Clarification on the scope and definition of medicinal law in relation to foodstuffs.

1. Background

Directive 2004/27/EC[1] on medicinal products, amending Directive 2001/83, provides a revision of the definition of medicinal product, reading as follows:

"*Medicinal product:*

(a) *Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or*

(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 concept of "pharmacological", "immunological" or "metabolic" action is inserted in order to specify the type of action that the medicinal product may exert on physiological functions. It has proved it's usefulness in medical devices legislation, where it is used to define the principle intended action as opposed to what is considered as medicinal.[2]
It is therefore necessary to include the same three principles in the general definition of medicinal product. Furthermore, this enumeration of actions is necessary in addition to cover a number of novel medicinal products such as gene therapy, radiopharmaceutical products as well as certain medicinal products for topical use, hitherto insufficiently covered by the current definition of medicinal product.

It should be noted that this definition of medicinal product is applicable only to medicinal products for human use intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process, as specified in article 2.
It has been devised precisely as largely as possible because of the necessity to encompass all types of products with a medicinal property, including such novel medicinal products as gene therapy etc.

Because of this, this definition, taken out of its medicinal context, might also cover non-medicinal products. However, it is absolutely clear, that that this is not the purpose, nor the intention. The definition of medicinal products must be considered in the context of medicinal legislation and cannot be applied to other categories of products that are regulated by specific legislation, as is indisputably clear from whereas 7[3], stating: *" ... Where a product comes clearly under the definition of other product categories, in*

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[1] Directive 2004/27/ec of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

[2] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1): "For the purposes of this Directive, the following definitions shall apply: (a) 'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:
— diagnosis, prevention, monitoring, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
— investigation, replacement or modification of the anatomy or of a physiological process,
— control of conception,
and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means"
Likewise though not completely identical : Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17); Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1):

[3] "Particularly as a result of scientific and technical progress, the definitions and scope of Directive 2001/83/EC should be clarified in order to achieve high standards for the quality, safety and efficacy of medicinal products for human use. In order to take account both of the emergence of new therapies and of the growing number of so-called 'borderline' products between the medicinal product sector and other sectors, the definition of 'medicinal product' should be modified so as to avoid any doubt as to the applicable legislation when a product, whilst fully falling within the definition of a medicinal product, may also fall within the definition of other regulated products. *This definition should specify the type of action*

particular food, food supplements, medical devices, biocides or cosmetics, this Directive should not apply. …".

Any definition, so also the definition of medicinal product, must be considered not partially but as a whole. Essential elements for a medicinal property are a therapeutic, preventive or diagnostic purpose (as defined in part 'a' of the definition). Products that would be in conformity with part 'b' only, thus being able to modify a physiological function, but without possessing (or being presented as having) therapeutic, preventive or diagnostic properties, can therefore not be considered a medicinal product. This definition therefore cannot be applicable to foodstuffs.

Likewise, the new article 2.2 that reads: "*In cases of doubt, where**, taking into account all its characteristics,** a product **may fall** within the definition of **a** 'medicinal product' **and within the definition of a product covered by other Community legislation the provisions of** this Directive shall apply.*", must not give doubt about its scope of application. It is only meant for 'borderline' products where it is not clearly possible, taking into consideration all their characteristics, including their therapeutic, preventive or diagnostic properties, to determine under which legislation the product should be regulated. If such doubt exists, then for the sake of consumer protection, medicinal law should prevail. It is not intended to challenge the status of products currently on the market in full compliance with relevant legislation, such as foodstuffs.

As a conclusion, the European Commission clearly states that the modification of the definition of a medicinal product and of scope of application of Directive 2001/83/EC does not aim at and should not be interpreted as prohibiting the marketing of a product or taking off the market a product that has fulfilled all the legal requirements set by EU food legislation.

In the light of the argumentation presented above, the legal status of a given product considered a case of doubt should be assessed on a case by case basis, taking into account all its characteristics, as established by Court jurisprudence (including, amongst others, the pharmacological properties of the product, the product characteristics, its composition, the adjuvants entering into the composition, the possible side-effects, the risk which its use may entail, in particular prolonged consumption, the products presentation and degree of distribution, the product's familiarity to the consumer).

Food legislation specifies that substances used in foods may have nutritional and physiological effects. Furthermore, the fact that certain substances can be used in both medicinal products and foodstuffs is clearly recognised by legislation on food supplements and traditional herbal medicinal products. The new medicinal product legislation was not intended to prohibit the use of these substances in non-medicinal products when such use occurs without therapeutic purpose and such products are fully in conformity with food legislation.

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that the medicinal product may exert on physiological functions. This enumeration of actions allows in addition to cover medicinal products such as gene therapy, radiopharmaceutical products as well as certain medicinal products for topical use. Also, in view of the characteristics of pharmaceutical legislation, provision should be made for such legislation to apply. With the same objective of clarifying situations, where a given product comes under the definition of a medicinal product but could also fall within the definition of other regulated products, it is necessary, in case of doubt and in order to ensure legal certainty, to state explicitly which provisions have to be complied with. **Where a product comes clearly under the definition of other product categories, in particular food, food supplements, medical devices, biocides or cosmetics, this Directive should not apply.** It is also appropriate to improve the consistency of the terminology of pharmaceutical legislation."