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))

158. In regulation 204 (amendment of Schedule 27 (package leaflets))—

(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) in paragraph (4)—

(i) for "Omit" substitute "In";

(ii) after "12" insert "after "Where the product" insert "is authorised for sale or supply in Northern Ireland and".";

(d) in paragraph (5)(a)—

(i) for "for" substitute "after";

(ii) for "substitute "regulation 202A"" substitute "insert "in the case of products for sale or supply in Northern Ireland, or the list referred to in regulation 202A, in the case of products for sale or supply in Great Britain,";";

(e) in paragraph (6), in the inserted Part 3 (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.