SCHEDULES

SCHEDULE 2

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

PART 4

Amendment of Part 5 (amendment of Part 5 (marketing authorisations))

37. In regulation 49 (amendment of regulation 50 (accompanying material))—

(a) after paragraph (1) insert—

"(1A) After paragraph (1) insert—

"(1A) An applicant for the grant of a UK marketing authorisation for a relevant medicinal product must provide—

(a) in the case of an application under the unfettered access route—

(i) the material specified in Schedule 8C, and

(ii) any material specified in Schedule 8 which is not included in the material specified in Schedule 8C, and

(b) in all other cases, the material specified in Schedule 8,

in relation to the product.";

(1B) After paragraph (3) insert—

"(3A) Paragraph (4) does not apply in respect of an application under the unfettered access route.".";

(b) for paragraph (2) substitute—

"(2) For paragraph (4) substitute—

"(4) If any of the medicinal products to which the application for a UK marketing authorisation relates—

(a) in the case of a UKMA(NI) or a UKMA(UK), is liable to be imported from a country other than an EEA State, or

(b) in the case of a UKMA(GB), is liable to be imported,

the material or information referred to in paragraph (3) may include an undertaking from the manufacturer of the product to comply with the matters set out in Schedule 9.".";

(c) in paragraph (3)—

(i) for the inserted paragraph (5A) substitute—

"(5A) The Secretary of State may by regulations in respect of Great Britain amend Schedule 8B (modifications of Annex I) in relation to a UKMA(GB) for the purpose of further modifying Annex I to the 2001 Directive in order to take account of scientific and technical progress.";

(ii) in the inserted paragraph (5C), for "exit day" substitute " IP completion day ";

(d) after paragraph (4) insert—

"(4A) In paragraph (6)—

(a) for sub-paragraph (a), substitute—

"(a) regulation 51 (application for UKMA(NI) relating to generic medicinal products)

(aa) regulation 51A (application for UKMA(GB) relating to generic medicinal products);

(ab) regulation 51B (application for UKMA(UK) relating to generic medicinal products);";

(b) for sub-paragraph (b), substitute—

"(b) regulation 52 (application for UKMA(NI) relating to certain medicinal products that do not qualify as generic etc)

(ba) regulation 52A (application for UKMA(GB) relating to certain medicinal products that do not qualify as generic etc);

(bb) regulation 52B (application for UKMA(UK) relating to certain medicinal products that do not qualify as generic etc);";

(c) for sub-paragraph (c), substitute—

"(c) regulation 53 (application for UKMA(NI) relating to similar biological medicinal products)

(ca) regulation 53A (application for UKMA(GB) relating to similar biological medicinal products);

(cb) regulation 53B (application for UKMA(UK) relating to similar biological medicinal products);".".

Commencement Information

I1 Sch. 2 para. 37 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, Paragraph 37.