STATUTORY INSTRUMENTS

2005 No. 2789

The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005

Requirement that manufacturer's licence holders comply with certain obligations in relation to the import from a third country of relevant medicinal products

3. In relation to the import from a third country of any relevant medicinal product, a manufacturer's licence holder shall—

(a) comply with the principles and guidelines of good manufacturing practice insofar as they are relevant to the import of relevant medicinal products;

(b) comply with the guidelines on good distribution practice;

(c) ensure that any relevant medicinal products (other than exempt relevant medicinal products) imported by him from a third country use active substances as starting materials only where those active substances have been manufactured in accordance with the principles and guidelines of good manufacturing practice applicable to starting materials;

(d) maintain such staff, premises, equipment and facilities for the handling, control, storage and distribution of the relevant medicinal products which he handles, stores and distributes under his licence, as are necessary to maintain the quality of those medicinal products;

(e) ensure that any arrangements he makes with any person for the storage and distribution of the medicinal products are adequate to maintain the quality of those products;

(f) not use any premises for the handling, control, storage or distribution of relevant medicinal products other than those specified in his licence as approved by the licensing authority for that purpose, or approved by the licensing authority for that purpose from time to time;

(g) inform the licensing authority before making any material alteration in the premises or facilities used under his licence, or in the operations for which they are used;

(h) inform the licensing authority of any change that he proposes to make to any personnel named in his licence as responsible for quality control of the medicinal products being imported by him including the person named as the qualified person for the purposes of regulation 4;

(i) for the purpose of enabling the licensing authority to ascertain whether there are any grounds—

(i) for suspending, revoking or varying any licence granted under Part II of the Act; or

(ii) suspending or terminating any licence in accordance with the provisions of Part II of the Act,

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 licence, as such person would have the right to carry out or take under the Act for the purpose of verifying any statement contained in an application for a licence**;** and

(j) where he distributes by way of wholesale dealing, any relevant medicinal product manufactured or assembled pursuant to his licence, comply with the requirements of regulations 8(1)(a) and (b) and (2), and 9 (2) and (3), as if he was the holder of a wholesale dealer's licence.