STATUTORY INSTRUMENTS.

S.I. No. 270 of 2022

MEDICINAL PRODUCTS (SAFETY FEATURES ON PACKAGING) REGULATIONS 2022

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I, STEPHEN DONNELLY, Minister for Health, in exercise of the powers conferred on me by section 32 (as amended by section 16 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006)) of the Irish Medicines Board Act 1995 (No. 29 of 1995) and for the purpose of giving full effect to Commission Delegated Regulation (EU) 2016/161 of 2 October 2015[1], Commission Delegated Regulation (EU) 2021/1686 of 7 July 2021[2] and Commission Delegated Regulation (EU) 2022/315 of 17 December 2021[3], hereby make the following regulations:

PART 1

GENERAL PROVISIONS

Citation

1. (1) These Regulations may be cited as the Medicinal Products (Safety Features on Packaging) Regulations 2022.

(2) The Regulations of 2019 and these Regulations may be cited together as the Medicinal Products (Safety Features on Packaging) Regulations 2019 and 2022.

Interpretation

2. (1) In these Regulations—

"Authority" means the Health Products Regulatory Authority;

"Directive" means Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001[4], as amended from time to time;

"EU Regulation" means Commission Delegated Regulation (EU) 2016/161 of 2 October 2015[1], as amended by Commission Delegated Regulation (EU) 2021/1686 of 7 July 2021[2] and Commission Delegated Regulation (EU) 2022/315 of 17 December 2021[3];

"health centre" means a health centre under the management or control of a hospital;

"healthcare institution" means a hospital, in- or outpatient clinic or health centre;

"hub" means the central information and data router of the repositories system referred to in Article 32 of the EU Regulation;

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[1] OJ No. L 32, 9.2.2016, p. 1.
[2] OJ No. L 332, 21.9.2021, p. 1.
[3] OJ No. L 55, 28.2.2022, p. 33.
[4] OJ No. L 311, 28.11.2001, p. 67.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 3rd *June,* 2022.

"in- or outpatient clinic" means an in- or outpatient, or day patient, clinic under the management or control of a hospital;

"manufacturer" means the holder of a manufacturer's authorisation, as defined in Regulation 3(1) of the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007);

"marketing authorisation holder" means the holder of a marketing authorisation, as defined in Regulation 3(1) of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007);

"packaging" means outer packaging or, in the case of a medicinal product with no outer packaging, the immediate packaging;

"Regulations of 2019" means the Medicinal Products (Safety Features on Packaging) Regulations 2019 (S.I. No. 36 of 2019);

"repositories system" means the system to be set up and managed under Chapter VII of the EU Regulation;

"safety features" means the unique identifier and anti-tampering device required to be placed on the packaging of medicinal products under the EU Regulation;

"Society" means the Pharmaceutical Society of Ireland;

"wholesaler" means the holder of a wholesaler's authorisation, as defined in Regulation 4(1) of the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007) and, for the avoidance of doubt, does not include a pharmacist supplying medicinal products pursuant to Regulation 6(c) of those Regulations.

(2) A word or expression that is used in these Regulations and is also used in the EU Regulation or the Directive has, unless the context otherwise requires, the same meaning in these Regulations that it has in the EU Regulation or the Directive.

Scope

3. These Regulations apply to—

(a) medicinal products subject to prescription other than those listed in Annex I to the EU Regulation, and

(b) medicinal products which are not subject to prescription and are listed in Annex II to the EU Regulation.

PART 2

OFFENCES – GENERAL

Placing of unique identifier on packaging

4. A person who places on the market a medicinal product which does not have a unique identifier placed on its packaging is guilty of an offence.

Composition of unique identifier

5. A person who places on the market a medicinal product with a unique identifier which fails to comply with the technical specifications set out in Article 4 of the EU Regulation is guilty of an offence.

Carrier of unique identifier

6. A person who places on the market a medicinal product with a unique identifier encoded otherwise than in accordance with Article 5 of the EU Regulation is guilty of an offence.

Quality of printing of unique identifier

7. A person who places on the market a medicinal product with a unique identifier which does not comply with the quality of printing requirements set out in Article 6 of the EU Regulation is guilty of an offence.

Human-readable elements of unique identifier

8. (1) Subject to paragraph (2), a person who places on the market a medicinal product which does not have the data elements listed in Article 7(1) of the EU Regulation (other than subparagraph (c) thereof) on its packaging in human-readable format is guilty of an offence.

(2) Paragraph (1) shall not apply where the sum of the two longest dimensions of the packaging equals or is less than 10 centimetres.

(3) Subject to paragraph (4), a person who places on the market a medicinal product which does not have the human-readable data elements referred to in paragraph (1) adjacent to the two-dimensional barcode carrying the unique identifier is guilty of an offence.

(4) Paragraph (3) shall not apply where the dimensions of the packaging of the medicinal product do not allow for the human-readable data elements to be adjacent to the two dimensional barcode.

Other barcodes on packaging

9. A person who places on the market a medicinal product which has on its packaging, for the purpose of identification and verification of authenticity, any visible two-dimensional barcode other than the two-dimensional barcode carrying the unique identifier, is guilty of an offence.

Unique identifiers which have been decommissioned

10. (1) Subject to paragraph (2), a person who further distributes or supplies to the public a medicinal product bearing a unique identifier which has been decommissioned is guilty of an offence.

(2) Paragraph (1) shall not apply where one of the exceptions listed in Article 12 of the EU Regulation applies.

Reversing the status of decommissioned unique identifier

11. (1) Subject to paragraph (2), a person who reverses the status of a decommissioned unique identifier is guilty of an offence.

(2) Paragraph (1) shall not apply where the conditions listed in Article 13(1) of the EU Regulation are fulfilled.

Record keeping

12. A person who places on the market a medicinal product and fails to comply with the record keeping requirements set out in Article 15 of the EU Regulation in respect of such medicinal product is guilty of an offence.

PART 3

OFFENCES BY MANUFACTURERS

Verifications before removing or replacing safety features

13. A manufacturer who fails to perform verifications required under Articles 16 and 17 of the EU Regulation before removing, covering (either fully or partially) or replacing safety features is guilty of an offence.

Actions to be taken by manufacturers in case of tampering or suspected falsification

14. (1) Where a manufacturer has reason to believe that—

(a) the packaging of a medicinal product has been tampered with, or

(b) the verification of the safety features on a medicinal product indicates that the product may not be authentic,

the manufacturer is guilty of an offence if he or she—

(i) places the medicinal product on the market, or

(ii) fails to immediately inform the Authority after forming such belief.

PART 4

OFFENCES BY WHOLESALERS

Verification of authenticity of unique identifier

15. (1) Subject to paragraph (2), a wholesaler in physical possession of a medicinal product referred to in Article 20(a) or (b) of the EU Regulation who fails to verify the authenticity of the unique identifier on the product is guilty of an offence.

(2) Paragraph (1) shall not apply in the case of a medicinal product referred to in Article 20(b) of the EU Regulation in any of the situations listed in Article 21 of the EU Regulation.

Decommissioning of unique identifiers

16. A wholesaler in physical possession of a medicinal product referred to in Article 22 of the EU Regulation who fails to verify the authenticity of, and decommission, the unique identifier of the product is guilty of an offence.

Verifications of medicinal products for United Kingdom market

17. In the case of a shipment of medicinal products manufactured and labelled for the United Kingdom market, a wholesaler who fails to perform adequate verifications to ensure that the shipment complies with the requirement to bear safety features under Article 54a(1) of Directive 2001/83/EC when received from—

(a) the manufacturer,

(b) the marketing authorisation holder, or

(c) a wholesaler who is designated by the marketing authorisation holder, by means of a written contract, to store and distribute the products covered by his marketing authorisation on his behalf,

is guilty of an offence.

Actions to be taken in case of tampering or suspected falsification

18. (1) Where a wholesaler has reason to believe that—

(a) the packaging of a medicinal product has been tampered with, or

(b) the verification of the safety features on a medicinal product indicates that the product may not be authentic,

the wholesaler is guilty of an offence if he or she—

(i) distributes the medicinal product, or

(ii) fails to immediately inform the Authority after forming such belief.

Verification and decommissioning before supply

19. A wholesaler who fails to comply with Regulation 5(2) of the Regulations of 2019, where applicable, is guilty of an offence.

PART 5

OFFENCES BY PERSONS AUTHORISED TO SUPPLY MEDICINAL PRODUCTS TO THE PUBLIC

Verification and decommissioning

20. (1) Subject to paragraph (2), a person authorised to supply medicinal products to the public who fails to verify the safety features and decommission the unique identifier of any medicinal product bearing safety features, in accordance with Article 25(3) of the EU Regulation—

(a) before supplying that product to the public,

(b) in the case of a person operating within a healthcare institution, between the delivery of the product to the healthcare institution and the sale or supplying of it to the public,

(c) in the case of a medicinal product that cannot be returned to the wholesaler or manufacturer, while the product is in his or her physical possession,

(d) in the case of a medicinal product that is requested as a sample by the Authority or the Society, prior to providing such sample,

(e) in the case of a medicinal product that he or she supplies for subsequent use as authorised investigational medicinal products or authorised auxiliary medicinal products as defined in Article 2(2)(9) and (10) of Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014[5], at the time of such supply,

(f) in the case of the supply of only part of a pack of a medicinal product the unique identifier of which is not decommissioned, when the pack is opened for the first time, or

(g) where there are technical problems preventing verification and decommissioning, as soon as those problems are solved,

is guilty of an offence.

(2) Paragraph (1) shall not apply—

(a) in the case of a medicinal product provided, to a person authorised or entitled to supply medicinal products to the public, as a free sample in accordance with Article 96 of the Directive, and

(b) where the obligation to verify and decommission is on the wholesaler pursuant to Article 5(2) of the Regulations of 2019.

(3) Where paragraph (2)(b) applies, a person authorised to supply medicinal products to the public who fails to verify the authenticity of the anti-tampering device at the time the medicinal product is supplied to the public is guilty of an offence.

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[5] OJ No. L 158, 27.5.2014, p. 1.

Actions to be taken in case of tampering or suspected falsification

21. (1) Where a person authorised to supply medicinal products to the public has reason to believe that—

(a) the packaging of a medicinal product has been tampered with, or

(b) the verification of the safety features on a medicinal product indicates that the product may not be authentic,

the person is guilty of an offence if he or she—

(i) supplies the medicinal product, or

(ii) fails to immediately inform the Authority after forming such belief.

PART 6

OFFENCES BY MARKETING AUTHORISATION HOLDERS, PARALLEL IMPORTERS AND PARALLEL DISTRIBUTORS

Uploading of information in repositories system

22. (1) Subject to paragraph (2), a marketing authorisation holder who fails to—

(a) upload the information referred to in Article 33(2) of the EU Regulation to the repositories system, in the manner required under Article 33(3) of the EU Regulation, before releasing the medicinal product for sale or distribution by the manufacturer, or

(b) keep such information up to date thereafter,

is guilty of an offence.

(2) Paragraph (1) shall not apply in the case of parallel imported or parallel distributed medicinal products bearing an equivalent unique identifier for the purposes of complying with Article 47a of the Directive.

(3) In the case of parallel imported or parallel distributed medicinal products bearing an equivalent unique identifier for the purposes of complying with Article 47a of the Directive, if the person responsible for placing the products on the market fails to—

(a) upload the information referred to in Article 33(2) of the EU Regulation to the repositories system, in the manner required under Article 33(3) of the EU Regulation, before releasing the medicinal product for sale or distribution by the manufacturer, or

(b) keep such information up to date thereafter,

that person is guilty of an offence.

Repackaged or relabelled packs

23. For each batch of repackaged or relabelled packs of a medicinal product on which equivalent unique identifiers were placed for the purposes of complying with Article 47a of the Directive, the person responsible for placing the medicinal product on the market is guilty of an offence if he or she fails to upload to the hub—

(a) the batch number or numbers of the packs which are to be repackaged or relabelled and of the unique identifiers on those packs, or

(b) the batch number of the batch resulting from the repackaging or relabelling operations and the equivalent unique identifiers in that batch.

Products recalled, withdrawn or stolen

24. (1) Subject to paragraph (2), where a medicinal product is recalled, withdrawn or stolen, and the marketing authorisation holder fails to take the measures set out in Article 40 of the EU Regulation, the marketing authorisation holder is guilty of an offence.

(2) Paragraph (1) shall not apply in the case of parallel imported or parallel distributed medicinal products bearing an equivalent unique identifier for the purposes of complying with Article 47a of the Directive.

(3) In the case of parallel imported or parallel distributed medicinal products bearing an equivalent unique identifier for the purposes of complying with Article 47a of the Directive, where a medicinal product is recalled, withdrawn or stolen, and the person responsible for placing the product on the market fails to take the measures set out in Article 40 of the EU Regulation, that person is guilty of an offence.

Products to be supplied as free samples

25. A marketing authorisation holder intending to supply a medicinal product as a free sample in accordance with Article 96 of the Directive, where that product bears the safety features, who fails to—

(a) indicate it as a free sample in the repositories system, and

(b) ensure the decommissioning of its unique identifier before providing it to the persons qualified to prescribe it,

is guilty of an offence.

Removal of unique identifiers from repositories system

26. (1) Subject to paragraph (2), a marketing authorisation holder who uploads unique identifiers in the repositories system before having removed from therein older unique identifiers containing the same product code and serial number as the unique identifiers being uploaded is guilty of an offence.

(2) Paragraph (1) shall not apply in the case of parallel imported or parallel distributed medicinal products bearing an equivalent unique identifier for the purposes of complying with Article 47a of the Directive.

(3) In the case of parallel imported or parallel distributed medicinal products bearing an equivalent unique identifier for the purposes of complying with Article 47a of the Directive, where the person responsible for placing those medicinal products on the market uploads unique identifiers in the repositories system before having removed from therein older unique identifiers containing the same product code and serial number as the unique identifiers being uploaded, that person is guilty of an offence.

PART 7

OFFENCES BY ENTITIES MANAGING REPOSITORIES

Obligations of legal entities establishing and managing repository in State

27. A legal entity managing a repository in the State, as part of the repositories system, which fails to perform any of the actions listed in Article 37 of the EU Regulation is guilty of an offence.

Data protection and data ownership

28. (1) Subject to paragraph (2), a legal entity managing a repository in the State, as part of the repositories system, which accesses an audit trail (as referred to in Article 35(1)(g) of the EU Regulation) and the data contained therein without the written agreement of the legitimate data owners, as designated by Article 38(1) of the EU Regulation, is guilty of an offence.

(2) Paragraph (1) shall not apply in the case of access for the purpose of investigating potential incidents of falsification flagged in the system in accordance with Article 36(b) of the EU Regulation.

Access by Authority

29. A legal entity managing a repository used to verify the authenticity of or decommission the unique identifiers of medicinal products placed on the market in the State, as part of the repositories system, which refuses to grant the Authority access to that repository and the information contained therein for one of the purposes listed in Article 39 of the EU Regulation is guilty of an offence.

PART 8

TRANSITIONAL PROVISIONS

Transitional provisions

30. (1) A person is not guilty of an offence under these Regulations where he or she distributes or supplies to the public a medicinal product that had been placed on the market without the safety features in the State before the coming

into operation of these Regulations, provided the medicinal product is not repackaged or relabelled thereafter, until the expiry date of the medicinal product.

(2) Notwithstanding Regulation 17, until 31 December 2024 a wholesaler is not guilty of an offence for failure to verify the authenticity of and decommission the unique identifier of a medicinal product referred to in Article 22(a) of the EU Regulation where the medicinal product is manufactured and labelled for the United Kingdom market or for the United Kingdom market and the markets of Cyprus, Malta or the State, and which the wholesaler intends to distribute in the United Kingdom.

L.S.

GIVEN under my Official Seal,
1 June, 2022.

STEPHEN DONNELLY,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

The purpose of these Regulations is to introduce offences for breaches of Commission Delegated Regulation (EU) 2016/16 of 2 October 2015 and related offences.

These Regulations may be cited as the Medicinal Products (Safety Features on Packaging) Regulations 2022.

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