



IRISH MEDICINES BOARD

**TRADITIONAL HERBAL MEDICINAL PRODUCTS REGISTRATION
SCHEME**

CONSUMER Q&A DOCUMENT

14 April 2011

For some time herbal medicines available in EU countries were sold outside of a regulated system. This meant that herbal medicines could be sold without having to show that they had acceptable safety or quality.

As a result, to protect the health of consumers, the EU introduced the Traditional Herbal Medicinal Products Directive to allow for the regulation of what are known as 'traditional herbal medicines'.

This document provides Irish consumers with information about this new legislation, why it is being introduced and how it might impact those who use herbal medicines.

1. What are herbal medicines?

Some plants contain substances that may be used to treat diseases. Medicines that are made from these substances are known as herbal medicinal products or herbal medicines.

Even though herbal medicines are natural this does not necessarily mean that they are safe or without side effects. As a result, like any other medicine, herbal medicines should be used with care. This is also why they are covered by the same pharmaceutical legislation, which aims to protect public health by making sure that the herbal medicines you use are safe, effective and of good quality.

2. What is a traditional herbal medicine?

Within the group of herbal medicines, some have a long history of use. European Union (EU) legislation defines **traditional** herbal medicines as those that:

- have been used for at least 30 years, including at least 15 years within the EU, and
- are intended to be used for self medication without having to consult a doctor.

A more detailed definition is included in the relevant legislation on the [EU website](#).

3. What is the Traditional Herbal Medicinal Products Directive?

In the interests of public health, all medicines, including herbal medicines, need a licence (called a marketing authorisation) before they can be sold on the EU market.

However, traditional herbal medicines have particular characteristics, notably their long tradition and history of use. To take account of this, in 2004 the EU introduced new legislation to cover these particular medicines. This allows for a simpler and less costly registration process for

traditional herbal medicines, while at the same time making sure that they are safe, effective and of good quality.

The EU legislation is called the Traditional Herbal Medicinal Products Directive (2004/24/EC). It can be viewed on the [EU website](#).

4. Why did the EU introduce legislation on traditional herbal medicines?

The Traditional Herbal Medicinal Products Directive was introduced in order to protect the health and interests of consumers across Europe.

For some time herbal medicines available in EU countries were sold outside of a regulated system. This meant that these herbal medicines could be sold without having to show that they had acceptable safety or quality. They also did not have to provide useful patient information or detailed labelling.

In more recent years, there has been a large increase in the use of herbal medicines. While some consider these products “safe”, due to the fact they are herbal and natural, it has been shown that side effects and interactions (see below) between herbal medicines and other medicines can and do occur.

It is difficult for consumers to know which herbal medicines meet acceptable safety standards or which herbal medicines might react with other medicines they might be taking. As a result, to protect the health of consumers, the EU introduced this new legislation to allow for the regulation of traditional herbal medicines.

A side effect (or adverse reaction) is an unwanted or unexpected reaction that a person may experience after taking a medicine. A medicine interaction can occur when two or more medicines react with each other causing you to experience an unexpected side effect. More information is available in the IMB’s consumer leaflet [Medicines and Side Effects](#).

5. What specific Irish legislation covers traditional herbal medicines?

The EU legislation became law in Ireland on 23 July 2007 when the government introduced the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007). This national legislation covers all medicines including traditional herbal medicines.

6. What is the Traditional Herbal Medicinal Products Registration Scheme? What is the role of the IMB?

The Irish Medicines Board (IMB) is responsible for implementing the national legislation on traditional herbal medicines. The registration system the IMB has set up under the legislation is called the Traditional Herbal Medicinal Product Registration Scheme.

Under this scheme a company (or applicant) can apply for a licence, known as a certificate of traditional use registration, for a traditional herbal medicine. If the application is successful, the IMB will allocate that medicine a TR number which will be displayed on the label and / or packaging.

7. When does the registration scheme begin?

The national legislation states that after 23 July 2007 all medicines, including traditional herbal medicines, cannot be sold without a licence from the IMB. An extension until 30 April 2011 was allowed for traditional herbal medicines that were on the market before the 23 July 2007.

The time between 23 July 2007 and 30 April 2011 was referred to as the 'transition period'. Companies wishing to register their traditional herbal medicines were asked to send in applications to the IMB during this transition period.

8. How will this legislation benefit consumers?

Once the legislation comes into full effect, Irish consumers can have confidence that when they buy a traditional herbal medicine it will be registered with the IMB.

This means that registered traditional herbal medicines will:

- be manufactured to the same quality standard as other medicines;
- be safe when used as directed;
- work in a way that it has been traditionally known to work. This known and intended effect is based on the medicines long history of use;
- be labelled correctly and provide useful patient information.

To protect public health, the IMB will also continue to monitor the safety of traditional herbal medicines after they are registered. All reports of suspected side effects received from consumers will be reviewed to identify any new potential safety issue.

For information on how to report this information to the IMB, see our consumer leaflet [Medicines and Side Effects](#).

9. How might consumers be impacted after the 30 April 2011?

From 1 May 2011, the transition period for unlicensed traditional herbal medicines will have come to an end (see question 7).

The impact this will have on a consumer who takes a traditional herbal medicine will depend on whether or not the IMB has registered, or has received an application to register, that product.

Valid Application Received

- From 1 May, if a manufacturer has successfully registered a traditional herbal medicine with the IMB, or submitted a valid application to the IMB for that traditional herbal medicine, it can continue to supply that product to retailers (or wholesalers). This is provided that no safety or quality concerns arise with the traditional herbal medicine in question.
- This means that as long as the information submitted to the IMB as part of the application process meets the safety and quality standards required, there will be no impact on the availability of that product.
- If the traditional herbal medicine is successfully registered the packaging will be changed to include the new 'TR' number on the label.

No Application Received

- From 1 May, if manufacturers have not applied for registration of each of the traditional herbal medicines they produce, they can no longer supply these products to retailers (or

wholesalers). Therefore, after existing stocks of these products are sold by retailers they will no longer be available.

- If consumers find that a particular brand of herbal medicine they use is no longer available, they should check with their health store or pharmacist. It may well be that an alternative brand of the same herbal medicine will be available if its manufacturer has applied to have it registered.
- Additionally, other medicines, including alternative herbal medicines, may be available to treat the same condition or illness.

10. Will this legislation impact food or food supplements that contain herbs?

No, this legislation deals with herbal medicines only. It does not impact food supplements.

Herbal products can be classified as food or food supplements once they do not meet the [definition of a medicine](#) and once they comply with food law (Directive 2002/46/EC) and food labelling requirements.

11. In the future how do I know if the products I use are food supplements or traditional herbal medicines?

- Medicines registered under the Traditional Herbal Medicinal Products Registration Scheme will have a product number on the packaging that will start with the letters 'TR' – for example, 'TR1111/111/111'.
- In addition, if you wish to check the status of a herbal product and whether it is regulated by the IMB as a medicine, you can use the product search facility on the homepage of our website www.imb.ie.
- Further information about food supplements is available on the website of the Food Safety Authority of Ireland – www.fsai.ie.

12. What is the IMB doing to ensure manufacturers submit applications?

The EU legislation on traditional herbal medicines was introduced in 2004. The resulting Irish legislation was introduced in July 2007. Therefore, manufacturers have had many years notice of the 2011 deadline. During this period, the IMB has provided significant information and guidance about the registration scheme to manufacturers.

It is a decision for each manufacturer whether or not they register their products. The company itself will choose whether or not it wants to sell its products on the Irish market. The IMB has no influence on that decision. The 2004 legislation introduced a voluntary registration scheme and this is the situation throughout Europe.

If companies wish to have their traditional herbal medicines available to consumers on the Irish market going forward, they can still submit a valid application before 30 April 2011. The IMB can only register a product if we have received a valid application.

13. What action will the IMB be taking to ensure that the regulations are complied with?

As is current policy, the Irish Medicines Board will remove any products from market that pose a risk to consumer health and that are in breach of the regulatory requirements.

14. Aren't all herbal medicines already safe?

Herbal medicines, as with all other medicines, should be used with care.

The use of phrases such as 'natural', 'herbal' and 'derived from plants' to describe a medicine does not necessarily mean it is 'safe'. Some plants are not suitable for human consumption due to the powerful compounds they contain. Also, many pharmaceutical medicines have been developed from plants.

As with any other medicine, a herbal medicine is likely to have an effect on the body. You should consider the following before taking a herbal medicine;

- Do I need this medicine and is it the right option for me?
- What are the possible side effects?
Like any medicine, a herbal medicine has the potential to cause unwanted or adverse reactions.
- Am I currently taking any other medicines?
Herbal medicines can interact with other medicines. This could result in reduced effects of the medicines and other unwanted side effects. For this reason, it is important to make your doctor or pharmacist aware of any herbal medicines you are taking.

Finally, as with all medicines, herbal medicines should be kept out of the sight and reach of children.