

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

DEFINITION OF MEDICINAL PRODUCTS

Issue

This paper details the mechanism for the classification of medicinal products in the UK.

Background

1. The novel food regulation, (EC) 258/97, requires that all foods or food ingredients which have not been consumed to a significant degree prior in the EU prior to 15 May 1997 must undergo a premarket safety evaluation. Since (EC) 258/97 came into force, Member States have agreed a statutory definition of food. This definition appears in Article 2 of the 'General Food Law' regulation, (EC)178/2002 and states that **food** is:

“... any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment....”.

2. Article 2 of General Food Law also includes a number of categories that are not within the definition. These are:
 - (a) feed;
 - (b) live animals unless they are prepared for placing on the market for human consumption;
 - (c) plants prior to harvesting;
 - (d) medicinal products within the meaning of Council Directives 65/65/EEC and 92/73/EEC;**
 - (e) cosmetics within the meaning of Council Directive 76/768/EEC;
 - (f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC;
 - (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;
 - (h) residues and contaminants.
3. In the UK, responsibility for all aspects of medicinal legislation falls to the Medicines and Healthcare products Regulatory Agency (MHRA). Of particular relevance to the Food Standards Agency is the Medicines Borderline Section at the MHRA who determine whether or not a product is medicinal. A **medicinal product** is defined in Directive 83/2001/EC (as amended) and, in summary, must fulfil at least one of the following criteria:
 - (a) “Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; [*“the first limb”*]

and

(b) 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” [*“the second limb”*]

4. In determining whether a product falls within either or both limbs of the definition, MHRA Classifiers have to consider a wide range of issues not only relating to efficacy, but also aspects such as target populations, advertising material and labelling, perception, and the form that the product will be marketed (tablet, capsule). For additional information regarding classification MHRA have produced the Guidance Note, *A Guide to What is a Medicinal Product*, attached at **Annex 1**.
5. Medicinal legislation takes priority over food law so if the MHRA view a product as medicinal then, as indicated in paragraph 2, it cannot in law be a food. However unlike food law, whose interpretation is harmonised throughout the EU, the authorities in individual Member States are responsible for interpreting the medicinal products legislation and for determining whether a product is medicinal or not. They are obliged only to alter their view in respect of a judgement from the European Courts of Justice, who have confirmed that determinations of a given product may vary between Member States. On occasions this means that products which are viewed to be medicinal in some Member States can still seek authorisation via the novel food regulation (EC) 258/97 in order to be sold as foods in the others.
6. As a relatively large number of novel foods are developed with perceived ‘health benefits’ the Food Standards Agency regularly contacts the MHRA for a view on the status of individual products. If we are advised that a product is viewed to be medicinal then the Agency would not accept an application for authorisation under (EC) 258/97 as the ‘lead’ Member State. If the MHRA viewed a novel food which had been assessed by another Member State to be medicinal then this would be reflected in the UK response. If such a scenario were to arise the Committee could also be asked for advice on the product as a food, and any safety concerns would be also reflected in our official response.

Committee Action Required

7. Members are asked to note the position described in this paper. (A Classifier from the MHRA’s Medicines Borderline Section will be present to answer any questions that the Committee may have on the procedures for determining the medicinal status of products.)

**Secretariat
September 2009**

Annex attached:

Annex 1 MHRA Guidance Note 8 *A guide to what is a Medicinal Product*

ANNEX 1 to ACNFP/94/12

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**MHRA Guidance Note 8
'A guide to what is a Medicinal Product'**

**Secretariat
September 2009**