The term “nutraceutical” is believed to have originated in the late 1980s and has come to cover a wide range of products, such as fortified breakfast cereals, bio-yoghurts, vitamins, herbal remedies, energy drinks and even cholesterol-reducing margarine, all of which share a common characteristic of containing a specific component intended to give the product a specific medical or physiological advantage other than a purely nutritional benefit.

However, in the European Union at least, nutraceuticals do not constitute a legally-recognised category with their own regulatory regime. Instead, anyone seeking to market a nutraceutical product in the EU must consider whether the product falls into the regime covering medicinal products or that governing the sale of foods and in particular food supplements. This classification has a huge impact on the development, manufacture and marketing of the nutraceutical. Consequently a business wishing to market such a product must be aware of the rules governing classification at any early stage of product development. This article considers the factors to be taken into account when making the classification and then gives an overview of the implications that flow from this.

… classification principles

The starting point is European Parliament and Council Directive 2001/83 on the Community Code on Medicinal Products for Human Use (Directive 2001/83) which sets out the definition of a medicinal product. Case law of the European Court of Justice (ECJ) has established that where a product is found to be a medicinal product, then the medicinal products regime will apply to the exclusion of any other. Importantly for the field of nutraceuticals, there are in fact two alternative definitions; falling within either will lead to classification as a medicinal product, although often a product will fall within both.

The first definition covers “any substance or combination of substances presented as having properties for treating or preventing disease in human beings” and is therefore concerned with how the product is presented. The question of how the product is presented is assessed, according to the ECJ, through the eyes of an averagely well-informed consumer.

The concept of treating disease would include claims that the product relieves symptoms or that it cures, remedies or heals a specific disease. Similarly, claims that a product protects or helps avoid disease would generally be perceived as claim to prevent disease. On the other hand, claims that a product maintains or helps maintain health or a healthy lifestyle would not generally be considered to relate to treating or preventing disease.

The impression formed by the consumer may be formed both based on the express words of the packaging, labelling and accompanying literature as well as on
advertisements, product form and targets of promotional material or on implications
drawn from such matters.

The second definition concerns “any substance or combination of substances which
may be used in or administered to human beings either with a view to restoring,
correcting or modifying physiological functions by exerting a pharmacological,
immunological or metabolic action, or to making a medical diagnosis” or in other
words the product’s function. The underlined words were inserted in the recent
amendments to Directive 2001/83 to aid in product classification and makes it more
likely than previously that certain nutraceuticals would be classified as a medicinal
product.

Directive 2001/83 makes clear that if there is doubt as to whether a product such as a
nutraceutical is a medicinal product, it will generally be treated as a medicinal
product.

The various national regulatory authorities then offer a more or less formal procedure
whereby advice or a ruling may be obtained by manufacturers as to the classification
of a particular product. It should be noted that classification decisions are not taken
centrally within Europe, but rather by each national regulatory authority. A recent
decision of the ECJ confirmed that it is quite possible for one member state to classify
a product as a medicinal product even if it is already lawfully marketed in another as a
food stuff.

… consequences of classification as a medicinal product

If a nutraceutical product is found to qualify as a medicinal product, then
consequences for the manufacturer are expensive and time-consuming:

- The product will need to be registered for a marketing authorisation.
- Pre-clinical and clinical testing must be undertaken to demonstrate safety,
  quality and efficacy.
- The product must be manufactured in accordance with the principles of GMP.
- Manufacture within the EU requires a manufacturing authorisation.
- Distributors will require a wholesalers’ licence.
- Batch release must be undertaken by a Qualified Person.
- Restrictions on advertising including a ban on advertising to the general public
  of prescription only medicinal products.

An important partial exception to this and which is significant in the field of
nutraceuticals concerns herbal medicinal products. These are defined as medicinal
products consisting exclusively of herbal substances (all mainly whole, fragmented or
cut plants, plant parts, algae, fungi and lichen in an unprocessed form) and/or herbal
preparations (preparations obtained by subjecting herbal substances to treatments such
as extraction, distillation, expression, fractionation, purification, concentration or
fermentation.). Directive 2001/83 was recently amended to introduce a simplified
registration procedure for such products where the product has indications appropriate
to traditional herbal usage and is intended and designed to be suitable for self-
medication.
Where these conditions are satisfied, there is no need to submit the results of clinical testing, provided adequate bibliographic information is submitted, and the product is not subject to the provisions of Directive 2001/83 on labelling and advertising.

It is clear that in developing a nutraceutical, one must decide at an early stage what claims are to be made in promoting the product. Even if it is not functionally a medicinal product, making the wrong claims can result in a medicinal classification and hence the need to comply with the comparatively onerous medicinal products regime. Worse still, criminal liability may arise where a nutraceutical classified as a medicinal product is marketed without an appropriate marketing authorisation. In the UK, the penalty is up to two years’ imprisonment and an unlimited fine.

… what about food regulation?

However, a ruling by one of the national regulatory authorities that a nutraceutical is not confirmation that the product may be lawfully marketed and sold under the law governing food. In addition to the general provisions of food law requiring minimum standards of product safety and labelling, there are specific pieces of additional legislation of particular relevance to nutraceutical products.

Firstly, European Parliament and Council Directive 2002/46 (Directive 2002/46) establishes specific regulations regarding food supplements, which are defined as “foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients [i.e. vitamins and minerals] or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.”

Directive 2002/46 sets out an exhaustive list of which vitamins and minerals may be used in marketed food supplements and specifies purity requirements to be met in their manufacture. This list may at a later stage be expanded to include other types of ingredient used in food supplements. The legislation also sets out upper safe limits of vitamins and minerals together with labelling requirements for setting out the quantitative nutrient content of the supplement and various other safety-related statements.

Secondly, Regulation (EC) No. 258/97 concerning novel foods and novel food ingredients applies to the placing on the market within the EU of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the EU and which fall within certain categories. These categories include foods containing, consisting of or made from genetically modified organisms, made using a novel production process that significantly changes the composition of the food and food isolating from micro-organisms, fungi or algae.

Foods and food ingredients falling within the scope of this Regulation must not present a danger for the consumer, mislead the consumer nor differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer. The Regulation requires that the marketing of such a food is approved in advance by a
competent authority of the member state concerned and that the product is labelled in the prescribed manner in particular informing consumers of the novel nature of the ingredient concerned.

In addition, Council Directive 79/112 prohibits any claim in the labelling or advertising of a food that it has tonic or medicinal properties, and imposes conditions on making the following claims:

- claiming a food is for a particular uses (e.g. food must be capable of fulfilling these and marked accordingly);
- reduced or low energy value claims (e.g. Reduced - energy must not be more than ¾ of that of similar food, Low – Energy must be not more than 40Kcal per 100g);
- protein claims (e.g at least 12g of protein);
- vitamin claims (e.g. rich in vitamin x, must provide at least 50% of the RDA of that vitamin);
- mineral claims (as for vitamin claims);
- cholesterol claims (e.g. should be no more than 0.005% cholesterol or properly indicated);
- nutrition claims (e.g. food must be capable of fulfilling these and marked accordingly);
- claims which depend upon another food. (e.g benefit claimed must not be partly from other food intended to be consumed with this one).

… further proposals

The EU is now considering a further proposal for the regulation of food supplement labelling. As currently drafted, this would prohibit claims suggesting that not consuming a food could affect health and that make reference to the rate or amount of weight loss a product could induce as well as those making reference to recommendations from individual health professionals or specific associations. Non-specific claims could be used if accompanied by a specific health claim from an authorised list. There is currently still disagreement as to whether claims would require pre-approval by the European Food Standards Agency or merely notification with authorisation being conditional on respecting the overall nutrient profile of the food.

The lesson emerging from this broadly regulated field is that great care needs to be taken in formulating the claims that are made concerning a nutraceutical product. As well as the need to comply with the regulations governing the marketing and sale of food, one needs to take great not to make any claim that could lead to classification of the nutraceutical product as medicinal unless strategically the manufacturer is prepared at any early stage to make the necessary investment to obtain a medicinal product marketing authorisation.

For further information please contact George at gpickering@reedsmith.com or visit www.reedsmith.com