DRAFT STATUTORY INSTRUMENTS

2019 No.

The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

PART 18

Amendment of Part 17 (miscellaneous and general)

Amendment of regulation 341 (decisions under the Human Medicines Regulations 2012)

224. In regulation 341(4)(a), insert "UK" before "marketing authorisation".

Insertion of regulation 344A (modifications to deal with serious shortages) and 344B (regulation making powers)

225. After regulation 344 insert—

"**Modifications to deal with serious shortages**

344A.—(1) The Ministers may by regulations modify the application of any of the specified provisions in circumstances where the United Kingdom, or any part of the United Kingdom, is experiencing or may experience a serious shortage of medicinal products, or of medicinal products of a specified description, arising from the withdrawal of the United Kingdom from the European Union.

(2) Regulations may only be made under paragraph (1) for the purposes of preventing, remedying or mitigating the serious shortage that is being or may be experienced.

(3) For the purposes of paragraph (1), the "specified provisions" are the provisions of Parts 1, 3 to 5, 10 to 13 and 16, and of the associated Schedules.

(4) The reference in paragraph (1) to a serious shortage arising from the withdrawal of the United Kingdom from the European Union includes reference to a serious shortage where the withdrawal of the United Kingdom from the European Union is one but not the only significant factor contributing to the shortage.

(5) No regulations under paragraph (1) may be made, or have effect, after the end of the period of two years beginning with exit day.

Regulation making powers

344B.—(1) Regulations made under a power in the regulations listed in paragraph (2)—

(a) are to be made by statutory instrument;

(b) may make different provision for different purposes and different areas; and

(c) may include incidental, supplemental, consequential, transitional, transitory or saving provisions, including consequential amendments to these Regulations.

(2) The regulations referred to in paragraph (1) are—

(a) regulation B17(1) and (4) (good manufacturing practice);

(b) regulation 50(5A) (Annex I to the 2001 Directive);

(c) regulation 50G(5) (orphan criteria etc);

(d) regulations 59(3A) and 61(7A) (post-authorisation efficacy studies);

(e) regulation 65C(7) (variations of UK marketing authorisations);

(f) regulation 102(7) (homoeopathic medicinal products);

(g) regulation 205A(2) (further obligations in respect of pharmacovigilance activities);

(h) regulation 257E (certain forms of labelling); and

(i) regulation 344A (modifications to deal with serious shortages).

(3) A statutory instrument containing regulations made under the powers listed in paragraph (2) is subject to annulment in pursuance of a resolution of either House of Parliament.".

Amendment of regulation 345 (immunity from civil liability)

226. In regulation 345(5)—

(a) insert "UK" before "marketing authorisation";

(b) insert "or" after "certificate of registration"; and

(c) omit "or Article 126a authorisation".

Amendment of regulation 346 (Secretary of State to carry out a review of certain provisions)

227. In regulation 346(**1**)—

(a) in sub-paragraph (c), omit paragraphs (iia), (iiia), (iva), (xixa), (xxviiii) and (xxviiij); and

(b) in sub-paragraph (d), omit paragraphs (ia) and (ivab).

(**1**) Regulation 346 was substituted by S.I. 2013/1855 and then amended by S.I. 2013/2593, 2014/490 and 1878, 2015/323, 903 and 1503, 2016/186, 2017/715, 2018/199 and 2019/62.