SCHEDULES

SCHEDULE 2

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

PART 11

Amendment of Part 12 (amendment of Part 12 (dealings with medicinal products))

141. For regulation 187 (amendment of regulation 229 (exemption for supply by national health services bodies and local authorities)) substitute—

"**187.** In regulation 229(3), for sub-paragraph (f) substitute—

"(f) when the product is supplied—

(i) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), or

(ii) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.".".

142. For regulation 188 (amendment of regulation 230 (exemption for supply etc under a PGD to assist doctors or dentists)) substitute—

"**188.** For regulation 230(8) substitute—

"(8) Condition G is that when the product is supplied or (as the case may be) administered —

(a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), or

(b) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.".".

143. For regulation 189 (amendment of regulation 231 (exemption for supply etc under a PGD by independent hospitals etc)) substitute—

"**189.** For regulation 231(8) substitute—

"(8) Condition G is that when the product is supplied—

(a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), or

(b) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.".".

144. For regulation 190 (amendment of regulation 232 (exemption for supply etc under a PGD by dental practices and clinics: England and Wales)) substitute—

"**190.** For regulation 232(8) substitute—

"(8) Condition F is that when the product is supplied, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK) is in force in relation to it.".".

145. For regulation 191 (amendment of regulation 233 (exemption for supply etc under a PGD by a person conducting a retail pharmacy business)) substitute—

"**191.** For regulation 233(7) substitute—

"(7) Condition F is that when the prescription only medicine is supplied or (as the case may be) administered—

(a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), or

(b) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.".".

146. For regulation 192 (amendment of regulation 234 (exemption for supply etc of products under a PGD to assist the police etc)) substitute—

"**192.** For regulation 234(9) substitute—

"(9) Condition H is that when the product is supplied—

(a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), or

(b) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.".".

147. In regulation 193 (amendment of Schedule 17 (exemptions for sale, supply or administration by certain persons)—

(a) in paragraph (2), for "insert "UK" before "marketing authorisations"." substitute "for "marketing authorisations" substitute "UK marketing authorisations, EU marketing authorisations";

(b) in paragraph (3), for "insert "UK" before "marketing authorisation"." substitute "for "marketing authorisation" substitute "UK marketing authorisation, EU marketing authorisation".

148. In regulation 194 (amendment of regulation 249 (restrictions on persons to be supplied with medicinal products)), for paragraphs (b) and (c) substitute—

"(b) after sub-paragraph (a) insert—

"(aa) an EU marketing authorisation;".";

149. After regulation 194 (amendment of regulation 249 (restrictions on persons to be supplied with medicinal products) insert—

"**Amendment of regulation 251 (compliance with standards specified in certain publications)**

194A. In regulation 251 (compliance with standards specified in certain publications), after paragraph (5) insert—

"(6) In paragraph (1), (2) or (3) a product is to be treated as complying with the standard specified in the relevant monograph where—

(a) the product complies with the standard specified in a relevant marketing authorisation for the product concerned, and

(b) the standard specified in that marketing authorisation does not comply with the standard specified in the relevant monograph.

(7) In paragraph (6), "relevant marketing authorisation" means—

(a) an EU marketing authorisation;

(b) an authorisation granted by the licencing authority under Chapter 4 of Title III to the 2001 Directive; or

(c) a UKMA(GB) granted under the unfettered access route.".".

150. For regulation 196 (omission of regulation 255A to 255C (enforcement and offences relating to Commission Regulation 2016/161)) substitute—

"**Amendment of regulation 255A (enforcement notices relating to Commission Regulation 2016/161: persons authorised to supply medicinal products to the public)**

196. In regulation 255A(1), after "purpose of sale or supply," insert "in Northern Ireland,".

Amendment of regulation 255B (exception to Article 25 of Commission Regulation 2016/161: health care institutions)

196A. In regulation 255B, after "medicinal products to the public" in the first place it occurs insert "in Northern Ireland".".