EU HERBAL DIRECTIVE

"A simplified medicinal licensing system for phytopharmaceuticals"

Official reference:
Directive 2004/24/EC (a 'sub-Directive' of Medicines Directive, 2001/83/EC)
Synonyms:
Traditional Herbal Medicinal Products Directive, THMPD

Challenges for natural health

- A simplified medicines registration scheme, which involves proving quality and safety, but not efficacy, which is based instead on evidence of long standing safe use of product
- Stringent eligibility requirements for both proving long-standing safe usage (30 years, of which 15 years are in the EU) of specific products and combinations
- Only for products which are intended for use without the supervision of a practitioner (i.e. off-the-shelf products aimed for direct use by consumer)
- Only for minor, self-limiting conditions
- Locks out many, if not most, products associated with non-European traditions; prefers European phytopharmaceuticals, including single herb alcoholic/acetone extracts
- Non-herbal ingredients locked out, except 'ancillary' vitamins & minerals
- Technically very difficult and expensive to meet data requirements for quality and safety, as set out by the European Medicines Agency, especially for polyherbal products where herbs not present in European pharmacopoeia
- Very costly for polyherbal products

Solutions for natural health

- As for Medicines Directive
- Prevent regulators making unjustified medicinal classifications
- Use mutual recognition to stop products sold as food supplements in one EU Member State being classified as medicinal in another
- Judicial review aims to 'fix' deficiencies of THMPD to make it accessible to all herbal traditions
- A separate EU regulatory framework for the practice of traditional systems of medicine is required

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