SCHEDULE 1

Amendment of the Medicines (Products for Human Use) (Fees) Regulations 2016

Amendment of Schedule 1 (general interpretation provisions)

6. In Schedule 1—

(a) in paragraph 1—

[F1(ai) in the definition of "marketing authorisation", in paragraph (a) after "Human Medicines Regulations" insert "(and a reference to a UKMA(GB), UKMA(NI) or UKMA(UK) should be construed in accordance with those Regulations)";**]**

(i) in the definition of "medicinal product", for "includes any medicinal product for human use to which the 2001 Directive applies and" substitute " has the meaning given by regulation 2 of the Human Medicines Regulations and includes ",

(ii) for the definition of "orphan medicinal product" substitute—

""orphan marketing authorisation" has the meaning given by regulation 8(1) of the Human Medicines Regulations;",

(iii) in the definition of "variation", for "Article 2(1) of Commission Regulation (EC) No 1234/2008" substitute " regulation 8(1) of the Human Medicines Regulations ", and

(iv) at the appropriate places insert—

""Annex I to the 2001 Directive" has the meaning given by regulation 8(1) of the Human Medicines Regulations;";

""biological medicinal product" has the meaning given in paragraph 3.2.1.1.(b) of Part I of Annex I to the 2001 Directive;";

""the Committee for Medicinal Products for Human Use" means the committee established under Article 5(1) of Regulation (EC) No 726/2004;";

""the EMA" means the European Medicines Agency established by Regulation (EC) No 726/2004;"

[F2""under the unfettered access route" has the meaning given by regulation 8(1) of the Human Medicines Regulations;"**]**; and

(b) after paragraph 4 insert—

"**5.**—(1) For the purpose of these Regulations, a company is a medium company if, for the financial year before that in which the application is made, the total value of products it has sold or supplied for the financial year is not more than the amount for the time being specified in item 1 in section 465(3) of the Companies Act 2006 M1 (qualification of company as medium) and the conditions in sub-paragraph (2) are met.

(2) The conditions for the purposes of sub-paragraph (1) are—

(a) the company's balance sheet total as defined in section 465(5) of the Companies Act 2006 is not more than the amount for the time being specified in item 2 in section 465(3) of that Act; or

(b) the average number of persons employed by the company in the financial year before that in which the application is made (determined on a weekly basis) does not exceed the number for the time being specified in item 3 in section 465(3) of that Act.

(3) In this paragraph "financial year" is to be construed in accordance with section 390 of the Companies Act 2006.".

Textual Amendments

F1 Sch. 1 para. 6(ai) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(f)(i)**

F2 Words in Sch. 1 para. 6(a)(iv) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(f)(ii)**

Commencement Information

I1 Sch. 1 para. 6 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M1 Section 465 was amended by S.I. 2015/980

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, Paragraph 6.