STATUTORY INSTRUMENTS

# 2012 No. 1916

# The Human Medicines Regulations 2012

## PART 11

Pharmacovigilance

*Periodic Safety Update Reports*

### [F1Obligation on holder of a parallel import licence to submit periodic safety update reports

**191A.**—(1) The holder of a parallel import licence must submit reports known as periodic safety update reports ("PSURs") to the licensing authority if notified to do so by the licensing authority.

(2) Each PSUR must contain—

(a) summaries of data relevant to the benefits and risks of the product, including results of all studies, with a consideration of their potential impact on the licence for the product;

(b) a scientific evaluation of the risk-benefit balance of the product; and

(c) all data relating to the volume of sales of the product and any data the holder of the licence has relating to the volume of prescriptions, including an estimate of the population exposed to the product.

(3) For the purposes of paragraph (2)(b), the scientific evaluation must be based on all available data, including data from clinical trials conducted outside the terms of the authorisation for the product.

(4) Each PSUR must be submitted electronically.

(5) The PSUR must be submitted to the licensing authority within the period specified by that authority.**]**

**Textual Amendments**

**F1** Reg. 191A inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **20** and reg. 191A inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **20**

**Changes to legislation:**
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 191A.