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STATUTORY RULES OF NORTHERN IRELAND

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**2014 No. 324**

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

**Amendment of regulation 195**

**21.** In regulation 195 (obligation on the licensing authority to assess PSURs where EU single assessment procedure does not apply), for paragraph (1)(a) and (b) substitute—

- “(a) the medicinal product to which the PSUR relates—
  - (i) has not been authorised to be placed on the market in accordance with the 2001 Directive in an EEA State other than the United Kingdom; and
  - (ii) a harmonised EU reference date and frequency of submission of PSURs have not been established for that product under Article 107c of the 2001 Directive; or
- (b) the medicinal product is one that is imported into the UK under a parallel import licence.”