SCHEDULES

SCHEDULE 2

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

PART 14

Amendment of Part 15 (amendment of Part 14 (advertising))

167. For regulation 211 (amendment of regulation 279 (products without a marketing authorisation)) substitute—

"**211.** For regulation 279 substitute—

"**279.**—(1) A person may not publish an advertisement in Great Britain for a medicinal product unless one of the following is in force for the product—

(a) a UKMA(GB) or UKMA(UK);

(b) a COR(GB) or COR(UK); or

(c) a THR(GB) or THR(UK).

(2) A person may not publish an advertisement in Northern Ireland for a medicinal product unless one of the following is in force for the product—

(a) a UKMA(NI) or UKMA(UK);

(b) a COR(NI) or COR(UK);

(c) a THR(NI) or THR(UK);

(d) an EU marketing authorisation; or

(e) an Article 126a authorisation.

(3) A person may not publish an advertisement in the whole United Kingdom for a medicinal product unless, in relation to that product—

(a) one of the authorisations or registrations specified in paragraph (1) is in force in Great Britain; and

(b) one of the authorisations or registrations specified in paragraph (2) is in force in Northern Ireland.".".

Commencement Information

I1 Sch. 2 para. 167 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

168. In regulation 212 (amendment of regulation 280 (general principles))—

(a) for "280(1)" substitute " 280 ";

(b) in paragraph (a)—

(i) at the beginning, insert " in paragraph (1) ";

(ii) for "UK marketing authorisation or" substitute " UK marketing authorisation, EU marketing authorisation, ";

(c) for paragraph (b) substitute—

"(b) after paragraph (1) insert—

"(1A) Where an advertisement mentioned in paragraph (1) relates to a product in relation to which there is a separate authorisation or registration in force in Great Britain and in Northern Ireland, it may not be published in the whole United Kingdom unless it complies with the particulars listed in the summary of the product characteristics in each of those authorisations or registrations (as the case may be).".".

Commencement Information

I2 Sch. 2 para. 168 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

169. In regulation 213 (amendment of regulation 281 (duties of authorisation holders and registration holders)) for paragraphs (b) and (c) substitute—

"(b) omit "or" at the end of sub-paragraph (c); and

(c) in sub-paragraph (d), after "for a medicinal product" insert—

"; or

(e) an EU marketing authorisation for a medicinal product.".".

Commencement Information

I3 Sch. 2 para. 169 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

170. After regulation 213 (amendment of regulation 281 (duties of authorisation holders and registration holders)) insert—

"**Insertion of new regulation 284A (Medicines with differing classification status in Great Britain and Northern Ireland)**

213A. After regulation 284, insert—

"**Medicines with differing classification status in Great Britain and Northern Ireland**

284A. In the case of a medicinal product for sale or supply in Great Britain where the product concerned is not a prescription only medicine in Great Britain but is either—

(a) a prescription only medicine in Northern Ireland; or

(b) not authorised for sale or supply in Northern Ireland,

any advertisement to the public must include a statement that the medicinal product is not available without a prescription, or is not available for sale or supply, in Northern Ireland (as the case may be).".".

Commencement Information

I4 Sch. 2 para. 170 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

171. For regulation 214 (amendment of regulation 293 (prohibition of supply to the public for promotional purposes) substitute—

"**214.** For regulation 293(1) substitute—

"(1) The holder of—

(a) in the case of a medicinal product for sale or supply in Great Britain, a UKMA(GB), UKMA(UK), COR(GB), COR(UK), THR(GB) or THR(UK); or

(b) in the case of a medicinal product for sale or supply in Northern Ireland, a UKMA(NI), UKMA(UK), COR(NI), COR(UK), THR(NI), THR(UK), EU marketing authorisation or Article 126a authorisation,

may not sell or supply a medicinal product for a promotional purpose to a person who is not qualified to prescribe medicinal products.".".

Commencement Information

I5 Sch. 2 para. 171 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

172. After regulation 214 (amendment of regulation 293 (prohibition of supply to the public for promotional purposes) insert—

"**Amendment of regulation 294 (general requirements)**

214A. In regulation 294, after paragraph (4) insert—

"(5) In the case of an advertisement which relates to a medicinal product for sale or supply—

(a) in Northern Ireland only, the requirements of this regulation must be met in relation to the product for sale or supply in Northern Ireland,

(b) in Great Britain only, the requirements of this regulation must be met in relation to the product for sale or supply in Great Britain, and

(c) in the whole of the United Kingdom, the requirements of this regulation must be met in relation to both—

(i) the product for sale or supply in Great Britain, and

(ii) the product for sale or supply in Northern Ireland.".".

Commencement Information

I6 Sch. 2 para. 172 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

173. For regulation 215 (amendment of regulation 295 (abbreviated advertisements)) substitute—

"**215.** In regulation 295—

(a) for paragraph (2)(d) substitute—

"(d) the name and address of the holder—

(i) in the case of a medicinal product for sale or supply in Great Britain, of the UKMA(GB), UKMA(UK), COR(GB), COR(UK), THR(GB) or THR(UK) for the medicinal product, or

(ii) in the case of a medicinal product for sale or supply in Northern Ireland, the name and address of the holder of the UKMA(NI), UKMA(UK), COR(NI), COR(UK), THR(NI), THR(UK), EU marketing authorisation, or Article 126a authorisation for the medicinal product,

or the business name and address of the part of the holder's business that is responsible for the sale or supply of the medicinal product.";

(b) after paragraph (4) insert—

"(4A) In the application of this regulation to a medicinal product for sale or supply—

(a) in Northern Ireland only, the requirements of this regulation must be met in relation to the product for sale or supply in Northern Ireland,

(b) in Great Britain only, the requirements of this regulation must be met in relation to the product for sale or supply in Great Britain, and

(c) in the whole of the United Kingdom, the requirements of this regulation must be met in relation to both—

(i) the product for sale or supply in Great Britain, and

(ii) the product for sale or supply in Northern Ireland.".".

Commencement Information

I7 Sch. 2 para. 173 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

174. After regulation 215 (amendment of regulation 295 (abbreviated advertisements)) insert—

"**Amendment of regulation 298 (free samples for persons qualified to prescribe or supply medicinal products)**

215A. In regulation 298, for paragraph (5)(a) substitute—

"(a) is no larger than the smallest presentation of the product that is available for sale—

(i) in the case of a medicinal product for sale or supply in Great Britain, in Great Britain, or

(ii) in the case of a medicinal product for sale or supply in Northern Ireland, in Northern Ireland;".".

Commencement Information

I8 Sch. 2 para. 174 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

175. For regulation 216 (amendment of Schedule 30 (particulars for advertisements to persons qualified to prescribe or supply)) substitute—

"**216.** In Schedule 30—

(a) in paragraphs 1, 2 and 6, for "marketing authorisation," substitute " UK marketing authorisation, EU marketing authorisation ";

(b) after paragraph 2 insert—

"**2A.** In relation to an advertisement in Great Britain (other than an advertisement falling within the exception in regulation 296) where the medicinal product concerned is authorised under a UKMA(GB), a statement that the product concerned is authorised under a UKMA(GB).".".

Commencement Information

I9 Sch. 2 para. 175 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

176. In regulation 217 (amendment of regulation 299 (medical sales representatives)), for "for "marketing authorisation" to the end substitute "for "marketing authorisation," substitute " UK marketing authorisation, EU marketing authorisation ".".

Commencement Information

I10 Sch. 2 para. 176 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

177. After regulation 217 (amendment of regulation 299 (medical sales representatives)) insert—

"**Amendment of regulation 305 (invitation to make representations about compatibility)**

217A. In regulation 305—

(a) for paragraph (3)(a) substitute—

"(a) state that the Ministers are minded to make a determination under regulation 306 that the advertisement is incompatible with the prohibitions imposed by Chapter 2 and specify whether the incompatibility is insofar as the advertisement is for publication—

(i) in Great Britain;

(ii) in Northern Ireland; or

(iii) in both Great Britain and Northern Ireland;";

(b) in paragraph (4), after "the advertisement" insert—

"(a) in Great Britain;

(b) in Northern Ireland; or

(c) in both Great Britain and Northern Ireland".

Amendment of regulation 306 (decision about compatibility)

217B. In regulation 306—

(a) in paragraph (2), after "Chapter 2" insert—

"and specify whether the incompatibility is insofar as the advertisement is for publication—

(a) in Great Britain;

(b) in Northern Ireland; or

(c) in both Great Britain and Northern Ireland";

(b) in paragraph (4)—

(i) in sub-paragraph (a), after "Chapter 2" insert—

"insofar as the advertisement is for publication—

(i) in Great Britain;

(ii) in Northern Ireland; or

(iii) in both Great Britain and Northern Ireland";

(ii) after "no longer applies" insert " in Great Britain, Northern Ireland, or both Great Britain and Northern Ireland (as appropriate) ";

(c) in paragraph (5), after "Chapter 2" insert—

"insofar as the advertisement is for publication—

(a) in Great Britain;

(b) in Northern Ireland; or

(c) in both Great Britain and Northern Ireland";

(d) in paragraph (7)(b), after "no longer applies" insert—

",

and where that original notice related to both Great Britain and Northern Ireland, the new notice may be expressed to apply in relation to either of or both Great Britain and Northern Ireland";

(e) in paragraph (8), after "the advertisement" insert—

"(a) in Great Britain;

(b) in Northern Ireland; or

(c) in both Great Britain and Northern Ireland".

Amendment of regulation 307 (corrective statement)

217C. In regulation 307—

(a) in paragraph (1)(a), after "subject of the notice" insert—

"in—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland";

(b) in paragraph (1)(b), after "that advertisement" insert—

"in—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland";

(c) in paragraph (2)(a), for ", either in full or in part; and" substitute—

"in respect of—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland,

either in full or in part; and".

Amendment of regulation 311 (application for injunction)

217D. In regulation 311—

(a) in paragraph (1)(a), for "Chapter 2; and" substitute—

"Chapter 2 in respect of—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland; and";

(b) in paragraph (3), after " the advertisement" insert—

"in—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland,

as the case may be.".".

Commencement Information

I11 Sch. 2 para. 177 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 14.