STATUTORY RULES OF NORTHERN IRELAND

2014 No. 324

MEDICINES

The Human Medicines (Amendment) (No. 2) Regulations 2014

Made - - - -	*16th July 2014*
Laid before Parliament	*18th July 2014*
Coming into force in accordance with regulation 1	

The Secretary of State and the Minister for Health, Social Services and Public Safety make the following Regulations. They do so in the 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 and commencement

1.—(1) These Regulations may be cited as the Human Medicines (Amendment) (No. 2) Regulations 2014 and subject to paragraph (2) shall come into force on 1st October 2014.

(2) Regulation 25 comes into force immediately after regulation 27.

Amendment of the Human Medicines Regulations 2012

2. The Human Medicines Regulations 2012(**3**) are amended as follows:

Amendment of regulation 48

3. In regulation 48(2) (definitions in relation to the Part on marketing authorisations), after the definition of "generic medicinal product" insert—

""parallel import licence" means a licence that—

(a) is granted by the licensing authority in compliance with the rules of European Union Law relating to parallel imports; and

(b) authorises the holder to place on the market a medicinal product imported into the United Kingdom from another EEA State;".

(**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**) See S.I. 1972/1811 regarding the designation of Ministers.

(**3**) S.I. 2012/1916 as amended by S.I. 2013/235, 1855, 2593, 2014/490.

Amendment of regulations 49, 50, 59, 62, 68, 69, 71, 75, 76, 77, 96, 98, 101

4.—(1) In the headings and provisions listed in paragraph (2) after the words "marketing authorisation" insert "or parallel import licence".

(2) The listed headings and provisions are—

(a) Heading to regulation 49;

(b) 49(2);

(c) 50(2);

(d) Heading to regulation 59;

(e) 59(4) and (6);

(f) Heading to regulation 62;

(g) 62(1), (3) and (5);

(h) Heading to regulation 68;

(i) 68(1)(**4**);

(j) 69(1) and (7);

(k) 71(1);

(l) 75(1), (6) or (8);

(m) 76(1);

(n) 77;

(o) 96(1);

(p) 98(2)(a);

(q) 101(1).

Amendment of regulation 49

5. In regulation 49 (applications for the grant of UK marketing authorisations) for paragraph (1) substitute—

"(1) The licensing authority may grant—

(a) subject to regulation 58, a UK marketing authorisation; or

(b) a parallel import licence,

for a relevant medicinal product in response to an application made in accordance with this Part."

Amendment of regulation 50

6.—(1) Regulation 50 (material to accompany applications for UK marketing authorisations) is amended as follows.

(2) After paragraph (1) insert—

"(1A) An applicant for the grant of a parallel import licence for a relevant medicinal product must provide the material specified in Schedule 8A in relation to the product."

(3) In paragraph (4) after "application" insert "for a UK marketing authorisation".

(4) In paragraph (5) after "regulation" insert "for the purposes of a UK marketing authorisation".

(**4**) Regulation 68 was amended by S.I. 2013/1855

(5) In paragraph (6) for "This" substitute "Unless the application is for a parallel import licence this".

Insertion of regulation 57A

7. After regulation 57 (obligation to update information supplied in connection with application for UK marketing authorisation) insert—

"**Obligation to update information supplied in connection with parallel import licence application**

57A.—(1) The applicant for a parallel import licence must update information supplied in accordance with Schedule 8A (material to accompany an application for a parallel import licence) in connection with the application.

(2) The applicant must update information supplied in connection with the application to include any further information that is relevant to the evaluation of the safety, quality or efficacy of the product concerned.

(3) Updated information within paragraphs (1) or (2) must be provided as soon as is reasonably practicable after the applicant becomes aware of it."

Amendment of regulation 59

8.—(1) Regulation 59 (general conditions for a UK marketing authorisation) is amended as follows.

(2) In paragraph (1) for "The licensing authority" substitute "Unless paragraph (1A) applies the licensing authority".

(3) After paragraph (1) insert—

"(1A) Where the application concerns a parallel import licence, the licensing authority may—

(a) grant a parallel import licence subject to one or more of the conditions in paragraph (2)(a), (c), (d) or (e); or

(b) vary or remove a condition in paragraph (2)(a), (c), (d) or (e) to which the parallel import licence is subject."

(4) In paragraph (4) for "where necessary" substitute "where relevant and necessary".

Insertion of regulation 65A

9. After regulation 65 (validity of UK marketing authorisation) insert—

"**Validity of parallel import licence**

65A.—(1) Unless paragraph (2) applies, a parallel import licence remains in force for a period of 5 years from the date it is granted or renewed.

(2) A parallel import licence will cease to be valid if—

(a) the information supplied in the application for a licence no longer matches the information currently approved for the reference product by the licensing authority;

(b) details about the product imported under the licence are not consistent with the details supplied in the application; or

(c) the patient information leaflet supplied with the product is not consistent with latest version of the leaflet that is required to be issued with the product by the licensing authority, and

an application to vary the licence to update any details in relation to sub-paragraph (a) to (c) has not been granted by the licensing authority because the condition in regulation 68(11) has not been met."

Insertion of regulation 66A

10. After regulation 66 (application for renewal of authorisation) insert—

"**Application for renewal of a parallel import licence**

66A.—(1) The licensing authority may renew a parallel import licence in response to an application made in accordance with this regulation.

(2) The applicant must be established in the European Union.

(3) The application must be—

(a) made in writing

(b) signed by or on behalf of the applicant; and

(c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.

(4) An application is treated as signed for the purposes of paragraph (3)(b) if it is signed with an electronic signature.

(5) The application must be made so that it is received by the licensing authority within three months of the end of a period expiring 5 years after the date of grant or (as the case may be) latest renewal of the licence."

Amendment of regulation 68

11.—(1) Regulation 68 (revocation, variation and suspension of UK marketing authorisation) is amended as follows.

(2) For paragraph (4) substitute—

"(4) Condition C is that the licensing authority thinks that there has been a breach of—

(a) a term of the authorisation or licence;

(b) in the case of a UK marketing authorisation, a requirement imposed by Part 13 (packaging and leaflets); or

(c) in the case of a parallel import licence, a requirement in relation to packaging and leaflets imposed by the licensing authority."

(3) For paragraph (5) substitute—

"(5) Condition D is that the licensing authority thinks that a condition to which—

(a) the UK marketing authorisation or parallel import licence is subject by virtue of regulation 59 (conditions of UK marketing authorisations or parallel import licence: general); or

(b) the UK marketing authorisation is subject by virtue of regulations 60 (conditions of UK marketing authorisations: exceptional circumstances) or 61 (conditions of UK marketing authorisations: new obligations post-authorisation),

has not been fulfilled."

(4) In paragraph (13) for "This" substitute "Except in the case of a parallel import licence, this".

Amendment of regulation 69

12. In regulation 69 (suspension of use etc of relevant medicinal product), in paragraph (10) for "This" substitute "Except in the case of a parallel import licence, this".

Amendment of regulation 71

13. In regulation 71 (withdrawal of medicinal product from the market), in paragraph (2) after "authorisation" insert "or related parallel import licence".

Amendment of regulation 75

14.—(1) Regulation 75 (obligation to provide information relating to safety etc) is amended as follows.

(2) In paragraph (2), after the first occurrence of the word "holder" insert "of a UK marketing authorisation".

(3) After paragraph (2) insert—

"(2A) The holder of a parallel import licence must, in particular, provide the licensing authority with—

(a) information about any prohibition or restriction imposed in relation to the product to which the licence relates by the competent authority of any country in which the product is on the market; and

(b) other information that the holder considers might influence the evaluation of the benefits and risks of the product."

(4) In paragraph (3), for "or (2)" substitute "to (2A)".

(5) After paragraph (4) insert—

"(4A) The licensing authority may require the holder of a parallel import licence to provide further information specified by the licensing authority."

(6) In paragraph (5) after "(4)" insert "or (4A)".

(7) In paragraph (6) for "or (4)" substitute ", (4) or (4A)".

(8) In paragraph (8) for "(4) or " substitute "(4), (4A) or".

Insertion of regulation 80A

15. After regulation 80 (urgent safety restrictions) insert—

"**Urgent safety restrictions: parallel import licences**

80A. The holder of a parallel import licence is guilty of an offence if the holder—

(a) fails to inform the licensing authority that the holder has taken urgent safety restrictions on the holder's own initiative;

(b) fails to implement an urgent safety restriction imposed on the holder by the licensing authority; or

(c) fails to submit an application for variation of the parallel import licence to the licensing authority before the end of a period of fifteen days beginning on the day after—