Macedonian Pharmaceutical Bulletin, 72 (Suppl 1) 195 - 196 (2026)
Online ISSN: 1857-8969
DOI: 10.33320/maced.pharm.bull.2026.72.03.093
Short communication

Food for special medical purpose for rare diseases: Regulatory requirements and practical challenges in North Macedonia

Natasha Churevski*, Angelina Nanevska*, Marija Taleska Velkovski, Aleksandra Petrovska

Replek AD, Kozle 188 1000 Skopje, R.N.Macedonia

Introduction

A disease is considered rare if fewer than five in 10,000 people have it. Around 30 million people in the European Union (EU) suffer from a rare disease, which means one in 17 people. Finding effective treatment for these rare diseases is a huge challenge.

The most prevalent "rare" disease worldwide, cystic fibrosis, is an autosomal recessive multisystem disease, caused by mutations in the *CFTR* gene. In people with mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) genes cause the CFTR protein to not function properly. When the protein is not working correctly, it's unable to help move chloride a part of salt to the cell surface. Without the chloride to attract water to the cell surface, the mucus in various organs becomes thick and sticky. It affects different organs like lungs, pancreas, liver and reproductive organs. (Terzic et al., 2019)

Food for special medical purposes (FSMPS) is a category of food for special nutritional use that is specially processed or has a specific composition and is intended for the dietary management of patients, including infants, used under medical supervision. (European Parliament and Council of the European Union, 2013; European Food Safety Authority (EFSA), 2021)

Materials and methods

In North Macedonia, food business operators can place a FSMP on the market with prior mandatory approval by the Food and Veterinary Agency of the Republic of North Macedonia; meaning, specific requirements for the safety of food for special nutritional use and food for special medical purposes must be met regarding composition and labeling.

Our aim is to present the National Regulatory Requirements and identify key practical challenges in North Macedonia, during the registration process of two Foods for Special Medical Purposes (FSMPs), both intended for the dietary management of patients with cystic fibrosis.

Procedures

The first step in the process of placing Food for Special Medical Purposes on the market in R.N. Macedonia is submitting a Request for issuing an Opinion for placing on the market a product from the group of food for special nutritional use in the Food and Veterinary Agency.

Documentation to be submitted in addition to the Request are:

- A sample of the original packaging or a conceptual design of the packaging;

*natasha.churevski@replek.mk; angelina.nanevska@replek.mk

- Labeling in Macedonian language with all information about the product in accordance with the original labeling;
- Specification for the qualitative and quantitative composition of the product issued by the manufacturer;

Additional documentation that may be submitted:

- Certificate of analysis of the product - results of laboratory analysis on the composition or safety of the product;
- Confirmation of registration of the product in the Register of Food for Special Nutritional Uses, in the EU - proof from the competent body in the country of production and/or EU member states that the product is on the market in that country;
- Scientific studies confirming the safety of the use of substances with nutritional and/or physiological effects in the composition of the product
- Proof that the costs and fees of the Opinion issuance procedure have been covered (Agency for - Food and Veterinary/ Rulebook 2011; FVA Law on Food Safety, 2015).

Discussion and conclusion

Several challenges are associated with the development and use of FSMP.

- The high cost of these specialized products can impose a significant financial burden on patients, potentially limiting their access.
- In certain regions, the availability of specific FSMP products may be limited, hindering optimal nutritional management
- Regulatory complexities and vague definitions and classifications of FSMP often pose challenges for manufacturers and regulators. Moreover, there is a recognized need for greater product diversity to meet the varied nutritional needs of different medical conditions, especially rare diseases.
- With the increasing FSMP availability through online platforms, maintaining strict quality control and ensuring the accuracy of product information are crucial (Kang et al., 2025).

Additional practical challenges included:

- adaptation of labeling in accordance with national regulatory requirements,
- harmonization of technical documentation and product specifications,
- communication with competent authorities during the evaluation process.

At the same time, continuous communication and professional cooperation with the Food and Veterinary Agency of the Republic of North Macedonia significantly contributed to the preparation of the regulatory submission and approval without delays.

References

EFSA Scientific Committee, 2021. Scientific and technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013. EFSA J. 19, 6544. https://doi.org/10.2903/j.efsa.2021.6544

European Parliament and Council of the European Union, 2013. 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. Off. J. Eur. Union L 181, 35–56. https://eur-lex.europa.eu/eli/reg/2013/609/oj/eng

Food and Veterinary Agency of the Republic of North Macedonia, 2011. Rulebook on special requirements for the safety of food for special nutritional use: dietetic food for special medical purposes. Food and Veterinary Agency of the Republic of North Macedonia. https://fva.gov.mk/mk/zakon-bezbednost-hranata/pravilnik/2011-157-pravilnik-posebnite-baranja-bezbednost-hranata-posebna-nutritivna-upotreba-dietetska-hrana-posebni

Food and Veterinary Agency of the Republic of North Macedonia, 2025. Food Safety Act: consolidated text. Food and Veterinary Agency of the Republic of North Macedonia. https://fva.gov.mk/mk/zakon-bezbednost-hranata-2015-123

Kang, H.J., Park, Y.K., 2025. Food for special medical purposes: a global review of usage trends, regulatory frameworks, and key growth drivers. Clin. Nutr. Res. 14, 146–156. https://doi.org/10.7762/cnr.2025.14.2.146

Terzic, M. et al., 2019. Cystic fibrosis mutation spectrum in North Macedonia: a step toward personalized therapy. Balkan J. Med. Genet. 22, 35–40. https://doi.org/10.2478/bjmg-2019-0009