STATUTORY INSTRUMENTS

2021 No. 1452

MEDICINES

The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021

Made - - - -	*15th December 2021*
Laid before Parliament	*16th December 2021*
Coming into force	*1st January 2022*

The Secretary of State, in exercise of the powers conferred by section 8C of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**a**), makes the following Regulations:

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021.

(2) These Regulations come into force on 1st January 2022.

(3) These Regulations extend to the whole of the United Kingdom.

Amendments to the Human Medicines Regulations 2012

2. The Human Medicines Regulations 2012(**b**) are amended in accordance with regulations 3 to 26.

Amendments to regulation 5 (classification of medicinal products)

3. In regulation 5(**c**), in paragraphs (3)(b) and (4)(b), after "Northern Ireland" insert "(that is not a listed NIMAR product)".

Amendments to regulation 8 (general interpretation)

4. In regulation 8(**d**), in paragraph (1), at the appropriate places insert—

> ""the 2018 Regulations" means the Health Service Products (Provision and Disclosure of Information) Regulations 2018(**e**);";
>
> ""listed NIMAR product" means a product included in a list maintained in accordance with regulation 167B on the date it is dispatched from Great Britain to Northern Ireland;";

(**a**) 2018 c. 16; section 8C was inserted by the European Union (Withdrawal Agreement) Act 2020 (c. 1), section 21.
(**b**) S.I. 2012/1916.
(**c**) Regulation 5, amended by S.I. 2019/775 as amended by S.I. 2020/1488.
(**d**) Regulation 8, amended by S.I. 2013/1855, 2593, 2015/1503, 2016/186, 190 and 696, 2017/715, 2018/199, 2019/62, 593, 703, 775 and 1094 and 2020/1125; there are other amending instruments but none is relevant.
(**e**) S.I. 2018/677, to which there are amendments not relevant to these Regulations.

""NIMAR" means Northern Ireland MHRA authorised route;".

Amendments to regulation 18 (wholesale dealing in medicinal products)

5. In regulation 18(**a**)—

(a) in paragraph (1)—

(i) at the end of sub-paragraph (b), remove "or";

(ii) after sub-paragraph (c), insert—

"; or

(d) supply a listed NIMAR product from Great Britain to Northern Ireland.";

(b) in paragraph (4) after "a product" insert "(including a listed NIMAR product)";

(c) in paragraph (6)—

(i) at the end of sub-paragraph (a), remove "or";

(ii) after sub-paragraph (b), insert—

"or

(c) in the case of a listed NIMAR product, a UKMA(GB) or UKMA(UK) is in force in respect of the product,".

Amendment to regulation 19 (exemptions from requirement for wholesale dealer's licence)

6. In regulation 19(**b**), paragraph (1)(a)(i), after "in Great Britain" insert "(including a listed NIMAR product for sale or supply from Great Britain to Northern Ireland)".

Amendments to regulation 26 (general power to suspend, revoke or vary licences)

7. In regulation 26(**c**), paragraph (5)(a)—

(a) at the end of paragraph (i), remove "or";

(b) after paragraph (ii), insert—

"or

(iii) in the case of a listed NIMAR product, a UKMA(GB) or UKMA(UK) (an "authorisation"),".

Amendments to regulation 37 (manufacturing and assembly)

8. In regulation 37(**d**), paragraphs (5)(b) and (6)(b)(i), after "in Great Britain" insert "(including a listed NIMAR product for sale or supply from Great Britain to Northern Ireland)".

Amendment to regulation 39 (further requirements for manufacturer's licence)

9. In regulation 39(**e**), substitute paragraph (8) with—

"(8) In distributing a medicinal product by way of wholesale dealing, the licence holder must comply with the following as if they are a holder of a wholesale dealer's licence—

(a) regulations 43(1), (2) and (5), 43ZA and 44(5) and (6), and

(b) regulation 43A, if applicable, where the product is being distributed in NI.".

(**a**) Regulation 18, amended by S.I. 2013/1855 and 2019/775.
(**b**) Regulation 19, amended by S.I. 2013/1855, 2019/775 as amended by S.I. 2020/1488 and 2020/1125.
(**c**) Regulation 26, amended by S.I. 2019/775 as amended by S.I. 2020/1488.
(**d**) Regulation 37, amended by S.I. 2013/1885, and 2019/775 as amended by 2020/1488.
(**e**) Regulation 39, amended by S.I 2019/775; there are other amending instruments but none is relevant.

Amendments to regulation 42 (conditions for wholesale dealer's licence)

10. In regulation 42(**a**)—

(a) paragraph (1)—

(i) after "Regulations 43 to 45 insert "(not including regulation 43ZA)";

(ii) after "regulations 43 to 45AA" insert "(including regulation 43ZA)";

(b) after paragraph (5), insert—

"(6) Paragraph (4) does not apply in relation to listed NIMAR products in Northern Ireland.".

New regulation 43ZA (obligations of licence holder – listed NIMAR products)

11. After regulation 43(**b**) (obligations of licence holder), insert—

"Obligations of licence holder in Great Britain supplying listed NIMAR products to Northern Ireland

43ZA.—(1) This regulation applies only to licence holders in Great Britain supplying listed NIMAR products to Northern Ireland.

(2) A licence holder must comply with the guidelines on good distribution practice, published under, or that apply by virtue of, regulation C17.

(3) So that the needs of patients in Northern Ireland are met, the licence holder must ensure, within the limits of the holder's responsibility, the continued supply of listed NIMAR products to—

(a) registered pharmacies in Northern Ireland;

(b) any person who may lawfully sell those products by retail sale or may lawfully supply them in circumstances corresponding to retail sale in Northern Ireland;

(c) any person who may lawfully administer prescription only medicines in Northern Ireland.

(4) The licence holder must provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of listed NIMAR products under the licence as are necessary—

(a) to maintain the quality of the products; and

(b) to ensure their proper distribution.

(5) The licence holder must inform the licensing authority of any proposed structural alteration to, or discontinuance of use of, premises to which the licence relates or which have otherwise been approved by the licensing authority.

(6) The licence holder must not sell or supply, or offer for sale or supply, listed NIMAR products to a person in Northern Ireland, unless—

(a) there is a UKMA(UK) or UKMA(GB) in force in relation to that product; and

(b) the sale or supply is in accordance with that authorisation (except for the fact the product will be in Northern Ireland).

(7) The licence holder must—

(a) keep documents relating to the sale or supply of listed NIMAR products under the licence which may facilitate the withdrawal or recall from sale of such products in accordance with paragraph (b);

(**a**) Regulation 42, amended by S.I. 2013/1855, 2019/62, and 775 as amended by S.I. 2020/1488.
(**b**) Regulation 43, amended by S.I. 2013/1855, S.I. 2016/186 and S.I. 2019/775 as amended by S.I. 2020/1488.

(b) maintain an emergency plan to ensure effective implementation of the recall from the market of a listed NIMAR product where recall is—

(i) ordered by the licensing authority or

(ii) carried out in co-operation with the manufacturer of, or the holder of the corresponding UKMA(GB) or UKMA(UK) for the product; and

(c) keep records in relation to the receipt, dispatch or brokering of listed NIMAR products, of—

(i) the date of receipt,

(ii) the date of despatch,

(iii) the date of brokering,

(iv) the name of the listed NIMAR product,

(v) the quantity of the product received, dispatched or brokered,

(vi) the name and address of the person from whom the products were received or to whom they are dispatched; and

(d) provide the records in sub-paragraph (c) to the licensing authority on request.

(8) For the purposes of enabling the licensing authority to determine whether there are grounds for suspending, revoking or varying the licence, the licence holder must permit a person authorised in writing by the licensing authority, on production of identification, to carry out any inspection, or to take any samples or copies, which an inspector could carry out or take under Part 16 (enforcement).

(9) The licence holder must maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities.

(10) The licence holder must immediately inform the licensing authority of medicinal products which the licence holder receives or is offered which the licence holder—

(a) knows or suspects; or

(b) has reasonable grounds for knowing or suspecting,

to be falsified.

(11) Where the listed NIMAR product is obtained through brokering, a licence holder must verify that the broker involved fulfils the requirements set out in regulation 45A(1)(b).
".

Amendment to regulation 45 (requirement as to responsible persons)

12. In regulation 45(**a**), paragraph (2)(b)(ii), after "marketing authorisations," insert "requirements of regulation 167A,".

Amendment to regulation A81 (application of regulations 81 to 94)

13. In regulation A81(**b**), after "Northern Ireland" insert "(that are not in Northern Ireland by virtue of regulation 167A)".

New regulation 167A (NIMAR supply to Northern Ireland) and new regulation 167B (list of NIMAR products)

14. After regulation 167(**c**) (supply to fulfil special patient needs), insert—

(**a**) Regulation 45, amended by S.I. 2019/775 as amended by 2020/1488.
(**b**) Regulations A81, inserted by S.I. 2019/775 as amended by 2020/1488.
(**c**) Regulation 167, amended by S.I. 2017/715 and 2019/775 as amended by 2020/1488.

"NIMAR supply to Northern Ireland

167A.—(1) If the following conditions are met—

(a) the prohibitions in regulation 46 (requirement for authorisation) do not apply in relation to a medicinal product sold or supplied, or offered for sale or supply, in Northern Ireland, and

(b) that product is classified in Northern Ireland as a prescription only medicine.

(2) Condition A is that a UK marketing authorisation of a following type is in force for the product—

(a) a UKMA(UK);

(b) a UKMA(GB).

(3) Condition B is that the product is classified as a prescription only medicine in accordance with regulation 5(3) for the purposes of sale and supply in Great Britain.

(4) Condition C is that the product is a listed NIMAR product.

(5) Condition D is that if the product is to be distributed by wholesale dealing by a person ("P") in Northern Ireland, P must be a holder of a wholesale dealer's licence.

(6) Condition E is that if the product is manufactured or assembled in Great Britain, it is supplied to Northern Ireland—

(a) by the holder of a manufacturer's licence in respect of that product; or

(b) by the holder of a wholesale dealer's licence.

(7) Condition F is that if the product is manufactured outside of the UK and imported into Great Britain, it is supplied to Northern Ireland—

(a) by a holder of a manufacturer's licence in respect of that product; or

(b) by the holder of a wholesale dealer's licence.

List of NIMAR products

167B.—(1) The licensing authority must maintain a list for the purposes of regulation 167A(4).

(2) In relation to each listed NIMAR product, the list must specify the date the NIMAR product was added to the list.

(3) The licensing authority must publish the list and keep it up to date.

(4) A product may only be included on the list if the following conditions are satisfied—

(a) Condition A is that the Secretary of State has in relation to Northern Ireland been provided with at least one of the following—

(i) information requested under regulation 28 (provision of information about availability of health service medicines) of the 2018 Regulations;

(ii) information under regulation 29 (requirement to provide information about discontinuation or anticipated supply shortage of certain health service medicines) of the 2018 Regulations;

(b) Condition B is that the holder of a UK marketing authorisation, has notified the Secretary of State that—

(i) in relation to a medicinal product to which a UKMA(UK) relates, the qualified person who is at the disposal of the holder of a manufacturer's licence is unable to secure the matters mentioned in paragraph 12A of Schedule 7 for the purpose of supplying the product into Northern Ireland from Great Britain; or

(ii) in relation to a medicinal product to which a UKMA(GB) relates, the inability of a qualified person who is at the disposal of the holder of a manufacturer's

licence to secure the matters mentioned in paragraph 12A of Schedule 7 prevents the holder of the UKMA(GB) from converting it into a UKMA(UK);

(c) Condition C is that the licensing authority considers that clinical needs in Northern Ireland for the product may be unmet.

(5) The licensing authority must remove a product from the list if the licensing authority considers that medicinal products, not including listed NIMAR products, available in Northern Ireland are capable of meeting clinical need.".

Amendment to regulation 187 (recording obligations on holders)

15. In regulation 187(**a**), paragraph (1), after "to the product" insert "(including listed NIMAR products in Northern Ireland)".

Amendment to regulation 188 (reporting obligations on holders)

16. In regulation 188(**b**), paragraph (1), after "the product" insert "(including listed NIMAR products in Northern Ireland)".

Amendment to regulation 229 (exemption for supply by national health service bodies and local authorities)

17. In regulation 229(**c**), paragraph (3)(f)(i), after "or THR(UK)," insert "or, in the case of a listed NIMAR product, a UKMA(UK) or UKMA(GB),".

Amendment to regulation 230 (exemption for supply etc under a PGD to assist doctors or dentists)

18. In regulation 230(**d**), paragraph (8)(a), after "or THR(UK)" insert "or, in the case of a listed NIMAR product, a UKMA(UK) or UKMA(GB),".

Amendment to regulation 231 (exemption for supply etc under a PGD by independent hospitals etc)

19. In regulation 231(**e**), paragraph (8)(a), after "or THR(UK)" insert "or, in the case of a listed NIMAR product, a UKMA(UK) or UKMA(GB),".

Amendment to regulation 233 (exemption for supply etc under a PGD by person conducting a retail pharmacy business)

20. In regulation 233(**f**) paragraph (7)(a), after "or THR(UK)" insert "or, in the case of a listed NIMAR product, a UKMA(UK) or UKMA(GB),".

(**a**) Regulation 187, amended by S.I. 2019/775 as amended by S.I. 2020/1488.
(**b**) Regulation 188, amended by S.I. 2019/775 as amended by S.I. 2020/1488; there are other amending instruments but none is relevant.
(**c**) Regulation 229, amended by S.I. 2019/775 as amended by S.I. 2020/1488, and 2020/1594; there are other amending instruments but none is relevant.
(**d**) Regulation 230, amended by S.I. 2019/775 as amended by S.I. 2020/1488, and 2020/1125 and 1594; there are other amending instruments but none is relevant.
(**e**) Regulation 231, amended by S.I. 2019/775 as amended by S.I. 2020/1488, and 2020/1125 and 1594.
(**f**) Regulation 233, amended by S.I. 2019/775 as amended by S.I. 2020/1488; there are other amending instruments but none is relevant.

Amendment to regulation 234 (exemption for supply etc of products under a PGD to assist the police etc)

21. In regulation 234(**a**), paragraph (9)(a), after "or THR(UK)," insert "or, in the case of a listed NIMAR product, a UKMA(UK) or UKMA(GB),".

Amendment to regulation 247A (protocols relating to coronavirus and influenza vaccinations and immunisations)

22. In regulation 247A(**b**), paragraph (5)(c), after "UK marketing authorisation" insert "(including in Northern Ireland if supply is in accordance with regulation 167A)".

Amendment to regulation 346 (review)

23. In regulation 346(**c**), in paragraph (2)(c), after paragraph (xxviiia) insert—

"(xxviiiaza) regulations 167A and 167B,".

Amendments to Schedule 4 (standard provisions of licences under Part 3) Part 2 (manufacturer's licence relating to the import of medicinal products from a state other than an EEA State/Country other than an Approved Country for Import)

24. In Schedule 4(**d**), after paragraph 15, insert—

"**15A.** The provisions of this Part are standard provisions of a manufacturer's licence relating to the supply of a listed NIMAR product from Great Britain to Northern Ireland.".

25. In Schedule 4, after paragraph 23, insert—

"**23ZA.** The licence holder in Great Britain must take all reasonable precautions and exercise due diligence to ensure that any information provided to the licensing authority which is relevant to an evaluation of the safety, quality or efficacy of a product for human use which is supplied from Great Britain into Northern Ireland by virtue of regulation 167A handled, stored or distributed under the licence is not false or misleading in a material particular.".

Amendment to Schedule 7 (qualified persons) Part 3 (obligations of qualified person)

26. In Schedule 7(**e**), in paragraph 12A, insert after sub-paragraph (1)—

"(2) This paragraph does not apply in relation to listed NIMAR products in Northern Ireland.".

Sajid Javid
Secretary of State,
Department of Health and Social Care

15th December 2021

(**a**) Regulation 234, amended by S.I. 2015/323, 2019/775 as amended by 2020/1488, and 2020/1125.
(**b**) Regulation 247A, inserted by S.I. 2020/1125.
(**c**) Regulation 346, amended by S.I. 2013/2593; there are other amending instruments but none is relevant.
(**d**) Schedule 4, amended by S.I. 2019/775 as amended by 2020/1488.
(**e**) Schedule 7, amended by S.I. 2019/62, and 2019/775 as amended by S.I. 2020/1488.

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 human medicines for human use.

Subject to various exceptions, medicines for human use may only be sold or supplied if they have been granted a marketing authorisation by the licensing authority (which is either, or both, of the Secretary of State and the Minister of Health in Northern Ireland). One of those exemptions is found in regulation 167 (supply to fulfil special patient needs), originally deriving from Article 5(1) of Directive 2001/83/EC of the European Parliament. This provides a tightly governed route to lawfully supply unlicensed medicines. In order to have a means of lawful supply of prescription only medicines to Northern Ireland from Great Britain, new regulations 167A and 167B introduce a new exemption that also derives from Article 5(1) (regulation 14). This exemption, or route, is called the Northern Ireland MHRA authorised route ('NIMAR') (regulation 4). Products supplied to Northern Ireland using this route are classified in Northern Ireland as a prescription only medicine (regulations 3 and 14).

There are two methods by which listed NIMAR products may find their way to clinicians in Northern Ireland, either directly from marketing authorisation holders and wholesale dealers based in Great Britain or via wholesale dealers based in Northern Ireland. Amendments provide that a holder of a wholesale dealer's licence can lawfully supply listed NIMAR products to Northern Ireland (regulation 5). Amendments also provide appropriate governance, such as new regulation 43ZA, which sets out the obligations that are placed on holders of wholesale dealer's licences in Great Britain supplying listed NIMAR products to Northern Ireland (regulation 11). Regulation 12 also ensures that responsible persons in Northern Ireland verify whether products are or are not supplied into Northern Ireland in accordance with NIMAR. Governance of those with manufacturer's licence is provided (regulations 6, 7, 8, 9, 10, 24, 25 and 26).

Part 11 of the 2012 Regulations contain provisions relating to pharmacovigilance. Amendments have been made to ensure that marketing authorisation holders in Great Britain are under an obligation to record and report adverse reactions that occur in Northern Ireland that they are made aware of (regulations 15 and 16).

Prescription only medicines may only be sold or supplied in accordance with a prescription of, or administered parenterally by, a health care professional who is classed as an appropriate practitioner. The 2012 Regulations already provide for either or both of these Part 12 restrictions to be set aside by instruments known as Patient Group Directions (PGDs). Amendment have been made to ensure that what can be done by way of PGDs can include listed NIMAR products (regulations 17 to 22).

The review provision in the 2012 Regulations has also been modified to take account of these Regulations (regulation 23).

A full Impact Assessment has not been produced for this instrument as it is not expected to have a significant impact on the public or voluntary sectors and only minimal impact on the private sector is foreseen. A Regulatory Triage Assessment of the effect that this instrument will have on the costs of business and the voluntary sector has been produced. The Explanatory Memorandum is published alongside these Regulations on www.legislation.gov.uk.

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