SCHEDULES

SCHEDULE 4 Regulation 24

Standard provisions of licences under Part 3

PART 1

Manufacturer's licence relating to manufacture and assembly

1. The provisions of this Part are standard provisions of a manufacturer's licence relating to the manufacture or assembly of medicinal products.

2. 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 1(2)(g) of Schedule 3.

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

4. The licence holder must provide such information as may be requested by the licensing authority—

(a) about the products currently being manufactured or assembled by the licence holder; and

(b) about the operations being carried out in relation to such manufacture or assembly.

5. The licence holder must inform the licensing authority of any change that the licence holder proposes to make to a person named in the licence as—

(a) the person whose duty it is to supervise the manufacturing or assembling operations;

(b) in charge of the animals from which are derived substances used in the production of the medicinal products being manufactured or assembled; or

(c) responsible for the culture of living tissues used in the manufacture of the medicinal products being manufactured or assembled.

6. 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 authorised person to take copies or make extracts from such documentation.

7. The licence holder must keep readily available for examination by a person authorised by the licensing authority the samples in each batch of finished medicinal product referred to in Article 11(4) of the Good Manufacturing Practice Directive.

8. 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 for the finished product; or

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

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

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

10. Where the manufacturer's licence relates to the assembly of a medicinal product or class of product, and the licence holder supplies the product at such a stage of assembly that does not fully comply with the provisions of the product specification which relate to labelling, the licence holder must communicate the particulars of those provisions to the person to whom that product has been supplied.

11. Where—

(a) the manufacturer's licence relates to the assembly of a medicinal product;

(b) the medicinal product is not manufactured by the licence holder; and

(c) particulars of the name and address of the manufacturer of the product, or the person who imports the product, have been given by the licence holder to the licensing authority,

the licence holder must immediately notify the licensing authority in writing of any changes in the particulars.

12. The licence holder must keep readily available for examination by a person authorised by the licensing authority durable records of the details of the manufacture of intermediate products held by the licence holder for use in the manufacture of biological medicinal products, and the records must—

(a) be in such form as to ensure that the licence holder has a comprehensive record of all matters that are relevant to an evaluation of the safety, quality and efficacy of a finished biological medicinal product manufactured using those intermediate products; and

(b) not be destroyed without the consent of the licensing authority until the records of the details of manufacture of finished medicinal products which were or may be manufactured using those intermediate products may be destroyed in accordance with the requirements of these Regulations.

13. Where—

(a) animals are used in the production of medicinal products; and

[[F1](b) in the case of a product for sale or supply—

(i) in Great Britain, a UK marketing authorisation, certificate of registration or traditional herbal registration, or

(ii) in Northern Ireland, a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration,

contains provisions relating to them,**]**

the manufacturer's licence holder must arrange for the animals to be housed in such premises, and managed in such a manner, as facilitates compliance with those provisions.

Textual Amendments

F1 Sch. 4 para. 13(b) substituted (31.12.2020) by S.I. 2019/775, **reg. 20(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(a)**)

14. The licence holder must take all reasonable precautions and exercise all due diligence to ensure that any information provided to the licensing authority is not false or misleading in any material particular if—

(a) it relates to a medicinal product which the licence holder manufactures or assembles; or

(b) it relates to any starting materials or intermediate products held by the licence holder which are for use in the manufacture of medicinal products.

[F2 14A. 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

F2 Sch. 4 para. 14A inserted (31.12.2020) by S.I. 2019/775, regs. 1, **20(2A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(b)**)

PART 2

Manufacturer's licence relating to the import of medicinal products from a state other than an EEA State **[F3**/ Country other than an Approved Country for Import**]**

Textual Amendments

F3 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 **[F4**from—

(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

F4 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)**)

[F5 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

F5 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 **[F6**, 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, 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 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 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 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

F6 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)**)

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 **[**[F7], 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

F7 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)**)

[[F8]**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

F8 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**

[[F9]**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

F9 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)**)

PART 3

Manufacturer's licence relating to exempt advanced therapy medicinal products

24. The provisions of paragraphs 25 to 27 are incorporated as additional standard provisions of a manufacturer's licence relating to the manufacture and assembly of exempt advanced therapy medicinal products.

25. The licence holder must ensure that the immediate packaging of an exempt advanced therapy medicinal product is labelled to show the following particulars—

(a) the name of the exempt advanced therapy medicinal product;

(b) the expiry date in clear terms including the year and month and, if applicable, the day;

(c) a description of the active substance, expressed qualitatively and quantitatively;

(d) where the product contains cells or tissues of human or animal origin—

(i) a statement that the product contains such cells or tissues, and

(ii) a short description of the cells or tissues and of their specific origin;

(e) the pharmaceutical form and the contents by weight, volume or number of doses of the product;

(f) a list of excipients, including preservative systems;

(g) the method of use, application, administration or implantation and, if appropriate, the route of administration, with space provided for the prescribed dose to be indicated;

(h) any special storage precautions;

(i) specific precautions relating to the disposal of the unused product or waste derived from the product and, where appropriate, reference to any appropriate collection system;

(j) the name and address of the holder of the manufacturer's licence;

(k) the manufacturer's licence number;

(l) the manufacturer's batch number;

(m) the unique donation code **[**F10assigned by a tissue establishment pursuant to—

(a) paragraph 1 of Schedule 3A to the Human Fertilisation and Embryology Act 1990, as regards human gametes and embryos; and

(b) paragraph 1 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007, as regards other human tissues and cells**]**; and

(n) where the exempt advanced therapy medicinal product is for autologous use, the unique patient identifier and the words “for autologous use only”.

Textual Amendments

F10 Words in Sch. 4 para. 25(m) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **20(5)**; 2020 c. 1, Sch. 5 para. 1(1)

26. The licence holder must ensure that the package leaflet of the exempt advanced therapy medicinal product shall include the following particulars—

(a) the name of the exempt advanced therapy medicinal product;

(b) the intended effect of the medicinal product if correctly used, applied, administered or implanted;

(c) where the product contains cells or tissues of human or animal origin—

(i) a statement that the product contains such cells or tissues, and

(ii) a short description of the cells or tissues and, where such cells or tissues are of animal origin, their specific origin;

(d) where the product contains a medical device or an active implantable medical device, a description of that device and, where that device contains cells or tissues of animal origin, their specific origin;

(e) any necessary instructions for use, including—

(i) the posology,

(ii) the method of use, application, administration or implantation and, if appropriate, the route of administration,

(iii) a description of symptoms of overdose,

(iv) action to be taken in the event of overdose, including any emergency procedures,

(v) action to be taken if one or more doses have been missed, and

(vi) a recommendation to consult the doctor or pharmacist for any clarification on the use of the product;

(f) where adverse reactions are known, a description of those which may occur under recommended conditions of use of the product and, if appropriate, an indication of action to be taken in such a case;

(g) an instruction that the patient report any adverse reaction not specified in the package leaflet to the doctor or pharmacist;

(h) the expiry date in clear terms and a warning against using the product after that date;

(i) any special storage precautions;

(j) a description of any visible signs of deterioration;

(k) a complete qualitative and quantitative composition;

(l) the name and address of the holder of the manufacturer's licence; and

(m) the date on which the package leaflet was last revised.

27. The licence holder must keep the data referred to in paragraph 8 of Schedule 6 for such period, being a period of longer than 30 years, as may be specified by the licensing authority.

PART 4

Wholesale dealer's licence

All wholesale dealer's licences

28. The provisions of this Part are standard provisions of a wholesale dealer's licence.

29. The licence holder must not use any premises for the handling, storage or distribution of medicinal products other than those specified in the licence or notified to the licensing authority from time to time and approved by the licensing authority.

30. The licence holder must provide such information as may be requested by the licensing authority concerning the type and quantity of medicinal products which the licence holder handles, stores or distributes.

31. The licence holder must take all reasonable precautions and exercise all due diligence to ensure that any information provided by the licence holder to the licensing authority which is relevant to an evaluation of the safety, quality or efficacy of a medicinal product which the licence holder handles, stores or distributes is not false or misleading.

Wholesale dealer's licence relating to special medicinal products

32. The provisions of paragraphs 33 to 42 are incorporated as additional standard provisions of a wholesale dealer's licence relating to special medicinal products.

33. Where and in so far as the licence relates to special medicinal products, the licence holder may only import such products from **[**F11, in the case of an import into Great Britain, an approved country for import and in the case of an import into Northern Ireland, an EEA State**]**—

(a) in response to an order which satisfies the requirements of regulation 167, and

(b) where the conditions set out in paragraphs 34 to 41 are complied with.

Textual Amendments

F11 Words in Sch. 4 para. 33 substituted (31.12.2020) by S.I. 2019/775, **reg. 20(6)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(e)**)

34. No later than 28 days prior to each importation of a special medicinal product, 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 paragraph 38; 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.

35. 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 paragraph 34, the licensing authority has notified the licence holder in writing that the product should not be imported.

36. 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 paragraph 35, that the product may be imported.

37. Where the licence holder sells or supplies special 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.

38. 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 paragraph 34(d).

39. 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 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.

40. The licence holder must not publish any advertisement, catalogue, or circular relating to a special medicinal product or make any representations in respect of that product.

41. The licence holder must cease importing or supplying a special 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.

[F12 41A. 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

F12 Sch. 4 para. 41A inserted (31.12.2020) by S.I. 2019/775, regs. 1, **20(7)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(f)**)

42. In this Part—

"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.

Wholesale dealer's licence relating to exempt advanced therapy medicinal products

43. The provisions of paragraph 44 are incorporated as additional standard provisions of a wholesale dealer's licence relating to exempt advanced therapy medicinal products.

44. The licence holder shall keep the data referred to in paragraph 16 of Schedule 6 for such period, being a period of longer than 30 years, as may be specified by the licensing authority.

Status:
Point in time view as at 01/01/2022.

Changes to legislation:
The Human Medicines Regulations 2012, SCHEDULE 4 is up to date with all changes known to be in force on or before 22 August 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.