

STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 11

Pharmacovigilance

Obligations on licensing authority in relation to pharmacovigilance

Obligation on licensing authority to audit pharmacovigilance system

180.—(1) The licensing authority must perform a regular audit of its pharmacovigilance system [F1relating to medicinal products for sale or supply in Great Britain]F2....

[F3(1A) The licensing authority must perform a regular audit of its pharmacovigilance system relating to medicinal products for sale or supply in Northern Ireland and report the results of that audit to the European Commission.]

(2) The F4... audit referred to in paragraph (1) must be [F5performed]—

- (a) on the first occasion no later than 21st September 2013; and
- (b) every two years after the first occasion.

[F6(3) The results of the audit referred to in paragraph (1A) must be reported to the European Commission—

- (a) on the first occasion no later than 21st September 2021;
- (b) every two years after the first occasion.]

Textual Amendments

- F1** Words in reg. 180(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 140(2)(a)** (as inserted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 109(a)(i)**)
- F2** Words in reg. 180(1) omitted (31.12.2020) by virtue of [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), regs. 1, **140(2)(b)** (as amended by S.I. 2020/1488, reg. 1, Sch. 2 para. 109(a)(ii)); 2020 c. 1, Sch. 5 para. 1(1)
- F3** Reg. 180(1A) inserted (31.12.2020) by S.I. 2019/775, **reg. 140(2A)** (as inserted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 109(b)**)
- F4** Words in reg. 180(2) omitted (31.12.2020) by virtue of [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), regs. 1, **140(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F5** Word in reg. 180(2) substituted (31.12.2020) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), regs. 1, **140(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F6** Reg. 180(3) inserted (31.12.2020) by S.I. 2019/775, **reg. 140(4)** (as inserted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 109(c)**)

Changes to legislation:

There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 180.