

---

STATUTORY RULES OF NORTHERN IRELAND

---

**2014 No. 324**

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

**Insertion of regulation 80A**

15. After regulation 80 (urgent safety restrictions) insert—

**“Urgent safety restrictions: parallel import licences**

**80A.** The holder of a parallel import licence is guilty of an offence if the holder—

- (a) fails to inform the licensing authority that the holder has taken urgent safety restrictions on the holder’s own initiative;
- (b) fails to implement an urgent safety restriction imposed on the holder by the licensing authority; or
- (c) fails to submit an application for variation of the parallel import licence to the licensing authority before the end of a period of fifteen days beginning on the day after—
  - (i) the taking of urgent safety restrictions under paragraph (a) or, as the case may be,
  - (ii) the imposition of urgent safety restrictions under paragraph (b).”