

2019 No.

MEDICINES

The Human Medicines (Amendment) Regulations 2019

Made - - - - - ***
Laid before Parliament ***
Coming into force - - - - - ***

The Secretary of State and the Minister of Health in Northern Ireland make the following Regulations. They do so in the exercise of the powers conferred by section 2(2) and (5) of the European Communities Act 1972(a), having been designated for the purposes of section 2(2) of that Act in relation to medicinal products(b).

Citation and commencement

1. These Regulations may be cited as the Human Medicines (Amendment) Regulations 2019 and shall come into force on 9 February 2019.

Amendment of the Human Medicines Regulations 2012

2. The Human Medicines Regulations 2012(c) are amended as follows.

Amendment of regulation 8 (general interpretation)

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

““care home”—

- (a) in relation to England, has the meaning given by section 3 of the Care Standards Act 2000;
- (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;
- (c) in relation to Scotland, has the meaning given by paragraph 2 of Schedule 12 to the Public Services Reform (Scotland) Act 2010; and
- (b) 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;

“Commission Regulation 2016/161” means Commission Delegated Regulation (EU) 2016/161 supplementing Directive 2001/83/EC of the European Parliament and of the

(a) 1972 c.68. Section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c.51) and section 3(3) of and Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c.7). Section 2(5) was amended by section 41(1) of and Part 1 of Schedule 6 to the Northern Ireland Constitution Act 1973 (c.36).
(b) See S.I. 1972/1811 regarding the designation of Ministers.
(c) S.I. 2012/1916 as amended by S.I. 2013/235, 1855 and 2593, 2014/490 and 1878, 2015/323, 903 and 1503 and 2016/186.
(d) Regulation 8(1) has been previously amended by S.I. 2013/1855 and 2016/186.

Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use;

“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”.

Amendment of regulation 36 (conditions for manufacturer’s licence)

4. In regulation 36, after paragraph (3) insert—

“(4) The requirements and obligations contained in a provision of Commission Regulation 2016/161 listed in paragraph (5) have effect as if they were provisions of a manufacturer’s licence under this Part.

(5) The provisions mentioned in paragraph (4) are—

- (a) Article 4 (composition of the unique identifier);
- (b) Article 5 (carrier of the unique identifier);
- (c) Article 6 (quality of the printing of the two-dimensional barcode);
- (d) Article 7 (human-readable format);
- (e) Article 10 (verification of the safety features) insofar as it relates to manufacturers;
- (f) Article 11 (verification of the authenticity of the unique identifier) insofar as it relates to manufacturers;
- (g) Article 12 (unique identifiers which have been decommissioned);
- (h) Article 13 (reversing the status of a decommissioned unique identifier) insofar as it relates to manufacturers;
- (i) Article 14 (verification of the two-dimensional barcode);
- (j) Article 15 (record keeping);
- (k) Article 16 (verification to be performed before removing or replacing the safety features);
- (l) Article 17 (equivalent unique identifier); and
- (m) Article 18 (actions to be taken in case of tampering or suspected falsification).

(6) In distributing a medicinal product by way of wholesale dealing, the requirements and obligations contained in a provision of Commission Regulation 2016/161 listed in paragraph (7) shall apply to the holder of a manufacturer’s licence and have effect as if they were provisions of the licence.

(7) The provisions mentioned in paragraph (6) are—

- (a) Article 20 (verification of the authenticity of the unique identifier), subject to the exemption contained in Article 21 (derogations from Article 20(b));
- (b) Article 22 (decommissioning of unique identifiers); and
- (c) Article 24 (actions to be taken in case of tampering or suspected falsification).”.

Amendment of Regulation 39 (further requirements for manufacturer’s licence)

5. In regulation 39(a), in paragraph (8), after “43(1), (2) and (5)” insert “, 43A”.

Amendment of regulation 42 (conditions for wholesale dealer’s licence)

6. In regulation 42, after paragraph (3) insert—

(a) Regulation 39 was amended by S.I.2013/1855 and 2015/354.

“(4) The requirements and obligations contained in a provision of Commission Regulation 2016/161 listed in paragraph (5) have effect as if they were provisions of a wholesale dealer’s licence under this Part.

(5) The provisions mentioned in paragraph (1) are—

- (a) Article 10 (verification of the safety features) insofar as it relates to wholesalers;
- (b) Article 11 (verification of the authenticity of the unique identifier) insofar as it relates to wholesalers;
- (c) Article 12 (unique identifiers which have been decommissioned);
- (d) Article 13 (reversing the status of a decommissioned unique identifier) insofar as it relates to wholesalers;
- (e) Article 20 (verification of the authenticity of the unique identifier), subject to the exemption contained in Article 21 (derogations from Article 20(b));
- (f) Article 22 (decommissioning of unique identifiers); and
- (g) Article 24 (actions to be taken in case of tampering or suspected falsification).”.

Insertion of regulation 43A

7. Immediately after regulation 43(a) (obligations of licence holder), insert—

“43A. Requirement for wholesale dealers to decommission the unique identifier

(1) This regulation only applies to medicinal products that are required to bear safety features pursuant to Article 54a of the Directive.

(2) The licence holder must verify the safety features and decommission the unique identifier of a medicinal product before supplying that medicinal product to a person who falls within one of the classes specified in paragraph (4).

(3) The licence holder must verify the safety features and decommission the unique identifier in accordance with the requirements laid down in Commission Regulation 2016/161.

(4) The classes of person mentioned in paragraph (2) are—

- (a) where the supply is to a person in the United Kingdom—
 - (i) persons authorised or entitled to supply medicinal products to the public who do not operate within a healthcare institution or within a pharmacy;
 - (ii) persons who receive the product for the purpose of selling, supplying or administering it as a veterinary medicinal product;
 - (iii) dentists;
 - (iv) registered optometrists or registered dispensing opticians;
 - (v) registered paramedics;
 - (vi) persons who are members of Her Majesty's armed forces;
 - (vii) a police force in England, Wales or Scotland or the Police Service of Northern Ireland;
 - (viii) government institutions maintaining stocks of medicinal products for the purposes of civil protection or disaster control;
 - (ix) universities or other institutions concerned with higher education or research, other than healthcare institutions;
 - (x) a prison service;
 - (xi) persons carrying on the business of a school;

(a) Regulation 43 was amended by S.I. 2013/1855 and 2016/186.

- (xii) care homes;
- (xiii) hospices.”.

Insertion of regulation 94A

8. Immediately after regulation 94 (failure to submit report to EMA), insert—

“Offences relating to the safety features appearing on the packaging of medicinal products

94A. Offences relating to Commission Regulation 2016/161

(1) The holder of a marketing authorisation or parallel import licence, or a parallel distributor, is guilty of an offence if the holder fails to comply with a requirement or obligation contained in a provision of Commission Regulation 2016/161 listed in paragraph (2).

(2) The provisions mentioned in paragraph (1) are—

- (a) Article 33 (Uploading of information in the repositories system);
- (b) Article 40 (Products recalled, withdrawn or stolen);
- (c) Article 41 (Products to be supplied as free samples); and
- (d) Article 42 (Removal of unique identifiers from the repositories system).

(3) In this regulation “parallel distributor” means a person who imports from another EEA state a product which has been granted a marketing authorisation under Regulation (EC) No 726/2004 and in relation to which that person is not the holder of marketing authorisation, Article 126a authorisation, certificate of registration or a traditional herbal registration”.

Insertion of regulation 255A

9. Immediately after regulation 255 (offences relating to dealings with medicinal products), insert—

“255A. Offences relating to Commission Regulation 2016/161: persons authorised to supply medicinal products to the public

(1) This regulation applies to a person who, in the course of a business carried on by that person, sells or supplies, or offers to sell or supply the product, or possesses the product for the purpose of sale or supply.

(2) A person to whom this regulation applies is guilty of an offence if the person fails to comply with a requirement or obligation contained in a provision of Commission Regulation 2016/161 listed in paragraph (2).

(3) The provisions mentioned in paragraph (1) are—

- (a) Article 10 (verification of the safety features) insofar as it relates to persons authorised or entitled to supply medicinal products to the public;
- (b) Article 11 (verification of the authenticity of the unique identifier) insofar as it relates to persons authorised or entitled to supply medicinal products to the public;
- (c) Article 12 (unique identifiers which have been decommissioned);
- (d) Article 13 (reversing the status of a decommissioned unique identifier) insofar as it relates to persons authorised or entitled to supply medicinal products to the public;
- (e) Article 25 (obligations of persons authorised or entitled to supply medicinal products to the public), subject to the exemptions contained in Article 26 (derogations from Article 25);
- (f) Article 27 (obligations when applying the derogations);
- (g) Article 28 (obligations when supplying only part of a pack);

- (h) Article 29 (obligations in case of inability to verify the authenticity and decommission the unique identifier); and
 - (i) Article 30 (actions to be taken by persons authorised or entitled to supply medicinal products to the public in case of suspected falsification).
- (4) A person guilty of an offence under paragraph (2) is liable—
- (a) on summary conviction to a fine; or
 - (b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.

255B. Offences relating to Commission Regulation 2016/161: management of the repository system

(1) A legal entity established to set up and manage the repositories system pursuant to Article 31 of Commission Regulation 2016/161, is guilty of an offence if the legal entity fails to comply with a requirement or obligation contained in a provision of Commission Regulation 2016/161 listed in paragraph (2).

- (2) The provisions mentioned in paragraph (1) are—
- (a) Article 31 (establishment of the repository system);
 - (b) Article 32 (structure of the repositories system);
 - (c) Article 33 (uploading of information in the repositories system);
 - (d) Article 34 (functioning of the hub);
 - (e) Article 35 (characteristics of the repository system);
 - (f) Article 36 (operations of the repositories system);
 - (g) Article 37 (obligations of legal entities establishing and managing a repository);
 - (h) Article 38(2) (data protection); and
 - (i) Article 39 (access by national competent authorities).
- (3) A person guilty of an offence under paragraph (1) is liable—
- (a) on summary conviction to a fine; or
 - (b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.”.

Insertion of regulation 257A

10. Immediately after regulation 257 (packaging requirements: general), insert—

“257A. Packaging Requirements: medicinal products required to bear safety features

(1) The information specified in paragraph (18a) of Schedule 24 must not be removed or covered, either fully or partially, unless the following conditions are met—

- (a) a person who is the holder of a manufacturer's licence verifies, prior to partially or fully removing or covering the features, that the medicinal product concerned is authentic and that it has not been tampered with;
- (b) the holder of the manufacturer’s licence replaces the features with ones which are equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering of the medicinal product; and
- (c) the replacement of the features is conducted in accordance with the applicable principles and guidelines for good manufacturing practice set out in the Good Manufacturing Practice Directive.

(2) For the purposes of paragraph (1)(b), the features shall be considered equivalent if they—

- (a) comply with the requirements set out in Commission Regulation 2016/161; and

(b) are equally effective in enabling the verification of authenticity and identification of the medicinal product and in providing evidence of tampering with the medicinal product.

(3) In performing the activities referred to in paragraph (1), the holder of a manufacturer's licence shall be regarded as a producer for the purposes of the Consumer Protection Act 1987(a).

257B. Transitional Arrangements

(1) The information specified in paragraph (18a) of Schedule 24 does not need to appear on the packaging of a medicinal product released for sale or distribution before 9 February 2019, unless the product has been repackaged or relabelled after that date.”.

Amendment of regulation 268 (offences relating to packaging and package leaflets: holder of authorisation etc)

11. In regulation 268(2)(a), after “of this Part”, insert “, Article 9 of Commission Regulation 2016/161”.

Amendment of regulation 269 (offences relating to packaging and package leaflets: other persons)

12. In regulation 269(2)(a), after “of this Part”, insert “, Article 9 of Commission Regulation 2016/161”.

Amendment of regulation 323 (enforcement in England, Wales and Scotland)

13. In regulation 323,

(a) in paragraph (3)—

(i) in paragraph (b) omit “and”; and

(ii) after sub-paragraph (c) insert—

“and

(d) regulation 255A (offences relating to Commission Regulation 2016/161: persons authorised to supply medicinal products to the public).”; and

(b) after paragraph (4) insert—

“(4A) Arrangements made with the General Pharmaceutical Council under paragraph (2)(a) in relation to regulation 255A are to be limited to the enforcement of that provision in respect of medicinal products sold or supplied, or offered for sale or supply, from premises that are registered pharmacies.”.

Amendment of regulation 327 (powers of inspection, sampling and seizure)

14. In regulation 327—

(a) after sub-paragraph (2)(g) insert—

“(ga) information and documents relating to compliance with the requirements of Commission Regulation 2016/161C.”;

(b) after paragraph (4) insert—

“(4A) The inspector may for the purposes specified in paragraph (1) require a legal entity established to set up and manage the repositories system pursuant to Article 31 of Commission Regulation 2016/161, or a person employed in connection with

(a) 1987 c.43.

such a entity, to produce information or documents relating to the repositories system which are in the entity's possession or under the entity's control.”;

- (c) in sub-paragraph (5)(a), for “or (g)” substitute “, (g) or (ga)”;
- (d) in sub-paragraph (5)(b), after “paragraph (4)” insert “or 4A”.

Amendment of Schedule 7 (qualified persons)

15. In schedule 7, in paragraph (12)—

- (a) in sub-paragraph (a) omit “and”;
- (b) after sub-paragraph (b) insert—
 - “and
 - (c) in the case of medicinal products required to bear safety features pursuant to Article 54a of the Directive and not intended to be exported to a third country, that the features specified in regulation 259A(2) have been affixed on the packaging.”.

Amendment of Schedule 24 (packaging information requirements)

16. In schedule 24, after paragraph 18 insert—

“(18a) In the case of a medicinal product, other than a radiopharmaceutical, that is required by Article 54a of the Directive to bear safety features—

- (a) a unique identifier which complies with the technical specifications set out in Chapter II of Commission Regulation 2016/161; and
- (b) an anti-tampering device allowing verification of whether the packaging of the medicinal product has been tampered with.”.