

ANH PRACTITIONERS SUMMARY: HUMAN MEDICINAL PRODUCTS DIRECTIVE (HMPD)

Official 'Europa EU' Summary of Legislation
<http://europa.eu/scadplus/leg/en/lvb/l21230.htm>

'This Directive establishes a Community code which brings together, in a single instrument, all the provisions in force governing the placing on the market, production, labelling, classification, distribution and advertising of medicinal products for human use'.

The Directive states that 'no medicinal product may be placed on the market of a Member State unless an authorisation has been issued by the competent authorities of that Member State or the European Medicines Agency...Certain particulars and documents must be included with the authorisation request, including the name and constituents of the medicinal product, the manufacturing method, therapeutic indications, contra-indications and side-effects, posology, method and route of administration, expected shelf-life, precautionary and safety measures during storage and administration of the medicinal product and disposal of waste, the risk to the environment, a description of control tests employed by the manufacturer, the results of pharmaceutical, pre-clinical and clinical tests, and a copy of any marketing authorisation obtained in another Member State or non-member country'.

- **The Law that can turn Natural Health Products into Medicine.** The directive's definition of a medicinal product effectively makes all foods technically drugs as it indicates that 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*" should be classified as a medicinal product. It is only a weak paragraph in the preamble of the directive (Recital 7) that excludes products which are "*clearly foods and food supplements*" from the onerous imposition of a full drugs regime.

Following the amendment to HMPD in 2004, homeopathy and homeopathic medicines now reside within this directive, although they are subject to a simplified authorisation procedure.

- **The 'Loaded Gun' Supremacy Clause.** This directive for European pharmaceutical products includes a supremacy clause (Article 2(2)), which gives ultimate power, in cases of "*doubt*", over any other EC law, even if another law applied previously. It effectively represents the 'loaded gun' that can be used, at the regulators' discretion, to classify virtually any food, supplement, or product as a medicine, and arbitrarily enforce upon it a 'drugs regime'.