SCHEDULES

[F1SCHEDULE 7A

Regulation 45N(5)(b)

Information to be provided for registration as an importer, manufacturer or distributor of active substances

Textual Amendments

F1 Sch. 7A inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **33**

1. The name and address of the applicant.

2. The name and address of the person (if any) making the application on the applicant's behalf.

3. The address of each of the premises where any operations to which the registration relates are to be carried out.

4. The address of any premises not mentioned by virtue of the above requirement, where—

(a) the applicant proposes to keep any living animals, from which substance(s) used in the production of the active substance(s) to which the application relates are to be derived;

(b) materials of animal origin from which an active substance is to be derived, as mentioned in the above sub-paragraph, are to be kept.

5. The address of each of the premises where active substances are to be stored, or from which active substances are to be distributed.

6. The address of each of the premises where any testing associated with the manufacture or assembly of active substances to which the registration relates.

7. The name, address, qualifications and experience of the person whose duty it will be to supervise any manufacturing operations, and the name and job title of the person to whom they report.

8. The name, address, qualifications and experience of the person who will have responsibility for the quality control of active substances, and the name and job title of the person to whom they report.

9. The name, address, qualifications and experience of the person whose duty it will be to supervise any importation, storage or distribution operations, and the name and job title of the person to whom they report.

10. The name, address and qualifications of the person to be responsible for any animals kept as mentioned in paragraph 4(a).

11. The name, address and qualifications of the person to be responsible for the culture of any living tissue for use in the manufacture of an active substance.

12. For each active substance to be manufactured, imported, or distributed—

(a) the CAS registration number assigned to that active substance by the Chemical Abstracts Service, a division of the American Chemical Society;

(b) where applicable, the Anatomical Therapeutic Category code assigned to that active substance under the Anatomical Therapeutic Chemical Classification System used for the classification of drugs by the World Health Organisation's Collaborating Centre for Drug Statistics Methodology;

(c) either—

(i) the International Union of Pure and Applied Chemistry nomenclature, or

(ii) the common name; and

(d) the intended quantities of each active substance to be manufactured, imported or distributed.

13. Details of the operations to which the registration relates, including a statement of whether they include—

(a) the manufacture of active substances;

(b) the importation of active substances [F2]...;

(c) the storage of active substances; or

(d) the distribution of active substances.

Textual Amendments

F2 Words in Sch. 7A para. 13(b) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **43(2)**; 2020 c. 1, Sch. 5 para. 1(1)

14. A statement of the facilities and equipment available at each of the premises where active substances are to be manufactured, stored or distributed.

15. A statement as to whether the particular active substances are intended for—

(a) use in a medicinal product with an EU marketing authorisation;

(b) use in a special medicinal product; or

(c) export [F3]....

Textual Amendments

F3 Words in Sch. 7A para. 15(c) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **43(3)**; 2020 c. 1, Sch. 5 para. 1(1)

16. A separate statement in respect of each of the premises mentioned in the application of—

(a) the manufacturing, storage or distribution operations carried out at those sites, and the specific active substances to which those activities relate; and

(b) the equipment available at those premises for carrying out those activities.

17. A statement of the authority conferred on the person responsible for quality control to reject unsatisfactory active substances.

18. A description of the arrangements for the identification and storage of materials before and during the manufacture of active substances.

19. A description of the arrangements for the identification and storage of active substances.

20. A description of the arrangements at each of the premises where the applicant proposes to store active substances for ensuring, as far as practicable, the turn-over of stocks of active substances.

21. A description of the arrangements for maintaining—

(a) production records, including records of manufacture and assembly;

(b) records of analytical and other tests used in the course of manufacture or assembly for ensuring compliance of materials use in manufacture, or of active substances, with the specification for such materials or active substances;

(c) records of importation;

(d) records of storage and distribution.

22. A description of the arrangements for keeping reference samples of—

(a) materials used in the manufacture of active substances; and

(b) active substances.

23. Where the application relates to active substances intended for use in an advanced therapy medicinal product, an outline of the arrangements for maintaining records to allow traceability containing sufficient detail to enable the linking of an active substance to the advanced therapy medicinal product it was used in the manufacture of and vice versa.

24. Details of—

(a) any manufacturing, importation, storage or distribution operations, other than those to which the application for registration relates, carried on by the applicant on or near each of the premises, and

(b) the substances or articles to which those operations relate.**]**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, SCHEDULE 7A.