SCHEDULES

SCHEDULE 2

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

PART 13

Amendment of Part 14 (amendment of Part 13 (packaging and leaflets))

152. In regulation 198 (amendment of regulation 257 (packaging requirements: general))—

(a) in paragraph (2), after "257C" insert "where the product is for sale or supply in Great Britain only";

(b) in paragraph (3), in the inserted paragraph (8), after "product" insert "for sale or supply in Great Britain only".

153. For regulation 199 (omission of regulations 257A and 257B (packaging requirements: medicinal products required to bear safety features and associated transitionals)) substitute—

"**Amendment of regulation 257A (packaging requirements: medicinal products required to bear safety features)**

199. In regulation 257A, after "either fully or partially," insert "from a product to which Article 54a of the 2001 Directive applies".

Amendment of regulation 257B (transitional arrangements)

199A. In regulation 257B, after "unless the product" insert "is one to which Article 54a of the 2001 Directive applies and".".

154. In regulation 200 (insertion of regulations 257C (packaging requirements: advanced therapy medicinal products) and 257D and 257E (guidance and regulations in relation to packing, leaflets and labelling))—

(a) in the inserted regulation 257C(1)—

(i) in sub-paragraph (a), after the first reference to "advanced therapy medicinal product" insert "for sale or supply in Great Britain only";

(ii) in sub-paragraph (b), for "of the product" substitute "of that product"

(b) for the inserted regulation 257D substitute—

"**257D.**—(1) The licensing authority may publish guidance on packaging and package leaflets applicable to products for sale or supply in the whole United Kingdom or parts of the United Kingdom, as appropriate.

(2) Guidance published under paragraph (1) may, in particular, include—

(a) the wording of certain special warnings for certain categories of medicinal products;

(b) the particular information needs relating to products that are a pharmacy medicine;

(c) the legibility of particulars on the labelling and package leaflet;

(d) the methods of identification and authentication of medicinal products;

(e) the list of excipients which must feature on the labelling of medicinal products and the way in which these excipients must be indicated.

(3) Until such time as the licensing authority publishes guidance under paragraph (1), any guidance published by the Commission pursuant to Article 65 of the 2001 Directive(**1**), insofar as that guidance was in force immediately before IP completion day, continues to apply as if it had been published by the licensing authority under paragraph (1).".

155. In regulation 201 (amendment of Schedule 24 (packaging information requirements))—

(a) in paragraph (2), after "regulation 257D" insert "in the case of products for sale or supply in Great Britain, or in the case of products for sale or supply in Northern Ireland, any guidance published pursuant to Article 65 of the 2001 Directive(**2**) or under regulation 257D that is applicable to such products.";

(b) in paragraph (3), for "for "marketing authorisation"" to the end substitute "for "marketing authorisation," substitute "UK marketing authorisation, EU marketing authorisation".";

(c) omit paragraph (4);

(d) in paragraph (5)—

(i) in the inserted Part 4 (outer and immediate packaging: advanced therapy medicinal products), in the heading, after "products" insert "for sale or supply in Great Britain only";

(ii) in the inserted Part 5 (immediate packaging: blister packs and small packaging (advanced therapy medicinal products)), in the heading, after "products" insert "for sale or supply in Great Britain only".

156. In regulation 202 (amendment of regulation 259 (packaging requirements: information for blind and partially sighted patients)), for "for "marketing authorisation" to the end substitute "for "marketing authorisation," substitute "UK marketing authorisation, EU marketing authorisation".".

157. In regulation 203 (amendment of regulation 260 (package leaflets))—

(a) in paragraph (2), in the inserted paragraph (1A), after the first reference to "advanced therapy medicinal product" insert "for sale or supply in Great Britain only";

(b) in paragraph (3), in the inserted text, after "advanced therapy medicinal product," insert "for sale or supply in Great Britain only";

(c) in paragraph (4)—

(i) omit ", Article 126a authorisation";

(ii) after "UK marketing authorisation" insert ", EU marketing authorisation,".

158. In regulation 204 (amendment of Schedule 27 (package leaflets))—

(a) in paragraph (2), after "regulation 257D" insert "in the case of products for sale or supply in Great Britain, or in the case of products for sale or supply in Northern Ireland, any guidance

(**1**) The guidelines are available at: https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012 and a hard copy may be obtained from the Medicines and Healthcare products Regulatory Agency at the address given in the Explanatory Note.

(**2**) The guidelines are available at: https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012 and a hard copy may be obtained from the Medicines and Healthcare products Regulatory Agency at the address given in the Explanatory Note.

published pursuant to Article 65 of the 2001 Directive(**3**) or under regulation 257D that is applicable to such products.";

(b) in paragraph (3), for "for "marketing authorisation" to the end substitute "for "marketing authorisation," substitute "UK marketing authorisation, EU marketing authorisation".";

(c) in paragraph (4)—

(i) for "Omit" substitute "In";

(ii) after "12" insert "after "Where the product" insert "is authorised for sale or supply in Northern Ireland and".";

(d) in paragraph (5)(a)—

(i) for "for" substitute "after";

(ii) for "substitute "regulation 202A"" substitute "insert "in the case of products for sale or supply in Northern Ireland, or the list referred to in regulation 202A, in the case of products for sale or supply in Great Britain,";";

(e) in paragraph (6), in the inserted Part 3 (advanced therapy medicinal products), in the heading, after "products" insert "for sale or supply in Great Britain only".

159. Omit regulation 205 (amendment of regulation 266 (language requirements etc)).

160. In regulation 206 (amendment of regulation 267 (submission of mock-ups of packaging and leaflets to licensing authority)) for ", in each place where it occurs" to the end substitute "before "marketing authorisation", in each place where it occurs, insert "UK".".

161. In regulation 207 (amendment of regulation 268 (offence relating to packaging and package leaflets))

(a) after paragraph (1) insert—

"(1A) In the heading to the regulation, after "packaging and package leaflets" insert "in Great Britain".";

(b) for paragraph (2) substitute—

"(2) In paragraph (1)—

(a) for "marketing authorisation, Article 126a authorisation" substitute "UKMA(UK), UKMA(GB)";

(b) after "the purpose of sale or supply" insert ", in Northern Ireland".".

162. After regulation 207 (amendment of regulation 268 (offence relating to packaging and package leaflets)) insert—

"**Insertion of new regulation 268A (offence relating to packaging and package leaflets in Northern Ireland: holder of authorisation etc)**

207A. After regulation 268 insert—

"**Offence relating to packaging and package leaflets in Northern Ireland: holder of authorisation etc**

268A.—(1) This regulation applies to the holder of a UKMA(UK), UKMA(NI), EU marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for a medicinal product who sells or supplies,

(**3**) The guidelines are available at: https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012 and a hard copy may be obtained from the Medicines and Healthcare products Regulatory Agency at the address given in the Explanatory Note.

offers to sell or supply, or possesses for the purpose of sale or supply, in Northern Ireland, a medicinal product to which the authorisation, certificate or registration relates.

(2) A person to whom this regulation applies is guilty of an offence if—

(a) a package or package leaflet relating to the product does not comply with the applicable requirements of this Part, Article 9 of Commission Regulation 2016/161 or Article 28 or 32 of the Paediatric Regulation; or

(b) the product is not accompanied by a package leaflet when one is required by virtue of this Part.".".

163. In regulation 208 (amendment of regulation 269 (offences relating to packaging and package leaflets: other persons))—

(a) after paragraph (1) insert—

"(1A) In the heading to the regulation, after "packaging and package leaflets" insert "in Great Britain".";

(b) for paragraph (2) substitute—

"(2) In paragraph (1)—

(a) for "marketing authorisation, Article 126a authorisation" substitute "UKMA(UK), UKMA(GB)";

(b) after "the purpose of sale or supply" insert ", in Great Britain".";

(c) after paragraph (2) insert—

"(2A) In paragraph (2), after "for the purpose of sale or supply," insert "in Great Britain".".

164. After regulation 208 (amendment of regulation 269 (offences relating to packaging and package leaflets: other persons)) insert—

"**Insertion of new regulation 269A (offences relating to packaging and package leaflets in Northern Ireland: other persons)**

208A. After regulation 269 insert—

"**Offences relating to packaging and package leaflets in Northern Ireland: other persons**

269A.—(1) This regulation applies to a person, other than the holder of a UKMA(UK), UKMA(NI), EU marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for a medicinal product, who, in the course of a business carried on by that person, sells or supplies, or offers to sell or supply the product, or possesses the product for the purpose of sale or supply in Northern Ireland.

(2) A person to whom this regulation applies is guilty of an offence if the person sells or supplies, or offers to sell or supply, the product, or possesses the product for the purpose of sale or supply, in Northern Ireland knowing or having reasonable cause to believe—

(a) that a package or package leaflet relating to the medicinal product does not comply with the applicable requirements of this Part, Article 9 of Commission Regulation 2016/161 or Article 28 or 32 of the Paediatric Regulation; or

(b) that the product is not accompanied by a package leaflet when one is required by virtue of this Part.".".

165. In regulation 209 (amendment of regulation 270 (non-compliance with requirements of this Part)) for "for "marketing authorisation" to the end substitute "for "marketing authorisation," substitute "UK marketing authorisation, EU marketing authorisation,".

166. After regulation 209 (amendment of regulation 270 (non-compliance with requirements of this Part)) insert—

"**Amendment of regulation 271 (offences: penalties)**

209A. In regulation 271 for "268, 269" substitute "268, 268A, 269, 269A".".