SCHEDULES

SCHEDULE 2

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

PART 12

Amendment of Part 13 (omission of Part 12A (sale of medicines to the public at a distance))

151. For regulation 197 (omission of Part 12A) substitute—

"**Amendment of Part 12A**

197.—(1) Before regulation 256A (interpretation) insert—

"**Application of Part**

256ZA. This part applies to Northern Ireland only.".

(2) In regulation 256A(1) (interpretation)—

(a) in the definition of "the list", for "competent authority of a member State in which the person named on the list is established" substitute " licensing authority ";

(b) omit the definition of "relevant website of the member State";

(c) at the appropriate place in the alphabetical order insert—

""website of the licensing authority" means a website of the licensing authority providing information on—

(a) the national legislation applicable to the offering of medicinal products for sale at a distance to the public by information society services;

(b) the differences between Northern Ireland and EEA States regarding classification of medicinal products and the conditions for their supply;

(c) the purpose of the common logo;

(d) the list of persons offering medicinal products for sale at a distance by means of information society services as well as their website addresses;

(e) background information about the risks related to medicinal products supplied illegally to the public by means of information society services;

(f) a hyperlink to the website of the EMA;";

(d) in the definition of "website of the EMA"—

(i) in paragraph (a)—

(aa) for "relevant website of the member State" substitute " website of the licensing authority ";

(bb) for "that member State" substitute " Northern Ireland ";

(ii) in paragraph (e), for "hyperlinks to the relevant website of the member State" substitute " a hyperlink to the website of the licensing authority ".

(3) In regulation 256B (person who may sell medicinal products by information society services)—

(a) before paragraph (1) insert—

"(A1) This regulation applies to a person who is an established service provider (as defined in regulation 2(1) of the Electronic Commerce (EC Directive) Regulations 2002 [M1]) in Northern Ireland.";

(b) in paragraph (2), omit "of persons selling medicinal products at a distance that is published on the relevant website of the member State";

(c) for paragraph (3) substitute—

"(3) Condition B is that the product to be sold by information society services is covered by a UK marketing authorisation or an authorisation granted—

(a) under Regulation (EC) No 726/2004; or

(b) by a competent authority of the member State in which that product is destined to be sold.

(3A) Condition B does not apply to—

(a) a special medicinal product;

(b) a medicinal product where the product is the result of a process of manufacture to which regulation 17(1) does not apply by virtue of any provision of section 10 of the Medicines Act 1968 [M2]; or

(c) a medicinal product where—

(i) the product is a result of a process of assembly of a medicinal product that is an authorised medicinal product within the meaning of regulation 3(15);

(ii) regulation 17(1) does not apply to the process of assembly by virtue of any provision of section 10 of the Medicines Act 1968;

(iii) the process of assembly results in a change in the presentation of the authorised medicinal product; and

(iv) by reason of the change in paragraph (iii) the product does not comply with condition B.";

(d) in paragraph (4), omit "in the member State in which that person is established";

(e) in paragraphs (6), for "the competent authority in a member State in which the person is established" substitute " the licensing authority ";

(f) in each of paragraphs (8)(b) and (c), for "the competent authority of a member State" substitute " the licensing authority ".

(4) In regulations 256C (notification requirements for sellers of medicinal products at a distance) to 256M (offences: breach of regulations and false information), for "competent authority of a member State" in each place it occurs (including in the headings to regulations 256F and 256J) substitute " licensing authority ".

(5) In regulation 256C (notification requirements for sellers of medicinal products at a distance), in paragraph (2)(b)(iv), for "informantion" substitute " information ".

(6) In regulation 256D(3) (procedure for listing persons who may supply medicinal products at a distance), for "that competent authority" in both places substitute " the licensing authority ".

(7) In regulation 256G (grant or refusal to list a person)—

(a) in paragraph (2), for "that competent authority" substitute " the licensing authority ";

(b) in paragraph (3)—

(i) for "that competent authority" substitute " the licensing authority ";

(ii) for "relevant website of the member State" substitute " website of the licensing authority ".

(8) In regulation 256H(3) (conditions to be met by a person entered on the list)—

(a) in sub-paragraph (a), omit "which is responsible for maintaining the list on which the person selling products at a distance is included";

(b) in sub-paragraph (b), for "relevant website of the Member State" substitute " website of the licensing authority ".

(9) In regulation 256J (procedure where the licensing authority proposes to suspend, vary or remove a person's entry on the list), omit sub-paragraph (6)(b) (and the "and" at the end of sub-paragraph (a)).

(10) In regulation 256K(1) (suspension of a person's entry on the list in cases of urgency), for "that competent authority" substitute " the licensing authority ".

(11) In regulation 256L (variation of a person's entry on the list on the application of that person)—

(a) in paragraph (3), for "that competent authority" substitute " the licensing authority ";

(b) in paragraph (6)(b), for "that competent authority's" substitute "the licensing authority's".".

Commencement Information

I1 Sch. 2 para. 151 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

Marginal Citations

M1 S.I. 2002/2013, as amended by S.I. 2012/1809 and prospectively amended with effect from IP completion day by S.I. 2019/87.

M2 1968 c.67, as amended by section 26 of the Health Act 2006 (c.28) and S.I. 1971/1445, 1994/2987, 2006/2407, 2011/2581 and 2012/1916, and in relation to Scotland by paragraph 5 of Schedule 3 to the Regulation of Care (Scotland) Act 2001 (asp 8).

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, Paragraph 151.