STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 5

Marketing authorisations

Application for UK marketing authorisation

Application for grant of UK marketing authorisation [F1or parallel import licence]

49.—**[**F2(1) The licensing authority may grant—

(a) subject to regulation 58, **[**F358C, 58E, 58F and 58G,**]** a UK marketing authorisation; or

(b) a parallel import licence,

for a relevant medicinal product in response to an application made in accordance with this Part.**]**

[F4(1A) The licensing authority may accept an application meeting reduced or alternative requirements specified in this Part ("under the unfettered access route") and grant a UKMA(GB) only where—

(a) there is already in place, or will be at the time the UKMA(GB) is granted, a marketing authorisation in respect of the product authorising sale or supply in Northern Ireland,

(b) the applicant complies with the requirements in regulation 50(1A), and

(c) the medicinal product satisfies the definition of qualifying Northern Ireland goods.

(1B) The licensing authority may only grant a parallel import licence if it is able to obtain the information necessary, whether from a competent authority of an EEA State or otherwise, to satisfy itself that the medicinal product to be imported—

(a) has been granted an EU marketing authorisation or a marketing authorisation under the 2001 Directive; and

(b) is essentially similar to a product that has already been granted a UK marketing authorisation.

(1C) A marketing authorisation or parallel import licence must state whether it is in force in—

(a) the whole United Kingdom;

(b) Great Britain only; or

(c) Northern Ireland only,

and in these Regulations the meaning of a reference to that authorisation or licence being "in force" is limited to that territory.**]**

(2) A marketing authorisation **[**F5or parallel import licence**]** granted under paragraph (1) shall contain terms approved by the licensing authority.

[F6(3) The applicant, where it is applying for—

[F7(a) a UKMA(UK) or UKMA(NI), must be established in the United Kingdom or an EEA State;**]**

(b) a UKMA(GB)—

(i) under the unfettered access route, must be established in Northern Ireland;

(ii) other than under the unfettered access route, must be established in the United Kingdom **[**F8or an EEA State**]**;

(c) a **[**F9parallel import licence**]**, must be established in the United Kingdom.**]**

[F10(3A) An application for a parallel import licence may not be made by—

(a) the holder of the marketing authorisation, within the meaning of the 2001 Directive, or the EU marketing authorisation, in respect of the relevant medicinal product to be imported; or

(b) a company which is in the same group as the holder of that marketing authorisation.**]**

(4) The application must be—

(a) made in writing;

(b) signed by or on behalf of the applicant; and

(c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.

(5) An application is treated as signed for the purposes of paragraph (4)(b) if it is signed with an electronic signature.

(6) The application and any accompanying material must be in English.

(7) The application must include a statement indicating whether the product to which the application relates should be available—

(a) only on prescription;

(b) only from a pharmacy; or

(c) on general sale.

(8) The application must include a statement indicating—

(a) whether any terms of the authorisation are proposed relating to the method of sale or supply of the product (including, in particular, any proposed restrictions affecting the circumstances of the use or promotion of the product); and

(b) if so, what terms are proposed.

[F11(9) The application must include a statement indicating whether the authorisation or licence sought is for sale or supply of the product in—

(a) the whole United Kingdom;

(b) Great Britain only; or

(c) Northern Ireland only.

(10) In this regulation "group" has the same meaning as in Part 15 of the Companies Act 2006 (see section 474(1) of that Act).**]**

Textual Amendments

F1 Words in reg. 49 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. 49 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)(a)**

F2 Reg. 49(1) substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **5** and reg. 49(1) substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **5**

F3 Words in reg. 49(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **48(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F4 Reg. 49(1A)-(1C) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **48(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 36(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F5 Words in reg. 49(2) 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. 49(2) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(b)**

F6 Reg. 49(3) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **48(4)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 36(b)**)

F7 Reg. 49(3)(a) substituted (17.5.2023) by The Human Medicines (Amendment) Regulations 2023 (S.I. 2023/437), regs. 1(1), **4(a)**

F8 Words in reg. 49(3)(b)(ii) inserted (17.5.2023) by The Human Medicines (Amendment) Regulations 2023 (S.I. 2023/437), regs. 1(1), **4(b)**

F9 Words in reg. 49(3)(c) substituted (17.5.2023) by The Human Medicines (Amendment) Regulations 2023 (S.I. 2023/437), regs. 1(1), **4(c)**

F10 Reg. 49(3A) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **48(5)**; 2020 c. 1, Sch. 5 para. 1(1)

F11 Reg. 49(9)(10) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **48(6)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 36(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 49.