STATUTORY INSTRUMENTS

2019 No. 775

The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

PART 12

Amendment of Part 12 (dealings with medicinal products)

Amendment of regulation 213 (interpretation of Part 12)

179. In regulation 213(1)(**1**)—

(a) insert at the appropriate place—

> ""approved country health professional" means a person who is practising in a profession included in the list published under regulation 214(6A) in a country that is included in that list in relation to that profession;";

(b) omit the definition of "EEA health professional"(**2**); and

(c) in the definition of "relevant prescriber", for "EEA health professional" substitute "approved country health professional".

Amendment of regulation 214 (sale or supply of prescription only medicines)

180.—(1) Regulation 214(**3**) is amended as follows.

(2) In paragraph (2)(a), for "EEA health professional" substitute "approved country health professional".

(3) In paragraph (6), for "EEA health professional" substitute "approved country health professional".

(4) After paragraph (6) insert—

> "(6A) The licensing authority must publish a list of approved countries and professions for the purposes of the definition of "approved country health professional".
>
> (6B) In order to determine whether a country or profession should be included in the list published under paragraph (6A), the licensing authority may, in particular, take into account—
>
> (a) the country's standards of professional qualification;
>
> (b) the country's system for ensuring that qualified professionals have undergone training which meets the requirements that apply in that country;
>
> (c) the effectiveness of enforcement of professional standards;

(**1**) Regulation 213 was amended by S.I. 2013/235 and 2014/490 and 1878.
(**2**) The definition was substituted by S.I. 2014/1878.
(**3**) Regulation 214 was amended S.I. 2013/1855, 2014/490, 2016/186 and 2018/199.

(d) the mechanisms the country has in place to assist members of the public in obtaining information in respect of a qualified professional who is established there; and

(e) the regularity and rapidity of information provided by that country relating to non-compliant professionals.

(6C) The licensing authority must—

(a) review a country or profession it has included in the list published under paragraph (6A) to determine if it is still satisfied that they should remain on the list, and if it is not so satisfied, remove it from that list; and

(b) undertake such a review at least every 3 years beginning with the date on which that country or profession was included in that list.".

Amendment of regulation 216 (exceptions to regulation 215)

181. In regulation 216(2), for "EEA health professional" substitute "approved country health professional".

Amendment of regulation 217 (requirements for prescriptions: general)

182. In regulation 217(8)(a)(**4**), for "EEA health professional" substitute "approved country health professional".

Amendment of regulation 217A (requirements for prescriptions to be dispensed in an EEA State)

183.—(1) Regulation 217A(**5**) is amended as follows.

(2) In the heading, omit "other than the UK".

(3) In paragraph (2)(a), omit "other than the UK".

Amendment of regulation 218 (requirements for prescriptions: EEA health professionals)

184.—(1) Regulation 218(**6**) is amended as follows.

(2) In the heading, and each place where it subsequently occurs, for "EEA health professional" substitute "approved country health professional".

(3) In paragraph (5)(c) and (d)(ii)(bb), for "EEA health professional's" substitute "approved country health professional's".

(4) In paragraph (2)(a), for "relevant European State except the United Kingdom" substitute "country included in the list published under regulation 214(6A)".

Amendment of regulation 219 (electronic prescriptions)

185. In regulation 219(2)(**7**), for "EEA health professional" substitute "approved country health professional".

(**4**) Regulation 217 was amended by S.I. 2014/490.
(**5**) Regulation 217A was inserted by S.I. 2014/490.
(**6**) Regulation 218 was amended by S.I. 2014/490 and 1878 and 2015/903.
(**7**) Regulation 219 was amended by S.I. 2015/903 and 2016/696.

Amendment of regulation 219A (electronic prescriptions: EEA health professionals)

186.—(1) Regulation 219A(**8**) is amended as follows.

(2) In the heading, for "EEA health professionals" substitute "approved country health professionals".

(3) In paragraph (2), for "EEA health professional" substitute "approved country health professional".

Amendment of regulation 229 (exemption for supply by national health services bodies and local authorities)

187. In regulation 229(3)(f)(**9**), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

Amendment of regulation 230 (exemption for supply etc under a PGD to assist doctors or dentists)

188. In regulation 230(8)(**10**), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

Amendment of regulation 231 (exemption for supply etc under a PGD by independent hospitals etc.)

189. In regulation 231(8), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

Amendment of regulation 232 (exemption for supply etc under a PGD by dental practices and clinics: England and Wales)

190. In regulation 232(8), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

Amendment of regulation 233 (exemption for supply etc under a PGD by a person conducting a retail pharmacy business)

191. In regulation 233(7)(**11**), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

Amendment of regulation 234 (exemption for supply etc of products under a PGD to assist the police etc)

192. In regulation 234(9)(**12**), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

Amendment of Schedule 17 (exemptions for sale, supply or administration by certain persons)

193.—(1) Schedule 17(**13**) is amended as follows.

(**8**) Regulation 219A was amended by S.I. 2015/903.
(**9**) Regulation 229 was amended by S.I. 2013/325, 2015/323, 2016/186 and 2018/199.
(**10**) Regulation 230 was amended by S.I. 2013/325.
(**11**) Regulation 233 was amended by S.I. 2013/235 and 2015/1503.
(**12**) Regulation 234 was amended by S.I. 2015/323.
(**13**) Schedule 17 was amended by S.I. 2014/1878, 2015/1503, 2016/186 and 2017/715,

(2) In the table in Part 1, in column 1 in entry 10, insert "UK" before "marketing authorisations".

(3) In the table in Part 4, in columns 1 and 2 in entry 9, insert "UK" before "marketing authorisation".

Amendment of regulation 249 (restrictions on persons to be supplied with medicinal products)

194. In regulation 249(2)—

(a) in sub-paragraph (a), insert "UK" before "marketing authorisation";

(b) in sub-paragraph (b), insert "and" at the end; and

(c) omit sub-paragraph (d) (and "and" immediately preceding it).

Amendment of regulation 254 (prohibitions concerning traceability of treatment with advanced therapy medicinal products)

195. In regulation 254(2)(a), for the words from "laid down in" to the end, substitute—

"imposed pursuant to—

(a) as regards gametes and embryos, sections 12(3), and 33A to 33D of, and paragraph 1 of Schedule 3A to, the Human Fertilisation and Embryology Act 1990(**14**);

(b) as regards blood cells, regulations 8, 9(e) and 14 of the Blood Safety and Quality Regulations 2005(**15**); and

(c) as regards other cells and tissues, regulations 13 and 16 of, and paragraph 1 of Schedule 2 to, the Human Tissue (Quality and Safety for Human Application) Regulations 2007(**16**);".

Omission of regulation 255A to 255C (enforcement and offences relating to Commission Regulation 2016/161)

196. Omit regulations 255A to 255C(**17**).

(**14**) 1990 c. 37. Sections 33A to 33D were inserted by the Human Fertilisation and Embryology Act 2008, c. 22.
(**15**) S.I. 2005/50. It has been amended by S.I. 2005/1098 and 2898, 2006/2013, 2007/604, 2008/525 and 941, 2009/372 and 3307, 2010/604, 2017/1320 and 2018/231.
(**16**) S.I. 2007/1523.
(**17**) Regulations 255A to 255C were inserted by S.I. 2019/62.