Press Release

Date: Thursday 21 November 2013
Time: 10:00
Contact: Press Office 020 3080 7651
Out of hours 07770 446 189
press.office@mhra.gsi.gov.uk

Medicines watchdog takes further action to protect public from unlicensed herbal medicines

In a move to help people buy and use safe herbal medicines that meet acceptable standards of safety and quality, the Medicines and Healthcare products Regulatory Agency (MHRA) has announced that from 30 April 2014, all manufactured herbal medicines will have to be authorised in order to be sold and supplied lawfully in the UK.

This means that after this date herbal retailers will no longer be able to sell unlicensed herbal medicines that are not registered under the Traditional Herbal Registration (THR) scheme in the UK.

Products registered under the THR scheme meet safety and quality standards and are accompanied by patient information about the product and how it should be used. Registered products can be identified by the THR logo and a THR number on their label.

Dr Linda Anderson, MHRA Licensing Division, said:

“Natural doesn’t always mean safe and some unlicensed herbal products can be harmful and some may have serious side effects.

“We know that people buy and use herbal medicines, so it’s only right that they have access to products that are safe and meet good quality standards. And that’s where we come in – our THR scheme can help assure you that these products meet these standards.

”It is now nearly ten years since the implementation of the European Directive on herbal medicines. Companies have had this time to bring products up to appropriate standards and apply for a THR registration. ”

The requirements for the THR scheme are set out in the Traditional Herbal Medicinal Products Directive (THMPD) which was introduced in 2004 and came into effect on 30 April 2011.

For those herbal medicines that were on the UK market before April 2011, the MHRA allowed retailers to “sell through” their stock because it was

anticipated that they would be sold within an 18-24 month period - the average shelf-life of these products. This transitional protection also allowed manufacturers to bring their production up to the required standards to meet the directive.

However, these unlicensed herbal medicines are still being sold and in July 2013, the MHRA launched a consultation to seek views about ending the sell-through period. The responses have now been considered and 30 April 2014 is the deadline for retailers to stop selling these products.

Ends

Notes to Editor

1. The MHRA has been providing help and advice to the herbal industry since the introduction of the herbals directive about manufacturing and quality standards. Herbal manufacturers have had seven years to bring their products up to the required safety standards and the MHRA have had continual dialogue with the herbal industry to help them ensure that they meet the required manufacturing and quality standards.
2. Further information on the MHRA's THR scheme and details of products granted a THR can be found on the MHRA website: List of products granted a Traditional Herbal Registration (THR)
3. With the introduction of Directive 2004/24/EC, all manufactured over-the-counter herbal medicines in the UK, require either a Traditional Herbal Medicines Registration (THR) or a full Marketing Authorisation (MA). This includes patent Traditional Chinese Medicines.
4. Products with a Traditional Herbal Registration have a "THR" number on the label. Licensed medicines have a PL number (Product Licence).
5. A summary of the responses to the consultation can be found at: Proposal to end sell-through period for unlicensed herbal medicines (external link)
6. When the MHRA grants a traditional herbal registration this means that the company concerned has permission to market a particular product. It is for the company to decide how quickly they can make the product available for sale.
7. Herbal remedies should be used with the same caution and care as any other medicine as their use will have an effect on the body. While many herbal remedies are reasonably safe, it is important to remember that just because it contains natural ingredients and extracts this doesn't guarantee it is safe. People should always consult with a pharmacist or doctor to make sure that a herbal remedy is suitable for them to take and will not interact with any other medicines they may be taking. Stay safe when using herbal remedies, follow us on Twitter @MHRAherbals
8. The MHRA is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. Underpinning all our work lies robust and fact-based judgements to ensure that the benefits justify any risks. The MHRA is a centre of the Medicines and Healthcare Products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The MHRA is an executive agency of the Department of Health.