The Importance of Medical Foods, a Robust Reimbursement System & Strict Regulations

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Malnutrition and dehydration are both causes – and often consequences – of illness, so ensuring that patients receive adequate nutritional care is critical for improving their overall health outcomes. Medical foods can play an important role in the management of several diseases, disorders and medical conditions, as well as the management and prevention of disease-related malnutrition, but what are medical foods, how do patients access them, and how strictly are they regulated?

Medical foods, otherwise known as Foods for Special Medical Purposes (FSMPs), may be indicated for conditions such as cows' milk protein allergy, cancer, stroke, neurological conditions, frailty, patients with dysphagia, Crohn's disease and COPD, just to name a few. Used from infancy to older age and under the supervision of a healthcare professional (HCP), most FSMPs are obtained under prescription and can be used at home, in hospital or in care homes. Patients may be prescribed a FSMP as their sole source of nutrition or to supplement their diet, for short-term use or for life. FSMPs are governed by strict regulatory criteria under Regulation (EU) 2016/128 and are defined according to Art. 2(2)g of Regulation (EU) 609/2013 as follows:[1] *"…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."*

FSMPs can be oral nutritional supplements (ONS), enteral tube feeds or specialist infant formulae and come in a range of formats.

If a patient is able to feed orally, nutrition support can take the form of ONS. These can either be standard or disease specific formulations, and include milkshake and juice style sip feeds, dessert style products, thickening agents and other disease-specific formulations. NICE QS24 recognises that ONS are a clinically cost-effective way to manage disease-related malnutrition when a person is unable to meet their nutritional requirement through food alone.[2] These quality standards highlight the role of providing food fortification as an alternative to ONS in supporting energy and/or protein intake. However, they also advise that care should be taken when solely providing fortification to food, as these strategies may not necessarily provide sufficient or adequate micronutrient and mineral levels. Therefore, it is important that manufacturers remain dynamic and innovative, so that patients have access to products that fulfil their nutritional requirements while offering choice to maximise compliance. Despite all the guidance and strong evidence surrounding the benefits of ONS, there is considerable variation in prescribing practice across the UK. When prescribed appropriately, ONS can prevent the complications associated with malnutrition and significantly improve patients' health outcomes, offering a clinical, and cost-effective, solution.[3, 4]

For those who cannot safely chew or swallow food and therefore who struggle to feed orally, enteral tube feeds (including ONS) can be administered directly into the stomach or small intestine via the gastrointestinal tract, either by a nasogastric tube (NGT) or percutaneous endoscopic gastrostomy (PEG).

Specialist infant formulae also exist for infants for a number of conditions, including pre-term, gastrointestinal issues and allergies. Like adult products, a variety of formats exist on the market (i.e. powder and liquid products in a range of volume and pack sizes) to fulfil patient requirements and preferences.

Many manufacturers of FSMPs in the UK not only produce the vital nutrition sources for patients, but they also provide services to support patients. Manufacturers provide training, guidance and support after discharge, deliver the medical food directly to the patient's home, deliver the necessary equipment (e.g. pumps, giving sets, etc.), provide the necessary nursing staff and have call centres available for support and advice. In the UK over 23,000 people use long-term tube feeding at home, keeping them out of hospital and providing a better quality of life.[5] Even more are on ONS at home. Research has shown that the use of FSMP can reduce hospital admissions and readmissions, shorten the length of hospital stay, and result in fewer healthcare needs in the community, such as GP visits.[6, 7]

The regulatory framework for FSMPs

As previously highlighted, the regulation of FSMPs in the UK originated in, and still reflects, the EU legislation in place. Prior to the UK's exit from the EU, products in the UK were governed by EU regulations. On leaving the EU, this legislation was retained in domestic law. FSMPs are regulated as a category of Foods for Specific Groups (FSG).[1] The FSG regulation sets down the definition of a FSMP and, very importantly, sets the principle that communication to 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 a FSMP is placed on the market in the UK.[8]

FSMP Regulation 2016/128 describes three categories of product:[8]

a) Nutritionally complete food with a standard nutrient formulation which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom it is intended;
(These products must comply fully with the nutritional composition criteria in the Regulation.)[8]
b) Nutritionally complete food with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom it is intended;
(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])
c) Nutritionally incomplete food with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which is not suitable to be used as the sole source of nourishment.
(In general, these products must comply with the nutrient maximum levels laid down but can also deviate in composition based on their intended use. Many products sit in this category, reflecting the diversity of FSMPs and their uses [e.g. products designed for management of inherited metabolic disorders].)

Composition of FSMPs

The FSMP regulation sets down principles for nutritional composition criteria of vitamins and minerals for all ages, but 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 FSMPs, 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 FSMPs

The labels of FSMPs are unique because the information on the label is not just intended for the consumer or patient but also for the HCP. There are a number of additional mandatory labelling requirements for FSMPs, 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 FSMPs is the requirement to label the properties and characteristics of the product, describing the special processing, formulation and/or nutrient content of the product, (e.g. the statement 'high protein' for a patient with increased protein requirements).

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This information should not be confused with nutrition and health claims which are not permitted for FSMPs. Information on properties and characteristics of a FSMP generally relate to the nutrient content for use 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 FSMPs

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 DHSC. FSMPs are not generally sold at the retail level in the UK. The notification process informs DHSC and Trading Standards that the product is on the UK market, allowing 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 HCP that regulatory compliance will be monitored.

Reimbursement in the UK

In the UK, the reimbursement authority responsible for approval of FSMPs on prescription is the Advisory Committee on Borderline Substances (ACBS). The ACBS, which is supported by the DHSC, was established in the 1970s and is responsible for advising the Secretary of State for Health and Social Care on the prescribing of borderline substances for the Drug Tariff in primary care. Every ACBS approved medical food is included in Part XV of the Drug Tariff. The Drug Tariff is a freely available resource online and is updated every month.[9]

The ACBS is made up of a one person Secretariat and a Committee of volunteers who are responsible for assessing applications from manufacturers for these products to be approved for Part XV of the Drug Tariff through an application process. This ensures the products are safe and appropriate for the management of the disease, disorder or medical condition the product is intended for, providing reassurance to HCPs. Applications can be one of three types:

- Type 1 – a new and innovative product
- Type 2 – a new product which is broadly similar to a product which is already listed on the Drug Tariff
- Type 3 – a minor change to an existing 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 ACBS Committee is responsible for reviewing all types of applications and holds three meetings a year to do this. The reviewing of applications is paramount to not only ensure products are safe and appropriate, but also to ensure that patients can access the most up-to-date FSMPs available, which can only be done on FP10, or GP10 in Scotland, if a product is listed on the Drug Tariff.

The UK Government has been clear that 'growth' is its number one priority, while the NHS wants to see value for patients and taxpayers, and a resilient supply chain. To achieve this, the medical food sector needs a robust and consistent reimbursement system to ensure the continuity of supply to the NHS and ultimately to patients.

Summary

Manufacturers of FSMPs provide vital products which are strictly regulated for people who require medical nutritional support and offer important services to support patients being at home. Achieving the best products to support patient care requires a medical food industry that has the flexibility and freedom to innovate and improve products. An efficient regulatory and reimbursement 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.

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