
STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 7

Traditional herbal registrations

Application of Part

Traditional herbal medicinal products

125.—(1) This Part applies to a herbal medicinal product (a “traditional herbal medicinal product”) if the following conditions are met.

(2) Condition A is met if by virtue of its composition and indications the product is appropriate for use without the need for a medical practitioner to—

- (a) diagnose the condition to be treated by the product;
- (b) prescribe the product; or
- (c) monitor the product's use.

(3) Condition B is met if the product is intended to be administered at a particular strength and in accordance with a particular posology.

(4) Condition C is met if the product is intended to be administered externally, orally or by inhalation.

(5) Condition D is met if—

- (a) the product has been in medicinal use for a continuous period of at least 30 years, and
- (b) the product has been in medicinal use in the European Union for a continuous period of at least 15 years.

(6) It is immaterial for the purposes of condition D whether or not during a period mentioned in that condition—

- (a) the sale or supply of the product has been based on a specific authorisation; or
- (b) the number or quantity of the ingredients (or any of them) has been reduced.

(7) Condition E is met if there is sufficient information about the use of the product as mentioned in condition D (referred to in this Part as its “traditional use”), so that (in particular)—

- (a) it has been established that the traditional use of the product is not harmful; and
- (b) the pharmacological effects or efficacy of the product are plausible on the basis of long-standing use and experience.

Status:

Point in time view as at 14/08/2012. This version of this provision has been superseded.

Changes to legislation:

The Human Medicines Regulations 2012, Section 125 is up to date with all changes known to be in force on or before 19 August 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.