STATUTORY RULES OF NORTHERN IRELAND

2014 No. 324

The Human Medicines (Amendment) (No. 2) Regulations 2014

Insertion of regulation 191A

20. After regulation 191 (obligation on holder to submit periodic safety update reports: general requirements) insert—

"**Obligation 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."