Foods for Special Medical Purposes, from Regulation to Reimbursement


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The value of clinical nutrition products is well recognised in the management of a wide variety of diseases, disorders and medical conditions both within and outside the National Health Service. In a previous article in *Complete Nutrition*, BSNA reviewed the historical development and innovation in clinical nutrition.[1] Innovation is supported in this category by a robust but flexible regulatory framework, and patient access to clinical nutrition is facilitated by a well-established reimbursement system. This article will provide information on the regulation and reimbursement in the UK of clinical nutrition products known as Food for Special Medical Purposes (FSMP) or Medical Foods.

The regulatory framework for FSMP

The regulation of FSMP in the UK originated in, and still reflects, the EU legislation in place. Prior to Brexit, products in the UK were governed by EU regulations. On leaving the EU, this legislation was retained in domestic law. FSMP is regulated as a category of Foods for Specific Groups (FSG).[2] This framework legislation was introduced in 2013 to control categories of foods for vulnerable consumers and specifically those who may rely on these foods as a sole source of nutrition such as infant formula, FSMP and total diet replacements for weight management.

The FSG regulation sets down the definition of FSMP and, very importantly, sets the principle that communication to healthcare professionals (HCPs) and provision of information related to the use of the products is essential.

There is also a specific FSMP regulation which sets down broad compositional criteria for nutritionally complete products, sets additional labelling requirements and includes the requirement to notify the Department of Health and Social Care (DHSC) when FSMP are placed on the market in the UK.[3]

Definition of FSMP

FSMP include oral nutritional supplements (ONS), enteral tube feeds and specialist infant formulae, and can be used across a wide range of age groups.

FSMP are defined in Article 2(2)(g) of the FSG regulation:[2]

'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 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.'

This definition recognises the variety of FSMP necessary to meet the needs of patients with a wide range of diseases, disorders and medical conditions who can benefit from nutritional intervention; it is also broad enough to allow for future innovation in the category. However, it is important to understand that FSMP may be needed for several reasons including when modification of the normal diet is impractical, unsafe or there is a clinical benefit of using a specialised product over general foods.

FSMP Regulation 2016/128 describes three categories of product:

- Nutritionally complete standard – with a standard nutrient formulation which may be used to supplement a person's diet or as the sole source of nutrition. These products must comply fully with the nutritional composition criteria in the Regulation e.g., standard ONS for disease related malnutrition.[3]
- Nutritionally complete nutrient adapted – may have a nutrient adapted formulation, which may be used to supplement the diet or as the sole source of nutrition. There is flexibility to deviate from the nutritional composition criteria to meet the specific needs of the disease, disorder or medical condition e.g., ONS with low electrolyte concentration suitable for patients with renal disease.
- Nutritionally incomplete – may have a standard or nutrient adapted formulation but is not suitable to be used as the sole source of nutrition. In general, they must comply with the nutrient maximums, but can also deviate in composition based on their intended use. A large number of products sit in this category, reflecting the diversity of medical nutrition products and their uses e.g., products designed for management of inherited metabolic disorders.

Composition of FSMP

The FSMP regulation sets down nutritional composition criteria for infants and for children and adults. There is flexibility to deviate from these minimum and maximum levels to accommodate the needs of a specific disease, disorder or medical condition and also for nutritionally incomplete FSMP, where there is a rationale to do so. There is also the flexibility in terms of ingredient composition. This is very important to accommodate innovation in the category as the level of research and generally available literature on nutritional management grows.

Labelling of FSMP

FSMP must be labelled in accordance with general food labelling rules set down in the Food Information to Consumers Regulation (e.g., ingredients list, net weight, nutrition information).[4] However, the labels of FSMP are unique in that the information on the label is not just intended for the consumer or patient but also for the healthcare professional and is usually provided by means of healthcare professional data cards as well as physically on the package.

There are a number of additional mandatory labelling requirements for FSMP, including the legal name (Food for Special Medical Purposes), a statement that the product is for the dietary management of a specific disease or medical condition, indication of use only under medical supervision, age suitability and any precautions and contraindications. These labelling elements are essential to ensure the appropriate recommendation and use of the FSMP.

Also essential to the identification and appropriate use of FSMP is the requirement to label the properties and characteristics of the product, describing the special processing, formulation and/or nutrient content of the product. This information may appear in the product description or be displayed more prominently to clearly identify the key characteristics of the product in the healthcare setting. Clear presentation of the properties and characteristics on the product can also inform the patient of the suitability of the FSMP to help manage the nutritional needs of their medical condition e.g., the statement high protein for a patient with increased protein requirements. The label may also describe the rationale for the nutritional profile in relation to the disease, disorder, or medical condition.

This information should not be confused with nutrition and health claims which are not permitted for FSMP. Information on properties and characteristics of a FSMP relate the nutrient content to the use of the product in a medical condition, whereas nutrition and health claims describe the role of a nutrient in a food for the general healthy population.

Notification of FSMP

The FSMP Regulation states that when a FSMP is placed on the market, the food business operator shall notify the competent authority for monitoring purposes. In the UK the competent authority is the Department of Health and Social Care (DHSC).

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References: 1. James C, Wong E. (2022). Clinical Nutrition Research Through the Years. CN Magazine April 2022. Accessed online: chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://bsna.co.uk/uploads/web-documents/Clinical-Nutrition-Research-Apr-2022.pdf (May 2022). 2. Legislation Gov UK (2013). Retained Regulation (EU) No. 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. Accessed online: www.legislation.gov.uk/eur/2013/609/contents# (May 2022). 3. Legislation Gov UK (2013). Retained Commission Delegated Regulation (EU) 2016/128 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes. Accessed online: www.legislation.gov.uk/eur/2016/128/contents (May 2022). 4. Legislation Gov UK (2013). Retained Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers. Accessed online: www.legislation.gov.uk/eur/2011/1169/contents# (May 2022).

British Specialist Nutrition Association Ltd
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About the British Specialist Nutrition Association

BSNA is the trade association representing the manufacturers of products designed to meet the particular nutritional needs of individuals; these include specialist products for infants and young children (including infant formula, follow-on formula, young child formula and complementary weaning foods), medical nutrition products for diseases, disorders and medical conditions, including oral nutritional supplements, enteral tube feeding and parenteral nutrition, as well as companies who aseptically compound chemotherapy, parenteral nutrition and CIVAS.

FSMP are not generally sold at the retail level in the UK and in many instances are not readily available to sample for enforcement authorities such as local Trading Standards. The notification process informs the DHSC and Trading Standards that the product is on the UK market, and this allows Trading Standards to undertake monitoring activities such as label review or sampling for enforcement purposes. It is the responsibility of the manufacturer or importer to the UK to comply with all regulations, but the notification process provides an additional level of confidence for the patient and healthcare professional that compliance can be monitored where necessary.

The reimbursement process

First established in 1971, the Advisory Committee on Borderline Substances (ACBS) is the body which advises the Secretary of State for Health and Social Care on those 'borderline substances' – foodstuffs and cosmetic products – which they have determined are safe and suitable for NHS prescription in the community. It is responsible for advising on the prescribing of certain foodstuffs which are specifically formulated for use as part of the clinical management of people in the community with specified medical conditions, on the basis of clinical efficacy and price.

ACBS advice takes the form of its 'recommended list' which is published as Part XV of the Drug Tariff. GPs and other approved prescribers use the list to identify products that are approved for reimbursement by the NHS to help them meet the specific nutritional needs of their patients.

For a borderline substance to appear on Part XV of the Drug Tariff, a stringent application must be followed which varies according to whether a product requires a Type 1, Type 2, or Type 3 application:

- Type 1 application: for new and innovative products.
- Type 2 application: when a similar product already exists on the market.
- Type 3 application: for minor changes to an existing product e.g., a change to the product name; a minor formulation change which does not significantly alter the product.

Manufacturers can spend many years on research and development of products before submitting an application to the ACBS, especially for a Type 1 product. Innovation is exponentially growing in this area as research continues to support the significant role of nutrition in the management of diseases, disorders and medical conditions.

The application looks at all aspects of the product formulation and labelling along with the requirement to provide clinical evidence to support the patient benefit, including acceptability data (tolerance, compliance and palatability).

Before submitting an application to the ACBS, manufacturers will, as required under the FSMP regulation, notify the DHSC Nutrition Legislation Team (NLT) of the product to be placed on the market.[3] The NLT will acknowledge receipt of notification and may require further information about a particular product. A copy of the acknowledgement is required by the ACBS when an application for a new FSMP is submitted. Although they are independent entities, the ACBS and NLT each play an important role in ensuring patients and HCPs have timely access to the products they need.

FSMP manufacturers, ACBS and NLT all have a duty of care to the patient. FSMP manufacturers must prepare quality submissions for products that meet patient needs, the NLT must provide timely acknowledgment of notifications and the ACBS must diligently review applications in a timely manner. Delays in the process may restrict access to products for HCPs and patients and can cause problems such as stock shortage or wastage. Innovation in this sector is currently supported by a robust but flexible regulatory framework. Both Brexit and the COVID-19 pandemic have posed challenges to the industry, regulators and the clinicians on the ACBS committee to manage the process of development, notification and approval of clinical nutrition products over recent years. In future there are risks that non-harmonisation of UK and EU legislation will limit availability and choice of FSMP products in the UK and access to innovative products for patients. It is incumbent on all stakeholders to come together to ensure that we overcome challenges and maintain the development, quality, availability and evolution of clinical nutrition products into the future to continue supporting HCPs and patients.

Summary

FSMP are highly regulated products. The regulatory framework and reimbursement process for FSMP should ensure that patients have timely access to appropriate, high quality and innovative medical foods. An efficient regulatory and review process supports a robust industry which is in the longer-term interests of both patients and the wider NHS. All stakeholders have an important role to play to ensure this system continues to meet the needs of patients now and in the future.