STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 11

Pharmacovigilance

Recording, reporting and assessment of pharmacovigilance data

Recording obligations on holders

187.—(1) Subject to paragraph (2), the holder must record all suspected adverse reactions to the product **[**[F1](including listed NIMAR products in Northern Ireland)**]** occurring **[**[F2]in the United Kingdom or another country**]** which are brought to its attention irrespective of whether the reaction—

(a) is reported spontaneously by patients or health care professionals; or

(b) occurred in the context of a post-authorisation study.

(2) Paragraph (1) does not apply where the suspected adverse reaction occurred in the context of a clinical trial within the meaning of the Clinical Trials Regulations.

(3) The holder must not refuse to consider reports of suspected adverse reactions to the product received electronically or by any other appropriate means from patients or from health care professionals.

(4) The holder must ensure that reports recorded under paragraph (1) are accessible (electronically or physically) at a single point within the **[**[F3]United Kingdom**]**.

Textual Amendments

F1 Words in reg. 187(1) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **15**

F2 Words in reg. 187(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 147(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 114**)

F3 Words in reg. 187(4) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **147(3)**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 187.