SCHEDULE 1

Regulation 6

STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE RELATING TO THE MANUFACTURE AND ASSEMBLY OF RELEVANT MEDICINAL PRODUCTS

1. The manufacturer's licence holder 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 7(2) of Schedule 1 to the Applications Regulations as being responsible for quality control.

2. The manufacturer's licence holder 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.

3. The manufacturer's licence holder shall provide such information as may be requested by the licensing authority—

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

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

4. The manufacturer's licence holder shall inform the licensing authority of any change that he proposes to make to any personnel named in his licence as respectively—

(a) responsible for supervising the production operations;

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

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

5. The manufacturer's licence holder 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.

6. The manufacturer's licence holder shall keep readily available for examination by a person authorised by the licensing authority, the samples of each batch of finished relevant medicinal product referred to in Article 11(4) of Commission Directive 2003/94/EC.

7. Where the manufacturer's licence holder has been informed by the licensing authority that any batch of any relevant medicinal product to which his licence 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, the Act or any other regulations under the Act that are applicable to the relevant medicinal product,

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

8. The manufacturer's licence holder shall ensure that any tests for determining conformity with the standards and specifications applying to any particular product used in the manufacture of a relevant medicinal product shall, 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 in the manufacture as may be approved by the licensing authority.

9. Where the manufacturer's licence relates to the assembly of any relevant medicinal product or class of product, and the licence holder supplies that relevant medicinal product at such a stage of

assembly that does not fully comply with the provisions of the product specification that relate to labelling, the licence holder shall communicate the particulars of those provisions to the person to whom that product has been so supplied.

10. Where—

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

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

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

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

11. The licence holder shall keep readily available for examination by a person authorised by the licensing authority durable records of the details of manufacture of any intermediate products held by him which are for use in the manufacture of biological medicinal products for human use, and these records shall—

(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 any finished biological medicinal product for human use which he manufactures 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 any finished medicinal products which were or may be manufactured using those intermediate products may be destroyed in accordance with the requirements of these Regulations.

12. Where—

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

(b) relevant marketing authorizations contain provisions relating to them,

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

13. The licence holder shall take all reasonable precautions and exercise all due diligence to ensure that any information he provides to the licensing authority which is relevant to an evaluation of the safety, quality or efficacy of—

(a) any medicinal product for human use which he manufactures or assembles; or

(b) any starting materials or intermediate products that he holds which are for use in the manufacture of relevant medicinal products,

is not false or misleading in any material particular.

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

– Regulations revoked by S.I. 2012/1916 Sch. 35