The EU Traditional Herbal Medicines Directive 2004/24/EC

Costs: Earlier cost estimates to register herbal medicines - £50,000 potential maximum cost per medicine (£20,000 to compile a dossier, and extra costs for site inspections, registration fees etc).

As the Directive came into force, estimates ranged from £80,000 to £120,000 for the licensing process.

Talking Points

Cost

Small producers of herbal medicines simply won't be able to afford to register their products and receive a license to place new, innovative herbal medicines on the UK market. Global Regulatory Services have estimated the cost at £50,000 per item. The UK Regulator, Medicinal and Healthcare Products Registration Agency, has estimated the cost at $70,000 (roughly £45,000).

Impractical

The 30-year-rule prohibits the use of older remedies as well as new remedies being put on the market. The directive stifles innovation and investment in the traditional herbal medicine sector.

Choice

Before the directive, individuals were free to choose between pharmaceutical medicines and traditional herbal medicines to treat ailments. Now by applying pharmaceutical-style testing to traditional herbal medicines, the directive applies costs affordable by big pharmaceutical companies but not by small herbal outlets. The resulting costs limit the choice offered to consumers as smaller producers pull products from the market.

What is it?

A directive to regulate the sale of traditional herbal medicines in the EU.

The directive creates an EU-wide regulatory approval system for all traditional herbal medicines previously sold over the counter. The UK Medicines and Healthcare Products Regulatory Agency (MHPRA) is the UK body to approve all herbal medicines sold in the UK and ensure they meet EU standards through the Traditional Medicines Registration Scheme. The directive forces regulatory bodies to apply pharmaceutical-style tests to herbal medicinal products to demonstrate safe use.

Anyone who places herbal medicines on the UK market will have to apply for a registration license for every medicinal product from the MHPRA. Importers and wholesalers of herbal medicines will need to apply for a license to handle traditional herbal medicinal products.

The directive states that traditional herbal medicines must be shown to have been in safe use for 30 years in the EU (or at least 15 years in the EU and 15 years elsewhere) for it to be licensed and obtainable over the counter. Obviously, this means that herbal medicines out of fashion can still be sold but newer herbal medicines are blocked under the directive. On the flip side, those that were used more than 30 years ago, and may come back into fashion, will be blocked by the directive.

All products sold as herbal medicines will need to gain a license by 2011 or will be prohibited under the directive.

The medicines suitable for registration from 2011 include herbal medicines that:

- Are taken orally, externally or by inhalation. Medicines that are taken intravenously are prohibited.
- Are intended to be used without a doctor's supervision.
- Are proven to have been safely used for at least 30 years (15 in the EU, 15 outside, minimum) and the medicinal make up recognised by the regulator.
- The regulator must be satisfied that the products are safe, of a suitable quality and effective, along the same guidelines to test pharmaceuticals.
- Provide sufficient genotoxic data.
- Comply with pharmaceutical 'good management practices'.

Third Party Opinions

"Several tens of thousands of pounds are the additional costs associated with registering a product under the Directive as compared with the cost for an unlicensed herbal remedy placed on the largely unregulated market." Wieland Peschel, Centre for Pharmacognosy and Phytotherapy, School of Pharmacy, University of London

"Herbs have been freely available to herbalists and the public since the beginning of time and this should be allowed to continue. Herbalists have been able to practise freely under common law and voluntary self regulation of their professional associations, maintaining an excellent safety record and this should be allowed to continue." Save our Herbs Campaign.

"Ric Hobby, chairman of the UK's Council for Responsible Nutrition (CRN), said the costs of registering herbal medicines, establishing Good Manufacturing Processes and tracing herbs back to

the farm will compel some traders to pull products from the market, others to increase prices and others to go out of business completely." Ric Hobby, Chairman, Council for Responsible Nutrition quoted in Functional Ingredients Magazine.

"At least 50 herbs, including horny goat weed (so-called natural Viagra), hawthorn berry, used for angina pain, and wild yam will no longer be stocked in health food shops" British Herbal Medicine Association.