

## SCHEDULES

### SCHEDULE 2

Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

#### PART 5

Amendment of Part 6 (amendment of Part 6 (certification of homoeopathic products))

**80.** In regulation 102 (amendment of regulation 110 (revocation, variation and suspension of certificate of registration))—

(a) for paragraph (2) substitute—

“(2) In paragraph (7) for “established in the European Union” substitute—

“established in—

(a) the United Kingdom; or

(b) in relation to a COR(NI), either the United Kingdom or the European Union, in accordance with the requirements of these Regulations.””;

(b) after paragraph (2) insert—

“(2A) After paragraph (8A) insert—

“(8B) Condition I is that the licensing authority thinks that the revocation, variation or suspension is necessary or expedient in light of the Protocol on Ireland/Northern Ireland in the withdrawal agreement.””.

#### Commencement Information

**II** Sch. 2 para. 80 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

**81.** For regulation 107 (amendment of regulation 116 (obligation in relation to product information)) substitute—

#### “Amendment of regulation 116 (obligation in relation to product information)

**107.** For regulation 116(2), substitute—

“(2) In this regulation “current scientific knowledge” includes the conclusions of the assessment and recommendations made public by means of—

(a) in the case of a medicinal product authorised by a COR(NI) or COR(UK)—

(i) the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004, and

(ii) the UK web-portal established in accordance with regulation 203(1);

(b) in the case of a medicinal product authorised by a COR(GB), the UK web-portal established in accordance with regulation 203(1).””.

**Changes to legislation:** There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, PART 5. (See end of Document for details)

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**Commencement Information**

**I2** Sch. 2 para. 81 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

**Changes to legislation:**

There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, PART 5.