THE BORDER LINE BETWEEN MEDICINES AND FOOD IN THE EU

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In the United Kingdom, the Veterinary Medicines Directorate (VMD) is responsible for the regulation of veterinary medicinal products (VMPs) and contributes to the assessment of feed additives, although the latter are ultimately, the responsibility of a different authority in the UK, the Food Standards Agency (FSA), who work closely with the European Food Safety Authority (EFSA). Regulation of human medicines is carried out by the Medicines and Healthcare products Regulatory Agency (MHRA).

European legislation provides the definition of the various products that may be given to animals and humans but there are many occasions where it is not immediately obvious under which category a particular product or group of products falls. These are often known as "borderline products" and a considerable amount of time and effort is invested by Member States to decide how, if at all, each product should be regulated. Since a lot of EU legislation is also transposed into national law, different member states sometimes have different interpretations which can add further confusion to these matters, although there is a growing amount of cooperation to reduce this to a minimum.

Generally, for human products, the range of definitions is much better developed, and therefore it is often necessary to consider these also when considering how to classify products for animal use. Since a lot of products, especially those that people will choose to buy to administer to themselves or to their animals, are oral formulations, the borderline between medicines, food and food supplements/ additives is one of the most commonly encountered situations.

Some definitions from primarily human legislation are presented below:

MEDICINE

Article 1(2) of Directive 2001/83/EC (as amended): "Any substance, or combination of substances presented as having properties for treating or preventing human diseases...or administered....with a view to restoring, correcting or modifying physiological, immunological or metabolic action..."

(It is worth noting here that there is no EU definition of 'disease', but in the UK the MHRA have their own: "any injury, ailment or adverse condition, whether of body or mind".)

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HERBAL MEDICINES

It claim to treat/cure/prevent a disease/ adverse condition or restore/correct/modify physiological function. As a result of the Traditional Herbal Medicinal Products Directive (THMPD), since April, 2011 all herbal products in the UK have to be registered with the MHRA and their health claims must be supported by scientific evidence and be understandable for the average consumer.

BOTANICALS

Although there is no EU legal definition, EFSA uses this term to describe 'whole, fragmented or cut plants, or parts thereof, algae, fungi and lichens' which can have physiological function and may make claims for effect (to maintain/improve/support/ optimise normal physiological processes within the boundaries of homeostasis).

FOOD

Article 2 of Regulation (EC)178/2002: "Any substance or product, whether processed, partially processed or unprocessed intended to be, or reasonably expected to be ingested by humans...."

Human food ingredients can also make health claims and even disease risk reduction claims, subject to approval by EFSA following assessment of the data submitted. Since 2009, 40,000 applications from across all 27 EU Member States have been collated (a lot of which were duplications) and approximately 3,000 health claims were assessed (all 1,549 claims relating to botanicals failed). These can all now be found on the European Commission's website.

DIETETIC FOODS

Regulation (EC) 178/2002 also describes PARNUTs (foods for PARticular NUTritional use) which include foods for special medical purposes, 'slimming foods', foods for athletes and for infants and young children.

FOOD SUPPLEMENTS

Directive 2002/46/EC explains that these are foodstuffs to supplement the normal diet which are concentrated sources of nutrients or other substances with a nutritional or physiological effect and are marketed in dose form and hence designed to be taken in measured small unit quantities. However it also states that "There is a wide range of nutrients that might be present in food supplements including..various plant and herbal extracts.....Other than vitamins and minerals....until specific Community rules are adopted,...national rules may be applicable".

Due to these various definitions, it is possible for a single food type to be formulated and presented in different ways so that garlic can be regarded as a food, a food supplement and an herbal medicine.

For completeness, whilst considering the situation for human products, it should also be noted that there are other legal definitions that must be considered when trying to classify a product.

MEDICAL DEVICES

Only occur in human legislation and are subject to Directives 93/42/EC and 98/79/EC. Their classification takes into account their intended purpose, their presentation and the method by which the principal intended action is achieved, which must be primarily through physical means (they may only be *assisted* by pharmacological, immunological or metabolic means).

The fact that there is no legislation for medical devices in animals means that, certainly in the UK, we have some products which have been classified as veterinary medicines even though their action is mainly physical (eg Animalintex a poultice dressing for use in horses).

COSMETICS

Directive 76/768/EC, as amended: "any substance or preparation intended to be placed in contact with the various external parts of the human body... or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition". Therefore any product seeking a claim to treat gingivitis must be approved as medicine (eg Corsadyl mouthwash in the UK).

In considering these two further categories, it soon becomes obvious that another food ingredient, ginger, could similarly also be classified as a food supplement, a medicinal product or a cosmetic. Furthermore, in the UK, an identical formulation of a product, known as E45 cream is sold as three different products; a cosmetic, a device, and a medicine.

Having explored the way that human products are classified, it is interesting to see how this has been transposed to the veterinary situation. As there is a less comprehensive list of definitions, the classification at times ultimately falls down to a hierarchy where one set of legislation takes precedence over others.

In January 2011 the European Commission published a recommendation establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products, the highlights of which are summarised below:

ANIMAL FEED

Article 3(4) of Regulation (EC) No 178/2002 (1): **"**any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals."

Following on from this broad definition of feed, recital 3 of Regulation (EC) No 767/2009 states that 'feed may take the form of feed materials, compound feed, feed additives, premixtures or medicated feedingstuffs.'

'Feed materials'

Products of vegetable or animal origin, whose principal purpose is to meet animals' nutritional needs, in their natural state, fresh or preserved, and products derived from the

industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of premixtures;

'Carrier': A substance used to dissolve, dilute, disperse or otherwise physically modify a feed additive in order to facilitate its handling, application or use without altering its technological function and without exerting any technological effect itself;

PARNUTs ('feed intended for particular nutritional purposes'): Feed which can satisfy a particular nutritional purpose by virtue of its particular composition or method of manufacture, which clearly distinguishes it from ordinary feed. Examples of particular nutritional purposes approved by EFSA include 'support of liver function in the case of chronic liver insufficiency', 'reduction of urate stones formation' or 'reduction of the risk of milk fever'. Feed intended for particular nutritional purposes does not include medicated feedingstuffs within the meaning of Directive 90/167/EEC;

FEED ADDITIVES

Article 2(2)(a) of Regulation (EC) No 1831/2003 (2): "substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more specific functions that are enumerated in Article 5(3) of the Regulation:

(a) favourably affect the characteristics of feed;

(b) favourably affect the characteristics of animal products;

(c) favourably affect the colour of ornamental fish and birds;

(d) satisfy the nutritional needs of animals;

(e) favourably affect the environmental consequences of animal production;

(f) favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs; or

(g) have a coccidiostatic or histomonostatic effect."

It is only products in section (g) that the VMD helps to assess. From the above it is also worth noting that a product cannot be a feed material and a feed additive at the same time, and although feed additives are defined by their functions as laid down in Article 5(3) of Regulation (EC) No 1831/2003. However, these functions are not exclusive to feed additives. Thus, a feed material can also exert an additive function (e.g. as a thickener) but this should not be the only intended use. It should also be noted here that there is no definition for veterinary food supplements.

BIOCIDAL PRODUCTS

Article 2(1) of Directive 98/8/EC (1): "active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a

controlling effect on any harmful organism by chemical or biological means"

Annex V to Directive 98/8/EC contains an exhaustive list of 23 product types with an indicative set of descriptions within each type. Product-type 20 has the following definition:

'Preservatives for food or feedstocks': Products used for the preservation of food or feedstocks by the control of harmful organisms.

However, Point 1(a) of Annex I to Regulation (EC) No 1831/2003 also has the definition:

'Preservatives': substances or, when applicable, micro-organisms which protect feed against deterioration caused by micro-organisms or their metabolites.

By virtue of Article 1(2) of Directive 98/8/EC, products that are defined or that fall under the scope of the feed legislation, including preservatives, are not biocidal products but are to be considered as feed as the feed legislation takes precedence over the legislation on biocidal products.

VETERINARY MEDICINAL PRODUCTS

Article 1 of Directive 2001/82/EC (1) very much mirrors the human definition with two limbs:

"(a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or

(b) any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis"

Fulfilling the criteria of the first limb is said to make the product "medicinal by presentation" and if the criteria the second limb apply it is deemed to be "medicinal function".

MEDICATED FEEDINGSTUFFS

Directive 2001/82/EC defines these as "any mixture of a veterinary medicinal product or products and feed or feeds which is ready prepared for marketing and intended to be fed to animals without further processing, because of its curative or preventive properties or other properties as a medicinal product covered by the definition '*veterinary medicinal product*." It should be noted, however, that medicated feedingstuffs are not VMPs but, according to recital 3 of Regulation (EC) No 767/2009 "a form of feed containing medicated pre-mixes and being subject to a prescription by a veterinarian."

Finally, Article 2(2) of Directive 2001/82/EC also states "In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'veterinary medicinal product' and within the definition of a product covered by other Community legislation, the provisions of this Directive shall apply."

Therefore, if, after consideration of all the characteristics of an unclassified product, the conclusion is that it might be a VMP, it should be considered a VMP as this legislation takes precedence over feed legislation, except for authorised feed additives.

As has been demonstrated above, the classification of veterinary medicinal products is certainly not an easy process so takes considerable resource. In the UK, the VMD is responsible for enforcing the legislation to ensure that no products that fulfil either of the limbs of the definition of a VMP are marketed without a Marketing Authorisation. Since October 2011 the VMD has run a formal classification scheme to give companies the assurance their products do not fall under the definition of a VMP. Since it has also been noted above that a single formulation can satisfy the criteria for more than one type of product, we require all the labelling and promotional material for the product to be submitted so that any claims for the product can also be assessed. There is a fee for this service and full details of the scheme can be found in "Veterinary Medicines Guidance Note 1 – Controls of Veterinary Medicines" which is available on the VMD's website. www.vmd.defra.gov.uk.

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EU MEDICINES DIRECTIVE "The loaded gun that can turn foods and supplements into drugs" Official reference: Directive 2001/83/EC, as amended, including Directive 2004/27/EC ANH EU law thumbnail summary No 1 (April 2011)