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Herbal medicines: Product licence to traditional herbal registration in the UK

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When the Medicines Act 1968 was introduced in the UK, herbal medicines that were on the market were given a product licence of right (PLR). In 1975, a new European Community (EC) Directive highlighted that all PLRs, including herbal medicines, should be reviewed by May 1990. In 1988, the UK Medicines and Healthcare products Regulatory Agency (MHRA) began their review of these herbal medicines and completed the task in the mid-1990. Subsequently the PLRs were granted a full Marketing Authorisation (MA) also referred to as Product Licence (PL). On 30 April 2011, the new European Traditional Herbal Medicinal Products Directive (THMPD) came into effect. The Directive established a regulatory approval process for herbal medicines in the European Union (EU). It required each EU Member State to set up traditional herbal registration scheme for manufactured traditional herbal medicines that were suitable for use without medical supervision. Companies were no longer permitted to sell manufactured unlicensed herbal medicines unless they had an appropriate product licence; either as a full MA based on the safety, quality and efficacy of the product or a Traditional Herbal Registration (THR) based on the safety, quality and evidence of traditional use of the product throughout a period of 30 years of which at least 15 years must have been within the European Union. THMPD was adopted in acknowledgment of the fact that companies could not provide evidence, in particular, for efficacy to meet the full requirements of an MA. In the UK, all transfers of PL to THR status were completed in 2013. The MHRA granted the THR on a condition that at first renewal, (5 years from date of grant) a full Common Technical Document (CTD) Module 3 must be submitted to avoid cancellation of the THR.

Biography

Mariam Aslam has over 8 years of experience in Regulatory Affairs, 3 years of which has been with working with herbal medicines. Her current role is working as a Regulatory Manager on the CTD Module 3 for Traditional Herbal Medicines at Vifor Pharma UK Ltd., Potters Division. Her experience also includes working with conventional medicines, cosmetics and medical devices regulations internationally. She studied a degree in Chemistry at the Manchester Metropolitan University and is a member of ESCOP (European Scientific Cooperative of Phototherapy) Scientific Committee.

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