

2016 No. 000

MEDICINES

The Human Medicines (Amendment) (No. 2) Regulations 2016

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

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Human Medicines (Amendment) (No. 2) Regulations 2016 and come into force on 1st October 2016.

(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) S.I. 1972/1811.

(2) In these Regulations, “the 2012 Regulations” means the Human Medicines Regulations 2012(a).

Amendment of regulation 3 of the 2012 Regulations

2.—(1) Regulation 3 of the 2012 Regulations (scope of these Regulations: special provisions) is amended as follows.

(2) For paragraph (9) substitute—

“(9) This condition is that—

- (a) in a case of assembly, the process of assembly is neither industrial preparation of a medicinal product nor manufacture of a medicinal product by a method involving an industrial process; or
- (b) in a case of manufacture, the medicinal product that results from that process of manufacture is neither prepared industrially nor manufactured by a method involving an industrial process.”.

(3) In paragraph (10)—

- (a) omit “or (12)”; and
- (b) omit from “, except to the” to “shall apply”.

(4) In paragraph (11)—

- (a) after “manufacture” insert “or assembly”; and
- (b) omit “(5) or”.

(5) After paragraph (11) insert—

“(11A) Subject to paragraph (11B), Chapter 1 of Part 13, apart from regulations 258A, 269, 269A and 271, does not apply in respect of the sale or supply, or an offer for the sale or supply, of a medicinal product—

- (a) assembled as provided for in paragraph (4); or
- (b) manufactured or assembled as provided for in paragraph (5).

(11B) Paragraph (11A) does not apply in the case of a medicinal product assembled as provided for in paragraph (4) or (5), where the only process of assembly undertaken—

- (a) is undertaken in relation to an authorised medicinal product;
- (b) does no more than change the appearance of the outer packaging of the product, or if there is no outer packaging the immediate packaging of the product; and
- (c) notwithstanding the change, the product remains authorised.

(6) Omit paragraphs (12) to (14).

(7) In paragraph (15)—

- (a) for “and regulation 4 (special provisions for pharmacies etc.),” substitute “and regulations 4A and 4C,”; and
- (b) after sub-paragraph (a) insert—
“(aa) a parallel import licence;”.

Revocation of regulation 4 of the 2012 Regulations

3. Regulation 4 of the 2012 Regulations (special provisions for pharmacies etc.) is revoked.

(a) S.I. 2012/1916.

New regulations 4A to 4C of the 2012 Regulations

4. Before regulation 5 of the 2012 Regulations (classification of medicinal products), insert—

“Pharmacists: special provisions relating to Article 2 of the 2001 Directive

4A.—(1) Regulation 17(1) does not apply in respect of the assembly at a relevant clinical setting of a medicinal product which is assembled—

- (a) for dispensing at or from a relevant clinical setting by or under the supervision of a pharmacist; and
- (b) for sale or supply in accordance with a prescription or direction given by a health care professional or with a patient group direction.

(2) Subject to paragraph (3), regulation 46 does not apply in respect of—

- (a) the dispensing at or from a relevant clinical setting of a medicinal product which—
 - (i) was assembled at a relevant clinical setting as provided for in paragraph (1), and
 - (ii) is dispensed for an individual patient by or under the supervision of a pharmacist; or
- (b) the sale or supply of that medicinal product in accordance with—
 - (i) the prescription or direction given by a health care professional, or
 - (ii) the patient group direction,in pursuance of which it was dispensed.

(3) Paragraph (2) does not apply in the case of a medicinal product assembled as provided for in paragraph (2)(a)(i), where the only process of assembly undertaken—

- (a) is undertaken in relation to an authorised medicinal product;
- (b) does no more than change the appearance of the outer packaging of the product, or if there is no outer packaging the immediate packaging of the product; and
- (c) notwithstanding the change, the product remains authorised.

(4) Regulation 17(1) does not apply in respect of the preparation at a registered pharmacy, by or under the supervision of a pharmacist, of a medicinal product in accordance with a specification furnished by the person (P1) to whom the medicinal product is sold or supplied, where the product is prepared for administration to P1 or to a person under P1’s care.

(5) Regulation 46 does not apply in respect of—

- (a) the dispensing at or from a registered pharmacy of a medicinal product which—
 - (i) was prepared at a registered pharmacy as provided for in paragraph (4), and
 - (ii) is dispensed for administration to P1 or a person under P1’s care; or
- (b) the sale or supply of that medicinal product for the purposes of that administration.

(6) Regulation 17(1) does not apply in respect of the preparation at a registered pharmacy, by or under the supervision of a pharmacist, of a medicinal product for administration to a person (P2), which is—

- (a) at the request of P2 or a person caring for P2, who is present at the registered pharmacy at the time of the request; and
- (b) in accordance with the pharmacist’s own judgment as to the treatment required for P2.

(7) Regulation 46 does not apply in respect of—

- (a) the dispensing at or from a registered pharmacy of a medicinal product which—
 - (i) was prepared at a registered pharmacy as provided for in paragraph (6), and

- (ii) is dispensed for administration to P2 or the person caring for P2; or
 - (b) the sale or supply of that medicinal product for the purposes of that administration.
- (8) Preparation as provided for in—
- (a) paragraph (4) may be in anticipation of the specification being furnished; or
 - (b) paragraph (6) may be in anticipation of the request being received,
- but only if the medicinal product is for sale or supply either by the registered pharmacy to which the specification is furnished or at which the request is made, or by another registered pharmacy that is part of the same retail pharmacy business.
- (9) Paragraphs (1), (4) and (6) do not apply where—
- (a) in a case of assembly, the process of assembly is either industrial preparation of a medicinal product or manufacture of a medicinal product by a method involving an industrial process; or
 - (b) in a case of preparation, the medicinal product that results from that process of manufacture is either prepared industrially or manufactured by a method involving an industrial process.
- (10) Subject to paragraph (11), Chapter 1 of Part 13, apart from regulations 258A, 269, 269A and 271, does not apply in respect of the sale or supply, or an offer for the sale or supply, which is or is to be a sale or supply to which paragraph (2)(b), (5)(b) or (7)(b) applies.
- (11) Paragraph (10) does not apply in the case of a medicinal product assembled as provided for in paragraph (2)(a)(i), where the only process of assembly undertaken—
- (a) is undertaken in relation to an authorised medicinal product;
 - (b) does no more than change the appearance of the outer packaging of the product, or if there is no outer packaging the immediate packaging of the product; and
 - (c) notwithstanding the change, the product remains authorised.

Pharmacists: special provisions relating to Article 3 of the 2001 Directive

- 4B.**—(1) Regulation 17(1) does not apply in respect of the preparation at a relevant clinical setting of a medicinal product which is—
- (a) prepared in accordance with—
 - (i) a prescription for an individual patient issued by a health care professional which specifies the composition and pharmaceutical form of a medicinal product in sufficient detail to allow for preparation of the product in a relevant clinical setting, or
 - (ii) the prescriptions of a pharmacopoeia,
 or both;
 - (b) for dispensing at or from a relevant clinical setting by or under the supervision of a pharmacist; and
 - (c) for sale or supply in accordance with a prescription or direction given by a health care professional or with a patient group direction.
- (2) Regulation 46 does not apply in respect of—
- (a) the dispensing at or from a relevant clinical setting of a medicinal product which—
 - (i) was prepared at a relevant clinical setting as provided for in paragraph (1)(a), and
 - (ii) is dispensed for an individual patient by or under the supervision of a pharmacist; or
 - (b) the sale or supply of that medicinal product in accordance with—
 - (i) the prescription or direction given by a health care professional, or

- (ii) the patient group direction,
in pursuance of which it was dispensed.

(3) If the relevant clinical setting at or from which a medicinal product is dispensed is different from the relevant clinical setting at or from which it is sold or supplied, paragraph (2) does not apply in the case of a product—

- (a) that was prepared in accordance with the prescriptions of a pharmacopoeia; and
- (b) the composition and pharmaceutical form of which was completed—
 - (i) in advance of the prescription or direction mentioned in paragraph (2)(b)(i) being issued, or
 - (ii) if the product is sold or supplied in under a patient group direction, in advance of the identity of the individual patient being known to the person dispensing the medicinal product.

(4) Chapter 1 of Part 13, apart from regulations 258A, 269, 269A and 271, does not apply in respect of the sale or supply, or an offer for the sale or supply, which is or is to be a sale or supply to which paragraph (2)(b) applies.

Patient group directions: special provisions

4C.—(1) Subject to paragraphs (2) and (3), regulation 17(1) does not apply in respect of the preparation or assembly by a health care professional, acting in the course of their profession, of a medicinal product that is sold, supplied or administered to a person by the health care professional in accordance with a patient group direction.

(2) Paragraph (1) only applies in the case of assembly, if—

- (a) the process of assembly is neither industrial preparation of a medicinal product nor manufacture of a medicinal product by a method involving an industrial process; and
- (b) the process of assembly is necessary for the purposes of—
 - (i) giving effect to the terms of the patient group direction, or
 - (ii) changing the appearance of the outer packaging of the product, or if there is no outer packaging the immediate packaging of the product, in order to include information specified in Schedule 25 or 26,or both of these purposes.

(3) Paragraph (1) only applies in the case of preparation, if—

- (a) the process of preparation is neither industrial preparation of a medicinal product nor manufacture of a medicinal product by a method involving an industrial process; and
- (b) the process of preparation is necessary for the purposes of giving effect to the terms of the patient group direction.

(4) Regulation 46 does not apply in respect of the sale or supply, or an offer for the sale or supply, by a health care professional, acting in the course of their profession, of a medicinal product which is not an authorised medicinal product but which—

- (a) is or is to be sold or supplied in accordance with a patient group direction; and
- (b) was assembled as provided for in paragraph (2) or prepared as provided for in paragraph (3).

(5) Subject to paragraph (6), Chapter 1 of Part 13, apart from regulations 258A, 269, 269A and 271, does not apply in respect of the sale or supply, or an offer for the sale or supply, by a health care professional of a medicinal product assembled as provided for in paragraph (2) or prepared as provided for in paragraph (3).

(6) Paragraph (5) does not apply in the case of a medicinal product assembled as provided for in paragraph (2), where the only process of assembly undertaken—

- (a) is undertaken in relation to an authorised medicinal product;
- (b) does no more than change the appearance of the outer packaging of the product, or if there is no outer packaging the immediate packaging of the product; and
- (c) notwithstanding the change, the product remains authorised.”.

Amendment of regulation 8 of the 2012 Regulations

5. In regulation 8 of the 2012 regulations(a) (general interpretation), in paragraph (1), at the appropriate place in the alphabetical order insert—

““health service” has the same meaning as in section 266(6) of the National Health Service Act 2006 (controls: supplementary);”;

““health service medicine” has the same meaning as in section 266(6) of the National Health Service Act 2006;”;

““relevant clinical setting” means a registered pharmacy, a hospital, a health centre, a surgery or a care home service, and for these purposes—

(a) “care home service” has the meaning given by paragraph 2 of Schedule 12 to the Public Services Reform (Scotland) Act 2010; and

(b) “surgery” includes premises at or from which primary medical services are provided as part of the health service;”.

Amendment of regulation 18 of the 2012 Regulations

6. In regulation 18 of the 2012 Regulations(b) (wholesale dealing in medicinal products), after paragraph (5) insert—

“(5A) In the case of a medicinal product which is—

(a) dispensed at or from a relevant clinical setting (C1)—

(i) for an individual patient by or under the supervision of a pharmacist, and

(ii) in pursuance of a prescription or direction given by a health care professional or a patient group direction; and

(b) sold or supplied by C1 to another relevant clinical setting (C2) for the purpose of sale or supply by C2 to or for the individual patient for whom the product was dispensed,

the sale or supply of the product by C1 to C2 referred to in sub-paragraph (b) is not a sale or supply for the purposes of paragraph (4)(a).”.

Amendment of regulation 46 of the 2012 Regulations

7. In regulation 46 of the 2012 Regulations (requirement for authorisation), in paragraph (7), before sub-paragraph (a) insert—

“(za) regulations 4A to 4C;”.

New regulation 234A of the 2012 Regulations

8. After regulation 234 of the 2012 Regulations (exemption for supply etc. of products under a PGD to assist the police etc.), insert—

(a) Amended by S.I. 2013/1855 and 2593 and 2015/1503.

(b) Substituted by S.I. 2013/1855.

“Changes to products to give effect to the terms of a PGD

234A.—(1) If this paragraph applies, the reference to a time of supply or administration in the following provisions—

- (a) regulation 229(3)(f);
- (b) regulation 230(8);
- (c) regulation 231(8);
- (d) regulation 232(8);
- (e) regulation 233(7); and
- (f) regulation 234(9),

if the supply or administration is of a product (“the dispensed product”) that has been prepared or assembled in accordance with regulation 4C, is to be treated as a reference to the time of the supply of a product (“the source product”) to the person who used the source product to prepare or assemble the dispensed product in accordance with regulation 4C.

(2) Paragraph (1) only applies if the process of preparation or assembly was necessary to give effect to the terms of the patient group direction.”.

Amendment of regulation 258 of the 2012 Regulations

9. In regulation 258 of the 2012 Regulations (packaging requirements: specific provisions), for paragraph (1) substitute—

“(1) In addition to the other information required by this Part, where a medicinal product (whether or not it is a prescription only medicine) is sold or supplied in accordance with a patient group direction, or a prescription or direction given by a person who is a relevant prescriber, the information specified in—

- (a) paragraphs 1 to 3 of Schedule 25 must appear on the outer packaging of the product, or if there is no outer packaging on the immediate packaging of the product, when the product is sold or supplied;
- (b) paragraphs 4, 6 and 6A of Schedule 25 must, subject to paragraph (2), appear on the outer packaging of the product, or if there is no outer packaging on the immediate packaging of the product, when the product is sold or supplied, if the conditions for inclusion of the information specified in those paragraphs are met.”.

New regulation 258A of the 2012 Regulations

10. After regulation 258 of the 2012 Regulations, insert—

“Labelling requirements for exempt products: specific provisions

258A.—(1) This paragraph applies where a medicinal product (whether or not it is a prescription only medicine) is sold or supplied in circumstances where the medicinal product was manufactured, prepared or assembled by a health care professional as provided for in regulation 3(4) or (5) or 4C, unless in the case of assembly the only process of assembly undertaken—

- (a) was undertaken in relation to an authorised medicinal product;
- (b) did no more than change the appearance of the outer packaging of the product, or if there is no outer packaging on the immediate packaging of the product; and
- (c) notwithstanding the change, the product remains authorised.

(2) Where paragraph (1) applies, subject to paragraphs (5) to (9), the information specified in—

- (a) paragraphs 1 to 3 of Schedule 26 must appear on the outer packaging of the product, or if there is no outer packaging on the immediate packaging of the product, when the product is sold or supplied;
 - (b) paragraph 4 or 4A must appear on the outer packaging of the product, or if there is no outer packaging on the immediate packaging of the product, when the product is sold or supplied, if the conditions for inclusion of the information specified in those paragraphs are met.
- (3) This paragraph applies where a medicinal product (whether or not it is a prescription only medicine) is sold or supplied in circumstances where the product was prepared or assembled by or under the supervision of a pharmacist as provided for in regulation 4A or 4B, unless in the case of assembly the only process of assembly undertaken—
- (a) was undertaken in relation to an authorised medicinal product;
 - (b) did no more than change the appearance of the outer packaging of the product, or if there is no outer packaging the immediate packaging of the product; and
 - (c) notwithstanding the change, the product remains authorised.
- (4) Where paragraph (3) applies, subject to paragraphs (5) to (9), the information specified in—
- (a) paragraphs 5 to 7 of Schedule 26 must appear on the outer packaging of the product, or if there is no outer packaging on the immediate packaging of the product, when the product is sold or supplied;
 - (b) paragraphs 8, 10, 11, 11A and 11B must appear on the outer packaging of the product, or if there is no outer packaging on the immediate packaging of the product, when the product is sold or supplied, if the conditions for inclusion of the information specified in those paragraphs are met.
- (5) Where, as a consequence of a process of assembly, more than one medicinal product in a solid dosage form is included in the immediate packaging of a medicinal product and the packaging of the medicinal product is designed to support the taking of doses of different medicinal products at the same time by an individual patient—
- (a) the requirements of this regulation that information must appear on the outer packaging of the product, or if there is no outer packaging on the immediate packaging of the product, are to be construed as requirements that the information must appear on the outer packaging or the immediate packaging, or a combination of both, as appropriate; but
 - (b) the information in paragraph 1 and 2 of Schedule 26 must in these circumstances, wherever possible, appear on both the outer packaging (if there is outer packaging) and the immediate packaging of the product.
- (6) For the purposes of this regulation, the requirements of paragraph 8 or 10 of Schedule 26 are treated as satisfied in relation to the packaging for a medicinal product if that medicinal product is included in packaging containing a number of packages of medicinal products of the same description and the information specified in those paragraphs is included on one of those packages.
- (7) Nothing in this regulation or Schedule 26 requires information to appear on—
- (a) a package containing a medicinal product where part of the package is transparent or open, provided that the information required by this regulation and that Schedule is clearly visible through the transparent or open part of that package;
 - (b) a paper bag or similar wrapping in which a package that contains a medicinal product, provided that the information required by this regulation and that Schedule appears on that medicinal product;
 - (c) an ampule or other container of not more than 10 millilitres' normal capacity which is enclosed in a package, provided that the information required by this regulation and that Schedule appears on that package;

(d) a blister pack or similar packaging enclosed in a package, provided that the information required by this regulation and that Schedule appears on that package.

(8) Nothing in this regulation or Schedule 26 applies to a container for an anti-viral medicine which is in the form of a solution and which is to be used for the treatment of a child under the age of one year, if—

- (a) on the container appears—
 - (i) the name of the child to whom the medicine is to be administered,
 - (ii) the date on which the medicine is sold or supplied, and
 - (iii) the necessary instructions for proper use; and
- (b) the medicine is sold or supplied for the purpose of treating a disease which is—
 - (i) a serious risk to human health, or potentially a serious risk to human health, and
 - (ii) pandemic or imminently pandemic.

(9) Nothing in this regulation or Schedule 26 applies to a traditional herbal medicinal product or a registrable homoeopathic medicinal product.

(10) Nothing in this regulation or Schedule 26 precludes the inclusion on the packaging of a medicinal product as mentioned in paragraph (1) or (3) of information that would be required by this Part if the medicinal product were authorised.

(2) For the purposes of this regulation, “authorised” is to be construed in accordance with regulation 3(15).”.

Amendment of regulation 269 of the 2012 Regulations

11.—(1) Regulation 269 (offences relating to packaging and package leaflets: other persons) is amended as follows.

(2) In paragraph (2), before “a person to” insert “Subject to paragraph (3).”.

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

“(3) No offence is committed under paragraph (2)(a) if a package does not comply with the applicable requirements of this Part as a consequence of the inclusion, as provided for in regulations 258 and 258A, on the outer packaging of a medicinal product, or if there is no immediate outer packaging on the immediate packaging of a medicinal product, of—

- (a) none, or only some but not all, of the information that may be included as specified paragraph 6A of Schedule 25, or 4A or 11A of Schedule 26; or
- (b) information that may be included, as specified paragraph 6A of Schedule 25, or 4A or 11A of Schedule 26, but the included information is false or misleading.”.

New regulation 269A of the 2012 Regulations

12. After regulation 269 of the 2012 Regulations, insert—

“Dispensing labels and arrangements for the provision of NHS pharmaceutical services

269A. Nothing in these Regulations precludes the inclusion, in arrangements for the provision of pharmaceutical services as part of the health service, of terms or conditions in respect of—

- (a) requiring the inclusion on the packaging of a health service medicine of information that may be included on the packaging, as specified in paragraph 6A of Schedule 25 or paragraph 6A or 11A of Schedule 26; or
- (b) prohibiting the inclusion on the packaging of a health service medicine of information which—

- (i) is of the type specified in paragraph 6A of Schedule 25, or paragraph 6A or 11A of Schedule 26, but
- (ii) is false or misleading.”.

Amendment of regulation 368 of the 2012 Regulations

13. In regulation 346 of the 2012 Regulations(a) (review), in paragraph (2)(c)—

- (a) before paragraph (i) insert—
“(zi) 4A to 4C,”; and
- (b) after paragraph (xxviii) insert—
“(xxviih) 258(1) and 258A,”.

Amendment of Schedule 25 to the 2012 Regulations

14. In Part 1 of Schedule 25 to the 2012 Regulations (packaging requirements: specific provisions – medicines on prescription), after paragraph 6 insert—

- “**6A.** In the case of a health service medicine, if this is required by arrangements for the provision of pharmaceutical services as part of the health service—
 - (a) the price determined for the product by virtue of those arrangements (which may be a price listed in the applicable Drug Tariff);
 - (b) a statement about how the cost of the product is met (for example, a statement to the effect that it is met by taxpayers).”.

Amendment of Schedule 26 to the 2012 Regulations

15.—(1) Schedule 26 to the 2012 Regulations (packaging requirements: special provisions) is amended as follows.

(2) In the heading of Part 1, after “and midwives” insert “, or in accordance with a patient group direction”.

(3) In Part 1—

- (a) for paragraph 2 substitute—

“**2.—**(1) Subject to sub-paragraph (2), the name and address of the person who sells or supplies the product.

(2) For the purposes of sub-paragraph (1), if a product has been dispensed and the person who dispensed it is not the same as the person who sells or supplies it, the name and address of the person who dispensed it may appear instead of or in addition to the name and address of the person who sells or supplies it.”.

- (b) after paragraph 4 insert—

“**4A.** In the case of a health service medicine, if this is required by arrangements for the provision of pharmaceutical services as part of the health service—

- (a) the price determined for the product by virtue of those arrangements (which may be a price listed in the applicable Drug Tariff);
- (b) a statement about how the cost of the product is met (for example, a statement to the effect that it is met by taxpayers).”.

(4) In Part 2 (pharmacy exemptions), after paragraph 11 insert—

“**11A.** In the case of a health service medicine, if this is required by arrangements for the provision of pharmaceutical services as part of the health service—

(a) Substituted by S.I. 2013/1855 and then amended by S.I. 2013/2593, 2014/323, 2015/178, 259 and 1503.

- (a) the price determined for the product by virtue of those arrangements (which may be a price listed in the applicable Drug Tariff);
- (b) a statement about how the cost of the product is met (for example, a statement to the effect that it is met by taxpayers).

11B. Where—

- (a) as a consequence of a process of assembly, more than one product in a solid dosage form is included in the immediate packaging of a product; and
- (b) the packaging of the product is designed to support the taking of doses of different products at the same time by an individual patient,

such information as to allow the different products to be identified and distinguished by the patient as the person under whose responsibility that process of assembly is undertaken considers appropriate.”.

Repeal of sections 10 and 15 of the Medicines Act 1968

16.—(1) Section 10 of the Medicines Act 1968 (exemptions for pharmacists) is repealed.

(2) Section 15 of the Medicines Act 1968 (provision for extending or modifying exemptions) is repealed.

Amendment of section 69 of the Medicines Act 1968

17. In section 69 of the Medicines Act 1968(a) (general provisions), after subsection (2) insert—

“(2A) Where a business dispenses a medicinal product on behalf of another business for the purposes of—

- (a) the retail sale of the product, or
- (b) the supply of the product in circumstances corresponding to retail sale,

but does not sell the product by retail, or supply it in circumstances corresponding to retail sale, subsection (2B) applies.

(2B) For the purposes of the application of this Part—

- (a) the business referred to in subsection (2A) that does not sell the product by retail, or supply it in circumstances corresponding to retail sale, is nevertheless treated as doing so via an intermediary; and
- (b) accordingly, both the premises at which the product is dispensed and the premises of the other business referred to in that subsection at which the product is sold by retail, or supplied in circumstances corresponding to retail sale, are premises where a retail pharmacy business is carried on.”.

Signed by the authority of the Secretary of State

Date

Parliamentary Under Secretary of State
Department of Health

Date

Minister for Health, Social Services and Public Safety

(a) Section 69 has been amended by the Statute Law (Repeals) Act 1993 (c. 50), Schedule 1(12), paragraph 1, and by S.I. 2007/289 and 3101 and 2010/231.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012 (“the 2012 Regulations”), which govern the arrangements, across the United Kingdom, for the licensing, manufacture, wholesale dealing and sale or supply of medicines for human use. They do so largely by way of implementation of Directive 2001/83/EC of the European Parliament and of the Council on the Community Code relating to medicinal products for human use^(a).

Part 1 of the 2012 Regulations includes, amongst other matters, general exemptions from the requirements to hold marketing authorisations for individual products – and to hold manufacturing licences. The exemptions that related to the dispensing of medicines by or under the supervision of a pharmacist that were previously contained in section 10 of the Medicines Act 1968 and regulation 4 of the 2012 Regulations, which have been repealed and revoked.

The new regulations 4A and 4B of the 2013 Regulations provide that, generally, preparation or assembly of a medicine by or under the supervision of a pharmacist in a relevant clinical setting (a term that encompasses registered retail pharmacies, hospitals, health centres, surgeries and care home services) – if the medicine is to be dispensed in pursuance of a prescription or direction of a prescriber or a patient group direction – does not require a manufacturer’s licence. Also, the resultant product does not require a marketing authorisation – although if the act of assembly (for example, inclusion of a dispensing label) does not displace the marketing authorisation, any sale or supply of the medicine will still need to be in accordance with its marketing authorisation’s terms.

There are four key changes from the previous arrangements. Firstly, the previous provisions prevented dispensed medicines assembled by retail pharmacy businesses being supplied first between different businesses and then on to or for the patient. This prevented the retail pharmacy business that sold or supplied a medicine to or for the patient from using the services of a different legal entity to dispense the medicine on its behalf. This bar has been removed. However, where retail pharmacy businesses do rely on this new flexibility, both the premises at which the product is dispensed and the premises at which the product is supplied will need to register as pharmacies.

Secondly, relevant clinical settings that prepare their own medicines will only be able to hold stocks of pre-prepared medicines that are based on the prescriptions of a pharmacopoeia, if these medicines are for supply to patients directly from the relevant clinical setting in question. They will not be able to hold such stocks and then supply patients indirectly via another relevant clinical setting. This clarification is in the light of the Court of Justice of the European Union’s decision in *Abcur AB v Apoteket Farmaci AB* (CJEU 17.07.2015 C-544/13).

Thirdly, separate provision is made for assembly of medicines for sale or supply under a patient group direction – which affects all health care professionals who are authorised to supply medicines under patient group directions, not just pharmacists. It is made clear that assembly by a health care professional for the purposes of giving effect to a patient group direction does not require a manufacturing licence, and sale or supply of a medicine under a patient group direction can be otherwise than in accordance with a marketing authorisation if this is necessary to give effect to the terms of the patient group direction.

Fourthly, the interrelationship between the exemptions for pharmacists, the new exemption for patient group directions – and other existing exemptions for doctors, dentists, nurses and midwives – and the labelling provisions of the 2012 Regulations is clarified. In essence, where the medicinal products that are supplied under these exemptions are in an authorised form, one set of rules is applied (regulation 258 of and Schedule 25 to the 2012 Regulations), and another set of rules is applied in the case of products that are not in an authorised form (the new regulation 258A, and Schedule 26). At the same time, the opportunity has been taken to apply the additional labelling

(a) OJ No. L 311, 28.11.2001, p.67. Directive 2001/83/EC was last amended by Directive 2011/62/EU (OJ No. L 174, 1.7.2011, p.74).

requirements of the 2012 Regulations – most typically, the affixing of a dispensing label – to products supplied under directions from prescribers and patient group directions as well as those supplied on prescription.

The new regulation 258A of the 2012 Regulations also includes new provisions relating to the labelling of multiple dosage systems. These systems are the product of the assembly of different medicines in the same packaging to support patients in taking different medicines at particular times. There are new labelling requirements allowing for information to be included which will enable the different medicines to be identified and distinguished by the patient. Flexibility is also given so that most of the information that would normally need to be on one or other of the outer packaging or the immediate packaging can in the case of multiple dosage systems be on a combination of either or both of these types of packaging. An exception is made in the case of the name of the patient and the name of the person supplying the medicine, which for multiple dosage systems has to be on both types of packaging. However, in any the case where different businesses dispense and supply the medicine, the packaging can include either or both names, as appropriate.

Changes are also made to the labelling requirements of the 2012 Regulations to permit the inclusion on the labelling of NHS medicines the cost of the medicines and a statement about how the costs are met. Any such requirements will have to be introduced via NHS terms of service, and will be enforced via the NHS arrangements for securing compliance with such terms, not via criminal proceedings under the 2012 Regulations.

An assessment of the impact of these Regulations has been made. A copy of this impact assessment is published with the Explanatory Memorandum alongside the instrument on www.legislation.gov.uk. Copies may also be obtained from the Medicines and Healthcare products Regulatory Agency, 151 Buckingham Palace Road, Victoria, London, SW1W 9SZ.