Food for Special Medical Purposes (FSMP): New specific CJEU requirements

In a decision dated 27 October 2022, the Court of Justice of the European Union (CJEU) specified the requirements for a product to be qualified as Food for Special Medical Purposes (FSMP). In its preliminary ruling (Case C-418/21), it held that it is not sufficient that the patient derives a general benefit from the intake of the product because the substances that it contains counteract the disorder or alleviate its symptoms; rather, a product constitutes an FSMP only if the disease results in increased or specific nutritional requirements which the food is intended to cover.

By Celine Weber
MLaw, Attorney at Law
Managing Associate
Phone +41 58 658 56 17
celine.weber@walderwyss.com

1. Facts

VSW, an association with the aim to ensure compliance with the rules on fair competition, had brought an action against the pharmaceutical company Orthomol which markets the products «Orthomol Immun» and «Orthomol AMD extra» as FSMP.

Orthomol promoted these products by stating that the first was used to «support the immune system using nutritional science» for «the dietary management of nutrition-related immune deficiencies» (e.g., recurrent respiratory infections) and that the second was used for the «dietary management of advanced age-related macular degeneration» («AMD»). VSW sought a prohibition of the marketing of these products as FSMP.

2. Definition of FSMP

According to Article 2(2)(g) of Regulation No 609/2013:

- FSMP means 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:

  (i) with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, («**first alternative**») or

  (ii) with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone («**second alternative**»).

3. Question referred to CJEU

The court of first instance, the Landgericht Düsseldorf, upheld VSW's action, arguing that for a product to be classified as FSMP, it is not sufficient that the nutrients have positive effects on the occurrence or course of a disease in that they contribute to preventing, mitigating or curing it.
Orthomol brought an appeal against that decision before the Oberlandesgericht Düsseldorf. The latter referred the following question to the CJEU:
«Under what circumstances are there other medical nutrient requirements pursuant to the second alternative in Article 2(2)(g) of Regulation No 609/2013?

Namely: do they require – in addition to the limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food, as referred to in the first alternative – that there is an increased nutrient requirement brought about by illness, which is to be covered by the food, or is it sufficient that the patient … benefits generally from the intake of that food because substances contained therein counteract the disorder or alleviate its symptoms?»

4. Decision

The CJEU ruled that:

- FSMP have two characteristics distinguishing them from other categories of products:

  (i) they are foodstuffs intended for the exclusive or partial feeding of patients with a specific disease, disorder or medical condition; and

  (ii) they are specially processed or formulated to meet the particular nutritional needs resulting from such a disease, disorder or medical condition (para. 25).

- A product cannot be classified as an FSMP solely on the ground that its nutrients have positive effects in the sense that they bring general benefit to the patient and contribute to preventing, alleviating or curing that patient's illness, disorder or medical condition (para. 34).

- FSMP do not, as such, make it possible for a disease, disorder or medical condition to be counteracted; rather, they are intended to meet a patient's nutritional needs (para. 39 and 40).

- Article 2(2)(g) of Regulation No 609/2013 and, in particular, the concept of «other medically determined nutrient requirements», must therefore be interpreted as meaning that a product constitutes an FSMP **if the disease results in increased or specific nutritional requirements which the food is intended to cover**, such that it is **not sufficient**, for the purposes of such a qualification, **that the patient derives a general benefit from the intake of that food** because the substances that it contains counteract the disorder or alleviate its symptoms (para. 59).

5. Implications

This decision provides important guidance with regard to the requirements of an FSMP and the differentiation between FSMP, other foodstuffs (e.g. food supplements) and medicines. FSMP are intended to **feed** patients with **nutritional needs caused by a particular disease, disorder or medical condition, not** to **treat** patients.

Since the definition of FSMP in Switzerland (cf. art. 23 of the Regulation on Food for Persons with Special Nutritional Needs, **VLBE**; SR 817.022.104) is almost identical to the definition in Article 2(2)(g) of Regulation No 609/2013, the decision by the CJEU will very likely have implications for companies in Switzerland as well.

It is advisable that companies examine whether this decision has implications for the qualification of the FSMP they currently have on the market.