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 [F1or parallel import licence]

68.—(1) The licensing authority may revoke, vary or suspend a UK marketing authorisation **[**F2or parallel import licence**]** 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.

[F3(4) Condition C is that the licensing authority thinks that there has been a breach of—

(a) a term of the authorisation or licence;

(b) in the case of a UK marketing authorisation, a requirement imposed by Part 13 (packaging and leaflets); or

(c) in the case of a parallel import licence, a requirement in relation to packaging and leaflets imposed by the licensing authority.**]**

[F4(5) Condition D is that the licensing authority thinks that a condition to which—

(a) the UK marketing authorisation or parallel import licence is subject by virtue of regulation 59 (conditions of UK marketing authorisations or parallel import licence: general); or

(b) the UK marketing authorisation is subject by virtue of regulations 60 (conditions of UK marketing authorisations: exceptional circumstances) **[**F5, regulation 60A (conditions as to testing of samples by the appropriate authority)**]** 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 **[**F6or licence**]** has ceased to be **[**F7established in—

(a) the United Kingdom; or

(b) in relation to a UKMA(NI), either the United Kingdom or the European Union,

in accordance with the requirements of these Regulations.**]**

(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 **[**F8countries other than approved countries for import**]**), 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 F9...; 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 **[**F10authorisation or licence.**]**

F11(b) . . . . . .

(11) Condition J is that—

(a) the holder applies to vary the authorisation **[**F12or licence**]**; and

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

[F13(11A) Condition K is that the manufacture of the product to which the authorisation relates is not carried out in compliance with the particulars provided under paragraphs 5 and 9 of Schedule 8.**]**

[F14(11B) Condition L is that the licensing authority thinks that the term of the authorisation which specifies the way in which the product is to be made available, as described in regulation 62(1), is incorrect.

(11C) Condition M is that, in respect of a parallel import licence, the UK marketing authorisation in respect of the medicinal product that was specified in the application for that licence under paragraph 4 of Schedule 8A, has been varied, suspended or revoked by the licensing authority under this regulation.

(11D) Condition N is that, in respect of a parallel import licence, the licensing authority is no longer satisfied that the product is essentially similar to a product that has been granted a UK marketing authorisation.

(11E) The licensing authority may not exercise its powers under paragraph (1) by virtue of the condition in paragraph (11D)—

(a) before the end of the period of one year beginning with IP completion day; and

(b) in any event, in a way that prevents the import of any medicinal product in respect of which a qualified person undertook the certification referred to in Article 51(3) of the 2001 Directive before IP completion day.

(11F) Condition O is that the licensing authority thinks that a variation of a UK marketing authorisation is necessary as a result of the submission of the results of a study by the holder of that authorisation under regulation 78A(14).

(11G) Condition P is that the licensing authority thinks that the revocation, variation or suspension is necessary or expedient in light of the Protocol on Ireland/Northern Ireland in the withdrawal agreement.**]**

(12) Schedule 11 makes provision about advice and representations in relation to a proposal to revoke, vary or suspend a UK marketing authorisation **[**F15or parallel import licence**]**, other than a proposal to vary an authorisation **[**F16or licence**]** on the application of its holder.

F17(13) . . . . . .

Textual Amendments

F1 Words in reg. 68 heading inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 68 heading inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(h)**

F2 Words in reg. 68(1) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 68(1) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(i)**

F3 Reg. 68(4) substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **11(2)** and reg. 68(4) substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **11(2)**

F4 Reg. 68(5) substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **11(3)** and reg. 68(5) substituted (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **11(3)**

F5 Words in reg. 68(5) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F6 Words in reg. 68(7) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F7 Reg. 68(7)(a)(b) and words substituted for words (31.12.2020) by S.I. 2019/775, **reg. 77(3)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 57(a)**)

F8 Words in reg. 68(8)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(4)**; 2020 c. 1, Sch. 5 para. 1(1)

F9 Words in reg. 68(9)(a) omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 77(5)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 57(b)**)

F10 Words in reg. 68(10)(a) substituted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(6)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F11 Reg. 68(10)(b) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(6)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F12 Words in reg. 68(11)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(7)**; 2020 c. 1, Sch. 5 para. 1(1)

F13 Reg. 68(11A) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **17**

F14 Reg. 68(11B)-(11G) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(8)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 57(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F15 Words in reg. 68(12) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(9)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F16 Words in reg. 68(12) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(9)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F17 Reg. 68(13) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(10)**; 2020 c. 1, Sch. 5 para. 1(1)

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 **[**[F18]or parallel import licence**]** 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 **[**[F19]or parallel import licence**]**.

(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.

[F20](10) . . . . . .

Textual Amendments

F18 Words in reg. 69(1) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 69(1)(7) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(j)**

F19 Words in reg. 69(7) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 69(1)(7) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(j)**

F20 Reg. 69(10) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **78**; 2020 c. 1, Sch. 5 para. 1(1)

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

[F21]70. . . . . . .

Textual Amendments

F21 Reg. 70 omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **79**; 2020 c. 1, Sch. 5 para. 1(1)

Withdrawal of medicinal product from the market

71.—(1) This regulation applies if—

[[F22](a) under regulation 68 the licensing authority revokes or suspends a UK marketing authorisation or parallel import licence; or**]**

[[F23](b) under—

(i) regulation 69 the licensing authority suspends the use, sale, supply or offer for sale or supply within Great Britain of a product to which a UKMA(GB) relates; or

(ii) 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 Northern Ireland of a product to which a UKMA(NI) or UKMA(UK) 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 **[**[F24]or related parallel import licence**]** 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.

Textual Amendments

F22 Reg. 71(1)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **80(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F23 Reg. 71(1)(b) substituted (31.12.2020) by S.I. 2019/775, **reg. 80(2)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 58**)

F24 Words in reg. 71(2) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **13** and words in reg. 71(2) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **13**

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

[[F25](a) in the case of a medicinal product authorised for sale or supply by a UKMA(GB), regulation 69;

(b) in the case of a medicinal product authorised for sale or supply by a UKMA(NI) or UKMA(UK), regulation 69 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.

Textual Amendments

F25 Reg. 72(1)(a)(b) substituted for words in reg. 72(1) (31.12.2020) by S.I. 2019/775, **reg. 81** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 59**)

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.