
STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 7

Traditional herbal registrations

Validity of traditional herbal registration

Validity of traditional herbal registration

- 132.**—(1) Subject to the following paragraphs, a traditional herbal registration remains in force—
- (a) for an initial period of five years beginning with the date on which it is granted; and
 - (b) if the registration is renewed under regulation 133 for an unlimited period after its renewal.
- (2) The licensing authority may on the first application for renewal of a registration determine on grounds relating to pharmacovigilance, including exposure of an insufficient number of patients to the medicinal product concerned, that it should be necessary for the holder to make one further application for renewal.
- (3) In that event, the registration remains in force—
- (a) for a further period of five years beginning with the date on which it is first renewed; and
 - (b) if the registration is further renewed under regulation 133 for an unlimited period after its further renewal.
- (4) If an application for the renewal or further renewal of a registration is made in accordance with regulation 133 the certificate remains in force until the licensing authority notifies the applicant of its decision on the application.
- (5) This regulation is subject to—
- (a) regulation 134 (failure to place on the market); and
 - (b) regulation 135 (revocation etc of traditional herbal registration).

Changes to legislation:

There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 132.