
STATUTORY INSTRUMENTS

2005 No. 2750

The Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005

Consideration, and grant or refusal, of an application for, or for renewal or variation of, a traditional herbal registration

6.—(1) The licensing authority shall—

- (a) consider every application for the grant, renewal or variation by them of a traditional herbal registration in accordance with the relevant Community provisions, and (where applicable) the rules of Community law relating to parallel imports, and
- (b) grant, renew or vary, or refuse to grant, renew or vary the registration in accordance with those provisions and (where applicable) the rules of Community law relating to parallel imports.

(2) Schedule 2 shall have effect to regulate the procedure for receiving advice and representations before granting, renewing or varying, or refusing to grant, renew, or vary a traditional herbal registration, or after notification of a decision relating to an application to vary such a registration.

(3) A parallel import licence shall, unless previously renewed or revoked, be valid for the period specified in it, but where an application to renew it is made in accordance with regulation 5(6) it shall remain in force pending the decision of the licensing authority on that application.

(4) Subject to paragraph (6), a traditional herbal registration other than a parallel import licence shall, unless previously revoked, be valid for an unlimited period unless—

- (a) it has not been renewed on the basis of a re-evaluation by the licensing authority of the risk-benefit balance in accordance with, and on the basis of the data set out in, Article 24(2) of the 2001 Directive; or
- (b) it has been so renewed, but the licensing authority considers on justified grounds relating to pharmacovigilance that it should be subject to one additional renewal five years after the date of the first renewal, and it has not yet been subject to that additional renewal.

(5) Subject to paragraph (6), where, by reason of paragraph (4), a traditional herbal registration is not valid for an unlimited period, it shall, unless previously revoked, be valid for a period of five years beginning with the date on which it is granted or was renewed, whichever is the later, but where an application for its renewal is made in accordance with Article 24 of the 2001 Directive the traditional herbal registration shall remain in force pending the decision of the licensing authority on that application.

(6) A traditional herbal registration (other than a parallel import licence) shall cease to be valid if at any time after it is granted the medicinal product to which it relates is not placed on the market in the United Kingdom for a period of three consecutive years, unless an exemption is granted in accordance with Article 24(6) of the 2001 Directive.

(7) Each traditional herbal registration granted by the licensing authority shall be granted subject to a condition that the traditional herbal medicinal product to which the registration relates is to be available—

- (a) only from a pharmacy; or

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(b) on general sale.