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STATUTORY INSTRUMENTS

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**2013 No. 1855**

**The Human Medicines (Amendment) Regulations 2013**

**PART 2**

**Amendment of the Human Medicines Regulations 2012**

**Amendment of regulation 84**

**18.** In regulation 84 (EU marketing authorisations: failure to provide information as to safety etc), in paragraph (2) for “16(4)” substitute “16(3a)(1)”.

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(1) Article 16(4) of Regulation (EC) No 726/2004 was re-numbered as Article 16(3a) by virtue of the Corrigendum (OJ L 348, 31.12.2010, p1) to Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicines for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medical Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products.