L.N. 234 of 2022

MEDICINES ACT
(CAP. 458)

Medicinal Products for Human Use (Derogations from certain obligations) Regulations, 2022

IN EXERCISE of the powers conferred by article 106 of the Medicines Act, the Minister responsible for public health, after consultation with the Licensing Authority, has made the following regulations:-

Citation.

1. The title of these regulations is the Medicinal Products for Human Use (Derogations from certain obligations) Regulations, 2022.

Commencement.

2. These regulations shall be deemed to have come into force on the 1st January 2022.

Scope.

3. The scope of these regulations is to transpose Directive (EU) 2022/642 of the European Parliament and of the Council of 12 April 2022 amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta.

Derogations.

4. The derogations stipulated in these regulations are for the purpose of preventing shortages of medicinal products and ultimately to ensure a high level of public health protection. By virtue of these derogations medicinal products from or transiting through parts of the United Kingdom, may temporarily be allowed.

Part I

Amendments to the Medicines (Marketing Authorisation) Regulations

Amendments to the Medicines (Marketing Authorisation) Regulations. S.L. 458.34.

5. This Part amends the Medicines (Marketing Authorisation) Regulations and it shall be read and construed as one with the Medicines (Marketing Authorisation) Regulations, hereinafter in this Part referred to as the "the principal regulations".

Adds new regulation 2A to the principal regulations.

6. Immediately after regulation 2 of the principal regulations

there shall be added the following new regulation:

"List of medicinal products to be published.

2A. (1) The Licensing Authority shall establish, notify to the Commission and publish on its website a list of medicinal products to which it has applied or intends to apply the derogations as set out in Directive (EU) 2022/642 of the European Parliament and of the Council of 12 April 2022;

(2) The Licensing Authority shall ensure that the list referred to in sub-regulation (1) is updated and managed in an independent manner, at least on a six-monthly basis.".

Adds new regulation 4A to the principal regulations.

7. Immediately after regulation 4 of the principal regulations there shall be added the following new regulation:

"Derogation for products from the United Kingdom.

4A. (1) By way of derogation from regulation 4(2), until the 31st December 2024, in the absence of a marketing authorisation or of a pending application for a marketing authorisation, the Licensing Authority may authorise for justified public health reasons the placing on the market of a medicinal product authorised in parts of the United Kingdom other than Northern Ireland:

Provided that the Licensing Authority may also maintain in force or, until the 31st December 2024, extend marketing authorisations that were granted pursuant to this sub-regulation before the 20th April 2022 which authorise the placing on the market of a medicinal product authorised in parts of the United Kingdom other than Northern Ireland:

Provided further that authorisations that are granted, extended or maintained in force pursuant to the provisions of this sub-regulation shall not be valid after the 31st December 2026.

(2) By way of derogation from regulation 5(1)(b), the Licensing Authority may grant marketing authorisations as referred to in regulation 4(2), to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.

(3) Where the Licensing Authority grants or extends a marketing authorisation as referred to in sub-regulation (1), it shall ensure compliance with the requirements of this regulation.

(4) Before granting a marketing authorisation pursuant to sub-regulation (1), the Licensing Authority:

(a) shall notify the marketing authorisation holder in parts of the United Kingdom other than Northern Ireland of the proposal to grant a marketing authorisation or to extend a marketing authorisation under this regulation in respect of the medicinal product concerned;

(b) may request the competent authority in the United Kingdom to submit the relevant information regarding the marketing authorisation of the medicinal product concerned.".

Amends regulation 5 of the principal regulations.

8. In regulation 5(1)(b) of the principal regulations the words "established in the Community;" shall be substituted by the words "established in the Community:" and immediately after there shall be added the following new provisos:

"Provided that by way of derogation from the above, marketing authorisations may be granted until the 31st December 2024, by the Licensing Authority in accordance with the mutual recognition or the decentralised procedure laid down under regulation 22 to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland:

Provided further that until the 31st December 2024 the Licensing Authority may extend marketing authorisations already granted prior to the 20th April 2022 to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland:

Provided further that marketing authorisations granted or extended by the Licensing Authority in accordance with the preceding two provisos shall cease to be valid at the latest on the 31st December 2026.".

Adds new regulation 5A to the principal regulations.

9. Immediately after regulation 5 of the principal regulations there shall be added the following new regulation:

"Obligations of the authorisation holder.
S.L. 458.35.

S.L. 458.36.

5A. The derogations set out in regulations 4A and 5(1) (b), regulations 4 and 22 of the Pharmacovigilance Regulations, and regulations 11A, 11B, 11C and 11D of the Manufacture and Importation of Medicinal Products for Human Use Regulations shall not affect the obligations of the marketing authorisation holder to ensure the quality, safety and efficacy of the medicinal product placed on the market as laid down in these regulations.".

Part II

Amendments to the Pharmacovigilance Regulations

Amendments to the Pharmacovigilance Regulations S.L. 458.35.

10. This Part amends the Pharmacovigilance Regulations and it shall be read and construed as one with the Pharmacovigilance Regulations, hereinafter in this Part referred to as the "the principal regulations".

Amends regulation 6 of the principal regulations.

11. In the proviso to regulation 6(4) of the principal regulations the words "and the Agency." shall be substituted by the words "and the Agency:" and immediately thereafter there shall be added the following new proviso:

"Provided further that by way of derogation from the preceding proviso, where the marketing authorisation is granted by the competent authority of the United Kingdom in respect of Northern Ireland, the qualified person referred to in paragraph (a) of this sub-regulation may reside and operate in parts of the United Kingdom other than Northern Ireland. This proviso shall not apply where the marketing authorisation holder already has at its disposal a qualified person who resides and operates in the European Union on 20 April 2022.".

Part III

Amendments to the Manufacture and Importation of Medicinal Products for Human Use Regulations

Amendments to the Manufacture and Importation of Medicinal Products for Human Use Regulations. S.L. 458.36.

12. This Part amends the Manufacture and Importation of Medicinal Products for Human Use Regulations and it shall be read and construed as one with the Manufacture and Importation of Medicinal Products for Human Use Regulations, hereinafter in this Part referred to as the "the principal regulations".

Amends regulation 11 of the principal regulations.

13. Regulation 11 of the principal regulations shall be amended as follows:

(a) in the Maltese version only, in paragraph (a) of sub-regulation (1) thereof, the words "konsenja ta' prodotti mediċinali manifatturati f'Malta tkun ġiet manifatturata u verifikata" shall be substituted by the words "lott ta' prodotti mediċinali manifatturati f' Malta jkun ġie manifatturat u verifikat";

(b) in the Maltese version only, in paragraph (b) of sub-regulation (1) thereof, the words "konsenja tal-produzzjoni għandha tkun għaddiet" shall be substituted by the words "lott

tal-produzzjoni għandu jkun għadda";

(c) in the Maltese version only, in the proviso to paragraph (b) of sub-regulation (1) thereof, the word "konsenji" shall be substituted by the word "lottijiet".

Adds new regulations 11A, 11B, 11C and 11D to the principal regulations.

14. Immediately after regulation 11 of the principal regulations there shall be added the following new regulations:

"Quality control testing in the United Kingdom.

S.L. 458.34.

11A. With regard to quality control testing, carried out in parts of the United Kingdom other than Northern Ireland, regarding medicinal products included in the list referred to in regulation 5A of the Medicines (Marketing Authorisation) Regulations other than those authorised by the Commission, until the 31st December 2022, the Licensing Authority, may consider there is a justifiable case within the meaning of regulation 11(1)(b), without carrying out a case-by-case assessment provided that:

(a) each batch of the medicinal products concerned is released by a qualified person on a site in the Union or in Northern Ireland or by a qualified person on a site in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in regulation 11;

(b) the establishment designated by the third party conducting the quality control testing is supervised by the competent authority of the United Kingdom, including by performing on-the-spot checks;

(c) where the batch release is carried out by a qualified person who resides and operates in parts of the United Kingdom other than Northern Ireland, the manufacturing authorisation holder declares that it does not have at its disposal a qualified person who resides and operates in the Union on the 20th April 2022.

Derogation from the requirement of an importers' licence.

11B. By way of derogation from sub-regulations 1(a) and (b) of regulation 3, until the 31st December 2024, the Licensing Authority shall allow medicinal products to be imported from parts of the United Kingdom other than Northern Ireland by holders of a wholesale distribution authorisation as referred to in regulation 4 of the Wholesale Distribution and Brokering of Medicinal Products and Active Substances Regulations, that are not in possession of a relevant manufacturing authorisation provided that all of the following conditions are fulfilled:

S.L. 458.37.

(a) the medicinal products have undergone quality control testing, either in the Union, as provided for in regulation 12 or in parts of the United Kingdom other than Northern Ireland in compliance with regulation 11(1)(b);

(b) the medicinal products have been subject to batch release by a qualified person in the Union in accordance with regulation 11(1) or, for medicinal products authorised by the Licensing Authority and the United Kingdom in respect of Northern Ireland, in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in regulation 11(1);

(c) the marketing authorisation for the medicinal product concerned has been granted in accordance with Union law, by the competent authority of a Member State or by the Commission or, as regards medicinal products placed on the market in Northern Ireland, by the competent authority of the United Kingdom in respect of Northern Ireland;

(d) medicinal products are only made available to patients or end-consumers in Malta;

(e) the medicinal products bear the safety features referred to in regulation 3(o) of the Medicinal Products (Labelling and Packaging) Regulations.

S.L. 458.33.

Certain derogations from importation controls.

11C. For batches of medicinal products exported to parts of the United Kingdom other than Northern Ireland from a Member State and subsequently imported into Malta until the 31st December 2024 the controls upon importation referred to in the sub-regulations (1) and (2) of regulation 11, shall not be required, provided that those batches have undergone such controls in a Member State prior to being exported to parts of the United Kingdom other than Northern Ireland and that they are accompanied by the control reports referred to in the said regulation.

Derogation regarding the place of operation of the qualified person.

11D. Where the manufacturing authorisation is granted by the competent authority of the United Kingdom in respect of Northern Ireland, the qualified person referred to regulation 11(1) may reside and operate in parts of the United Kingdom other than Northern Ireland, unless the manufacturing authorisation holder already has at its disposal a qualified person who resides and operates in the Union on 20 April 2022.".

Amends regulation 12 of the principal regulations.

15. In the Maltese version only, in regulation 12(1) the words "konsenja li tkun ġiet prodotta tkun tissodisfa" shall be substituted by the words "lott li jkun ġie prodott ikun jissodisfa".

Part IV

Amendments to the Wholesale Distribution and Brokering of Medicinal Products and Active Substances Regulations

Amendments to the Wholesale Distribution and Brokering of Medicinal Products and Active Substances Regulations. S.L. 458.37.

16. This Part amends the Wholesale Distribution and Brokering of Medicinal Products and Active Substances Regulations and it shall be read and construed as one with the Wholesale Distribution and Brokering of Medicinal Products and Active Substances Regulations, hereinafter in this Part referred to as the "the principal regulations".

Amends regulation 3 of the principal regulations.

17. In the Maltese version only, in the proviso to regulation 3(2) of the principal regulations the word "kunsinna" shall be substituted by the word "lott".

Amends regulation 8 of the principal regulations.

18. Regulation 8(2) of the principal regulations shall be amended as follows:

(a) in the proviso to paragraph (b) thereof, the words "end up on any Member State market;" shall be substituted by the words "end up on any Member State market:" and immediately after there shall be added the following new proviso:

"Provided further that the requirements of the above proviso shall not apply to the import of a medicinal product meeting the conditions laid down in regulation 11B of the Manufacture and Importation of Medicinal Products for Human Use Regulations;". S.L. 458.36.

(b) in the Maltese version only, in sub-paragraph (v) of paragraph (e) thereof, the word "kunsina" shall be substituted by the word "lott".

Amends regulation 9 of the principal regulations.

19. In the Maltese version only, in regulation 9(1) of the principal regulations the word "kunsinna" shall be substituted by the word "lott".

Part V

Amendments to the Good Clinical Practice and Requirements for Manufacturing or Import Authorisation of Investigational Medicinal Products (Human Use) Regulations

Amendments to the Good Clinical Practice and Requirements for Manufacturing or Import Authorisation of Investigational Medicinal Products (Human Use) Regulation. S.L. 458.47.

20. This Part amends the Good Clinical Practice and Requirements for Manufacturing or Import Authorisation of Investigational Medicinal Products (Human Use) Regulations and it shall be read and construed as one with the Good Clinical Practice and Requirements for Manufacturing or Import Authorisation of Investigational Medicinal Products (Human Use) Regulations, hereinafter in this Part referred to as the "the principal regulations".

Amends regulation 7 of the principal regulations.

21. In sub-regulation (1) of regulation 7 of the principal regulations the words "dividing up, packaging or presentation." shall be substituted by the words "dividing up, packaging or presentation:" and immediately after there shall be added the following new proviso:

"Provided that by way of derogation from sub-regulation (1), the Licensing Authority shall allow investigational medicinal products to be imported from parts of the United Kingdom other than Northern Ireland without such an authorisation provided that all of the following conditions are fulfilled:

(a) the imported investigational medicinal products have undergone certification of batch release either in the Union, as provided for in paragraph 3, point (a) of Article 13 (1) of Directive 2001/20/EC, or in parts of the United Kingdom other than Northern Ireland in compliance with the requirements set out in paragraph 3, point (b) of the same Directive;

(b) the imported investigational medicinal products are only made available in Malta.".

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