STATUTORY INSTRUMENTS.

S.I. No. 43 of 2022

MEDICINAL PRODUCTS (CONTROL OF MANUFACTURE) (AMENDMENT) REGULATIONS 2022

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The Minister for Health, in exercise of the powers conferred on him 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), hereby make the following regulations:

1. (1) These Regulations may be cited as the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2022.

(2) The Principal Regulations, the Regulations of 2009, the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2010 (S.I. No. 288 of 2010), the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2012 (S.I. No. 273 of 2012), the Regulations of 2013, Regulation 8 of the Medicinal Products (Safety Features on Packaging) Regulations 2019 (S.I. No. 36 of 2019), the Regulations of 2019 and these Regulations may be cited together as the Medicinal Products (Control of Manufacture) Regulations 2007 to 2022.

2. In these Regulations—

"Principal Regulations" means the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007);

"Regulations of 2009" means the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2009 (S.I. No. 4 of 2009);

"Regulations of 2013" means the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2013 (S.I. No. 163 of 2013);

"Regulations of 2019" means the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2019 (S.I. No 219 of 2019).

3. Point 4 of the Arrangement of Regulations in the Principal Regulations is amended by substituting "auxiliary medicinal products" for "investigational medicinal products".

4. Regulation 3(1) (as amended by Regulation 3 of the Regulations of 2013) of the Principal Regulations is amended—

(*a*) by substituting for the definition of "Act" the following:

> "'Act' means the Irish Medicines Board Act 1995, as amended by s. 197 of the Finance Act 1999 (No. 2 of 1999), Regulation 3 of the European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001 (S.I. No. 304 of 2001), Regulation 2 of the European Communities

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(Medical Devices) (Amendment) Regulations 2001 (S.I. 444 of 2001), Regulation 3 of the European Communities (Medical Devices) (Amendment) Regulations 2002 (S.I. 576 of 2002), the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006), the European Communities (Amendment of the Irish Medicines Board Act 1995) Regulations 2007 (S.I. No. 542 of 2007), the Health (Pricing and Supply of Medical Goods) Act 2013 (No. 14 of 2013), the Health (Miscellaneous Provisions) Act 2017 (No. 1 of 2017) and the European Union (Medical Devices and In Vitro Diagnostic Medical Devices) Regulations 2017 (S.I. No. 547 of 2017);",

(*b*) by inserting after the definition of "Agency" the following definition:

"'authorised auxiliary medicinal product' has the meaning assigned to it in Article 2(9) of the Clinical Trials Regulation;",

(*c*) by inserting after the definition of "authorised officer" the following definition:

"'auxiliary medicinal product' has the meaning assigned to it by Article 2(8) of the Clinical Trials Regulations;",

(*d*) by inserting after the definition of "certificate of traditional-use registration" the following definition:

"'Clinical Trials Regulation' means Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014;",

(*e*) in the definition of "2001 Directive" by substituting for "and Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011[1]" the following:

", Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011[1], Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012[2], Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017[3], Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018[4] and Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019[5]",

(*f*) by substituting for the definition of "GMP Directive" the following:

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[1] OJ No. L 174, 1.7.2011, p. 74.
[2] OJ No. L 299, 27.10.2012, p. 1.
[3] OJ No. L 117, 5.5.2017, p. 1.
[4] OJ No. L 4, 7.1.2019, p. 24.
[5] OJ No. L 198, 25.7.2019, p. 241.

"'GMP Directive' means Commission Directive (EU) 2017/1572 of 15 September 2017[6];",

(*g*) by substituting for the definition of "investigational medicinal product" the following:

"'investigational medicinal product' has the meaning assigned to it by Article 2(5) of the Clinical Trials Regulations;",

(*h*) by substituting for the definition of "medicinal product" the following:

"'medicinal product' includes an auxiliary medicinal product but excludes an investigational medicinal product;",

(*i*) in the definition of "qualified person"—

(i) by deleting "or" after subparagraph (b)(ii), and

(ii) by deleting subparagraph (c),

(*j*) in the definition of "Regulation (EC) No. 726/2004" by substituting for "and Regulation (EU) No. 1235/2010 of the European Parliament and of the Council of 15 December 2010[7]" the following:

", Regulation (EU) No. 1235/2010 of the European Parliament and of the Council of 15 December 2010[7], Regulation (EU) No. 1027/2012 of the European Parliament and of the Council of 25 October 2012[8], Regulation (EU) No. 2018/1718 of the European Parliament and of the Council of 14 November 2018[9] and Regulation (EU) No. 2019/5 of the European Parliament and the Council of 11 December 2018[10]", and

(*k*) In the definition of "Regulation (EU) 2016/161" by inserting ", as amended by Commission Delegated Regulation (EU) 2021/457 of 13 January 2021[11]" after "2 October 2015".

5. Regulation 11(6) of the Principal Regulations is amended by deleting "or in the case of an authorisation relating to an investigational medicinal product, Directive 2001/20/EC[12],".

6. Regulation 13 (as amended by Regulation 2 of the Regulations of 2019) of the Principal Regulations is amended—

[6] OJ No. 238, 16.9.2017, p. 44.
[7] OJ No. L 348, 31.12.2010, p. 1.
[8] OJ No. L 316, 14.11.2012, p. 38.
[9] OJ No. L 291, 16.11.2018, p. 3.
[10] OJ No. L 4, 7.1.2019, p. 24.
[11] OJ No. L 91, 17.3.2021, p. 1.
[12] OJ No. L 121, 1.5.2001, p. 34.

(*a*) in paragraph (3)—

(i) in subparagraph (a) by deleting "investigational medicinal products and",

(ii) in subparagraph (b) by deleting "other than investigational medicinal products,",

(iii) by deleting subparagraphs (c) to (e), and

(iv) by renumbering subparagraph (f) as subparagraph (c) and substituting "subparagraph (a) or (b)" for "sub-paragraphs (a), (b), (c), (d) or (e)",

(*b*) in paragraph (4)—

(i) in subparagraph (i) by substituting "The" for "(i) Except in the case of investigational medicinal products, the", and

(ii) by deleting subparagraph (ii), and

(*c*) in paragraph (8) by substituting "authorisation" for "licence".

9. Regulation 14B (inserted by Regulation 7 of the Regulations of 2013) of the Principal Regulations is amended by deleting paragraph (3).

10. Regulation 14C (inserted by Regulation 7 of the Regulations 2013) of the Principal Regulations is amended by deleting paragraph (7) and renumbering paragraph (8) as paragraph (7).

11. Schedule 1 to the Principal Regulations is amended—

(*a*) in paragraph 7(1) by deleting "and address", and

(*b*) in paragraph 7(2) by deleting "and address".

12. Schedule 2 (as amended by Regulation 2 of the Regulations of 2019) of the Principal Regulations is amended—

(*a*) in paragraph 16 by deleting "investigational medicinal products or",

(*b*) in paragraph 20 by deleting subparagraph (2),

(*c*) by substituting for paragraph 23(2)(d)the following:

"(d) to auxiliary medicinal products supplied in accordance with Article 59 of the Clinical Trials Regulation."

(*d*) in paragraph 34 by deleting "investigational medicinal products".

13. Schedule 3 (as amended by Regulation 7 of the Regulations of 2009) of the Principal Regulations is amended—

(*a*) by substituting for paragraph 3(2) the following:

"(2) The provisions of this paragraph shall not apply to auxiliary medicinal products supplied in accordance with Article 59 of the Clinical Trails Regulations.",

(*b*) by deleting paragraph 7(3), and

(*c*) by substituting for paragraph 12(2)(d) the following:

"(*d*) to auxiliary medicinal products supplied in accordance with Article 59 of the Clinical Trials Regulation.".

L.S.

GIVEN under the Official Seal of the Minister for Health,
31 January, 2022.

MUIRIS O'CONNOR,
A person authorised under section 15 of the Ministers and Secretaries Act 1924 to authenticate the seal of the Minister for Health.

EXPLANATORY NOTE

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

These Regulations amend the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007) to remove investigational medicinal products from the scope of those Regulations.

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