

---

STATUTORY INSTRUMENTS

---

**2019 No. 775**

**The Human Medicines (Amendment  
etc.) (EU Exit) Regulations 2019**

**PART 7**

Amendment of Part 7 (Traditional Herbal Registrations)

**Amendment of regulation 128 (accompanying material)**

[<sup>F1</sup>114.—(1) Regulation 128 (accompanying material) is amended as follows.

(2) For paragraph (1) substitute—

“**128.**—(1) The applicant for the grant of a traditional herbal registration other than a THR(GB) under the unfettered access route must provide the material specified in Schedule 12 in relation to the product.

(1A) The applicant for the grant of a THR(GB) under the unfettered access route must provide—

- (a) the application form submitted in connection with the granting of the THR(NI) which authorises the sale or supply of the product in Northern Ireland;
- (b) a copy of all material submitted in support of the application for the THR(NI) which authorises the sale or supply of the product in Northern Ireland; and
- (c) a copy of the THR(NI) which authorises the sale or supply of the medicinal product in Northern Ireland,

together with any material specified in Schedule 12 which is not included in the material specified in sub-paragraphs (a) to (c) in relation to the product.”.

(3) In paragraph (3), after “of the 2001 Directive” insert “where the application is for a THR(NI) or THR(UK), or the list established under regulation 126A where the application is for a THR(GB)”.]

---

**Textual Amendments**

**F1** Reg. 114 substituted (31.12.2020 immediately before IP completion day) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, [Sch. 2 para. 85](#)

---

**Commencement Information**

**I1** Reg. 114 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

**Changes to legislation:**

There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, Section 114.