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## STATUTORY INSTRUMENTS

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# 2012 No. 1916

## The Human Medicines Regulations 2012

### PART 7

#### Traditional herbal registrations

##### *Application for traditional herbal registration*

#### **Application for grant of traditional herbal registration**

**127.**—(1) The licensing authority may, subject to regulation 130, grant an application for a traditional herbal registration for a traditional herbal medicinal product in response to an application made in accordance with this Part.

[<sup>F1</sup>(1A) The licensing authority may accept an application meeting reduced or alternative requirements specified in this Part (“under the unfettered access route”) and grant a THR(GB) only where—

- (a) there is already in place, or will be at the time the THR(GB) is granted, a traditional herbal registration in respect of the product authorising sale or supply in Northern Ireland,
- (b) the applicant complies with the requirements in regulation 128(1A), and
- (c) the traditional herbal medicinal product satisfies the definition of qualifying Northern Ireland goods.

(1B) A traditional herbal registration must state whether it is in force in—

- (a) the whole United Kingdom;
- (b) Great Britain only; or
- (c) Northern Ireland only,

and in these Regulations the meaning of a reference to that traditional herbal registration being “in force” is limited to that territory.]

(2) A registration granted under paragraph (1) shall contain terms approved by the licensing authority.

(3) The applicant [<sup>F2</sup>, where it is applying for—

- (a) a THR(NI)—
  - (i) in accordance with Chapter 4 of Title III of the 2001 Directive, must be established in the European Union;
  - (ii) on any other basis, must be established in the United Kingdom;
- (b) a THR (GB)—
  - (i) under the unfettered access route, must be established in Northern Ireland;
  - (ii) other than under the unfettered access route, must be established in the United Kingdom;

- (c) a THR(UK), must be established in the United Kingdom.]
- (4) The application must be—
  - (a) made in writing;
  - (b) signed by or on behalf of the applicant; and
  - (c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.
- [<sup>F3</sup>(4A) The application must include a statement indicating whether the traditional herbal registration sought is for sale or supply of the product in—
  - (a) the whole United Kingdom;
  - (b) Great Britain only; or
  - (c) Northern Ireland only.]
  - (5) An application is treated as signed for the purposes of paragraph (4)(b) if it is signed with an electronic signature.
  - (6) The application and any accompanying material must be in English.
  - (7) The application must include a statement indicating whether the product to which the application relates should be available—
    - (a) only from a pharmacy; or
    - (b) on general sale.
  - (8) The application must include a statement indicating—
    - (a) whether any terms of the registration are proposed relating to the method of sale or supply of the product (including, in particular, any proposed restrictions affecting the circumstances of the use or promotion of the product); and
    - (b) if so, what terms are proposed.

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| <b>F1</b> | Reg. 127(1A)(1B) inserted (31.12.2020) by <a href="#">S.I. 2019/775</a> , <b>reg. 113(2)</b> (as substituted by <a href="#">The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488)</a> , <a href="#">reg. 1</a> , <b>Sch. 2 para. 84</b> )                               |
| <b>F2</b> | Reg. 127(3)(a)-(c) substituted for words in reg. 127(3) (31.12.2020) by <a href="#">S.I. 2019/775</a> , <b>reg. 113(3)</b> (as substituted by <a href="#">The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488)</a> , <a href="#">reg. 1</a> , <b>Sch. 2 para. 84</b> ) |
| <b>F3</b> | Reg. 127(4A) inserted (31.12.2020) by <a href="#">S.I. 2019/775</a> , <b>reg. 113(4)</b> (as substituted by <a href="#">The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488)</a> , <a href="#">reg. 1</a> , <b>Sch. 2 para. 84</b> )                                   |

**Changes to legislation:**

There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 127.