STATUTORY INSTRUMENTS

2019 No. 775

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

PART 3

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

Amendment of regulation 17 (manufacturing of medicinal products)

14.—(1) Regulation 17 is amended as follows.

[[F1](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).".**]**

[F2](3) . . . . . .

[[F3](4) In paragraph (4), after sub-paragraph (a) insert—

"(aa) a UK marketing authorisation; or".**]**

[[F4](5) In paragraph (5) omit "from a state other than an EEA State".**]**

[[F5](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.

(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.".**]**

Textual Amendments

F1 Reg. 14(2) 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. 9(a)**

F2 Reg. 14(3) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 9(b)**

F3 Reg. 14(4) 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. 9(c)**

F4 Reg. 14(5) 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. 9(d)**

F5 Reg. 14(6) inserted (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. 9(e)**

Commencement Information

I1 Reg. 14 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 14.