

SCHEDULES

SCHEDULE 2

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

PART 2

Amendment of Part 3 (amendment of Part 3 (manufacture and distribution of medicinal products and active substances))

9. In regulation 14 (amendment of regulation 17 (manufacturing of medicinal products))—

(a) for paragraph (2) substitute—

“(2) For paragraph (1) substitute—

“(1) A person may not except in accordance with a licence (a “manufacturer's licence”)—

- (a) manufacture a medicinal product,
- (b) assemble a medicinal product,
- (c) import a medicinal product into Great Britain from a country other than—
 - (i) Northern Ireland, or
 - (ii) an approved country for import,
- (d) import a medicinal product into Northern Ireland from a country other than an EEA State, or
- (e) possess a medicinal product for the purpose of any activity in sub-paragraphs (a) to (d).”;

(b) omit paragraph (3);

(c) for paragraph (4) substitute—

“(4) In paragraph (4), after sub-paragraph (a) insert—

“(aa) a UK marketing authorisation; or”;

(d) for paragraph (5) substitute—

“(5) In paragraph (5) omit “from a state other than an EEA State”;

(e) after paragraph (5) insert—

“(6) After paragraph (6) insert—

“(7) Paragraph (1) does not apply to imports into Northern Ireland from Great Britain of—

- (a) special medicinal products, and
- (b) medicinal products that have been released for sale, supply or distribution in an EEA State or the United Kingdom before IP completion day.

Changes to legislation: *There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, Paragraph 9. (See end of Document for details)*

(8) For the purposes of paragraph (7) a medicinal product has been released for sale, supply or distribution where, after the stage of manufacturing has taken place, the product is the subject matter of a written or verbal agreement between two or more persons for the transfer of ownership, any other property right, or possession concerning the product, or where the product is the subject matter of an offer to a person to conclude such an agreement.”.”.

Commencement Information

II Sch. 2 para. 9 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, Paragraph 9.