

Press release

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Contact: Press Office 0207 084 3535 / 3564 press.office@mhra.gsi.gov.uk
Out of hours 07770 446 189

Improved patient information and greater consumer choice – new rules to regulate homeopathic medicines

The Medicines and Healthcare products Regulatory Agency (MHRA) has today introduced a new scheme to improve and strengthen the regulation of homeopathic medicines in the UK. The National Rules Scheme for homeopathic medicines will enhance consumer confidence with respect to the safety, quality and use of these medicines.

From today, companies will be encouraged to register new homeopathic medicines under this scheme, with the option of re-registering certain existing products. For the first time since Product Licences of Right were issued in 1971, companies will be allowed to include information about the treatment and relief of minor, self-limiting conditions based on the use of the product within the homeopathic tradition. For example, labels may indicate that a product may relieve the symptoms of common colds and coughs, hay fever or chilblains. All homeopathic medicines authorised under the new scheme will have clear and comprehensive patient information leaflets to help consumers use their medicines safely and effectively.

Professor Kent Woods, Chief Executive of the MHRA, said, “This is a significant step forward in the way homeopathic medicines are regulated. Products authorised under the National Rules Scheme will have to comply with recognised standards of quality, safety and patient information.”

Penny Viner, Board Member of the British Association of Homeopathic Manufacturers (BAHM), said, “The British Association of Homeopathic Manufacturers welcomes the coming into force of this new scheme. This long-awaited regulatory development benefits the ever-growing number of users of homeopathic medicine: its provisions will both encourage growth in the range of products on the market, and enhance the consumer’s understanding of their benefits.”

Notes to Editors

1. The MHRA press office can assist you with any queries you have in making contact with homeopathic practitioners. Call 020 7084 3535/3564.
2. The National Rules Scheme for homeopathic medicines was introduced today following a full public consultation in 2005. There was widespread support for the proposals. The summary of responses can be seen at:
http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON1004429&ssTargetNodeId=373
3. Homeopathic medicines in the UK are currently covered by either the Product Licences of Right (PLRs), or by certificates of registration under the Simplified Registration Scheme. PLRs were issued to all medicines on the market when the Medicines Act 1968 was introduced. The National Rules Scheme will build on these existing regulatory frameworks, with a particular emphasis on indications and appropriate labelling and literature.
4. All homeopathic medicines fall within the scope of the Yellow Card Scheme, which will allow patients and healthcare professionals to report suspected side effects to the MHRA. For over 40 years, the Yellow Card Scheme has been the cornerstone of medicines safety monitoring in the UK. Since the Yellow Card scheme was set up, over 500,000 reports of suspected side effects (known as adverse drug reactions) have been completed, enabling the MHRA to identify and take action on a wide range of previously unrecognised medicines safety issues. Adverse effects associated with the use of homeopathic medicines should be reported to the MHRA using the Yellow Card Reporting Scheme.
www.yellowcard.gov.uk
5. The MHRA is the government agency that is responsible for ensuring that medicines and medical devices work, and are acceptably safe. We keep watch over medicines and devices, and we take any necessary action to protect the public promptly if there is a problem. No product is risk-free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks.