# **Traditional Herbal Registration Scheme for Traditional Herbal Medicinal Products: Guidance note on arrangements for companies to give the MHRA advance notice of intended applications**

## Introduction

The MHRA has a voluntary arrangement under which companies are invited to give the Agency advance notice of their intention to submit applications for traditional use registration(s). The purpose of this arrangement is to enable the MHRA:

* to plan effectively to meet likely workload and so provide an effective and efficient service to industry; and
* to offer scientific and regulatory advice to companies in sufficient time to facilitate them make valid application(s).

### Products covered

**The arrangements for advance notification cover any product(s) for which a company intends to seek traditional use registration.**

Information to be provided

The information we are requesting is set out in the attached template.

#### Action by potential applicants

**Please provide the information, in the form of a completed template and send to:** [**info@mhra.gov.uk**](mailto:info@mhra.gov.uk)

### Action by the MHRA

Following receipt of the information requested, the MHRA will contact the company to discuss its intended application(s) for registration. The information supplied to the MHRA will be held as commercial in confidence.

#### Further information

For further information about the Traditional Herbal Registration Scheme, companies should in the first instance visit the MHRA website or contact their trade association.

For any queries about the arrangements set out in this guidance please e-mail: [info@mhra.gov.uk](mailto:info@mhra.gov.uk)

**Template for companies to give the MHRA advance notice of intended applications to register product(s) under the Traditional Herbal Registration Scheme for Traditional Herbal Medicinal Products**

|  |  |
| --- | --- |
| Applicant |  |
| Company Name |  |
| Company Address Line 1 |  |
| Company Address Line 2 |  |
| Town |  |
| County |  |
| Postcode |  |
| Country |  |
| Telephone |  |
|  |  |
| E-mail |  |
| Contact Person |  |

Please fill in for each product. Reproduce table as required for additional products.

|  |  |
| --- | --- |
| Applicant |  |
| Name of Product |  |
| Pharmaceutical form |  |
| Formulation: |  |
| Active ingredients |  |
| Excipients |  |
| Vitamins/minerals (where included) |  |
| Therapeutic area/indications |  |
| Is product currently on UK market? |  |

|  |  |
| --- | --- |
| Product Manufacturer |  |
| Manufacturer Address Line 1 |  |
| Manufacturer Address Line 2 |  |
| Manufacturer Town |  |
| Manufacturer County |  |
| Manufacturer Postcode |  |
| Manufacturer Country |  |
| Manufacturer Telephone |  |
|  |  |
| Manufacturer e-mail |  |
| Manufacturer Contact Person |  |