SCHEDULES

SCHEDULE 2

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

PART 13

Amendment of Part 14 (amendment of Part 13 (packaging and leaflets))

155. In regulation 201 (amendment of Schedule 24 (packaging information requirements))—

(a) in paragraph (2), after "regulation 257D" insert "in the case of products for sale or supply in Great Britain, or in the case of products for sale or supply in Northern Ireland, any guidance published pursuant to Article 65 of the 2001 Directive(**1**) or under regulation 257D that is applicable to such products.";

(b) in paragraph (3), for "for "marketing authorisation"" to the end substitute "for "marketing authorisation," substitute "UK marketing authorisation, EU marketing authorisation".";

(c) omit paragraph (4);

(d) in paragraph (5)—

(i) in the inserted Part 4 (outer and immediate packaging: advanced therapy medicinal products), in the heading, after "products" insert "for sale or supply in Great Britain only";

(ii) in the inserted Part 5 (immediate packaging: blister packs and small packaging (advanced therapy medicinal products)), in the heading, after "products" insert "for sale or supply in Great Britain only".

(**1**) The guidelines are available at: https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012 and a hard copy may be obtained from the Medicines and Healthcare products Regulatory Agency at the address given in the Explanatory Note.