STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 11

Pharmacovigilance

Periodic Safety Update Reports

Harmonisation of PSUR frequency or date of submission

193.—**[**[F1](1) Where products that are subject to different authorisations or registrations contain the same active substance or the same combination of active substances, the frequency and dates of submission may be amended and harmonised in accordance with—

(a) Article 107c(4) of the 2001 Directive, where—

(i) any of the authorisations or registrations is a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation; and

(ii) none of the authorisations or registrations is a UKMA(GB) or THR(GB); or

(b) paragraphs (2A), (3) and (4A), where—

(i) any of the authorisations or registrations is a UKMA(GB) or THR(GB); and

(ii) none of the authorisations or registrations is a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation.**]**

(2) The holder **[**[F2]of a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation**]** may, where one or more of the grounds in paragraph (3) is met, submit a request in relation to the product to the EMA—

(a) to determine an EU reference date; or

(b) to change the frequency of submission of the PSUR.

[[F3](2A) Where one or more of the grounds in paragraph (3) is met, the holder of a UKMA(GB) or THR(GB) may submit a request in writing to the licensing authority, or the licensing authority may in any event decide, to—

(a) determine a UK reference date from which submission dates are calculated in respect of products that fall under paragraph (1); or

(b) change the frequency and date of submission of the PSUR.**]**

(3) The grounds in this paragraph are—

(a) reasons relating to public health;

(b) in order to avoid duplication of the assessment; or

(c) in order to achieve international harmonisation.

(4) The second paragraph of Article 107c(6) of the 2001 Directive has effect in relation to the submission and determination of a request under paragraph (2).

[F4(4A) Where the licensing authority makes a decision under paragraph (2) following a written request from a holder of a UKMA(GB) or THR(GB), it must notify that holder in writing of its decision to approve or refuse the request.**]**

(5) Where the frequency or dates of submission of a PSUR are changed in accordance with Article 107c(4) or Article 107c(6) of the 2001 Directive **[**F5or paragraph (2A) (as the case may be)**]**, the holder must apply to vary the product's authorisation or registration to reflect the new frequency or date of submission before the end of the period of six months beginning on the day after the change is made public by the EMA **[**F6or licensing authority (as the case may be)**]**.

(6) In this regulation, "EU reference date" in relation to a product means—

(a) the date of the first marketing authorisation in the EEA of a medicinal product containing the same active substance or the same combination of active substances as that product; or

(b) if the date referred to in point (a) cannot be ascertained, the earliest of the known dates of the marketing authorisations in the EEA for a medicinal product containing the same active substance or the same combination of active substances as that product.

[F7(6A) Subject to paragraph (6B), in this regulation, "UK reference date" means a date determined by the licensing authority under paragraph (2)(a) in respect of medicinal products containing the same active substance or the same combination of active substances.

(6B) Until the licensing authority makes a decision under paragraph (2), any—

(a) Union reference date in respect of medicinal products containing the same active substance or the same combination of active substances; or

(b) date of submission and frequency of periodic safety reports in respect of such products,

published by the EMA under Article 107c(7) of the 2001 Directive, is deemed to be the UK reference date or, as the case may be, the required date or frequency of PSUR submission, in respect of those medicinal products.**]**

[F8(7) The licensing authority must publish a list of—

(a) UK reference dates it determines under paragraph (2); and

(b) the required date of submission and frequency for PSURs in respect of medicinal products containing the same active substance or the same combination of active substances.

(8) Any change to the date of submission and frequency of PSURs as a result of the application of this regulation is to take effect after a 6 month period, such period beginning with the day after the licensing authority publishes that change under paragraph (7).**]**

Textual Amendments

F1 Reg. 193(1) substituted (31.12.2020) by virtue of S.I. 2019/775, **reg. 153(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(a)**)

F2 Words in reg. 193(2) inserted (31.12.2020) by S.I. 2019/775, **reg. 153(2A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(b)**)

F3 Reg. 193(2A) inserted (31.12.2020) by S.I. 2019/775, **reg. 153(3)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F4 Reg. 193(4A) inserted (31.12.2020) by S.I. 2019/775, **reg. 153(4)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F5 Words in reg. 193(5) inserted (31.12.2020) by S.I. 2019/775, **reg. 153(5)(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(e)(i)**)

F6 Words in reg. 193(5) inserted (31.12.2020) by S.I. 2019/775, **reg. 153(5)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(e)(ii)**)

F7 Reg. 193(6A)(6B) inserted (31.12.2020) by S.I. 2019/775, **reg. 153(6)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(f)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F8 Reg. 193(7)(8) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **153(7)**; 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 193.