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 19 (exemptions from requirement for wholesale dealer's licence)

17.—(1) Regulation 19 [M1] is amended as follows.

[[F1](2) For paragraph (1)(a) substitute—

"(a) the holder of—

(i) in the case of a product for sale or supply in Great Britain, a UKMA(GB), a UKMA(UK), a COR(GB), a COR(UK), a THR(GB) or a THR(UK) (an "authorisation") which relates to the product, or

(ii) in the case of a product for sale or supply in Northern Ireland, a UKMA(NI), a UKMA(UK), a COR(NI), a COR(UK), a THR(NI), a THR(UK), an EU marketing authorisation or an Article 126a authorisation (an "authorisation") which relates to the product,

including a holder of an authorisation who manufactured or assembled the product; or".**]**

(3) In paragraph (1)(b), after "or assembled the product" insert " in the United Kingdom ".

[[F2](4) At the end insert—

"(6) Regulation 18 does not apply to a person ("P") who imports a medicinal product into Great Britain from an approved country for import for administration to P or to any other person who is a member of P's household.".**]**

Textual Amendments

F1 Reg. 17(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. 11(a)**

F2 Reg. 17(4) 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. 11(b)**

Commencement Information

I1 Reg. 17 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M1 Regulation 19 was amended by S.I. 2013/1855.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, Section 17.