SCHEDULES

SCHEDULE 9

Regulation 50(4)

Undertakings by non-EEA manufacturers

1. The manufacturer must provide and maintain such staff, premises and plant as are necessary for the carrying out in accordance with the marketing authorisation of such stages of the manufacture and assembly of the medicinal products to which the authorisation relates as are undertaken by the manufacturer.

2. The manufacturer must provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of the medicinal products to which the marketing authorisation relates and which the manufacturer handles, stores or distributes as are necessary to avoid deterioration of the medicinal products.

3. The manufacturer must provide and maintain a designated quality control department having authority in relation to quality control and being independent of all other departments.

4. The manufacturer must conduct all manufacture and assembly operations in such a way as to ensure that the medicinal products to which the marketing authorisation relates conform with the standards of strength, quality and purity applicable to them under the marketing authorisation.

5. The manufacturer must maintain an effective pharmaceutical quality assurance system involving the active participation of the management and personnel of the different services involved.

6. Where animals are used in the production of any medicinal product and the marketing authorisation contains provisions relating to them the manufacturer must arrange for the animals to be housed in premises of such a nature and to be managed in such a way as will facilitate compliance with such provisions.

7. The manufacturer must make such adequate and suitable arrangements as are necessary for carrying out in accordance with the marketing authorisation any tests of the strength, quality or purity of the medicinal products to which the marketing authorisation relates.

8. The manufacturer must inform the holder of the marketing authorisation of any material alteration in the premises or plant used in connection with the manufacture or assembly of the medicinal products to which the marketing authorisation relates or in the operations for which such premises or plant are so used, and of any change since the granting of the relevant marketing authorisation in respect of any person—

(a) responsible for supervising the production operations;

(b) responsible for quality control of the medicinal products to which the marketing authorisation relates;

(c) in charge of the animals from which are derived any substance used in the production of the medicinal products to which the marketing authorisation relates; or

(d) responsible for the culture of any living tissues used in the manufacture of the medicinal products to which the marketing authorisation relates.

9.—(1) The manufacturer shall keep readily available for inspection by a person authorised by the licensing authority durable records of—

(a) the details of manufacture and assembly of each batch of the medicinal product to which the marketing authorisation relates; and

(b) the tests carried out on the product,

in such a form that the records will be easily identifiable from the number of the batch as shown on each container in which the medicinal product is exported from the country where it has been manufactured or assembled.

(2) The manufacturer shall permit the person authorised to take copies of or make extracts from such records.

(3) Such records shall not be destroyed for a period of five years from the date of release of the batch concerned, or one year after the expiry date of the batch, whichever is the later.

10. The manufacturer must keep readily available for examination by a person authorised by the licensing authority samples of—

(a) each batch of finished products for at least a period of one year after their expiry date; and

(b) starting materials (other than solvents, gases or water) for at least a period of two years after release of the medicinal product of which those materials formed part,

except where the manufacturer is authorised by the licensing authority to destroy such samples earlier.

11.—(1) The manufacturer must implement a system for recording and reviewing complaints in relation to medicinal products to which a marketing authorisation relates, together with an effective system for recalling promptly and at any time the medicinal products in the distribution network.

(2) The manufacturer must record and investigate all complaints described in sub-paragraph (1) and must immediately inform the licensing authority of any defect which could result in a recall from sale, supply or export or in an abnormal restriction on such sale, supply or export.

12. The manufacturer must inform the holder of the marketing authorisation of any material change since the day upon which the authorisation was granted in respect of—

(a) the facilities and equipment available at each of the premises of the manufacturer for carrying out any stage of the manufacture or assembly of the medicinal products to which the marketing authorisation relates;

(b) the facilities and equipment available at each of the premises of the manufacturer for the storage of the medicinal products to which the marketing authorisation relates on, and the distribution of the products from or between, such premises;

(c) any manufacturing operations, not being operations in relation to the medicinal products to which the marketing authorisation relates, which are carried on by the manufacturer on or near any of the premises on which medicinal products to which the marketing authorisation relates are manufactured or assembled, and the substances or articles in respect of which such operations are carried on;

(d) the arrangements for the identification and storage of materials and ingredients before and during manufacture or assembly of the medicinal products to which the marketing authorisation relates and the arrangements for the storage of the products after they have been manufactured or assembled;

(e) the arrangements for ensuring a satisfactory turnover of stocks of medicinal products to which the marketing authorisation relates;

(f) the arrangements for maintaining production records and records of analytical and other testing procedures applied in the course of manufacture or assembly of the medicinal products to which the marketing authorisation relates; or

(g) the arrangements for keeping reference samples of materials used in the manufacture of the medicinal products to which the marketing authorisation relates and reference samples of the medicinal products themselves.