SCHEDULES

SCHEDULE 2

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

PART 9

Amendment of Part 10 (amendment of Part 10 (exceptions to requirement for marketing authorisations etc))

102. Before regulation 135 (amendment of regulation 168 (use of non-prescription medicines in the course of a business) insert—

"**New regulation 135ZA (amendment of regulation 167 (supply to fulfil special patient needs))**

135ZA. In regulation 167 (supply to fulfil special patient needs)—

(a) in paragraph (6), for "or imported into the United Kingdom from a country other than an EEA State" substitute " , imported into Northern Ireland from a country other than an EEA State or Great Britain, or imported into Great Britain from a country other than an approved country for import or Northern Ireland ";

(b) in paragraph (7)—

(i) for "imported from an EEA State" substitute " imported into Northern Ireland from an EEA State or imported into Great Britain from a country other than an approved country for import ";

(ii) for sub-paragraph (a) substitute—

"(a) it is manufactured or assembled in that State or country (as appropriate) by a person who is the holder of an authorisation in relation to its manufacture or assembly in accordance with—

(i) in the case of a product for sale or supply in Northern Ireland, the provisions of the 2001 Directive as implemented in that State, and

(ii) in the case of a product for sale or supply in Great Britain, in accordance with the provisions applicable in that country; or";

(iii) for sub-paragraph (b) substitute—

"(b) it is manufactured or assembled as an investigational medicinal product in that State or country (as appropriate) by the holder of an authorisation in relation to its manufacture or assembly in accordance with—

(i) in the case of a product for sale or supply in Northern Ireland, Article 13 of the Clinical Trials Directive as implemented in that State, and

(ii) in the case of a product for sale or supply in Great Britain, regulations 13 and 43 of the Clinical Trials Regulations,".".

Commencement Information

I1 Sch. 2 para. 102 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

103. For regulation 135 (amendment of regulation 168 (use of non-prescription medicines in the course of a business)), substitute—

"**Amendment of regulation 168 (use of non-prescription medicines in the course of a business)**

135. In regulation 168 (use of non-prescription medicines in the course of a business), for paragraph (8) substitute—

"(8) Condition G is that if the medicinal product is—

(a) manufactured or assembled in the United Kingdom or imported into the United Kingdom from—

(i) in the case of a product for sale or supply in Northern Ireland, a country other than an EEA State, or

(ii) in the case of a product for sale or supply in Great Britain, a country other than an approved country for import,

it is manufactured, assembled or imported by the holder of a manufacturer's licence that relates specifically to the manufacture, assembly or importation of special medicinal products, or

(b) imported into—

(i) Northern Ireland from an EEA State, it is manufactured or assembled in that State by a person who is the holder of an authorisation in relation to its manufacture or assembly in accordance with the provisions of the 2001 Directive as implemented in that State, or

(ii) Great Britain from an approved country for import—

(aa) it is manufactured or assembled in that country by a person who is the holder of an authorisation in that country in relation to its manufacture or assembly, and

(bb) it is imported by the holder of a wholesale dealer's licence under Part 3 that includes the import of a medicinal product from such a country.".".

Commencement Information

I2 Sch. 2 para. 103 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

104. In regulation 136 (amendment of regulation 169 (mixing of general sale medicinal products)), for "insert " UK " before "marketing authorisation" " substitute "for "marketing authorisation" substitute " UK marketing authorisation or EU marketing authorisation "".

Commencement Information

I3 Sch. 2 para. 104 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

105. In regulation 137 (amendment of regulation 171 (exempt advanced therapy medicinal products)), for "substitute "regulation 49(1)"." substitute—

"substitute—

"(i) in the case of a product for sale or supply in Northern Ireland, Regulation (EC) No 726/2004, and

(ii) in the case of a product for sale or supply in Great Britain, regulation 49(1).".".

Commencement Information

I4 Sch. 2 para. 105 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

106. In regulation 138 (amendment of regulation 173 (exemption for certain radiopharmaceuticals)), for "insert " UK " before "marketing authorisation" " substitute "for "marketing authorisation" substitute " UK marketing authorisation or EU marketing authorisation "".

Commencement Information

I5 Sch. 2 para. 106 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, PART 9.