Medical Foods Workshop

Science, Regulation and Practical Aspects

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Foods for Special Medical Purposes (FSMPs) in the European Union (EU)

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Very long EU experience on FSMPs

- 1976: First EC Directive on Foodstuffs for Particular Nutritional Uses
- 1989: Revised EC Directive on Foodstuffs intended for Particular Nutritional Uses
  - In Annex I FSMPs specified as one category
- 1997: Opinion of Scientific Committee for Food on FSMPs
- 1999: Directive on FSMPs (1999/21/EC)
- 2009: Revised Directive on Foodstuffs intended for Particular Nutritional Uses 2009/39/EC
- 2013: Regulation 609/2013 on foods for specific groups- Abolition of the concept of Foods for Particular Nutrit. Uses
- 2016: Commission Regulation 2016/128 on FSMPs

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Provisions of the EU Regulations

- Definition
- Composition - minimal due to:
  - wide range of products
  - intention to encourage innovation/research
- Labelling – extensive
  - Most significant: statement "For the dietary management of …."
- Claims – prohibited (Regulation 2016/128)
- Placing on the market - notification

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Use of FSMPs

- FSMPs are critically important for the health of an increasing number of patients that need them
- Fake FSMPS can be dangerous for the health of misled users
- Inappropriate use of FSMPs may have serious detrimental effects on the health of patients
- **FSMPs must be placed on the market and controlled correctly**

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Guidelines for the classification as FSMPs

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European Commission guidance

Commission Notice on the classification of Food for Special Medical Purposes
(2017/C 401/01)

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Addressed to Food Business Operators and Controlling Authorities

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Definition of FSMPs

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'Food for special medical purposes' 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 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 ~~by other foods for particular nutritional uses, or by a combination of the two~~;

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To be used under medical supervision

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- A prominent labelling statement 'use under medical supervision' shall appear in the labelling of FSMPs
- Developed in close cooperation with health professionals
- Composition determined by the disease, disorder or medical condition for their use
- Certain FSMPs can pose a health hazard when consumed by persons not having the disease, disorder or medical condition for which they are intended

Use under medical supervision is essential but not the determining factor for classification

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The concept of dietary management

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Common element: the dietary management of the disease/disorder/medical condition 'cannot be achieved by modification of the normal diet alone'. Some examples:

- Inability to take sufficient quantities of ordinary food e.g. head and neck cancer or surgery, or from neurological impairment associated with stroke
- Inability to digest or absorb sufficient food/nutrients, e.g. impairment of the gastrointestinal tract (short bowel syndrome, gastrectomy)

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The concept of dietary management

- Inability to metabolise specific nutrients (e.g. due to genetic (inherited) metabolic disorder like phenylketonuria, Maple Syrup Urine Disease
- Inability to excrete certain nutrients or their metabolites as result of diseases of liver, kidney, respiratory systems (e.g. phosphate/potassium in kidney failure)
- Other medically-determined requirements, (e.g. increased protein or amino acids in pre/post-surgery, severe wounds or burns)

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The concept of dietary management

- In all the cases mentioned above, consider if it is impossible, impractical, unsafe or nutritionally/clinically disadvantageous for the patients suffering from the specific disease/disorder/medical condition to satisfy their nutritional needs through the exclusive consumption of foods other than FSMP.

- If, on the contrary, the nutritional needs of the patient can be satisfied by a normal diet, modified or not, **then a FSMP marketed for the disease, condition or medical disorder should not be accepted**

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The concept of dietary management

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Very important:

- The analysis of the concept of 'dietary management' should be applied on a case-by-case basis
- **Clearly distinguish** between
  - '**dietary management**' of a disease/condition/medical disorder by FSMPs and
  - **treatment** of a disease/condition/medical disorder by medicines

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Concept of modification of normal diet

The question is often posed as to what constitute a normal diet and concretely:

Whether food supplements and fortified foods should be taken into account in deciding if the nutritional needs of the patient can be met by a modification of the normal diet

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Concept of modification of normal diet

Clear references in EU legislation and also in relevant Codex Alimentarius measures that food supplements and fortified foods are part of the normal diet

Therefore, the concept of 'modification of the normal diet' should be interpreted in a broad way and the use of food supplements and fortified foods should be considered as part of it, as well as the use of foods for special dietary uses where the concept of these products still exists.

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Feasibility of modification of normal diet

Very important but controversial issues:

1. the potential for modification of the normal diet
2. the nutritional need of a patient 'cannot be achieved by a modification of the normal diet alone

Elements to consider:

- Is it possible or not?
- If possible, is it realistic? is it practical?
- The use of the specific FSMP would be safer, and nutritionally advantageous for the patient?

Therefore, critical appraisal of the situation, restrictive interpretation, but not absolute impossibility of using FSMPs as the optimal way to manage it.

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Feasibility of modification of normal diet

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Other factors to consider:

- Stage of development/severity of disease/disorder
- Impact on patient's health
- Role, composition, use of FSMPs v. normal diet
- Availability of other food products with similar composition (e.g. food supplements)
- The practical difficulties of fulfilling the patient's nutritional needs without the specific FSMP

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Dat FSMPs

efsa
European Food Safety Authority

EFSA Journal 2015;13(11):4300

SCIENTIFIC OPINION

Scientific and technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following a request from the European Commission, the EFSA Panel on Dietetic products, Nutrition and Allergies (NDA) was asked to provide scientific and technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013. The guidance presented in this document is to assist in the preparation and presentation of well-structured dossiers. It presents a common format for the organisation of the information and outlines the information and scientific data which could be included in the dossier, as well as the key issues which should be addressed in the dossier in order to assess the extent to which a food product notified as FSMP falls under the scope of Regulation (EU) No 609/2013, under the proposed use. It is intended that the guidance will be kept under review and will be further amended and updated as appropriate in the light of experience gained from the evaluation of dossiers for specific food products notified as FSMP, and in the light of future Community guidelines and legislation. The scope of this guidance is limited to FSMPs in the context of Article 3 of Regulation (EU) No 609/2013. Out of the scope of this guidance are: a) other categories of food falling under Regulation (EU) No 609/2013, such as infant formula and follow-on formula, processed cereal-based food and baby food, and total diet replacement for weight control; b) meal replacements for weight control; c) "gluten-free" and "lactose-free" foods.

KEY WORDS

food product, disease, disorder, medical condition, patients, dietary management

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Critical points for the control of FSMPs

- Sufficient characterisation/accurate description of the product

- Sufficient characterisation of disease/disorder/medical condition for which the specific product is intended

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Critical points for the control of FSMPs

- Practical/safety aspects to consume a normal diet (with/without modification)
- Nutritional or clinical disadvantages from consuming exclusively a normal diet.
- Specific role of the product in the dietary management of the disease/disorder/medical condition for which it is intended

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Critical points for the control of FSMPs

- Nutrition characteristics of patients suffering from the specific disease/disorder/medical condition

- The specific role of the product in the dietary management of the disease/disorder/medical condition, in particular if the specific product is different from/more suitable than foods that are not FSMPs

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Critical points for the control of FSMPs

- Does the product have a nutritional or clinical advantage for the patient?
- The reasons why the specific food product needs to be administered under medical supervision
- Potential restrictions of use, i.e. as the case may be, whether the specific food product may be unsafe if consumed by subjects other than patients for whom the specific product is intended

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Thank you for your attention

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