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STATUTORY RULES OF NORTHERN IRELAND

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**2014 No. 324**

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

**Insertion of regulation 66A**

10. After regulation 66 (application for renewal of authorisation) insert—

**“Application for renewal of a parallel import licence**

**66A.**—(1) The licensing authority may renew a parallel import licence in response to an application made in accordance with this regulation.

(2) The applicant must be established in the European Union.

(3) The application must be—

(a) made in writing

(b) signed by or on behalf of the applicant; and

(c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.

(4) An application is treated as signed for the purposes of paragraph (3)(b) if it is signed with an electronic signature.

(5) The application must be made so that it is received by the licensing authority within three months of the end of a period expiring 5 years after the date of grant or (as the case may be) latest renewal of the licence.”