STATUTORY INSTRUMENTS

# 2013 No. 2593

# MEDICINES

## The Human Medicines (Amendment) (No. 2) Regulations 2013

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| *Made - - - -* | *8th October 2013* |
| *Laid before Parliament* | *14th October 2013* |
| *Coming into force - -* | *11th November 2013* |

The Secretary of State and the Minister for Health, Social Services and Public Safety make the following Regulations. They do so in exercise of the powers conferred by section 2(2) and (5) of the European Communities Act 1972(**1**), having been designated for the purposes of section 2(2) of that Act in relation to medicinal products(**2**).

### Citation, commencement and interpretation

**1.**—(1) These Regulations may be cited as the Human Medicines (Amendment) (No. 2) Regulations 2013.

(2) These Regulations come into force on 11th November 2013.

(3) In these Regulations "the 2012 Regulations" means the Human Medicines Regulations 2012(**3**).

### Amendment of regulation 8 of the 2012 Regulations

**2.**—(1) Regulation 8(1) of the 2012 Regulations (general interpretation) is amended as follows.

(2) For the definition of "the 2001 Directive" substitute—

""the 2001 Directive" means Directive 2001/83/EC of the European Parliament and of the Council on the Community Code relating to medicinal products for human use;(**4**)

(3) For the definition of "Regulation (EC) No 726/2004" substitute—

""Regulation (EC) No 726/2004" means Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for

(**1**) 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).
(**2**) S.I. 1972/1811.
(**3**) S.I. 2012/1916, amended by S.I. 2013/1855; there is another amending instrument but it is not relevant.
(**4**) Directive 2002/83/EC was last amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 (OJ No L 299, 27.10.2012, p.1).

the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;(**5**)

**Amendment of regulation 73 of the 2012 Regulations**

**3.** After regulation 73(5) of the 2012 Regulations (obligation to notify placing on the market etc) insert the following paragraphs—

"(5A) The holder of a UK marketing authorisation must notify the licensing authority forthwith if the holder takes action to—

(a) request the cancellation of the authorisation;

(b) not apply for the renewal of the authorisation; or

(c) withdraw the product to which the authorisation relates from the market in a third country (whether temporarily or permanently) and the action is based on any of the grounds set out in Article 116 or 117(1) of the 2001 Directive.

(5B) A notification under paragraph (3) or (5A) must include the reasons for the action, in particular declaring if the action is based on any of the grounds set out in Article 116 or 117(1) of the 2001 Directive.

(5C) The holder of a UK marketing authorisation must also notify the EMA forthwith where the action which is the subject of a notification by the holder under paragraph (3) or (5A) is based on any of the grounds set out in Article 116 or 117(1) of the 2001 Directive."

**Amendment of regulation 82 of the 2012 Regulations**

**4.**—(1) Regulation 82(1) of the 2012 Regulations (EU marketing authorisations: failure to notify placing on market etc) is amended as follows.

(2) In sub-paragraph (a) omit "or".

(3) In sub-paragraph (b) for "market)." substitute "market); or".

(4) After sub-paragraph (b) add the following sub-paragraph—

"(c) Article 14b of Regulation (EC) No 726/2004 (requirement to notify suspending of marketing of the product etc)."

**Amendment of regulation 113 of the 2012 Regulations**

**5.** After regulation 113(3) of the 2012 Regulations (obligation to notify placing on the market etc) insert the following paragraph—

"(3A) A notification under paragraph (3) must include the reasons for the withdrawal in accordance with article 123(2) of the 2001 Directive."

**Amendment of regulation 142 of the 2012 Regulations**

**6.** After regulation 142(5) of the 2012 Regulations (obligation to notify placing on the market etc) insert the following paragraphs—

"(5A) The holder of a traditional herbal registration must notify the licensing authority forthwith if the holder takes action to—

(a) request the cancellation of the registration;

(b) not apply for the renewal of the registration; or

(**5**) Regulation (EC) No 726/2004 was last amended by Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 (OJ No L 316, 14.11.2012, p.38).

(c) withdraw the product to which the registration relates from the market in a third country (whether temporarily or permanently) and the action is based on any of the grounds set out in Article 116 or 117(1) of the 2001 Directive.

(5B) A notification under paragraph (3) or (5A) must include the reasons for the action, in particular declaring if the action is based on any of the grounds set out in Article 116 or 117(1) of the 2001 Directive.

(5C) The holder of a traditional herbal registration must notify the EMA forthwith where the action which is the subject of a notification by the holder under paragraph (3) or (5A) is based on any of the grounds set out in Article 116 or 117(1) of the 2001 Directive."

**Amendment of regulation 196 of the 2012 Regulations**

**7.**—(1) Regulation 196 of the 2012 Regulations (urgent action) is amended as follows.

(2) For paragraphs (1) and (2) substitute the following paragraphs—

"(1) The licensing authority must initiate the Section 4 procedure by informing the specified bodies where, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities,—

(a) it considers suspending or revoking an authorisation or registration of a medicinal product or class of medicinal products;

(b) it considers prohibiting the supply of a medicinal product or class of medicinal products;

(c) it considers refusing the renewal of an authorisation or registration of a medicinal product; or

(d) it is informed by a holder that, on the basis of safety concerns, the holder has—

(i) interrupted the sale or supply, or offer of sale or supply, of the product,

(ii) taken action to have the product's authorisation or registration cancelled or intends to do so, or

(iii) not applied for the renewal of the product's authorisation or registration.

(2) The licensing authority must inform the specified bodies where, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities, it considers it necessary to vary an authorisation or registration or a class of authorisations or registrations to include—

(a) a new contra-indication,

(b) a reduction to the recommended dose, or

(c) a restriction to the therapeutic indications.

(2A) The information provided under paragraph (2) must outline the action considered and the reasons for the action.

(2B) Where the licensing authority considers urgent action is necessary in relation to the information provided under paragraph (2), it must initiate the Section 4 procedure.

(2C) The information required to be provided under paragraph (1) or (2) must be provided by the end of the day on which the consideration arose under paragraph (1)(a) to (c) or (2) or the information was received under paragraph (1)(d) (as the case may be)."

(3) In paragraph (3) after "paragraph" insert "(1) or".

(4) In paragraph (4)—

(a) for "paragraph (1)" substitute "paragraph (1) or (2)"; and

(b) for "paragraph (2)" substitute "paragraph (1) or (2) (as the case may be)".

(5) In paragraph (5) for "paragraph (1)", both times it appears, substitute "paragraph (1) or (2)".

(6) In paragraph (7)—

(a) after "inform" insert "the specified bodies"; and

(b) omit from "the following" to the end of the paragraph.

(7) For paragraph (8) substitute—

"(8) In this regulation—

"EU urgent action procedure" means the procedure under Articles 107j and 107k of the 2001 Directive;

"Section 4 procedure" means the procedure under Section 4 of Chapter 3 of Title IX of the 2001 Directive; and

"specified bodies" means—

(a) the competent authority of each EEA State other than the United Kingdom,

(b) the EMA, and

(c) the European Commission."

**Amendment of regulation 346 of the 2012 Regulations**

**8.** In regulation 346(2)(b) of the 2012 Regulations(**6**) (review) insert the following paragraphs at the appropriate place—

"(xiva) 73(5A) to (5C),";

"(xviia) 82(1)(c),";

"(xxiva) 113(3A),";

"(xxviiia) 142(5A) to (5C),".

**Amendment of Schedule 17 to the 2012 Regulations**

**9.** In Part 4 of Schedule 17 to the 2012 Regulations (exemption for sale, supply or administration by certain persons), after item 10 in the table add—

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| "11. Operator or commander of an aircraft. | 11. All medicinal products on a general sale list. | 11. The medicinal product must—<br>(a) have been made up for sale or supply in a container elsewhere than at the place at which it is sold or supplied; and<br>(b) be stored in a part of the aircraft which the operator is able to close so as to exclude the public. |
| 12. The operator of a train. | 12. All medicinal products on a general sale list. | 12. The medicinal product must—<br>(a) have been made up for sale or supply in a |

(**6**) Regulation 346 of the 2012 Regulations has been amended by S.I. 2013/1855.

container elsewhere than at the place at which it is sold or supplied; and

(b) be stored in a part of the train which the operator is able to close so as to exclude the public."

Signed by authority of the Secretary of State for Health.

*Earl Howe*
Parliamentary Under-Secretary of State,
8th October 2013 Department of Health

*Edwin Poots*
Minister for Health, Social Services and Public
7th October 2013 Safety

## EXPLANATORY NOTE

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

These Regulations amend the Human Medicines Regulations 2012 (the 2012 Regulations) in order to implement Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance and Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending Regulation (EC) No 726/2004 as regards pharmacovigilance.

These Regulations further amend the 2012 Regulations in order to allow general sale medicinal products to be supplied or sold on aircrafts and trains.

Regulations 2 and 4 amend regulations 8 and 82 of the 2012 Regulations in order to ensure that the changes made to Regulation (EC) No 726/2004 by Regulation (EU) No 1027/2012 are enforceable in the United Kingdom.

Regulations 3, 5 and 6 amend regulations 73, 113 and 142 of the 2012 Regulations respectively in order to transpose the changes made to articles 23a and 123 of Directive 2001/83/EC by Directive 2012/26/EU insofar as they apply to marketing authorisations, homeopathic certificates of registration and traditional herbal registrations.

Regulation 7 amends regulation 196 of the 2012 Regulations in order to transpose the changes made to article 107i of Directive 2001/83/EC by Directive 2012/26/EU.

Regulation 8 amends regulation 346 of the 2012 Regulations in order to oblige the Secretary of State to carry out a review of regulations 73, 82, 113 and 142 of the 2012 Regulations.

Regulation 9 amends Schedule 17 to the 2012 Regulations in order that an operator or commander of an aircraft or an operator of a train is able to sell or supply general sale medicinal products.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, public or voluntary sectors is foreseen.