

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

Synonyms:

Human Medicinal Products Directive, Pharmaceutical Directive, Human Medicinal Code

Challenges for natural health

- Two limbs of definition; presentation (Article 1.2(a)) and functional (Article 1.2(b)) technically make all foods and cosmetics medicines
- Presentation limb makes any product presented to treat or prevent disease a medicine
- Functional limb makes any substance a medicine if it restores, corrects or modifies physiological functions and exerts a pharmacological, immunological or metabolic effect
- Exceptions for foods, supplements and cosmetics that are “clearly” such (7th sentence of 7th recital of amending Directive)
- If there is doubt, medicinal law has supremacy over any food or other EU law (=“rule of doubt”). This is the ‘loaded gun’ that can be used arbitrarily to classify any food or food supplement as a medicine
- The borderline between foods and medicines is unclear and implemented differently by different Member States
- Medicinal classification by function can be based on the presence of particular ingredients in a product as well as their amounts

Solutions for natural health

- Avoid making medicinal claims
- Prevent regulators making unjustified medicinal classifications
- Use mutual recognition to stop products sold as foods in one EU Member State being classified as medicinal in another
- Need more clarity from European Court of Justice on food/medicine borderline (ANH herb challenge aims to facilitate this)
- Scope of definition of a medicine needs to be amended by lobbying and/or challenge

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