

Traditional Herbal Medicines Registration Scheme

Guidance for Retailers, Wholesalers, Importers and Manufacturers on the Requirements of the THMRS

**MHRA
March 2007**

Manufactured, Finished, Over-The-Counter (OTC) Traditional Herbal Remedies and the Traditional Herbal Registration Scheme

Manufactured herbal medicines¹ placed on the UK market are required to have either a Traditional Herbal registration (THR) or a Marketing Authorisation (MA). This applies whether the product is marketed to consumers, herbal practitioners, retailers, or wholesalers.

There is one principal exception in relation to herbal medicinal products. Where a manufactured herbal remedy meets **both** the following requirements:

- it is legally on the UK market as an unlicensed herbal remedy in accordance with s12(2) of the Medicines Act 1968 **and**
- was also legally on the UK market under s12(2) at 30 April 2004

it can continue to be marketed as an unlicensed herbal remedy until 30 April 2011 provided it continues to comply with the requirements of s12(2).

This leaflet and flowchart has been produced in an effort to provide guidance which will help those working within the herbal medicine sector to understand and comply with the Traditional Herbal Medicines Registration Scheme (THMRS). The guide covers the key requirements of the THMRS. It does not cover in detail all the areas you will need to consider to meet the requirements of the registration scheme.

While the Medicines and Healthcare products Regulatory Agency (MHRA) has made every effort to ensure that the information provided in this short guide is correct, it is ultimately, the responsibility of manufacturers, wholesale dealers, importers, retailers and anyone placing traditional herbal medicinal products on the market to ensure that they comply with the law.

This leaflet can also be found on the MHRA website on the 'Herbal medicines regulation and safety' page².

¹ In this context, 'manufactured' means either prepared industrially or manufactured by a method involving an industrial process.

² http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=94

Can I place my herbal remedy on the UK market?

Is the product a medicine? A *“medicinal product”* is defined as any substance or combination of substances aimed at treating or preventing disease in people or which may be administered to people with a view to making a diagnosis or restoring, correcting or modifying a physiological function. Advice from the Agency's Borderline Unit on whether your product is likely to be medicinal can be obtained by completing the online [advice request form](#). Our section on [Borderline products and Guidance note 8](#) provides more information on the definition of a medicine.

No →

Product is not regulated under medicines legislation. However, it may fall within other legislation, for example covering food or cosmetics.

Yes
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Is the product legally sold under section 12(2) of the Medicines Act, meeting all of the requirements listed below?

- Contains only plant ingredients (other than water or other inert material)
- Has no written recommendation for use
- Does not have a trade name

No →

Product will require a marketing authorisation or a certificate of registration under the Traditional Herbal Products Registration Scheme before it can be sold in the UK. Licences, authorisation or inspection will also be needed for manufacture and distribution - manufacturer's and wholesale dealer's licences; clinical trials for new untested ingredients; premises and procedures to ensure necessary quality standards are met and maintained. [More information on licensing medicines](#) and the [Traditional Herbal Medicines Registration Scheme](#) can be found on the MHRA website.

Yes
↓

Was the product also legally on the UK market on or before 30 April 2004 meeting all the requirements listed below?

- Contains only plant ingredients (other than water or other inert material)
- Has no written recommendation for use
- Does not have a trade name

No →

Yes
↓

Providing the product is still compliant with the terms of the exemption it may potentially qualify for transitional protection and can continue to be placed on the market without a Traditional Herbal Registration (THR) or Marketing Authorisation (MA) until 30 April 2011. More information on [transitional protection](#) can be found on the MHRA website. After 2011, the product will need to be registered as a traditional herbal remedy if you wish to continue selling it. However, you should start planning now for registration. [More detailed information on the registration scheme can be found on the MHRA website](#) along with [guidance notes](#) on specific aspects of the scheme and information on the [registration fees](#)

Restrictions Applying to the Sale and Supply of Herbal Medicines

Does the product contain any Prescription Only Medicines (POM)? Medicines are classified as prescription only (POM), pharmacy (P) or general sale list (GSL). POM and P medicines can only be sold or supplied at registered pharmacy premises by or under the supervision of a pharmacist, subject to certain exemptions POM medicines can only be sold or supplied in accordance with a prescription from doctor, dentist or, an independent nurse prescriber or supplementary prescriber. GSL medicines can be sold from a wider range of premises such as supermarkets. [Click here for more information](#)

Yes →

Product may only be sold or supplied in response to a prescription at a registered pharmacy or by a doctor or dentist.

No
↓

Does the product contain any ingredients included on the list of prohibited or restricted ingredients? There are number of herbal ingredients which are subject to various restrictions on their sale and supply or use e.g. Kava Kava and Aristolochia. [A list of prohibited and restricted herbs can be found on the MHRA website](#)

Yes →

Product may only be sold or supplied in the circumstances outlined in the relevant orders or legislation.

No
↓

Product can be sold or supplied in the same circumstances as a General Sales List product. Product must continue to comply with the terms of the Section 12 exemption. [Click here for more information](#) **Remember if you do not have an MA or THR for your products by 30 April 2011 you will not be able to place new stocks on the UK market after this date. It can take a while to obtain an MA or Traditional Herbal Medicines Registration so you are advised to start preparing the information you need to apply now if you want your products to remain on the market.**

Who is responsible for applying for registration under the scheme?

- Anyone who is responsible for first placing a traditional herbal medicine on the market in the UK will need to obtain a product registration for that product.

In addition, anyone who is responsible for handling a traditional herbal medicinal product will need to obtain appropriate authorisation, this includes:

- Manufacturers (including those that manufacture for export),
- Importers,
- Wholesale dealers of medicinal products covered by the scheme

 [More information about the requirements for manufacturers, wholesale dealers and importers of traditional herbal medicinal products.](#)

I manufacture herbal medicinal products are there any specific requirements I will need to meet?

All UK manufacturers of traditional herbal medicinal products will require an appropriate authorisation known as a manufacturer's & importer authorisation (MIA) from the MHRA. This requirement also covers UK manufacturers who manufacture medicinal products purely for export to other countries. A MIA authorises the manufacture, as well as the distribution by wholesale, of the medicinal product(s) covered by it. A MIA can be granted for the manufacture and assembly of medicinal products or for the assembly of medicinal products. To obtain a MIA, you will need to meet approved standards of Good Manufacturing Practice. Granting of a licence will be subject to findings upon inspection by the MHRA. We carry out regular inspections of manufacturing sites both in the UK and non-European Union (EU) countries with which the EU does not have a Mutual Recognition Agreement

 [More information on how to obtain a manufacturer's licence](#)

I am a wholesale dealer what will I have to do?

All UK wholesale dealers of traditional herbal medicinal products will require an appropriate authorisation, known as a wholesale dealer's licence (WL), from the MHRA. To obtain a wholesale dealer's licence (WL), you will need to meet approved standards of Good Distribution Practice (GDP). Granting of the licence will be subject to findings upon inspection.

 [More information on how to obtain a wholesale dealer's licence](#)

I plan to import herbal products will I need an import licence?

Any company that imports traditional herbal medicines from a non-European Community (EC) or third country will need to obtain a manufacturer's & importer authorisation (MIA). To obtain a MIA, you will need to meet approved standards of Good Distribution Practice (GDP) and the relevant elements of Good Manufacturing Practice (GMP) in respect of batch release. You will need to submit a MIA application form to the MHRA. Granting of the licence will be subject to findings upon inspection.

 [More information on how to obtain a MIA \(import\) licence](#)

I am a retailer will I need to apply for a licence to sell herbal medicines?

In principal, as the retailer you would not normally need to register the products. This is the responsibility of the person to first place the product on the UK market. However if **you are the first person** to place the product on the market you will need to apply for a MA or THR unless one of a number of exceptions apply.

Do I need to register my products now?

If your products were legally on the UK market on 30 April 2004 in compliance with the requirements of s12 (2) of the Medicines Act, and continue to meet those requirements. You will have until 30 April 2011 to comply with the requirements of the new scheme which may include obtaining a manufacturer's or wholesale dealer's licence and registering your individual products.



Where an unlicensed herbal remedy benefits from transitional protection, you cannot continue to place supplies of the product on the UK market after 30 April 2011. This underlines the importance of getting any THRs that you need in good time for April 2011 if you wish to market herbal medicines after 2011 with no break in continuity.

How do I go about registering my products?

In order to obtain a product registration under the scheme you will need to prepare and submit a registration dossier. The scheme requires traditional herbal medicines to meet specific and appropriate standards of safety and quality, be accompanied by the necessary information on the safe use of the product and, provide evidence to support traditional use. These issues will need to be addressed in the dossier.



More information on the **key requirements** of the scheme and the requirements of **registration dossiers**



This information will take significant time to gather and put together, for example, you will need to ensure that stability data exists to support the shelf life of your product. Stability testing is necessary to ensure the product is of acceptable quality throughout its entire storage period. In order to do this, it is necessary to monitor compliance of the product with a suitable quality specification throughout the shelf life. The registration dossier must include a minimum of 6 months stability data, in accordance with current guidelines, at the time of the submission. In order to ensure that your product is registered before 30 April 2011 you will need to begin generating this information as soon as possible.

How long does the registration process take?

Once the application has been received and validated, the MHRA starts the evaluation procedures. The MHRA will endeavour to ensure that the evaluation is completed within 210 days - this does not take into account any 'clock-stops' for the applicant to provide a response to questions raised by the MHRA.



You should bear in mind that the assessment process may well take considerably more than 210 days if, for example, the Agency needs to request additional information or evidence to support the information provided in your dossier. Submitting an application for registration close to the 2011 deadline could potentially mean that your application will not be assessed in time and as a result, you will not be able to continue placing the product on the UK market after the deadline until a registration has been granted.

Even before submitting your application for a THR there are a number of other factors which will have a significant impact on the overall time it takes to have your product registered. You will need to consider:

- **whether your company has the technical expertise, in for example quality and manufacturing issues, needed to prepare technical dossiers - you will need to build into your timetable sufficient time to develop the necessary expertise, or buy it in.**
- **the resource implications of trying to progress a number of applications at the same time - in the first instance, it may be more sensible to submit one or two dossiers; this again would have implications for the time needed to get all your relevant products registered by 2011.**

Where can I go to get more information and advice?

A wealth of information can be found on the MHRA website. In our '[where to go for further advice](#)' section you will find contact points for various elements of the scheme. The '[forms and procedures](#)' pages provide direct links to, and downloadable copies of, relevant forms and procedure guides. The [guidance notes](#) pages provide a range of guidance notes to help you understand and comply with the requirements of the scheme.

If you are thinking of preparing an application for registration, the MHRA would strongly encourage you to take advantage of the pre-application notification scheme before carrying out extensive work on your application dossier. Under this scheme, potential applicants supply specific information about their intended products for registration. This helps MHRA plan its workload. In return, MHRA can provide applicants with helpful advice on how they can effectively progress their application(s). This advice can be particularly important if you lack experience in medicines regulation. The pre-application notification form can be found on the MHRA website [forms and procedures](#) page.

It may also be sensible for you to seek legal advice and or contact one of the following trade associations with interests and expertise in herba medicine:



The Herbal Forum
The Old Vicarage,
65 Church Street,
Langham,
Rutland LE15 7JE
Tel/Fax: 0044 (0) 1572 771115
Email: – Pennyviner@btconnect.com

The Health Food Manufacturers' Association
63 Hampton Court Way, Thames Ditton, Surrey KT7 0LT
Telephone: 0208 398 4066
Fax: 0208 398 5402
Email: hfma@hfma.co.uk

Aromatherapy Trade Council
P.O. Box 387
Ipswich
IP2 9AN
Tel/Fax: 01473 603630
Website: www.a-t-c.org.uk

Ayurvedic Company of Great Britain (TAPASI)
81 Wimpole Street
London
W1G 9RF
Tel: 020 7224 6070
Fax: 020 7224 6080

British Herbal Medicine Association
1 Wickham Road
Bournemouth
BH7 6JX
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Proprietary Association of Great Britain
Vernon House, Sicilian Avenue,
London WC1A 2QS
Tel: 020 7242 8331
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