Summary

The PARNUTS directive has been replaced with the Foods for Specific Groups Regulation. This seeks to ensure a consistent approach to Foods for Specific Groups (FSG) across Europe. The Regulation covers Foods for Special Medical Purposes (FSMP), Infant and follow on formula, weaning foods and weight loss foods. The use of FSMP in the UK is supported by a mature system where products are developed to meet the needs of patients, they are notified to the relevant government department and their effective and efficient use in clinical practice is led by the dietetic profession.

The development of new EU wide legislation on the use of FSMP is designed to ensure a consistent approach to these products across Europe. The British Dietetic Association (BDA) is concerned that some proposed changes to the legislation will compromise effective clinical practice and potentially impair outcomes for patients.

Dietitians, through the BDA, their professional body, can provide expert advice and provide the advice to the system nationally and locally. This will ensure the continuing provision and effective use of FSMP to support enhanced patient outcomes through nutritional care. The purpose of this policy statement is to provide members of the BDA with a brief overview of this complex area and both members and stakeholders with a statement of the BDA’s view of the proposed changes.

Recommendations

The BDA wishes to see

- The continuing effective and efficient use of FSMPs in clinical practice. Local systems should be in place, led by dietitians, to ensure the right products are available to meet patient's identified nutritional needs in a clinically and cost effective way.

- A strong, effective market with innovation in product development. Nutritional science and the role of nutritional care in optimising patient outcomes continues to evolve. Patients need to be able to access products which meet their nutritional needs and are demonstrated to be effective in improving outcomes.
• A key role for dietetic professional judgement in the use of FSMP in the health and care system. Dietitians are well placed to manage local systems, providing practice guidance and education for other professionals and provide advice on local formularies. Patient needs vary at different stages in their life or disease course and only the dietitian is able to integrate the patient’s nutritional needs, their values and desires and the evidence base to identify the best approach to nutritional care. This may include the use of FSMP and ensuring that these products are available as necessary to meet the assessed needs of patients.

• Dietitians being consulted in the evaluation of FSMP. Using their unique combination of knowledge and understanding of the role of nutrition in health and disease and clinical practice dietitians are best placed to evaluate new FSMP. The BDA expects dietitians to be included within the national notification systems and their advice sought.

Discussion

Dietitians’ key role in the use of Foods for Special Medical Purposes

Background
The PARNUTS Framework Directive (Directive 2009/39/EC established general rules for Foods for Particular Nutritional Uses (dietetic foods) and aimed to ensure product safety, suitability and appropriate consumer information. The PARNUTS directive has been replaced with the Foods for Specific Groups Regulation. This Regulation (Regulation (EU) No 609/2013) seeks to ensure a consistent approach to Foods for Specific Groups (FSG) across Europe. The Regulation covers Foods for Special Medical Purposes (FSMP), Infant and follow on formula, weaning foods and weight loss foods. This paper applies to FSMP only.

Definitions
FSMP are defined as:

‘A category of foods for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two’

To be defined as an FSMP the product also has to meet all the criteria listed below.
  a) The product is specially processed or formulated for its intended use.
  b) The product is intended for the dietary management of patients.
  c) The product is intended to be used under medical supervision.
  d) The product is intended as a sole source of nutrition or for partial feeding of a patient, including tube feeding,
  e) The product is intended for patients who are unable to take, digest, absorb, metabolise or excrete ordinary food, or nutrients contained therein or metabolites or who have medically-determined nutrient requirements
  f) The product is intended for the dietary management of a patient with whose requirements outlined in e) cannot be achieved by modification of the normal diet
Effective and efficient use of FSMP in clinical practice

FSMP are important in the management of conditions where the treatment contains a nutritional component. The new EU definition contained within the Foods for Specific Groups Regulation is ‘Vital for the management of certain conditions and/or essential to satisfy the nutritional requirements of certain clearly identified vulnerable groups’. These include, but are not restricted to, inflammatory bowel disease, metabolic conditions such as PKU and conditions where under nutrition impacts on the treatment and outcomes for the patients.

FSMP currently include

- nutritionally complete formula used to provide all or part of an individual’s nutritional requirements such as oral nutritional supplements and tube feeds
- nutritionally complete and adapted formula such as MCT containing complete formula for malabsorption
- nutritionally incomplete products including thickeners, carbohydrate modules, fat modules and nutritionally altered formula designed to treat specific conditions such as Phe reduced products for use in phenylketonuria.

Several FSMP products have clear uses; so a product with reduced Phe will usually only be used in the treatment of phenylketonuria. However, a nutritionally complete product will be used to support the nutritional intake of patients with a very wide range of conditions, at many different lifestages and/or with no clear diagnosis. Dietitians make reasoned clinical judgements based on their assessment and diagnosis of the nutritional issues and decide the most clinically relevant and cost effective products to use.

Misuse of products

The EU is concerned about the misuse of this category of products as there is differing interpretation of the legislation across Europe. There will be guidance to assist countries in determining whether a product an FSMP or not. The guidance will also address issues such as the status in relation to Infant Foods Regulations of FSMP designed for infants and the indications for use.

Issue for the UK

There is a possibility that some FSMP products may be reclassified as food supplements. The BDA expects that any decision regarding individual products will only be taken after consultation with the dietetic profession. Any reclassified product need to be carefully labelled and marketed to ensure appropriate use. Any decision to remove products from FSMP category needs to take account of any risks to the health of individuals who use the product and ensure the continuing access as appropriate.

Properties and characteristics

Currently product labels are able to include information about the specific characteristics of the product, and this may change to specifying which diseases or disorders a product is designed to treat. The label may not be able to indicate that special characteristics of the product such as ‘contains fibre’, ‘low sodium’. In clinical practice these descriptions of the characteristics help differentiate between products within a range including ‘contains fibre’, ‘low sodium’, ‘increased energy’. There have been a number of clinical incidents which have highlighted the difficulty for non-specialists on a busy ward or clinic in identifying characteristics of the appropriate items. It will be more difficult when they are not apparent on the label.
**Issue for the UK**

Patients and carers understand these characteristics, they can appreciate that they might require a product containing fibre to help bowel function. Having only clinical conditions on the label may lead to alarm in situations, for example, where a patient requires nutritional support to recover from surgery and the label specifies cancer related malnutrition.

Good prescribing practice would lead professionals to only use products which they are competent to use. However, having conditions on the label can lead to situations where a product is prescribed which is assumed to be appropriate for a specific patient's condition without taking into account the specific requirements of the individual. This could also cause confusion if more than one product states suitability for the same condition.

The BDA recommends that dietetic expertise and a nutritional assessment of the individual is used to support the correct product being used efficiently and therefore optimise patient outcomes. Condition specific labelling risks limiting access to the products necessary to optimise outcomes.

**FSMP for use with infants and toddlers**

Previously FSMP designed for the nutrition of infants were not subject to the Infant and Follow On Formula Regulations 2007. This 2007 regulations covers the labelling, notification and the avoidance of risk of confusion between infant formula and follow-on formula. It also covers advertising, promotion and the provision of information and education relating to infant and child feeding.

**Issue for the UK**

The BDA fully supports the aim of the Regulations to ensure that the promotion of infant formula does not discourage breast feeding. However, the circumstances in which FSMP are used for infants by their very nature, mean that breast feeding is usually undesirable or has already ceased.

Any proposal to apply the Infant and Follow-on Formula regulations to these products risks reducing access to information regarding the use and composition of the product and to factual information for patients (such as how to use the product) and samples including for diagnostic purposes. The BDA is not aware of major abuses of the current system or harm to patients from current practice.

The BDA would be very concerned if the regulations governing FSMP designed for feeding infants with complex nutritional needs were changed to the extent that would detract from high quality clinical practice and recommends that the profession is consulted before any changes take place.

**Summary**

Dietitians are currently the health professionals who are most familiar with the use of FSMP in clinical practice. This knowledge and expertise could be used to greater effect at all levels of the system.

Dietitians are well placed to manage local systems, providing practice guidance and education for other professionals and local formularies. Patient needs vary at different stages in their life or disease course and only the dietitian is able to integrate the patient’s nutritional needs, their values and desires and the evidence base to identify the best approach to nutritional care. This may include the use of FSMP where required to optimise patient outcomes.
Dietitians are also well placed to use their unique combination of knowledge and understanding of the role of nutrition in health and disease and their expert clinical practice to evaluate new FSMP. The British Dietetic Association | Policy Statement – Foods for special medical purposes (July 2014) Page | 5

Further Information and References

5. United Kingdom Department of Health (England) https://www.gov.uk/search?q=FOODS+FOR+SPECIFIC+GROUPS

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