ANH PRACTITIONERS SUMMARY:
TRADITIONAL HERBAL MEDICINAL PRODUCTS

Official 'Europa EU' Summary of Human Medicines Legislation:
http://europa.eu/scadplus/leg/en/lvb/l21230.htm
The Traditional Herbal Medicinal Products Directive is a sub-directive of the parent Human Medicinal Products Directive.

Official European Commission, Enterprise and Industry site:
http://ec.europa.eu/enterprise/pharmaceuticals/herbal/herbal_en.htm

'Fast-track Drugs Licensing Regime' for Limited Eligible Herbal Products. Provided that there is evidence that a herbal product has been used safely for 30 years (15 of which must be in Europe), and that it satisfies stringent pharmaceutical requirements, then the onerous safety and efficacy testing required for conventional drugs licensing is avoided for that herb. This directive effectively turns licensed herbal products into 'medicinal' products, and therefore allows 'medicinal claims' to be made (limited to products treating minor ailments only, which "are intended and designed for use without the supervision of a medical practitioner".

- **Discrimination against non-European Herbal Traditions**. The 30-year rule, requiring 15 years of EU use, discriminates against non-European traditions such as Ayurveda, Traditional Chinese Medicine, Amazonian, southern African and numerous other traditions, which are among the longest and most developed worldwide.

- **Food Supplements might be categorised as Herbal Medicinal Products**. There is a significant risk that, in some European member states, many botanicals (that should rightly be considered as food supplements) will be considered by competent authorities as 'herbal medicinal products'. If they then are not eligible, or the cost of obtaining the drugs license is prohibitive for the applicant, the use of such products will be lost forever.

- **Particular combinations of Herbal Products may be disallowed**. The traditional use must be for an individual herb or specific combination of herbs, thus preventing use of new or innovative combinations that might be supported by emerging science.

- **Herbal Products containing significant levels of nutrients will be prohibited.** Combinations with vitamins and minerals will be allowed only if the action of the nutrients is considered 'ancillary' to that of the herbal ingredients.

- **Products will be subject to Pharmaceutical Stability Tests**. It will be necessary for manufacturers to demonstrate six months' stability of mixtures, wholly inappropriate, difficult or impossible for organic, reactive polyherbal mixtures (especially complex tinctures containing 3 or more herbs), which contrast markedly from the stable, toxic, new-to-nature molecules which characterise most drugs. These mixtures have been used safely and with demonstrated benefit in specific medicinal cultures, often for centuries (eg Indian/Ayurvedic, southern African, South American, traditional Chinese, South-East Asian and other cultures).

- **Increased cost to consumer**. Significant compliance costs will apply, which will need to be passed on to consumers. This may make their cost uneconomic for some.

- **Committee control.** Authorisations will be controlled by the Committee for Herbal Medicinal Products, which is weighted strongly towards drug pharmacologists, as opposed to practising medical herbalists.