

## **The Traditional Herbal Registration (THR) Certification Mark: Guidance for Business**



### **What is a Certification Mark?**

A Certification Mark is a specific type of trade mark. It provides a guarantee that the goods bearing the mark meet certain defined standards or possess particular characteristics as defined by the owner of the mark.

### **What does THR Certification Mark mean?**

The Certification Mark indicates that the herbal medicine has been registered with the Medicines and Healthcare products Regulatory Agency (MHRA) under the Traditional Herbal Registration (THR) scheme; and meets the required standards relating to its quality, safety, evidence of traditional use and other criteria as set out under the Traditional Herbal Medicinal Products Directive (THMPD) 2004/24/EC.

### **Who owns the THR Certification Mark?**

The Certification Mark is owned by the MHRA. As the owner of the Mark, the MHRA can give permission to companies to use the certification mark on products registered under the THR scheme.

### **Who can use the Certification Mark?**

Only those companies granted a THR for their traditional herbal medicinal products will be authorised to use the THR Certification Mark for those registered products. As the right to use the Certification Mark is linked to a specific product, retailers or other 3<sup>rd</sup> parties who do not hold the actual THR cannot use the mark in their own right i.e. in relation to the promotion of their business. They may, however, use the Mark as part of promotional advertising provided by the THR holder or as part of general advice to customers to help them identify herbal medicines made to assured standards under the THR scheme.

### **Will all products registered under the THR scheme have to use the Certification Mark?**

No. Use of the Certification Mark is not compulsory. Companies can choose whether to include the THR Certification Mark on their registered products;

however, MHRA recommends its use in order to help consumers identify those herbal medicines made to assured standards under the THR scheme.

### **What permission is needed from MHRA to use the THR Certification Mark?**

Permission to use the THR Certification Mark would normally be granted as part of the THR registration process.

### **What happens if I already have a THR product?**

We will be contacting all companies who were granted a THR before the introduction of the Certification Mark to discuss/co-ordinate changes to their product packs and leaflets. Adding the Certification Mark to your labels will not at this stage incur a fee. Nevertheless you will need to submit the proposed packaging with the Certification Mark to the MHRA for formal approval prior to use.

### **What happens if I initially choose not to use the Certification Mark, will I be able to make use of the Mark at a later date?**

Yes. But you will need to notify the MHRA of your plans and submit updated documentation before you place the Mark on labelling or the patient information leaflet.

### **I already have a THR product but I have not yet had the product registration varied to incorporate the certification mark, can I use the certification mark in my other advertising and publicity material?**

Yes. But you will need explicit authorisation from the MHRA to do so. Once you have notified us of your wish to use the Certification Mark we will confirm in writing that your product is eligible to use the mark. You can then use the mark in advertising and we will advise you of the steps you need to take to enable the Mark to be placed on particular packaging components. Please note that it is a condition of use of the Certification Mark that you indicate that it is a Certification Mark. You can do this by including the text "Certification Mark" adjacent to the Mark itself.

You can also find specific guidance on consumer advertising for registered traditional herbal medicines here:

<http://www.mhra.gov.uk/Publications/Regulatoryguidance/Medicines/Othermedicinesregulatoryguidance/CON043820>

### **Are there any rules about how the Certification Mark is displayed on packs and leaflets?**

There are two versions of the Mark, one with a border, one without. You can use either version. But the Mark may only be displayed once on the pack or the patient information leaflet, or both. It should be subordinate in placement and prominence to the statutory information. It is also a condition of use that the Certification Mark shall not be used without indicating that it is a Certification

Mark. You can do this by including the text "Certification Mark" adjacent to the Mark itself.

### **Can I change the colour of the Certification Mark?**

No. The text, motif and outer border (where used) must always be in black. The background can be in white or the same colour as the product packaging.

### **What happens if the Certification Mark is used inappropriately in advertising by someone who is entitled to use it?**

The advertising of medicines is controlled by a combination of: statutory measures (with both criminal and civil sanctions) enforced by the MHRA; self-regulation through Codes of Practice administered by trade associations; and the Advertising Standards Authority. Misuse of the mark will be dealt with in the same manner as other breaches of the rules relating to the advertising of medicinal products.

### **What happens if the Certification Mark is used by someone not entitled to use it?**

As the owner of the Certification Mark, the MHRA will take appropriate regulatory or legal action against any company or individual who makes unauthorised use or misuses the Certification Mark in any way.

### **I want to complain about inappropriate use of the Certification Mark, what do I do?**

Complaints about inappropriate use of the THR Certification Mark may be made in writing to the MHRA, enclosing where possible a copy of the advertisement or promotional material. These should be sent to: MHRA Herbal Policy Unit, 16-1, MHRA, Market Towers, 1 Nine Elms Lane, London SW8 5NQ; or emailed to [thmrsqueries@mhra.gsi.gov.uk](mailto:thmrsqueries@mhra.gsi.gov.uk).

### **If I want to explain what the Certification Mark means, e.g. on a company website, what should I say?**

The MHRA strongly suggests that in order to avoid inappropriate use of the Certification Mark, you use the following statement:

*"The THR Certification Mark shows that a product has been registered by the Medicines and Healthcare products Regulatory Agency under the UK Traditional Herbal Registration Scheme. A product bearing this Mark meets the required standards for safety, quality and patient information. Under this scheme, the permitted indications for the medicine are based on traditional usage and not on evidence of effectiveness of the product. More information about the THR scheme can be found on the Traditional Herbal Medicines Registration Scheme webpage at [www.mhra.gov.uk](http://www.mhra.gov.uk).*

It is also acceptable, for example, where space is limited, to have a brief reference adjacent to the Certification Mark:

"For information see [www.mhra.gov.uk/thr](http://www.mhra.gov.uk/thr)."

