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## STATUTORY INSTRUMENTS

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# 2012 No. 1916

## The Human Medicines Regulations 2012

### PART 6

#### Certification of homoeopathic medicinal products

##### *Application for certificate of registration and consideration of application*

#### **Failure to place on the market etc**

**109.**—(1) A certificate of registration ceases to be in force if the product to which it relates is not placed on the market in the United Kingdom during the period of three years beginning immediately after the day on which it was granted.

(2) A certificate of registration for a product which has been placed on the market ceases to be in force if the product to which it relates is not sold or supplied in the United Kingdom for a period of three years.

(3) This regulation does not apply if the licensing authority grants an exemption from its operation.

(4) An exemption may be granted—

- (a) in response to an application in writing by the holder of the certificate of registration; or
- (b) by the licensing authority of its own motion.

(5) An exemption may be granted only—

- (a) in exceptional circumstances; and
- (b) on public health grounds.

(6) An exemption—

- (a) has effect for the period determined by the licensing authority, which may not exceed three years beginning with the day on which it is granted; and
- (b) may be renewed or further renewed.

**Status:**

Point in time view as at 31/03/2014. This version of this provision has been superseded.

**Changes to legislation:**

The Human Medicines Regulations 2012, Section 109 is up to date with all changes known to be in force on or before 18 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.