales to Cegedim, thus underestimating the totals. Only Fresubin indicates large sales among the important manufacturers, who are present on the market with more brands than respondents to our research reported (over 90 percent of the total).

m) *What feedback did the responders receive from their patients?*

We can group the feedback on two main aspects – how patients use the products and how they can source them.

Patients are generally happy with the products. However, patients are concerned about the availability of different flavours to suit specific needs in terms of usage, especially in the case of some patients whose tastes are altered during chemotherapy or radiotherapy. In addition, it is important to note that certain patients have expressed concerns about items being either too sweet or acidic in some circumstances.

Regarding sourcing, some patients expressed the necessity to place an order in advance, ask family members for information, or look up sources online. However, the biggest problem mentioned is that most patients need help to secure the funding necessary to buy the supplements during their therapy, especially in cases of a 6-7 weeks treatment scheme associated with the condition requiring FSMPs aid.

n) *The opinion of the physicians regarding FSMPs*

The most important objective for the participants in this research concerning the use of FSMP products is to help patients to go through the course of treatment in an acceptable physical shape, and nutritional status is paramount for such an aim. For example, one participant in the study reported that FSMP users were less likely to have stomatitis or mucositis. In addition, most survey respondents said that patients were better equipped nutritionally to withstand the effects of chemotherapy and/or radiotherapy over their whole course.

Since some patients cannot drink coffee during therapy, suggestions such as adding a coffee-like flavour were made. Since the financial burden currently exists for cancer patients, the added expense of FSMP products causes enormous obstacles for patients. Hence respondents to our poll emphasised the necessity for a method to pay these costs externally through reimbursement or a similar mechanism.

Doctors emphasise that these expenses (i.e. for FSMP) are less than what would be needed for chemotherapy or radiation therapy. Since this keeps the patients well enough to complete the course

successfully, the treatments are unquestionably worthwhile.

o) *Extra details provided by respondents*

We asked respondents about any specific subjects they would like to bring up after the interview, and the following we believe merits discussion:

- Using FSMP would lower the cost of patient care while being necessary for finishing the treatment.
- It might be beneficial to commission more patient education materials on FSMP.
- The help and collaboration of a nutritionist are critical since they free up the doctor from this responsibility and assist patients at risk.
- In some extreme cases (i.e. N.G. tube feeding), using FSMPs would lower the burden on the budget necessary for treatment and the patient's comfort.

IV. CONCLUSIONS

The study's findings provide insight into Romanian physicians' awareness, recommendation practices, and opinions regarding the use of FSMPs. Physicians recommend FSMPs to patients based on specific medical conditions, treatment schemes, taste preferences, and affordability. Disease stage and treatment scheme were identified as factors that influence the recommendation and use of FSMPs. Clinical experience was deemed essential for recommending FSMPs to patients, while patients' feedback regarding the usage and sourcing of FSMPs was generally positive. The study concludes that physicians play a crucial role in ensuring that patients have the necessary nutritional support during treatment. However, more patient education materials and collaboration with nutritionists may be required to improve patient outcomes and reduce patient financial burden. Overall, the study highlights the importance of FSMPs in patient care and the need for further research and collaboration between healthcare professionals to optimise the use of these products.

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REFERENCES RÉFÉRENCES REFERENCIAS

1. Bîrsanu SE, Banu OG, Nanu CA. Assessing Legal Responsibility in Romanian Pharmaceutical Practice. 2022. Farmacia. 70(3): 557–64.
2. Bushell C, Ruthsatz M. Revising the EU FSMP Regulatory Framework: Laying a Foundation for

- Future Nutritional Patient Care. 2018. Regulatory Affairs Professionals Society.
3. Carlotto A, Hogsett VL, Maiorini EM, Razulis JG, Sonis ST. The economic burden of toxicities associated with cancer treatment: review of the literature and analysis of nausea and vomiting, diarrhoea, oral mucositis and fatigue. 2013. *Pharmacoeconomics*. 31(9): 753–66
 4. Cegedim. Pharma & Hospital. 2022
 5. DataIntelo. Food for Special Medical Purpose (FSMP) Market Research Report 2021-2028. 2021. <https://dataintelo.com>
 6. Elting LS, Cooksley CD, Chambers MS, Garden AS. Risk, outcomes, and costs of radiation-induced oral mucositis among patients with head-and-neck malignancies. 2007. *Int J Radiat Oncol Biol Phys*. 68(4): 1110–20
 7. Elting LS, Keefe DM, Sonis ST, Garden AS, Spijkervet FKL, et al. Patient-reported measurements of oral mucositis in head and neck cancer patients treated with radiotherapy with or without chemotherapy: demonstration of increased frequency, severity, resistance to palliation, and impact on quality of life. 2008. *Cancer*. 113(10): 2704–13.
 8. European Commission. Commission Notice on the classification of Food for Special Medical Purposes. 2017.
 9. European Food Safety Authority (EFSA). FAQ: foods for special medical purposes. 2015. www.efsa.europa.eu
 10. European Parliament, Council of the European Union. Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. 2013.
 11. Frydrych A, Krosniak M, Jurowski K. The Role of Chosen Essential Elements (Zn, Cu, Se, Fe, Mn) in Food for Special Medical Purposes (FSMPs) Dedicated to Oncology Patients-Critical Review: State-of-the-Art. 2023. *Nutrients* 2023, Vol. 15, Page 1012. 15(4): 1012.
 12. Gauthier P, Cardot J-M. Health Care Digitalization, The Straightest Pathway To Personalization. 2021. *Farmacia*. 69(2):
 13. Ghimpău V, Sur D, Ruxandra Volovăţ S, Cazacu IM, Croitoru VM, et al. The Direct Costs Burden Of Bevacizumab In South-West Romania. 2022. *Farmacia*. 70: 1.
 14. Hague PN, Harrison M, Cupman J, Truman O. Market research in practice: an introduction to gaining greater market insight. 2016. Kogan Page. 3rd edition ed.
 15. Huang L, Lu J, Shi L, Zhang H. Regulation, production and clinical application of Foods for Special Medical Purposes (FSMPs) in China and relevant application of food hydrocolloids in dysphagia therapy. 2023. *Food Hydrocoll*, p. 108613.
 16. International Special Dietary Foods Industries. Foods for Special Medical Purposes (FSMP). 2020.
 17. Lalla R v, Sonis STB, Peterson DE. Management of Oral Mucositis in Patients with Cancer. 2008. *Dent Clin North Am*. 52(1): 61–viii.
 18. MenaFN. Food for Special Medical Purpose (FSMP) Market Is Booming Worldwide | Bayer, MeadJohnson, Nestle, Danone Nutricia. 2022. <https://menafn.com>
 19. Ministerul Sănătății. Ordinul nr. 820/2019 pentru stabilirea procedurii de noti icare pentru alimentele destinate unor scopuri medicale speciale. 2019.
 20. Mu D, Gong J, Wei Y, Chen M, Yu J, et al. Development of Core Outcome Sets of Food for Special Medical Purposes designed for type 2 diabetes mellitus: a study protocol. 2023
 21. Nonzee NJ, Dandade NA, Markossian T, Agulnik M, Argiris A, et al. Evaluating the supportive care costs of severe radiochemotherapy-induced mucositis and pharyngitis. 2008. *Cancer*. 113(6): 1446–52.
 22. Odelli C, Burgess D, Bateman L, Hughes A, Ackland S, et al. Nutrition support improves patient outcomes, treatment tolerance and admission characteristics in oesophageal cancer. 2005. *Clin Oncol (R Coll Radiol)*. 17(8): 639–45.
 23. Ozola L, Kampuse S. Concentration of Bioactive and Mineral Compounds in Enteral Tube Feed Products Made of Plant-Based Ingredients. 2022. Proceedings of the Latvian Academy of Sciences. Section B. Natural, Exact, and Applied Sciences. 76(1): 76–82
 24. Paccagnella A, Morello M, da Mosto MC, Baruffi C, Marcon ML, et al. Early nutritional intervention improves treatment tolerance and outcomes in head and neck cancer patients undergoing concurrent chemoradiotherapy. 2010. *Support Care Cancer*. 18(7): 837–45.
 25. Perugini M, Johnson TJ, Beume TM, Dong OM, Guerino J, et al. Are We Ready for a New Approach to Comparing Coverage and Reimbursement Policies for Medical Nutrition in Key Markets: An ISPOR Special Interest Group Report. 2022. *Value in Health*. 25(5): 677–84.
 26. Ren P, Wang H-Y, Li Z-N. Using the Delphi method to propose foods for special medical purposes health effect evaluation indicators. 2023.
 27. Ruthsatz M, Chen J, Wu C, Morck T. Foods for special medical purposes/ medical foods: A global regulatory synopsis. 2022. Regulatory Affairs Professionals Society.
 28. Schmidl M. Food Products for Special Medical Purposes. 2007.
 29. Stippler D, Bode V, Fischer M, Kollex K, Rohde E, et al. Proposal for a new practicable categorization

system for food for special medical purposes – Enteral nutritional products. 2015. Clin Nutr ESPEN. 10(6): e219–23.

30. Visiongain Research. Lt. Food for Special Medical Purpose (FSMP) Market is projected to reach US \$19.41 Billion by 2030. 2021. www.globenewswire.com
31. World Health Organisation (WHO). Standard for the Labelling of and Claims for Foods for Special Medical Purposes Codex Stan 180-1991. 1991

