STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 5

Marketing authorisations

Revocation, variation and suspension of marketing authorisation

Revocation, variation and suspension of UK marketing authorisation

68.—(1) The licensing authority may revoke, vary or suspend a UK marketing authorisation if any of the following conditions is met.

(2) Condition A is that the licensing authority thinks that—

(a) the product to which the authorisation relates is harmful;

(b) the positive therapeutic effects of the product do not outweigh the risks of the product to the health of patients or of the public;

(c) the product lacks therapeutic efficacy, in that therapeutic results cannot be obtained from the product; or

(d) the product's qualitative or quantitative composition is not as described in the application for the authorisation or the material supplied with it.

(3) Condition B is that the licensing authority thinks that the application or the material supplied with it is incorrect.

(4) Condition C is that the licensing authority thinks that there has been a breach of—

(a) a term of the authorisation; or

(b) a requirement imposed by Part 13 (packaging and leaflets).

(5) Condition D is that the licensing authority thinks that a condition to which the authorisation is subject by virtue of regulations 59 (conditions of UK marketing authorisations: general), 60 (conditions of UK marketing authorisations: exceptional circumstances) or 61 (conditions of UK marketing authorisations: new obligations post-authorisation) has not been fulfilled.

(6) Condition E is that the licensing authority thinks that the holder of the authorisation has not complied with regulation 75(1) to (3) (requirements to provide information).

(7) Condition F is that the holder of the authorisation has ceased to be established in the European Union.

(8) Condition G is that—

(a) the product to which the authorisation relates is manufactured in the United Kingdom; and

(b) the licensing authority thinks that the holder of the manufacturer's licence for the product has failed to comply in relation to the product with regulations 37 (manufacturing and assembly), 38 (imports from states other than EEA States), 39 (further requirements for

manufacturer's licence), 40 (obligation to provide information relating to control methods) or 41 (requirements as to qualified persons).

(9) Condition H is that—

(a) the product to which the authorisation relates is manufactured in a member State other than the United Kingdom; and

(b) the licensing authority thinks that the licensee under the manufacturer's licence for the product has failed to comply in relation to the product with provision giving effect to Article 41 of the 2001 Directive (requirements relating to manufacturing authorisations) in that member State.

(10) Condition I is that the licensing authority thinks that urgent action to protect public health is necessary, in which case it—

(a) may suspend the authorisation; and

(b) must notify the suspension to the EMA, the European Commission, and all other member States by the end of the next working day following the day on which the suspension comes into force.

(11) Condition J is that—

(a) the holder applies to vary the authorisation; and

(b) the licensing authority thinks that the application should be granted.

(12) Schedule 11 makes provision about advice and representations in relation to a proposal to revoke, vary or suspend a UK marketing authorisation, other than a proposal to vary an authorisation on the application of its holder.

(13) This regulation is subject to regulation 70 (authorisations granted under Chapter 4 of Title III of the 2001 Directive).

Suspension of use etc of relevant medicinal product

69.—(1) The licensing authority may, if any of the following conditions are met, suspend the use, sale, supply or offer for sale or supply within the United Kingdom of a product to which a UK marketing authorisation relates.

(2) Condition A is that the licensing authority thinks that—

(a) the product to which the authorisation relates is harmful;

(b) the positive therapeutic effects of the product do not outweigh the risks of the product to the health of patients or of the public;

(c) the product lacks therapeutic efficacy, in that therapeutic results cannot be obtained from the product; or

(d) the product's qualitative or quantitative composition is not as described in the application for the authorisation or the material supplied with it.

(3) Condition B is that the licensing authority thinks that the holder of the authorisation has not complied with regulation 75(7) (requirements to provide proof of controls on manufacturing process).

(4) Condition C is that the licensing authority thinks that there has been a breach of—

(a) a term of the authorisation; or

(b) a requirement imposed by Part 13 (packaging and leaflets).

(5) Condition D is that the licensing authority thinks that paragraph (4) or (5) of regulation 26 (power to revoke, suspend or vary manufacturers' licences) applies in relation to the manufacturer's licence for the product to which the authorisation relates.

(6) A suspension under this regulation may relate to batches of the product.

(7) The licensing authority must give notice in writing of a suspension under this regulation to the holder of the UK marketing authorisation.

(8) The licensing authority must provide in the notice that the suspension—

(a) is to take effect immediately or from a date specified in the notice; and

(b) is to apply for the period specified in the notice.

(9) Where a medicinal product is the subject of a suspension under this regulation, the licensing authority may—

(a) in exceptional circumstances; and

(b) for such a transitional period as the licensing authority may determine,

allow the supply of the medicinal product to patients who are already being treated with the medicinal product.

(10) This regulation is subject to regulation 70 (authorisations granted under Chapter 4 of Title III of the 2001 Directive).

Authorisations granted under Chapter 4 of Title III of the 2001 Directive

70.—(1) Regulations 68 and 69 do not apply in relation to a UK marketing authorisation that—

(a) was granted in accordance with the provisions of Chapter 4 of Title III of the 2001 Directive (mutual recognition procedure and decentralised procedure);

(b) was granted before 1st January 1995 in accordance with Article 4 of Council Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology [M1]; or

(c) was subject to the procedure laid down in Articles 32 to 34 of the 2001 Directive following a referral under Article 30 or 31 of that Directive, unless the procedure was limited to certain specific parts of the authorisation.

(2) A proposal by the licensing authority to vary, suspend or revoke a marketing authorisation within paragraph (1), or an application by the holder of such an authorisation to vary or revoke it, is to be determined in accordance with Chapter 4 of Title III of the 2001 Directive.

Marginal Citations

M1 OJ No L 15, 17.1.1987. p.38.

Withdrawal of medicinal product from the market

71.—(1) This regulation applies if—

(a) under regulation 68, regulation 70(2), Article 34(3) of the 2001 Directive or Regulation (EC) No 726/2004 the licensing authority or the European Commission revokes or suspends a marketing authorisation, or

(b) under regulation 69 or Article 20(4) of Regulation (EC) No 726/2004 the licensing authority suspends the use, sale, supply or offer for sale or supply within the United Kingdom of a product to which a marketing authorisation relates.

(2) The licensing authority may give written notice to the person who is, or immediately before its revocation was, the holder of the authorisation requiring that person to comply with both of the following requirements.

(3) Requirement A is to take all reasonably practicable steps to inform wholesalers, retailers, medical practitioners, patients and others who may be in possession of the product to which the authorisation relates of—

(a) the revocation or suspension;

(b) the reasons for the revocation or suspension; and

(c) any action to be taken to restrict or prevent further use, sale, supply or offer for sale or supply of the product.

(4) Requirement B is to take all reasonably practicable steps to withdraw from the market in the United Kingdom and recover possession of—

(a) the product; or

(b) the batches of the product specified in the notice,

within the time and for the period specified in the notice.

Sale etc of suspended medicinal product

72.—(1) This regulation applies if the use, sale, supply or offer for sale or supply of a medicinal product is suspended in accordance with regulation 69 or 70(2) or Article 20(4) of Regulation (EC) No 726/2004.

(2) A person must not—

(a) sell, supply or offer to sell or supply the product; or

(b) procure the sale, supply or offer for sale or supply of the product,

knowing, or having reasonable cause to believe, that such use, sale, supply or offer for sale or supply is suspended.

Status:
Point in time view as at 14/08/2012.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Cross Heading: Revocation, variation and suspension of marketing authorisation.