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 3 (applications for licences under Part 3)

18.—(1) Schedule 3 is amended as follows.

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

"(g) the name, address, qualifications and experience of the person with responsibility for quality control in relation to the medicinal products to be manufactured or assembled under the licence (and, if that responsibility is to be carried out by the holder of—

(i) in the case of a product for sale or supply in Great Britain, the UK marketing authorisation, certificate of registration or traditional herbal registration relating to the products, or

(ii) in the case of a product for sale or supply in Northern Ireland, the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration relating to the products,

a statement of that fact);".**]**

[[F2](3) For paragraph 2(1) substitute—

"**2.**—(1) This paragraph applies to an application for a manufacturer's licence relating to the import 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,

of medicinal products.".**]**

(4) In paragraph 3—

(a) in sub-paragraph (2)(d) at the end insert " or the responsible person (import) ".

(b) in sub-paragraph (3)(b)—

[[F3](i) for paragraph (i) substitute—

"(i) in the case of a product for sale or supply in Great Britain, a UK marketing authorisation,

(ia) in the case of a product for sale or supply in Northern Ireland, a marketing authorisation,",**]**

[F4(ii) in paragraph (iv) before "an Article" insert "in the case of a product for sale or supply in Northern Ireland,", and**]**

(iii) after paragraph (iii) insert—

"(v) an authorisation granted by an authority in a country other than the United Kingdom to sell or supply the medicinal product in that other country;";

(c) in sub-paragraph (3)(d)—

(i) in paragraph (i) omit "or",

(ii) in paragraph (ii) for "etc);" substitute " etc), or ",

(iii) at the end insert—

"(iii) to be distributed by means of export **[**F5from Great Britain**]** to an approved country for import;"; and

(d) for sub-paragraph (4) substitute—

"(4) In sub-paragraph (2)(d)—

"the responsible person" means the person who has the functions described in regulation 45(2);

"the responsible person (import)" means the person who has the functions described in regulation 45AA(4).".

Textual Amendments

F1 Reg. 18(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. 12(a)**

F2 Reg. 18(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. 12(b)**

F3 Reg. 18(4)(b)(i) 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. 12(c)(i)**

F4 Reg. 18(4)(b)(ii) 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. 12(c)(ii)**

F5 Words in reg. 18(4)(c)(iii) 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. 12(d)**

Commencement Information

I1 Reg. 18 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 18.