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 Schedule 4 (standard provisions of licences under Part 3)

20.—(1) Schedule 4 is amended as follows.

[[F1](2) For paragraph 13(b) substitute—

"(b) in the case of a product for sale or supply—

(i) in Great Britain, a UK marketing authorisation, certificate of registration or traditional herbal registration, or

(ii) in Northern Ireland, a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration,

contains provisions relating to them,".**]**

[[F2](2A) After paragraph 14 insert—

"**14A.** A licence holder—

(a) in Great Britain may only supply a special medicinal product to a person in Northern Ireland, and

(b) in Northern Ireland may only supply a special medicinal product to a person in Great Britain,

in response to an order which satisfies the requirements of regulation 167.".**]**

[[F3](3) In the heading of Part 2, after "State Other Than an EEA State" insert "/ Country other than an Approved Country for Import".**]**

[[F4](4) In paragraph 15, for "from a state other than an EEA State" substitute—

"from—

(a) in the case of an import into Great Britain, a country other than Northern Ireland or a country other than an approved country for import, or

(b) in the case of an import into Northern Ireland, a country other than an EEA State".

(4A) In paragraphs 22(1) and 23, for "a state other than an EEA State" substitute ", in the case of an import into Great Britain, a country other than Northern Ireland or a country other than an approved country for import and in the case of an import into Northern Ireland, a country other than an EEA State".

(4B) After paragraph 23, insert—

"**23A.** A licence holder—

(a) in Great Britain may only supply a special medicinal product to a person in Northern Ireland, and

(b) in Northern Ireland may only supply a special medicinal product to a person in Great Britain,

in response to an order which satisfies the requirements of regulation 167."**]**.

(5) In paragraph 25(m), for the words "referred to in Article 8(2) of Directive 2004/23/EC", substitute—

"assigned by a tissue establishment pursuant to—

(a) paragraph 1 of Schedule 3A to the Human Fertilisation and Embryology Act 1990 [M1], as regards human gametes and embryos; and

(b) paragraph 1 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 [M2], as regards other human tissues and cells.".

[[F5](6) In paragraph 33, for "another EEA State" substitute ", in the case of an import into Great Britain, an approved country for import and in the case of an import into Northern Ireland, an EEA State".**]**

[[F6](7) After paragraph 41 insert—

"**41A.** A licence holder—

(a) in Great Britain may only supply a special medicinal product to a person in Northern Ireland, and

(b) in Northern Ireland may only supply a special medicinal product to a person in Great Britain,

in response to an order which satisfies the requirements of regulation 167.".**]**

Textual Amendments

F1 Reg. 20(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. 14(a)**

F2 Reg. 20(2A) 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. 14(b)**

F3 Reg. 20(3) 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. 14(c)**

F4 Reg. 20(4)-(4B) substituted for reg. 20(4) (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. 14(d)**

F5 Reg. 20(6) 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. 14(e)**

F6 Reg. 20(7) 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. 14(f)**

Commencement Information

I1 Reg. 20 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 1990 c. 37. Schedule 3A was inserted by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007/1522, regulation 30.

M2 S.I. 2007/1523.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, Section 20.