ANH BRIEFING PAPER
Definition of a medicine: analysis of terms

This briefing paper attempts to show how the definition proposed by the European Commission (as shown in paragraph 9 of this paper) is scientifically irrational and leads to very substantial legal uncertainty, particularly when compared to the definition proposed by the Committee on the Environment, Public Health and Consumer Policy (paragraph 6 of this paper).

1. The proposed amended definition of "medicinal product" in Article 1(2) of the Pharmaceuticals Directive (Directive 2001/83/EC) is as follows:[1]

   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 **with a view to** making a medical diagnosis or to **restoring, correcting or modifying physiological functions**.

2. Physiological functions are clearly those functions relating the physiology of an organism, while physiology refers to the branch of biology or medicine "concerned with the vital functions of plants and animals, such as nutrition, respiration, reproduction, and excretion."[2]

   Narrowing the scope of the term physiology further, and applying it more specifically to the human and medical context, a definition of "physiology" is given[3]:

   > **Physiology:** The study of how living organisms function including such processes as nutrition, movement, and reproduction.
   >
   > The word "function" is important to the definition of physiology because physiology traditionally had to do with the function of living things while anatomy had to do with morphology, the shape and form, of things …
   >
   > Human physiological processes are the functions of living persons and their parts, and the physical and chemical factors and processes involved.

3. Therefore, a medicinal product, which is regarded by a long-standing definition (originating in Europe in Directive 65/65/EEC and reiterated in Directive 2001/83/EC) as any substance that restores, corrects or modifies physiological functions, must, by definition, include all nutritional substances. This must be the case as macro-nutrients (carbohydrates, fats, proteins) or micro-nutrient (vitamins minerals, amino acids, essential fatty acids, probiotics, enzymes, fibre, phytonutrients, etc.) constituting nutritional substances will give rise to some alteration in physiological function.

4. It is clear, therefore that the current definition of a medicinal product completely subsumes the new definition of a food supplement given in the Food Supplements (Directive 2002/46/EC), Article 2(a):

   > "food supplements" means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients 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

[1] Article 1(1)(b) of the Common Position.
[2] Oxford Concise Science Dictionary, Oxford University Press, 1987.
[3] Medical Dictionary, MedTerms.com: http://www.medterms.com/script/main/art.asp?ArticleKey=8223.

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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;

5. This situation can be seen schematically in Figure 1 below, both in relation to foods and food supplements:

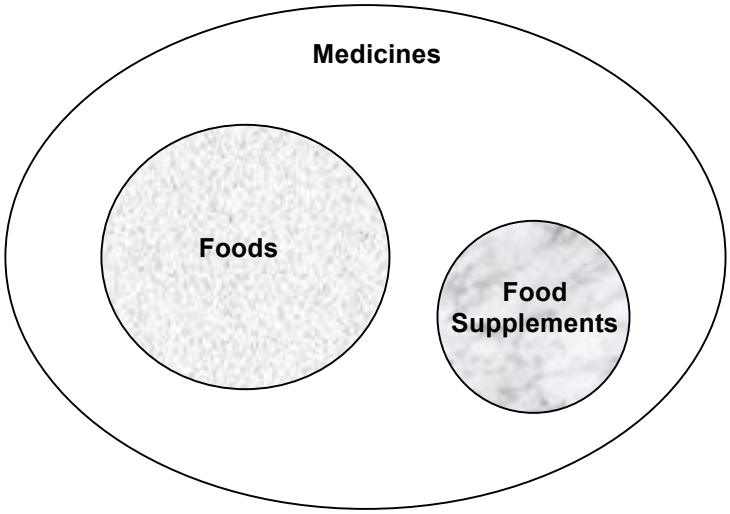

Figure 1. Broad definition of a medicine, subsumes both foods and food supplements.

6. The Committee on the Environment, Public Health and Consumer Policy ('Environment Committee') attempted to reduce the legal uncertainty caused by the broad definition of a medicine by suggesting that a medicine, as a subset of those substances that cause alterations of physiological functions, be distinguished by their more specific mode of action, namely their "pharmacological action"; viz[4]:

> Any substance or combination of substances which may be used in human beings ***either*** with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions ***by exerting a pharmacological action.***

7. "Pharmacological action" in the context of this modified definition is considered to be a drug-like action, since pharmacology refers to the discipline concerned with the study of drugs. Pharmacology can be defined as follows[5]:

> The study of drugs, their sources, their nature, and their properties. Pharmacology is the study of the body's reaction to drugs. It emerged as a major area in American medicine largely due to the efforts of John Jacob Abel (1857- 1938) who stressed the importance of chemistry in medicine, did research on the endocrine glands, first isolated epinephrine (adrenaline), crystallized insulin (1926), and became the first pharmacology professor in the U.S.

A more concise definition of pharmacology is:

[4] Amendment 7, Article 1 (2)(b), Recommendation for Second Reading on the common position adopted by the Council with a view to adopting a European Parliament and Council directive amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (10950/03/2003 – C5-0464/2003 – 2001/0253(COD)), Committee on the Environment, Public Health and Consumer Policy, 2 December 2003 (RR\515944EN.doc).

[5] Medical Dictionary, MedTerms.com: http://www.medterms.com/script/main/art.asp?ArticleKey=4859.

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The study of the origin, nature, properties, and actions of drugs and their effects on living organisms.[6]

8. Therefore, according to the definition proposed by the Environment Committee, a medicine is a substance, in principle, which has both a physiological effect *and* a drug-like action. Although there is undoubtedly some circularity of argument (because a medicine is equivalent to a drug), this definition creates an important delineation between drugs and other substances such as foods and food supplements which may have physiological effects, yet are not drug-like in their action, therefore are not used specifically with a view to "… restoring, correcting or modifying or physiological functions". This situation has given rise to a *status quo* among food supplement manufacturers who sell food supplements legally under national food laws without making medicinal or health claims.

   The delineation achievable through the Environment Committee's proposed definition is shown in Figure 2.

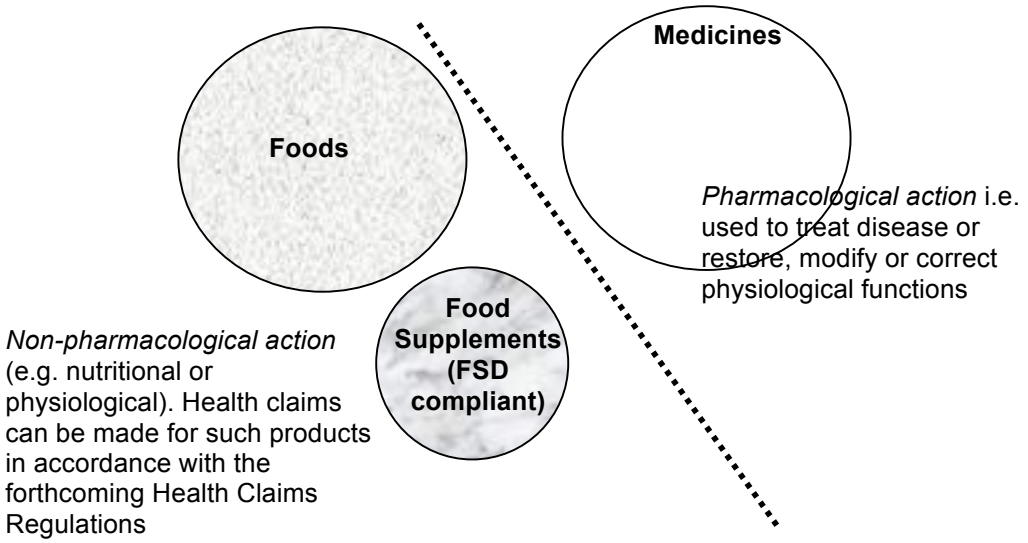

Figure 2. Division between medicinal products, food supplement and foods according to pharmacological action, as proposed by the Committee on the Environment, Public Health and Consumer Policy

9. The Commission, however, made a suggestion in April 2003 in its response to the Parliamentary position[7] which dramatically reduces clarity of the definition. This suggestion is again, at this very late stage, being put forward in a compromise package by the Rapporteur for the Directive, Mme Françoise Grossetête. The suggestion largely neutralises the clarification sought by adding "… exerting a pharmacological action" through inclusion also of "… metabolic and immunological actions." The relevant paragraph from the Commission's response is included below:

[6] Online Medical Dictionary: www.online-medical-dictionary.org/omd.asp?q=pharmacology.

[7] Commission of the European Communities, Amended proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, 3 April 2003, COM(2003) 163 final.

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Amendment 11 on further clarifications of the definition of a medicinal product. A reformulation is needed to refer, in addition to pharmacological action, to immunological and metabolic action. This addition helps to better specify the definition of medicinal product and is in line with Article 1(2)(a) of Council Directive 93/42/EEC on medical devices:

"Article 1, point 2 b:
b) Any substance or combination of substances which may be used in human beings ***either*** *with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions* ***by exerting a pharmacological, immunological or metabolic action.****"*

10. Since both immunological and metabolic actions (see paragraphs 11 and 12 below) can be construed to cover all possible actions that give rise to physiological functions in the body (principally because a 'metabolic action' is necessary in order to affect a physiological function), there is no scientific rationale in including the two terms "immunological" and "metabolic" in a revised definition. Indeed, it would again create unnecessary legal uncertainty, especially in comparison with the definitional change proposed by the Environment Committee. It would also further confuse the forthcoming and proposed Health Claims Regulations since any food or food supplement for which a health claim was made, would effectively become a medicinal product (cf. by contrast with Figure 2).

11. Since immunological actions are those that result from the bodies' response to foreign, or potentially harmful substances (including antigens, biocides, etc.), such actions may occur as a consequence of ingesting foods, particularly if they are contaminated with pathogens, tainted with chemicals (including biocides) or contain certain food additives. These situations are common: the Centre for Disease Control in the USA (where such data are readily accessible) estimates that foodborne pathogens cause 76 million human illnesses, 325,000 hospitalizations, 5,200 deaths, and an unknown number of chronic conditions annually.[8]

12. Metabolic actions refer to all those biochemical actions that occur within living organisms. An organism can only survive and maintain its health as a result of exposure to substances that ensure metabolic function. A metabolic action will result from consumption of all foods, water and other innocuous substances essential to survival and health. Therefore, inclusion of "metabolic action" in the definition of a medicine provides no refinement or further clarity compared with the original definition of a medicine as stated in the Common Position of the Council.

13. Therefore, for the purposes of scientific rationality and as a means of reducing legal uncertainty, the Environment Committee's suggested amendment to the Common Position would be a preferred approach to refinement of the definition of a medicine compared to that of the Common Position or compromise package. However, its weakness is the circularity of meaning inherent in the term pharmacological.

14. In order to minimise blurring between the definitions of medicines and other groups non-medicinal product such as foods, food supplements, cosmetics and medical devices, it would be appropriate to specify exclusions within the actual definition (Article 1), as indicated in a separate ANH Briefing Note.[9]

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[8] Surveillance for Foodborne Disease Outbreaks - United States, 1993-1997, Vol. 49, No SS01;1 03/17/2000: ftp://ftp.cdc.gov/pub/Publications/mmwr/SS/SS4901.pdf.

[9] *ANH Briefing Note*: Pharmaceuticals Review (Directive 2001/83/EC); included as a news item at http://www.alliance-natural-health.org/index.cfm?action=news&ID=56.

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