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NEWS

New European rules require all herbal medicines to be registered

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Since 1 May all traditional herbal medicines available in health food shops, pharmacies, and other outlets in the European Union must be formally registered and approved before they can be sold. The new rules mean that only products whose use is "plausible on the basis of longstanding use and experience" and whose quality and safety are guaranteed will be licensed.

The new requirements are set out in the EU's Traditional Herbal Products Directive. Agreed in 2004, the directive gave manufacturers of traditional herbal remedies a seven year transitional period to register their products already on sale in the EU with the relevant national authorities.

John Dalli, the EU health commissioner, said that the unusually long transitional period had given manufacturers and importers of traditional herbal medicines the necessary time to show that their products had an acceptable level of safety and effectiveness. "Patients can now be confident about the traditional herbal medicinal products they buy in the EU," he added.

A spokesman for the United Kingdom's Medicines and Healthcare Products Regulatory Agency confirmed that consumers can be assured that products listed on its traditional herbal registration scheme meet the necessary standards on safety, quality, manufacturing, and information for patients. Under the scheme, he added, it is not necessary for applicants to demonstrate their product's effectiveness, but registration will be refused if the stated effect is not plausible.

In theory, individual items that were not registered by 30 April can no longer be sold to the public. However, in practice, any products that a retailer has in stock can continue to be sold until none remain, suggesting that the full effect of the new measures will not be felt until next year or even later.

The legislation provides for a simplified registration procedure for applicants who can provide documentation that the item in question is not harmful when used as recommended. To satisfy the requirement they have to provide evidence of a blemish free track record, confirming safe use for at least 30 years in all, of which 15 must be in the EU.

The European Commission points out that this will make it possible to register traditional herbal medicines such as Chinese or Ayurvedic products and those from other traditions without the need for tests and trials of safety and efficacy. It also emphasises that the legislation does not ban vitamins, mineral supplements, herbal teas, alternative therapies, or homoeopathy.

A spokesman for the UK regulatory agency said that no products had yet been rejected from the scheme.

However, the Alliance for Natural Health believes that a large number of herbal products from non-European traditions will be banned and points out that it had been told that the cost of registering just one product could range from £80 000 (€90 400; $131 000) to £150 000. It is considering a legal challenge to the European legislation.

The British Medical Association believes that the new measures should reassure the public. Vivienne Nathanson, its director of professional activities, said, "If using these products, then patients will now know there is quality control. Many also use them alongside Western medicines, and we need to know what interaction there might be."

For more information see http://ec.europa.eu/health/human-use/herbal-medicines/index_en.htm.

Guidance on the MHRA's traditional herbal registration scheme is at www.mhra.gov.uk/Howweregulate/Medicines/Herbalmedicines/PlacingaherbalmedicineontheUKmarket/TraditionalHerbalMedicinesRegistrationScheme/index.htm.

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