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))

154. In regulation 200 (insertion of regulations 257C (packaging requirements: advanced therapy medicinal products) and 257D and 257E (guidance and regulations in relation to packing, leaflets and labelling))—

(a) in the inserted regulation 257C(1)—

(i) in sub-paragraph (a), after the first reference to "advanced therapy medicinal product" insert " for sale or supply in Great Britain only ";

(ii) in sub-paragraph (b), for "of the product" substitute " of that product "

(b) for the inserted regulation 257D substitute—

"**257D.**—(1) The licensing authority may publish guidance on packaging and package leaflets applicable to products for sale or supply in the whole United Kingdom or parts of the United Kingdom, as appropriate.

(2) Guidance published under paragraph (1) may, in particular, include—

(a) the wording of certain special warnings for certain categories of medicinal products;

(b) the particular information needs relating to products that are a pharmacy medicine;

(c) the legibility of particulars on the labelling and package leaflet;

(d) the methods of identification and authentication of medicinal products;

(e) the list of excipients which must feature on the labelling of medicinal products and the way in which these excipients must be indicated.

(3) Until such time as the licensing authority publishes guidance under paragraph (1), any guidance published by the Commission pursuant to Article 65 of the 2001 Directive [M1], insofar as that guidance was in force immediately before IP completion day, continues to apply as if it had been published by the licensing authority under paragraph (1).".

Commencement Information

I1 Sch. 2 para. 154 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

Marginal Citations

M1 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.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, Paragraph 154.