Statutory Document No. 2019/0102

*European Union and Trade Act 2019*

# EUROPEAN UNION AND TRADE ACT 2019 (DEFICIENCIES) (HEALTH AND SOCIAL CARE) REGULATIONS 2019

*Approved by Tynwald: 20 March 2019*
*Coming into Operation in accordance with regulation 2*

The Council of Ministers makes the following Regulations under section 12 of, and paragraph 1 of Schedule 4 to, the European Union and Trade Act 2019.

## 1 Title

These Regulations are the European Union and Trade Act 2019 (Deficiencies) (Health and Social Care) Regulations 2019.

## 2 Commencement

If approved by Tynwald[1] these Regulations come into operation on exit day.

## 3 Interpretation

In these regulations "exit day" has the same meaning as in the European Union and Trade Act 2019.

## 4 Dental Act 1985 amended

(1) The Dental Act 1985 is amended as follows.

(2) In section 2(1) (prohibition on practice of dentistry by layman), omit the words "or an EEA practitioner".

(3) In section 6(1) (prohibition on use of practitioners' titles by laymen), omit the words "or a visiting EEA practitioner".

(4) In section 11(1) (interpretation), omit the definition of "EEA Practitioner".

[1] Tynwald approval is required by section 12(1) of the European Union and Trade Act 2019.

## 5 Medicines Act 2003 amended

(1) The Medicines Act 2003 is amended as follows.

(2) In section 1 (introductory) —

(a) in subsection (1), omit from "United Kingdom" to the end of the subsection.

(b) in subsection (3) —

(i) for the definition of "Community authorisation", substitute —

> "**EU authorisation**" means a marketing authorisation granted or renewed by the European Commission under the EC Regulation;";

(ii) in the definition of "UK authorisation", for paragraph (a) substitute —

> "(a) a marketing authorisation granted or recognised as having effect as a UK marketing authorisation in accordance with the Human Medicines Regulations 2012 (of Parliament)[2];"; and

(iii) in the definition of "UK authorisation", for paragraph (b) substitute —

> "(b) a certificate of registration for a registrable homoeopathic medicinal product granted in accordance with the Human Medicines Regulations 2012 (of Parliament)[3];".

(3) In section 2(4) (restrictions on dealing with medicinal products) —

(a) in paragraph (a), omit "Community authorisations and"; and

(b) for paragraph (b), substitute —

> "(b) may provide for giving effect in the Island, subject to such conditions as may be prescribed, to EU authorisations and to any other authorisation licence, consent, certificate or other document relating to any activity mentioned in subsection (1) and granted or issued in the EU under any EU instrument".

(4) In section 4(1) (general sale of medicinal products) for "a Community authorisation or UK authorisation" substitute "an authorisation".

(5) In section 5(1) (medicinal products on prescription only) for "a Community authorisation or UK authorisation" substitute "an authorisation".

(6) In section 17(4) (interpretation), omit the definition of "authorisation".

[2] SI 2012/1916

[3] SI 2012/1916

(7) In section 32(3) (application of Parts 1 to 4 to veterinary medicinal products) omit paragraph (a).

(8) In Schedule 2 (interpretation) —

(a) after the definition of "assemble (in relation to a medicinal product or veterinary medicinal product)" insert —

| | |
|---|---|
| "**authorisation** | means a UK authorisation, an EU authorisation or any other authorisation that has effect in the Island pursuant to regulations made under section 2 or 52"; |

(b) omit the definition of "Community authorisation";

(c) for the definition of "EU instrument" substitute —

| | |
|---|---|
| "**EU instrument** | has the meaning given in the Interpretation Act 2015"; |

(d) for the definition of "EC Regulation" substitute —

| | |
|---|---|
| "**EC Regulation** | means Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;"; |

(e) in the definition of "UK medicines legislation", for paragraph (d) substitute —

"(d) any Parliamentary enactment or any EU-derived domestic legislation or retained direct EU legislation (within the meaning given to both terms by the European Union (Withdrawal) Act 2018 (of Parliament)) giving effect to any provision of —

(i) the EC Code,

(ii) the EC veterinary code,

(iii) the EC Regulation, or

(iv) any EU instrument from time to time amending or replacing any of the instruments mentioned in sub-paragraphs (i), (ii) and (iii).".

## 6 Public Health (Tobacco) Act 2006 amended

(1) The Public Health (Tobacco) Act 2006 is amended as follows.

(2) Omit section 1(4) (prohibition of tobacco advertising).

(3) For section 2A(1) (advertising: information society services) substitute —

"(1) This subsection applies where by means of an information society service, provided in the course of a business, a tobacco advertisement is published in the Island."

(4) In section 3(1) (advertising: exclusions) —

(a) in paragraph (c) —

(i) in subparagraph (i) for "relevant territory" substitute "Island"; and

(ii) in subparagraph (ii) for "one or more of the relevant territories (or any part of a relevant territory)" substitute "the Island (or any part of the Island)".

(b) in paragraph (d) —

(i) for "relevant territory" substitute "Island"; and

(ii) for "one or more relevant territories (or any part of a relevant territory)" substitute "the Island (or any part of the Island).".

(5) In section 4 (advertising: defences) —

(a) omit subsections (3A) and (5A); and

(b) in subsection (5)(c) for "relevant territory" substitute "Island".

(6) Omit section 4D(3) (displays on a website).

(7) Omit section 6(1A) (prohibition of free distributions).

(8) Omit section 8(5) (brandsharing).

(9) In section 13 (part 1: interpretation) —

(a) omit the definition of "EEA State";

(b) omit the definition of "member State"; and

(c) omit the definition of "relevant territory".

## 7 The Medicines for Human Use Regulations 2005 amended

(1) The Medicines for Human Use Regulations 2005[4] are amended as follows.

(2) In regulation 1(2) (citation, commencement and interpretation) —

(a) after the definition of "the Act", insert —

"**EU authorisation**" has the meaning given in section 1(3) of the Act;

[4] SD 9/05.

"**manufacturing licence"** has the meaning given in paragraph (d) of the definition of "UK authorisation" in section 1(3) of the Act;";

(b) for the definition of "relevant medicinal product" substitute —

"**"relevant medicinal product"** means a medicinal product for human use intended to be placed on the market and either prepared industrially or manufactured by a method involving an industrial process; and"; and

(c) for the definition of "UK authorisation" substitute—

"**"UK authorisation"** has the meaning given in section 1(3) of the Act.".

(3) Omit regulation 1(4) and (5).

(4) For regulation 2(1) (placing on the market and wholesale dealing) substitute —

"**2. Placing on the Market and Wholesale Dealing**

(1) Subject to paragraphs 1 and 3 of Schedule 1 —

(a) no relevant medicinal product shall be placed on the market; and

(b) no such product shall be distributed by way of wholesale dealing,

unless a UK authorisation or EU authorisation in respect of that product is for the time being in force in accordance with those provisions.".

(5) In regulation 4(1) (obligations of holders of marketing authorisations and offences by holders of marketing authorisations and other persons) for "a UK authorisation" substitute "an EU authorisation".

(6) After regulation 4(1) insert —

"(1A) Every holder of a UK authorisation for a relevant medicinal product shall comply with all obligations which relate to them by virtue of the Human Medicines Regulations 2012 (of Parliament)[5].".

(7) In regulation 4(2) —

(a) for the words "marketing authorisations" substitute "UK authorisations and EU authorisations"; and

(b) omit the words "arising under the EC code".

[5] SI 2012/1916

(8) In Schedule 1 (exemptions and exceptions from the provisions of regulation 2), for paragraph 2(e) substitute —

"(e) the relevant medicinal product is manufactured, assembled or imported by the holder of a manufacturing licence which relates specifically to the manufacture, assembly or import of relevant medicinal products to which paragraph 1 applies; and".

(9) In Schedule 2 (offences, penalties etc.) —

(a) in paragraph 1, for "a Community or UK authorisation" substitute "an EU authorisation";

(b) in paragraph 1, after the first sentence insert —

"Any person who, in breach of the Human Medicines Regulations 2012 (of Parliament)[6] or of these Regulations, places a relevant medicinal product on the market without holding a UK authorisation in respect of that product or otherwise than in accordance with the terms of such an authorisation shall be guilty of an offence.";

(c) in paragraph 3, after the words "UK authorisation" insert "or EU authorisation";

(d) for paragraph 4, substitute —

"4. Any holder of a UK authorisation who sells or supplies or procures the sale or supply of a relevant medicinal product to which the authorisation relates —

(a) which does not comply with the applicable requirements of the Human Medicines Regulations 2012 (of Parliament)[7] for packaging and package leaflets relating to medicinal products; or

(b) which is not accompanied by a package leaflet when one is required by virtue of the Human Medicines Regulations 2012 (of Parliament)[8],

shall be guilty of an offence.";

(e) after paragraph 4, insert —

"4A. Any holder of an EU authorisation who sells or supplies or procures the sale or supply of a relevant medicinal product to which the authorisation relates —

(a) which does not comply with the applicable requirements of the EC code for packaging and package leaflets relating to medicinal products; or

[6] SI 2012/1916
[7] SI 2012/1916
[8] SI 2012/1916

(b) which is not accompanied by a package leaflet when one is required by virtue of the EC code,

shall be guilty of an offence.";

(f) for paragraph 5(b) substitute —

"5. Where, in relation to a relevant medicinal product —

(a) the labelling of the product, or any package leaflet accompanying the product, does not comply with the applicable requirements of the Human Medicines Regulations 2012 (of Parliament)[9]; or

(b) the product is not accompanied by a package leaflet required to be provided by virtue of the applicable requirements of the Human Medicines Regulations 2012 (of Parliament)[10],

any person, other than the holder of the UK authorisation for that product, who in the course of a business carried on by them, sells or supplies or procures the sale or supply of that product knowing, or having reasonable cause to believe, that the labelling does not so comply or, as the case may be, that the product is not so accompanied, shall be guilty of an offence."; and

(g) after paragraph 5, insert —

"5A. Where, in relation to a relevant medicinal product —

(a) the labelling of the product, or any package leaflet accompanying the product, does not comply with the applicable requirements of the EC code; or

(b) the product is not accompanied by a package leaflet required to be provided by virtue of the applicable requirements of the EC code,

any person, other than the holder of the EU authorisation for that product, who in the course of a business carried on by them, sells or supplies or procures the sale or supply of that product knowing, or having reasonable cause to believe, that the labelling does not so comply or, as the case may be, that the product is not so accompanied, shall be guilty of an offence.".

(10) In Schedule 3 (labels), paragraph 2 for the words "Council Directive 92/27/EEC" and "Council Directive 92/26/EEC" substitute "the Human Medicines Regulations 2012 (of Parliament)[11]".

[9] SI 2012/1916

[10] SI 2012/1916

[11] SI 2012/1916

(11) Omit Schedule 4 (leaflets).

## 8 The Medicines (General Sales List) Regulations 2005 amended

(1) The Medicines (General Sales List) Regulations 2005[12] are amended as follows.

(2) In Schedule 2, at the end insert —

"FURTHER MODIFICATIONS TO THE MEDICINES (PRODUCTS OTHER THAN VETERINARY DRUGS) (GENERAL SALE LIST) ORDER 1984 (AS AMENDED) SUBJECT TO WHICH IT APPLIES TO THE ISLAND

1. For the definition of "marketing authorization" substitute —

"**marketing authorization**" means a marketing authorization granted by —

(a) the European Commission under Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency; or

(b) the licensing authority under the Human Medicines Regulations 2012 (of Parliament)[13]."."

## 9 The Prescription Only Medicines (Human Use) Regulations 2005 amended

(1) The Prescription Only Medicines (Human Use) Regulations 2005[14] are amended as follows.

(2) In Part 2 of Schedule 2, below the heading 'SPECIFIC MODIFICATIONS OF SI 1997/1830', in paragraph 1 —

(a) before subparagraph (a) insert —

"(za) for the definition of 'Community marketing authorization' substitute —

"**EU marketing authorisation**" means a marketing authorisation granted or renewed by the European Commission under Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and

[12] SD 10/05.
[13] SI 2012/1916
[14] SD 11/05.

veterinary use and establishing a European Medicines Agency;";

(b) after subparagraph (a) insert —

"(aa) For the definition of "marketing authorization" substitute —

"**marketing authorization**" includes a reference to both a United Kingdom marketing authorization and to an EU marketing authorisation;"; and

(c) after subparagraph (c) insert —

"(d) for the definition of "United Kingdom marketing authorization" substitute —

"**United Kingdom marketing authorization**" means a marketing authorisation granted or recognised as having effect as a UK marketing authorisation in accordance with the Human Medicines Regulations 2012 (of Parliament)[15]."."

(3) In Part 2 of Schedule 2, below the heading 'SPECIFIC MODIFICATIONS OF SI 1997/1830', after paragraph 1, insert —

"1A. In article 6(2), for "in respect of which a marketing authorization has been granted under Council Regulation 2309/93/EEC" substitute "with an EU marketing authorisation"."."

## 10 The Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 2005

(1) The Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 2005[16] are amended as follows.

(2) In Part 2 of Schedule 2, below the heading 'SPECIFIC MODIFICATIONS OF SI 1980/1923', after paragraph 2, insert —

"2A. In regulation 5(1), for "the holder of a marketing authorization within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994" substitute "the holder of a marketing authorisation within the meaning of the Human Medicines Regulations 2012 (of Parliament)[17]"."."

[15] SI 2012/1916

[16] SD 12/05.

[17] SI 2012/1916

## 11 The Medicines (Pharmacy and General Sale – Exemption) Regulations 2005 amended

(1) The Medicines (Pharmacy and General Sale – Exemption) Regulations 2005[18] are amended as follows.

(2) In Part 2 of Schedule 2, below the heading 'SPECIFIC MODIFICATIONS OF SI 1980/1924' —

(a) after paragraph 1(d), insert —

"(e) for the definition of "European Union marketing authorization" substitute —

> "**EU marketing authorisation**" means a marketing authorisation granted or renewed by the European Commission under Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;";

(f) omit the definition of "Directive 2001/83/EC";

(g) for the definition of "homoeopathic certificate of registration" substitute —

> "**homoeopathic certificate of registration**" means a certificate of registration for a registrable homoeopathic medicinal product granted in accordance with the Human Medicines Regulations 2012 (of Parliament)[19];";

(h) for the definition of "marketing authorization" substitute —

> "**marketing authorization**" means —
>
> (a) a UK marketing authorization; or
>
> (b) an EU marketing authorisation;";

(i) for the definition of "registered homoeopathic medicinal product for human use" substitute —

> "**registrable homoeopathic medicinal product**" has the meaning given in the Human Medicines Regulations 2012 (of Parliament)[20];";

(j) for the definition of "United Kingdom marketing authorization" substitute —

[18] SD 13/05.
[19] SI 2012/1916
[20] SI 2012/1916

"**UK marketing authorization"** means a marketing authorisation granted or recognised as having effect as a UK marketing authorisation in accordance with the Human Medicines Regulations 2012 (of Parliament)[21]."

1A. In Regulation 6A for "registered homoeopathic medicinal product for human use" substitute "registrable homoeopathic medicinal product";

(b) in paragraph 2(1) after subparagraph (b) insert —

"(c) in column 1 of head 11 —

(i) for "holders of marketing authorizations within the meaning of the Medicines for Human Use (Marketing Authorizations etc.) Regulations 1994" substitute "holders of marketing authorizations"; and

(ii) for "holders of certificates of registration granted pursuant to the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994" substitute "holders of homoeopathic certificates of registration".".

## 12 The Medicines (Advertising) Regulations 2005 amended

(1) The Medicines (Advertising) Regulations 2005[22] are amended as follows.

(2) In regulation 2(1) —

(a) in the definition of "essential information compatible with the summary of product characteristics" and associated definition of "essential information" omit ", and "essential information" has the meaning it bears in Council Directive 92/28/EEC"; and

(b) for the definition of "registered homoeopathic medicinal product" substitute —

"**registrable homoeopathic medicinal product"** has the meaning given in the Human Medicines Regulations 2012 (of Parliament)[23];".

(3) In regulations 3(2), 10(2)(a), 17(a), 22(1) and (2) and Schedule 5, for "registered homoeopathic medicinal product" wherever occurring substitute "registrable homoeopathic medicinal product".

(4) For the heading of Part 5 substitute —

[21] SI 2012/1916

[22] SD 294/05.

[23] SI 2012/1916

"REGISTRABLE HOMOEOPATHIC MEDICINAL PRODUCT".

(5) For the heading of regulation 22 substitute —

"Advertisements for registrable homoeopathic medicinal product".

(6) For the heading of Schedule 5 substitute —

"PARTICULARS WHICH MAY BE CONTAINED IN ADVERTISEMENTS FOR REGISTRABLE HOMOEOPATHIC MEDICINAL PRODUCTS".

## 13 Construction

To avoid doubt, any retained EU law is to be construed and have effect subject to these Regulations.

**MADE 1 MARCH 2019**

**W GREENHOW**
*Chief Secretary*

## *EXPLANATORY NOTE*

***(This note is not part of the Regulations)***

These Regulations amend the following statutes; the Dental Act 1985, the Medicines Act 2003 and the Public Health (Tobacco) Act 2006 to address deficiencies arising from the United Kingdom's withdrawal from the European Union.

These Regulations also amend the following statutory documents that are made under the Medicines Act 2003; the Medicines for Human Use Regulations 2005, the Medicines (General Sales List) Regulations 2005, the Prescription only Medicines (Human Use) Regulations 2005, the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 2005, the Medicines (Pharmacy and General Sale – Exemption) Regulations 2005 and the Medicines (Advertising) Regulations 2005.

The Dental Act 1985 is amended at section 2 (prohibition on practice of dentistry by layman), section 6 (prohibition on use of practitioners' title by laymen) and section 11 (interpretation), removing references in those sections to EEA practitioner so that the regulation of the profession of dentistry continues to operate as intended.

The primary amendment to the Medicines Act 2003 is the amendment of section 2 (restrictions on dealing with medicinal products). Pursuant to section 2 there is a statutory requirement for the Department of Health and Social Care, when making regulations under the Act, to give effect to licences that have been issued by the European Medicines Agency for human medicines. Section 2 is amended so that the Department of Health and Social Care can continue to recognise such licences but it will be at the Department's discretion as to whether it does so or not.

Further amendments to the Medicines Act 2003 are as a consequence of the amendment to section 2, as described above, or necessary, given that the systems of control for dealing with medicinal products will no longer be operating under European Union law.

The amendments to the Public Health (Tobacco) Act 2006 are necessary to reflect that EU obligations and reciprocal arrangements with EEA states will, upon the withdrawal of the United Kingdom from the European Union, no longer be relevant. Thus amendments are being made, omitting references to EEA state, member state and relevant territory.

The amendments to the Department of Health and Social Care's secondary legislation identified are necessary to ensure that each document continues to operate properly and appropriately upon the withdrawal of the United Kingdom from the European Union.