
STATUTORY INSTRUMENTS

2019 No. 62

The Human Medicines (Amendment) Regulations 2019

Amendment of regulation 8 (general interpretation)

3. In regulation 8(1)(1) at the appropriate places insert—

““care home”—

- (a) in relation to England, has the meaning given by section 3 of the Care Standards Act 2000(2);
- (b) in relation to Wales, has the meaning given by paragraph 1 of Schedule 1 to the Regulation and Inspection of Social Care (Wales) Act 2016(3);
- (c) in relation to Scotland, has the meaning given by paragraph 2 of Schedule 12 to the Public Services Reform (Scotland) Act 2010(4); and
- (d) in relation to Northern Ireland, means a nursing home as defined in article 11 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003(5);”;

““Commission Regulation 2016/161” means Commission Delegated Regulation (EU) 2016/161 supplementing [Directive 2001/83/EC](#) of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use(6);”;

““healthcare institution” has the meaning given by Article 3(2) of Commission Regulation 2016/161;”;

““hospice” means an institution whose primary function is the provision of palliative care to persons resident there who are suffering from a progressive disease in its final stages;”.

(1) Regulation 8 was amended by [S.I. 2013/1855](#) and [2593](#), [2015/1503](#), [2016/186](#), [190](#) and [696](#), [2017/715](#) and [2018/199](#).
(2) [2000 c.44](#); section 3 was amended by the Regulation and Inspection of Social Care (Wales) Act 2016 ([2016 anaw.2](#)) and the Health and Social Care Act 2008 ([2008 c.14](#)).
(3) [2016 anaw.2](#); paragraph 1 of Schedule 1 was amended by [S.I. 2018/195](#).
(4) [2010 asp. 8](#).
(5) [S.I. 2003/431 \(N.I. 9\)](#); article 11 was amended by the Health and Social Care (Reform) Act (Northern Ireland) 2009 ([2009 c.1](#)).
(6) OJ no. L 32, 9.2.2016, p. 1