STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 3

[[F1]Manufacture and distribution of medicinal products and active substances**]**

[[F1]CHAPTER 2**]**

Manufacturing and wholesale dealing

Conditions for holding a wholesale dealer's licence

[[F1]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);

(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).**]**

Textual Amendments

F1 Reg. 43ZA inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **11**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 43ZA.