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(**a**), having been designated for the purposes of section 2(2) of that Act in relation to medicinal products(**b**).

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(**c**) 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;".

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".

(**a**) 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).

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

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

(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)(**a**);

(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".

(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—

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

"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—

(i) the taking of urgent safety restrictions under paragraph (a) or, as the case may be,

(ii) the imposition of urgent safety restrictions under paragraph (b)."

Insertion of regulation 95A

16. After regulation 95 (offences in connection with marketing authorisation application) insert—

"Offences in connection with parallel import licence application

95A. A person is guilty of an offence if, in the course of an application for the grant, renewal or variation of a parallel import licence for a relevant medicinal product, the person—

(a) fails to provide the licensing authority with any information that is relevant to the evaluation of the safety, quality or efficacy of the product; or

(b) provides to the licensing authority any information that is relevant to the evaluation of the safety, quality or efficacy of the product but that is false or misleading in a material particular."

Substitution of regulation 97

17. For regulation 97 (breach of pharmacovigilance condition) substitute—

"Breach of pharmacovigilance condition

97.—(1) The holder of a marketing authorisation or a parallel import licence is guilty of an offence if the holder fails to comply with a condition to which the marketing authorisation or parallel import licence is subject by virtue of regulation 59 (conditions of a UK marketing authorisation or parallel import licence: general).

(2) The holder of a marketing authorisation is guilty of an offence if the holder fails to comply with a condition to which the marketing authorisation is subject by virtue of regulation 60 (conditions of a UK marketing authorisation: exceptional circumstances) or 61 (conditions of a UK marketing authorisation: new obligations post-authorisation)."

Amendment of regulation 172

18. In regulation 172 (parallel import licences) for paragraph (2) substitute—

"(2) In this regulation "parallel import licence" has the same meaning as in regulation 48(2)."

Amendment of regulation 177

19. In regulation 177 (pharmacovigilance provisions: application and interpretation), in paragraph (2) for the "References in" substitute "Except in regulation 191A, references in".

Insertion of regulation 191A

20. After regulation 191 (obligation on holder to submit periodic safety update reports: general requirements) insert—

"Obligation on holder of a parallel import licence to submit periodic safety update reports

191A.—(1) The holder of a parallel import licence must submit reports known as periodic safety update reports ("PSURs") to the licensing authority if notified to do so by the licensing authority.

(2) Each PSUR must contain—

(a) summaries of data relevant to the benefits and risks of the product, including results of all studies, with a consideration of their potential impact on the licence for the product;

(b) a scientific evaluation of the risk-benefit balance of the product; and

(c) all data relating to the volume of sales of the product and any data the holder of the licence has relating to the volume of prescriptions, including an estimate of the population exposed to the product.

(3) For the purposes of paragraph (2)(b), the scientific evaluation must be based on all available data, including data from clinical trials conducted outside the terms of the authorisation for the product.

(4) Each PSUR must be submitted electronically.

(5) The PSUR must be submitted to the licensing authority within the period specified by that authority."

Amendment of regulation 195

21. In regulation 195 (obligation on the licensing authority to assess PSURs where EU single assessment procedure does not apply), for paragraph (1)(a) and (b) substitute—

"(a) the medicinal product to which the PSUR relates—

(i) has not been authorised to be placed on the market in accordance with the 2001 Directive in an EEA State other than the United Kingdom; and

(ii) a harmonised EU reference date and frequency of submission of PSURs have not been established for that product under Article 107c of the 2001 Directive; or

(b) the medicinal product is one that is imported into the UK under a parallel import licence."

Amendment of regulation 213

22. In regulation 213(1)(interpretation provisions for dealings with medicinal products)—

(a) in the definition of "EEA health professional" after "means" insert "a person in a relevant European State who is"(**a**);

(b) after the definition of "repeatable prescription" insert—

""school" means—

(a) a maintained school (as defined in section 20(7) of the School Standards and Framework Act 1998(**b**));

(b) a maintained nursery school (as defined in section 22(9) of the School Standards and Framework Act 1998(**c**));

(c) an independent school (as defined in section 463 of the Education Act 1996(**d**)) entered on a register of independent schools kept under section 158 of the Education Act 2002(**e**);

(d) an independent educational institution (as defined in section 92(1) of the Education and Skills Act 2008(**f**)) entered on a register of independent educational institutions kept under section 95 of that Act;

(e) a school approved under section 342 of the Education Act 1996(**g**) (non-maintained special schools);

(f) a pupil referral unit (as defined in section 19 of the Education Act 1996(**h**));

(**a**) The definition of "EEA health professional" was substituted by S.I. 2014/490.

(**b**) 1998 c.31.

(**c**) Section 22(9) was amended by paragraph 10(2) of Part 1 of Schedule 2 to the Local Education Authorities and Children's Services Authorities (Integration of Functions) Order 2010 (S.I. 2010/1158).

(**d**) 1996 c.56. Section 463 was substituted subject to transitional provisions by section 172 of Chapter 2 of Part 10 of the Education Act 2002 (c.32). Certain words were further substituted by paragraph 7(2) of Schedule 2(1) to the Local Education Authorities and Children's Services Authorities (Integration of Functions) Order 2010.

(**e**) 2002 c.32. Section 158 has been amended by paragraph 17(b) of Schedule 1(1) and paragraph 1 of Schedule 2 to the Education and Skills Act 2005 (c.25).

(**f**) 2008 c.25. The Education and Skills Act 2008 has been modified by paragraph 3(3) of Schedule 1 to the School Standards and Organisation (Wales) Act 2013 (2013 anaw 1).

(**g**) Section 342 was substituted by paragraph 82 of Schedule 30 to the School Standards Framework Act 1998 (c.31) and further amended by sections 142(3)(a) and (4) and 143(2) and (3) of and paragraph 1 of Schedule 2 to the Education and Skills Act 2008.

(**h**) Relevant amendments to section 19 were made by paragraph 1 of Part 1 of Schedule 3 to the Children, Schools and Families Act 2010 (c.26), the Education Act 1996 (Amendment to section 19) (England) Regulations 2007 (S.I. 2007/1507) and the Local Education Authorities and Children's Services Authorities (Integration of Functions) Order 2010.

(g) an alternative provision Academy (as defined in section 1C(3) of the Academies Act 2010(**a**));

(h) a school as defined in section 135(1) of the Education (Scotland) Act 1980(**b**); and

(i) a school as defined in Article 2(2) of the Education and Libraries (Northern Ireland) Order 1986(**c**)."

Amendment of regulation 218

23. In regulation 218 (requirements for prescriptions: EEA health professionals), for paragraph (2)(**d**) substitute—

"(2) Condition A is that—

(a) the prescription is issued in a relevant European State except the United Kingdom; and

(b) the prescribing EEA health professional is legally entitled to issue a prescription of that kind in the country in which the prescription is issued."

Amendment of regulation 294

24.—(1) Regulation 294 (general requirements: advertising to persons qualified to prescribe or supply) is amended as follows.

(2) After paragraph (2) insert the following paragraphs—

"(2A) By way of an exception to paragraph (2), in the case of an advertisement that relates to a pharmacy medicine or a medicinal product subject to general sale, a person may publish the advertisement if it contains—

(a) the particulars set out in paragraphs 2 to 6 of Schedule 30; and

(b) the statement "Information about this product, including adverse reactions, precautions, contra-indications, and method of use can be found at:"; accompanied by

(c) a website address that corresponds to that statement.

(2B) The website at the address mentioned in paragraph (2A)(c) must make available—

(a) the particulars set out in paragraphs 1 to 8 of Schedule 30; or

(b) a copy of the summary of the product characteristics."

Amendment of regulation 346

25.—(1) Regulation 346 (Secretary of State to carry out a review of certain provisions) is amended as follows.

(2) For paragraph (2)(d)(iva)(**e**) (provisions in Schedule 17), substitute—

"(iva) 17, Part 1 item 12, Part 2 item 11, Part 4 items 11 and 12 and Part 5 item 18, and".

Insertion of Schedule 8A

26. After Schedule 8 (material to accompany a UK marketing authorisation) insert—

(**a**) 2010 c.32. Section 1C was added by section 53(7) of Part 6 of the Education Act 2011 (c.21).
(**b**) 1980 c.44. The definition of "school" was amended by section 2(2) of the Registered Establishments (Scotland) Act 1987 (c.4) and Schedule 3 to the Standards in Scotland's Schools Act 2000 (2000 asp 6).
(**c**) S.I. 1986/594 (N.I.3).
(**d**) Paragraph (2) was substituted by S.I. 2014/490.
(**e**) Paragraph (iva) was inserted by S.I. 2014/490.

“SCHEDULE 8A Regulation 50(1A)

Material to accompany an application for a parallel import licence

1. The name or corporate name and permanent address of the applicant.

2. The name of the medicinal product. This may be—

(a) an invented name that is not liable to confusion with the product’s common name; or

(b) a common or scientific name accompanied by a trademark or by the name of the person who is to be the parallel import licence holder.

3. Details of the product to be imported if requested by the licensing authority.

4. Details of the UK reference product.

5. If requested by the licensing authority, an evaluation of the potential environmental risks posed by the medicinal product, including an assessment of its environmental impact and a description of the proposed arrangements for limiting that impact on a case by case basis.

6. If requested by the licensing authority, a summary of the applicant’s pharmacovigilance system which shall include the following elements—

(a) proof that the applicant has at the applicant’s disposal an appropriately qualified person responsible for pharmacovigilance;

(b) the member States in which the appropriately qualified person resides and carries out his or her tasks;

(c) the contact details of the appropriately qualified person;

(d) a statement signed by the applicant to the effect that the applicant has the necessary means to fulfil the tasks and responsibilities listed in Part 11; and

(e) a reference to the location where the pharmacovigilance system master file for the medicinal product is kept.

7. If requested by the licensing authority, the risk management plan, together with a summary, that—

(a) describes the risk management system which the applicant will introduce for the medicinal product concerned; and

(b) shall be proportionate to the identified risks and the potential risks of the medicinal product, and the need for post-authorisation safety data.

8. If requested by the licensing authority, a summary of the product characteristics for the medicinal product in accordance with Part 2 of Schedule 8.

9. A mock-up, in accordance with Part 13 (packaging and leaflets) of—

(a) the outer packaging of the medicinal product;

(b) the immediate packaging of the medicinal product; and

(c) the package leaflet for the medicinal product.”

Amendment of Schedule 17

27.—(1) Schedule 17 (exemption for sale, supply or administration by certain persons) is amended as follows.

(2) In Part 1 (exemption from restriction on sale and supply of prescription only medicines), after item 11 in the table add—

"12. Persons selling or supplying prescription only medicines to a school.	12. A prescription only medicinal product comprising an inhaler containing salbutamol.	12. The sale or supply shall be— (a) subject to the presentation of an order signed by the principal or head teacher at the school concerned stating— (i) the name of the school for which the medicinal product is required, (ii) the purpose for which that product is required, and (iii) the total quantity required, and (b) for the purpose of supplying the medicinal product to pupils at the school in an emergency.**"**

(3) In Part 2 (exemption from the restriction on supply of prescription only medicines after item 10 in the table add—

"11. A person ("P") carrying on the business of a school who is trained to administer the relevant medicine.	11. A prescription only medicinal product comprising an inhaler containing salbutamol.	11. The supply shall be— (a) in the course of P carrying on the business of a school; (b) where supply is to a pupil at that school who is known to suffer from asthma; and (c) where the pupil requires the medicinal product in an emergency."

(4) In Part 5 (exemptions from the restrictions in regulation 220 and 221 for certain persons who supply certain medicinal products), after item 17 in the table add—

"18. A person ("P") carrying on the business of a school who is trained to administer the relevant medicine.	18. A prescription only medicinal product comprising an inhaler containing salbutamol.	18. The supply shall be— (a) in the course of P carrying on the business of a school; (b) where supply is to a pupil at that school who is known to suffer from asthma; and (c) where the pupil requires the medicinal product in an emergency."

Amendment of Schedule 27

28.—(1) Schedule 27 (package leaflets) is amended as follows

(2) In paragraph 13 omit the word "safety".

(3) For paragraph 14 substitute—

"**14.** A standardised text relating to adverse event reporting in accordance with the third sub-paragraph of Article 59(1) of the 2001 Directive."

Amendment of Schedule 30

29. In paragraph 7 of Schedule 30 (particulars for advertisements to persons qualified to prescribe or supply) for the opening word "A" substitute "The entries or a".

Signed by the authority of the Secretary of State for Health.

Earl Howe
Parliamentary Under-Secretary of State,
15th July 2014 Department of Health

Edwin Poots
16th July 2014 Minister for Health, Social Services and Public Safety

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012 ("the 2012 Regulations").

In particular, regulations 3 to 21 and 26 set out how parallel import licences are granted.

Regulations 22(a) and 23 amend provisions in the 2012 Regulations on the recognition of prescriptions issued by healthcare professionals in EEA States to make it clear that the rules also apply to prescriptions issued in Switzerland.

Regulations 22(b) and 27 insert a definition of "school" and amend Schedule 17 of the 2012 Regulations so that inhalers containing salbutamol can be supplied in schools in an emergency by persons trained to administer them to pupils who are known to require such medication.

Regulations 24 and 29 amend the requirements for advertisements for medicines that are aimed at persons qualified to prescribe or supply such products.

Regulation 24 enables advertisements for medicines available without a prescription to contain a website address where information on adverse reactions, precautions, contra-indications and methods of use can be found as an alternative to providing that information on the face of the advertisement.

Regulation 25 amends the 2012 Regulations to ensure that the new provisions on inhalers containing salbutamol are subject to review by the Secretary of State.

Regulation 28 amends the information that must be contained in the package leaflet that accompanies a medicine. Paragraph (2) corrects an error and paragraph (3) substitutes a general requirement to include text on adverse event reporting in place of a requirement to include prescribed text.

Regulation 29 enables advertisements to include relevant entries from the medicine's summary of product characteristics as an alternative to a summary of those entries.

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

Amendments to the Human Medicines Regulations 2012 are subject to the requirements of the Statutory Rules (NI) Order 1979 and the corresponding SI in respect of this Statutory Rule is S.I. 2014/1878.

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