

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))

61. For regulation 84 (amendment of regulation 76 (obligation in relation to product information)) substitute—

“**84.** For regulation 76(2), substitute—

“(2) In this regulation “current scientific knowledge” includes the conclusions of the assessment and recommendations made public by means of—

- (a) in the case of a medicinal product authorised for sale or supply by a UKMA(NI) or a UKMA(UK)—
 - (i) the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004, and
 - (ii) the UK web-portal established in accordance with regulation 203(1);
- (b) in the case of a medicinal product authorised for sale or supply by a UKMA(GB), the UK web-portal established in accordance with regulation 203(1).””.

Commencement Information

11 Sch. 2 para. 61 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 61.