SCHEDULE 7

STANDARD PROVISIONS FOR MANUFACTURING AUTHORISATIONS

PART 2

PROVISIONS WHICH MAY BE INCORPORATED IN AN AUTHORISATION RELATING TO THE MANUFACTURE OR ASSEMBLY OF INVESTIGATIONAL MEDICINAL PRODUCTS

1. The holder of the authorisation shall—

(a) provide and maintain such staff, premises and plant (including technical equipment) as are necessary for the carrying out, in accordance with his authorisation and the product specification, of such stages of the manufacture and assembly of the investigational medicinal products **[**F1or EAMS medicinal products**]** as are undertaken by him; and

(b) not carry out any such manufacture or assembly except at the premises specified in his manufacturing authorisation.

Textual Amendments

F1 Words in Sch. 7 Pt. 2 para. 1(a) 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), **18(2)(a)** (with reg. 19)

2. The holder of the authorisation shall—

(a) provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of the investigational medicinal products **[**F2or EAMS medicinal products**]** which he handles, stores or distributes under his authorisation as are necessary to maintain the quality of the investigational medicinal products **[**F2or EAMS medicinal products**]**;

(b) not use for such purposes premises other than those specified in the authorisation or which may be approved from time to time by the licensing authority; and

(c) ensure that any arrangements he makes with a person for the storage and distribution of the investigational medicinal products **[**F2or EAMS medicinal products**]** are adequate to maintain the quality of those products.

Textual Amendments

F2 Words in Sch. 7 Pt. 2 para. 2 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), **18(2)(b)** (with reg. 19)

3. The holder of the authorisation shall place the quality control system referred to in Article 11(1) of Commission Directive 2003/94/EC under the authority of the person notified to the licensing authority in accordance with paragraph 6(3) of Schedule 6 as being responsible for quality control.

4. The holder of the authorisation may use a contract laboratory pursuant to Article 11(2) of Commission Directive 2003/94/EC if operated by a person approved by the licensing authority.

5. The holder of the authorisation shall provide such information as may be requested by the licensing authority for the purposes of these Regulations or **[**F3the 2012 Regulations**]**—

(a) about the products currently being manufactured or assembled under his authorisation; and

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

Textual Amendments

F3 Words in Sch. 7 Pt. 2 para. 5 substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 62(a)(i)** (with Sch. 32)

6. The holder of the authorisation shall—

(a) inform the licensing authority before making any material alteration in the premises or plant used under his authorisation, or in the operations for which they are used; and

(b) inform the licensing authority of any change that he proposes to make in any personnel named in his authorisation as respectively—

(i) responsible for supervising the production operations, or

(ii) responsible for quality control of the investigational medicinal products being manufactured or assembled including the person named as the qualified person for the purposes of regulation 43 and paragraph 14.

7. The holder of the authorisation shall—

(a) keep readily available for inspection by a person authorised by the licensing authority the batch documentation referred to in Article 9(1) of Commission Directive 2003/94/EC; and

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

8. The holder of the authorisation shall keep readily available for examination by a person authorised by the licensing authority the samples of each batch of bulk formulated products referred to in Article 11(4) of Commission Directive 2003/94/EC.

9. Where the holder of the authorisation has been informed by the licensing authority that any batch of any investigational medicinal product **[**F4or EAMS medicinal product**]** to which his authorisation relates has been found not to conform as regards strength, quality or purity with—

(a) the specification of the relevant product; or

(b) the provisions of these Regulations, **[**F5or the 2012 Regulations**]** that are applicable to the investigational medicinal product **[**F4or EAMS medicinal product**]**,

he shall, if so directed, withhold such batch from distribution for use in clinical trials **[**F6or as part of the Early Access to Medicines Scheme**]**, so far as may be reasonably practicable, for such a period not exceeding six weeks as may be specified by the licensing authority.

Textual Amendments

F4 Words in Sch. 7 Pt. 2 para. 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), **18(2)(c)(i)** (with reg. 19)

F5 Words in Sch. 7 Pt. 2 para. 9 substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 62(a)(ii)** (with Sch. 32)

F6 Words in Sch. 7 Pt. 2 para. 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), **18(2)(c)(ii)** (with reg. 19)

10. The holder of the authorisation shall ensure that any tests for determining conformity with the standards and specifications applying to any particular product used in the manufacture shall,

except so far as the conditions of the product specification for that product otherwise provide, be applied to samples taken from the investigational medicinal product **[**F7or EAMS 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.

Textual Amendments

F7 Words in Sch. 7 Pt. 2 para. 10 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), **18(2)(d)** (with reg. 19)

11. Where the authorisation relates to the assembly of an investigational medicinal product **[**F8or EAMS medicinal product**]**, and the holder of the authorisation supplies that investigational medicinal product **[**F8or EAMS medicinal product**]** at such a stage of assembly that does not fully comply with the provisions of the product specification that relate to labelling, that holder of the authorisation shall communicate the particulars of those provisions to the person to whom that investigational medicinal product **[**F8or EAMS medicinal product**]** has been so supplied.

Textual Amendments

F8 Words in Sch. 7 Pt. 2 para. 11 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), **18(2)(e)** (with reg. 19)

12. Where—

(a) the manufacturing authorisation relates to the assembly of an investigational medicinal product **[**F9or EAMS medicinal product**]**;

(b) that investigational medicinal product **[**F9or EAMS medicinal product**]** is not manufactured by the holder of the authorisation; and

(c) particulars as to the name and address of the manufacturer of, or of the person who imports, that investigational medicinal product **[**F9or EAMS medicinal product**]** had been given by the holder of the authorisation to the licensing authority,

the holder of the authorisation shall forthwith notify the licensing authority in writing of any changes in such particulars.

Textual Amendments

F9 Words in Sch. 7 Pt. 2 para. 12 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), **18(2)(f)** (with reg. 19)

13. The holder of the authorisation, for the purpose of enabling the licensing authority to ascertain whether there are any grounds—

(a) for suspending, revoking or varying any authorisation or licence granted under these Regulations or **[**F10Parts 3 to 8 of the 2012 Regulations**]**;

[F11(aa) amending the conditions attached to or revoking an EAMS scientific opinion;**]**

(b) amending the clinical trial authorisation in accordance with regulation 23 or 24; or

(c) suspending or terminating any clinical trial in accordance with regulation 31,

shall permit, and provide all necessary facilities to enable, any person duly authorised in writing by the licensing authority, on production if required of his credentials, to carry out such inspection or to take such samples or copies, in relation to things belonging to, or any business carried on by, the holder of the authorisation, as such person would have the right to carry out or take under **[**F12the 2012 Regulations**]** for the purpose of verifying any statement contained in an application for an authorisation or licence.

Textual Amendments

F10 Words in Sch. 7 Pt. 2 para. 13 substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 62(a)(iii)(aa)** (with Sch. 32)

F11 Sch. 7 Pt. 2 para. 13(aa) 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), **18(2)(g)** (with reg. 19)

F12 Words in Sch. 7 Pt. 2 para. 13 substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 62(a)(iii)(bb)** (with Sch. 32)

14. The holder of the authorisation shall at all times provide and maintain such staff, premises, equipment and facilities as will enable the qualified person who is at his disposal pursuant to regulation 43(1) to carry out the duties referred to in **[**F13regulation 43(1A) or (2)**]**.

Textual Amendments

F13 Words in Sch. 7 Pt. 2 para. 14 substituted (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), **18(2)(h)** (with reg. 19)

[F14**14A.** The holder of the authorisation shall only manufacture or assemble EAMS medicinal products if and to the extent that such products are required for the Early Access to Medicines Scheme.**]**

Textual Amendments

F14 Sch. 7 Pt. 2 para. 14A 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), **18(2)(i)** (with reg. 19)

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, PART 2.