SCHEDULES

SCHEDULE 2

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

PART 23

Amendment of Schedule 8 (consequential provision)

194. In Schedule 8 (consequential provision)—

(a) in paragraph 4 (amendment of the Prescription Only Medicines (Human Use) Order 1997)—

(i) for "In article 5(1)" substitute " After article 5(1) "; and

(ii) for "insert " UK " before "marketing authorisation" " substitute "insert—

"(1A) In paragraph (1) "marketing authorisation" means—

(a) in relation to medicinal products for sale or supply in Great Britain, a UKMA(GB) or UKMA(UK);

(b) in relation to medicinal products for sale or supply in Northern Ireland, a UKMA(NI) or UKMA(UK), an EU marketing authorisation or a parallel import licence.";

(b) in paragraph 8 (amendment of the Blood Safety and Quality Regulations 2005)—

(i) for "as if reference" substitute " as if the reference ";

(ii) after "within the meaning of" insert " paragraph (a) of the definition of that term in ";

(c) for paragraph 7 (amendment of the Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003) substitute—

"**7.** In regulation 1(2) of the Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003 [M1] (citation, commencement and interpretation), for the definition of "unlicensed product" substitute—

""unlicensed product" means—

(a) in the case of a product to be imported or marketed in Great Britain, a medicinal product for human use, other than an excluded medicine, in respect of which no UKMA(GB), UKMA(UK), THR(UK) or THR(GB) has been granted;

(b) in the case of a product to be imported or marketed in Northern Ireland, a medicinal product for human use, other than an excluded medicine, in respect of which no UKMA(NI), UKMA(UK), THR(UK) or THR(NI), EU marketing authorisation or Article 126a authorisation has been granted,

and "Article 126a authorisation", "EU marketing authorisation", "THR(GB)", "THR(NI)", "THR(UK)", "UKMA(GB)", "UKMA(NI)" and "UKMA(UK)" have the meanings given in regulation 8 of the 2012 Regulations;.;".";

(d) in paragraph 16 (amendment of the Branded Health Service Medicines (Costs) Regulations 2018)—

(i) omit sub-paragraph (2)(a) to (d);

(ii) omit sub-paragraph (3);

(iii) omit sub-paragraph (4)(a)(i);

(iv) for sub-paragraph (4)(a)(ii) substitute—

"(ii) in sub-paragraph (b), after "Article 21" insert " or regulation 64(6) of the 2012 Regulations "; and";

(v) omit sub-paragraph (4)(b);

(vi) omit sub-paragraph (5);

(vii) omit sub-paragraph (6).

Commencement Information

I1 Sch. 2 para. 194 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

Marginal Citations

M1 S.I. 2003/1680. The definition of "unlicensed product" in regulation 1(2) was amended by S.I. 2004/3224, 2005/2750 and 2012/1916.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, PART 23.