



**GUIDE ON HOW TO COMPLETE THE
FORM REQUESTING
THE CLASSIFICATION OF A HERBAL MEDICINAL
PRODUCT**

Guide on how to complete the form requesting classification of a herbal medicinal product

A. Purpose of the classification form

The purpose of this Herbal Classification Form is to guide the importers of herbal medicinal products to decide whether a product is a Traditional Herbal Medicinal Product or Herbal Product with Well Established Use. If you are in doubt whether your product is a medicinal product or not, fill in the form anyway. You will be informed if the product is not a medicinal product. The [decision tree](#) and other information on the website may help you decide whether your product is medicinal or not.

A herbal medicinal product is any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations. Vitamins and minerals may be also added to herbal medicines.

The Application Form

All importers of herbal medicinal products that have been placed on the market before 30 April 2010 are requested to fill this Herbal Classification Form for each product. Stakeholders must submit online this form by 30 September 2010. The information gathered from these forms will be used to create a derogation list. The products on this list will benefit from a derogation period and will be allowed on the market if an application for a marketing authorization or a traditional herbal product licence is received by 31 December 2011. Some products may not fall within the definition of medicinal products and would not require registration.

Language to be used

The form should be completed in English.

B. Information to be submitted in order for product to be classified by the Herbals Committee:

1. Importing company

1a. Name of importing company placing the product on the market.

1b. Type of licence the importing company possesses if any.

An **import licence** is a formal document allowing a person or group to bring in medicinal products from outside the European Union. In this case batch release has to be carried out in Malta or another EU country before the product can be placed on the market.

Wholesale dealing involves any activity which includes the purchase, sale, import, export, or any other commercial transaction in medicinal products.

More information on these requirements may be found in the [Inspectorate](#) section of the Medicines Authority website.

1c. Address of importing company

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2. **Contact Person**

Name and e-mail address of contact person within the company.

3. **Product Name:**

Name of medicinal product as stated on the product labeling and packaging should be included.

4. **Dosage Form**

Dosage form refers to the formulation in which the herbal medicine is presented. Typical dosage forms include tablets, capsules, suspension and cream. Choose one from the drop down list provided.

5. **Route of Administration**

For traditional herbal medicinal products (THMPs), only oral, topical and inhalation routes are allowed. Therefore the product can be formulated in capsule, tablet, suspension (oral) forms; cream, ointment, liniments, herbal patch (topical) forms; nasal spray, steam bath (inhalation) forms, amongst others. However, the formulation of traditional herbals in the form of injections, suppositories, vaginal pessaries, eye/ear drops, is not permissible. These formulations go beyond self-diagnosis and administration and require a marketing authorization. In the case of herbals with well-established use, these dosage forms are only acceptable as long as the route is supported by clinical data. Choose one from the drop down list provided.

6. **Legal Status of the product**

Some medical conditions require professional diagnosis. In most cases, physicians prescribe medicines also known as prescription-only medicines. For such conditions, herbals with a well-established use (WEU) are more commonly prescribed than traditional herbal medicinal products (THMPs). THMPs are more intended for self-medication or mild conditions, and therefore these are more considered as over-the-counter medications i.e. not requiring a medical prescription.

7. **Product ingredients:**

Active ingredients are substances that contribute to the activity of the product. Apart from the herbal active ingredient, there may be other active ingredients that may include herbal substances and phytochemicals, drugs of animal or mineral origin, and synthetic drugs. If the product also contains medicinal active substances other than herbal substances, the product would not fall under the categories of herbal medicinal products.

Each herbal medicinal product should be accompanied by the quantitative content of active ingredients usually expressed per dose (E.g. 5mg per tablet, 250mg/5ml), and the dose frequency usually expressed per day (e.g. once a day or three times daily). Herbal medicinal products are not excluded from this obligation.

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Plant parts: For each active herbal ingredient select the plant part from the drop down list. Active constituents are usually found abundantly in specific plant parts. Therefore, the herbal medicine is characterized by extracts derived from these plant parts. Typical plant parts include bark, bulb, fruits and flowers.

Excipients are inert substances used as diluents or vehicles for medicinal drugs.

8. **Is the product combined with any other ingredient such as vitamins and/or minerals?**

Vitamins and minerals may also be added to herbal medicines. These may be considered as:

- (1) active constituents i.e. contributing to the activity of the herbal ingredient/s
- (2) adjunct/additive constituents i.e. considered as supplements.

9. **Product indications**

List all the indications or claims of the product as specified on the pack, patient information leaflet (in the 'Indications' section) and promotional material. These claims describe the medicinal use of the product. In some cases, medical conditions, such as diabetes, depression, hypertension and others are mentioned. It is the remit of the Medicines Authority to establish whether claims are medicinal in nature or not.

10. **Exporting member state (MS) or third country**

MS or country from where the product is imported should be indicated.

11. **Availability on the market in the exporting member state or third country.**

This information may be obtained from the foreign supplier. It should be stated whether the product is placed on the market in the exporting country.

12. **Status of the product in Malta:**

There are three main categories for the status classification of a herbal medicinal product (HMP):

- i. The HMP may have been on the market in Malta for a number of years but may have been withdrawn for some reason (excluding safety). These products are covered by the derogation period. Proof that the product was actually placed on the market may be requested.
- ii. The HMP may be in current use and therefore has been on the market for a number of years. Such a product is covered by the derogation period.
- iii. You may be interested in placing on the market new herbal medicinal products. These are not covered by the derogation period.

13. Number of years the herbal substances/ preparations has been used

Herbal substances and preparations in traditional herbal medicinal products should have been used for more than 30 years, with at least 15 years within the European Union. In the case of herbal substances and preparations with a WEU, these should exhibit efficacy for at least 10 years.

14. How the product is classified in the country of source:

In this section you should specify how the product is placed on the market in the source country – whether as a medicinal product, a traditional herbal medicinal product or a non-medicinal product (e.g. food supplement, cosmetic, etc).

There are three possible routes by which the product can be classified in the country of source (this depends whether the product is already authorized in the EU or not. The below classification is relevant to products placed on the market in the EU):

1. Traditional Herbal Medicinal Products

Products are required to meet specific standards of safety and quality and be accompanied by agreed indications, based on traditional usage, and systematic patient information allowing the safe use of the product.

2. Herbal medicinal products with well-established use

Some herbal medicines hold a marketing authorization just like any other medicine. These are required to demonstrate safety, quality and efficacy (or effectiveness) and be accompanied by the necessary information for safe usage.

3. Non-medicinal products (e.g. food supplement or cosmetic).

These do not require registration as medicinal products.

15a. Proof of Efficacy

This refers to the proof of a product's efficacy through clinical data i.e. scientific papers showing that the herbal medicinal product has been tested and exhibited a pharmacological effect in *in vitro* and *in vivo* animal and human trials. This is necessary for herbals with a well-established use. However, scientific proof falls outside the scope of the Traditional Medicinal Products registration. These require bibliographic literature reviews from old texts or articles showing traditional use of the product.

15b. Proof of Safety

The safety of a product is the main criterion for establishing whether it should be placed on the market or not. Although, for THMPs there is no scientific proof of efficacy, safety should be assessed scientifically by following a panel of *in vitro*/*in vivo* tests. A guideline to toxicity testing is found at the European Medicines Agency: <http://www.ema.europa.eu/pdfs/human/hmpc/10707907enfin.pdf>.

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Whether a THMP or a herbal with WEU, the herbal medicinal product still undergoes pharmacovigilance, to monitor any adverse effects after it is placed on the market.

15c. Proof of Quality

Both Traditional Herbal Medicinal Products and Herbals with Well Established Use must be processed under pharmaceutical manufacturing procedures. Reference to an official European or Community monograph can be made.

The applicant has to declare that the information is true and correct. Therefore the applicant should check the data, before submitting the form.

All personal information will be processed in accordance with the Data Protection Act, 2001. Commercially confidential information will not be made public.