SCHEDULES

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 **[**F1/ Country other than an Approved Country for Import**]**

Textual Amendments

F1 Words in Sch. 4 Pt. 2 heading inserted (31.12.2020) by S.I. 2019/775, regs. 1, **20(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(c)**)

15. The provisions of this Part are standard provisions of a manufacturer's licence relating to the import of medicinal products **[**F2from—

(a) in the case of an import into Great Britain, a country other than Northern Ireland or a country other than an approved country for import, or

(b) in the case of an import into Northern Ireland, a country other than an EEA State**]**.

Textual Amendments

F2 Sch. 4 para. 15(a)(b) substituted for words in Sch. 4 para. 15 (31.12.2020) by S.I. 2019/775, **reg. 20(4)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(d)**)

[F3**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.**]**

Textual Amendments

F3 Sch. 4 para. 15A inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **24**

16. The licence holder must place the quality control system referred to in Article 11(1) of the Good Manufacturing Practice Directive under the authority of the person notified to the licensing authority in accordance with paragraph 2(2)(h) of Schedule 3.

17. The licence holder may use a contract laboratory pursuant to Article 11(2) of the Good Manufacturing Practice Directive if operated by a person approved by the licensing authority.

18. The licence holder must provide such information as may be requested by the licensing authority concerning the type and quantity of any medicinal products which the licence holder imports.

19. The licence holder must—

(a) keep readily available for inspection by a person authorised by the licensing authority the batch documentation referred to in Article 9(1) of the Good Manufacturing Practice Directive; and

(b) permit the person authorised to take copies or make extracts from such documentation.

20. Where the licence holder has been informed by the licensing authority that the strength, quality or purity of a batch of a medicinal product to which the licence relates has been found not to conform with—

(a) the specification of the medicinal product in question; or

(b) those provisions of these Regulations that are applicable to the medicinal product,

the licence holder must, if so directed, withhold the batch from distribution, so far as reasonably practicable, for such a period (not exceeding six weeks) as may be specified by the licensing authority.

21. The licence holder must ensure that any tests for determining conformity with the standards and specifications applying to any ingredient used in the manufacture of a medicinal product must, except so far as the conditions of the product specification for that ingredient otherwise provide, be applied to samples taken from the medicinal product after all manufacturing processes have been completed, or at such earlier stage in the manufacture as may be approved by the licensing authority.

22.—(1) Where and in so far as the licence relates to special medicinal products, the licence holder may only import such products from **[**[F4], in the case of an import into Great Britain, a country other than Northern Ireland or a country other than an approved country for import and in the case of an import into Northern Ireland, a country other than an EEA State**]**—

(a) in response to an order which satisfies the requirements of regulation 167 (supply to fulfil special patient needs); and

(b) where the conditions set out in sub-paragraphs (2) to (9) are complied with.

(2) No later than 28 days before the day on which each importation of a special medicinal product takes place, the licence holder must give written notice to the licensing authority stating the intention to import the product and stating the following particulars—

(a) the brand name, common name or scientific name of the medicinal product and (if different) any name under which the medicinal product is to be sold or supplied in the United Kingdom;

(b) any trademark or the name of the manufacturer of the medicinal product;

(c) in respect of each active constituent of the medicinal product, any international non-proprietary name or the British approved name or the monograph name, or where that constituent does not have any of those, the accepted scientific name or any other name descriptive of the true nature of the constituent;

(d) the quantity of medicinal product to be imported, which must not exceed the quantity specified in sub-paragraph (6); and

(e) the name and address of the manufacturer or assembler of the medicinal product in the form in which it is to be imported and, if the person who will supply the medicinal product for importation is not the manufacturer or assembler, the name and address of the supplier.

(3) The licence holder may not import the special medicinal product if, before the end of 28 days beginning immediately after the date on which the licensing authority sends or gives the licence holder an acknowledgement in writing by the licensing authority that it has received the notice referred to in sub-paragraph (2), the licensing authority has notified the licence holder in writing that the product should not be imported.

(4) The licence holder may import the special medicinal product referred to in the notice where the licence holder has been notified in writing by the licensing authority, before the end of the 28-day period referred to in sub-paragraph (3) that the product may be imported.

(5) Where the licence holder sells or supplies special medicinal products **[**F5or EAMS medicinal products**]**, the licence holder must, in addition to any other records which are required by the provisions of the licence, make and maintain written records relating to—

(a) the batch number of the batch of the product from which the sale or supply was made; and

(b) details of any adverse reaction to the product sold or supplied of which the licence holder becomes aware.

(6) The licence holder must not, on any one occasion, import more than such amount as is sufficient for 25 single administrations, or for 25 courses of treatment where the amount imported is sufficient for a maximum of three months' treatment, and must not, on any one occasion, import more than the quantity notified to the licensing authority under sub-paragraph (2)(d).

(7) The licence holder must not publish any advertisement, catalogue or circular relating to a special medicinal product **[**F6or EAMS medicinal product**]** or make any representations in respect of that product.

(8) The licence holder must inform the licensing authority immediately of any matter coming to the licence holder's attention which might reasonably cause the licensing authority to believe that a special medicinal product **[**F7or EAMS medicinal product**]** imported in accordance with this paragraph can no longer be regarded as a product which can safely be administered to human beings or as a product which is of satisfactory quality for such administration.

(9) The licence holder must cease importing or supplying a special medicinal product **[**F8or EAMS medicinal product**]** if the licence holder receives a notice in writing from the licensing authority directing that, from a date specified in the notice, a particular product or class of products may no longer be imported or supplied.

(10) In this paragraph—

"British approved name" means the name which appears in the current edition of the list prepared by the British Pharmacopoeia Commission under regulation 318 (British Pharmacopoeia: lists of names);

"international non-proprietary name" means a name which has been selected by the World Health Organisation as a recommended international non-proprietary name and in respect of which the Director-General of the World Health Organisation has given notice to that effect in the World Health Organisation Chronicle; and

"monograph name" means the name or approved synonym which appears at the head of a monograph in the current edition of the British Pharmacopoeia, the European Pharmacopoeia or a foreign or international compendium of standards and "current" in this definition means current at the time the notice is sent to the licensing authority.

Textual Amendments

F4 Words in Sch. 4 para. 22(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 20(4A)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(d)**)

F5 Words in Sch. 4 para. 22(5) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **14(3)(a)** (with reg. 19)
F6 Words in Sch. 4 para. 22(7) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **14(3)(b)** (with reg. 19)
F7 Words in Sch. 4 para. 22(8) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **14(3)(c)** (with reg. 19)
F8 Words in Sch. 4 para. 22(9) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **14(3)(d)** (with reg. 19)

23. The licence holder 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 medicinal product for human use which is imported from **[**F9, in the case of an import into Great Britain, a country other than Northern Ireland or a country other than an approved country for import and in the case of an import into Northern Ireland, a country other than an EEA State**]**, handled, stored or distributed under the licence is not false or misleading in a material particular.

Textual Amendments

F9 Words in Sch. 4 para. 23 substituted (31.12.2020) by S.I. 2019/775, **reg. 20(4A)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(d)**)

[F10**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.**]**

Textual Amendments

F10 Sch. 4 para. 23ZA inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **25**

[F11**23A.** A licence holder—

(a) in Great Britain may only supply a special medicinal product to a person in Northern Ireland, and

(b) in Northern Ireland may only supply a special medicinal product to a person in Great Britain,

in response to an order which satisfies the requirements of regulation 167.**]**

Textual Amendments

F11 Sch. 4 para. 23A inserted by S.I. 2019/775, regs. 1, **20(4B)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(d)**)

[F12**23B.** A licence holder may only import EAMS medicinal products if and to the extent that such products are required for the Early Access to Medicines Scheme.**]**

Textual Amendments

F12 Sch. 4 para. 23B inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **14(4)** (with reg. 19)

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, PART 2.