STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 3

[F1Manufacture and distribution of medicinal products and active substances]

[F1CHAPTER 2]

Manufacturing and wholesale dealing

Grant etc of licences

General power to suspend, revoke or vary licences

26.—(1) The licensing authority may in accordance with the procedure specified in regulation 27—

(a) suspend a licence under this Part for such period as the authority thinks fit;

(b) revoke a licence under this Part; or

(c) vary the provisions of a licence under this Part.

(2) The suspension or revocation of a licence may be—

(a) total;

(b) limited to medicinal products of one or more descriptions; or

(c) limited to medicinal products manufactured, assembled or stored on specified premises or a specified part of any premises.

(3) The powers conferred by this regulation may not be exercised in relation to a manufacturer's licence or a wholesale dealer's licence except on one or more of the grounds specified in—

(a) paragraph (4) (in relation to either a manufacturer's licence or a wholesale dealer's licence);

(b) paragraph (5) (in relation to a manufacturer's licence); or

(c) paragraph (6) (in relation to a wholesale dealer's licence).

(4) Those grounds are that—

(a) the information in the application as a result of which the licence was granted was false or incomplete in a material respect;

(b) a material change of circumstances has occurred in relation to any of the matters stated in the application;

(c) the holder of the licence has materially contravened a provision of it; or

(d) the holder of the licence has without reasonable excuse failed to supply information to the licensing authority with respect to medicinal products of a description to which the licence relates when required to do so under regulation 30(2).

(5) In relation to a manufacturer's licence, the powers conferred by this regulation may also be exercised on either or both of the following grounds—

(a) that the holder of the manufacturer's licence has manufactured or assembled medicinal products to the order of a person who holds a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration (an "authorisation") and has habitually failed to comply with the provisions of that authorisation; or

(b) that the holder of the manufacturer's licence does not have appropriate facilities to carry out processes of manufacture or assembly authorised by the licence.

(6) In relation to a wholesale dealer's licence, the powers conferred by this regulation may also be exercised on the grounds that the equipment and facilities available to the holder of the licence for storing or distributing medicinal products are inadequate to maintain the quality of medicinal products of one or more descriptions to which the licence relates.