SCHEDULES

SCHEDULE 2

Capital fees for applications for, and variations to, marketing authorisations, licences, registrations and certificates

PART 1

General: interpretation and categories of applications and variations

Type II Complex Variation Application

23. A Type II Complex Variation Application is an application for a variation of a marketing authorisation, other than an Extended Type II Complex Variation Application, which relates to a change—

(a) in the formulation of a medicinal product comprising one or more of the following changes, other than a change to which **[**F1in the case of a UKMA(NI) or UKMA(UK), paragraph 1 (changes to active substances) or paragraph 2 (changes to strength, pharmaceutical form and route of administration) of Annex I to Commission Regulation (EC) No 1234/2008 applies or, in the case of a UKMA(GB), sub-paragraph (a) (changes to active substances) or sub-paragraph (b) (changes to strength, pharmaceutical form and route of administration) of the definition of "extension of a UK marketing authorisation" in paragraph 1 of Schedule 10A to the Human Medicines Regulations applies**]** —

(i) a change which necessitates in-vivo bioavailability studies to be performed on that product;

(ii) a change in that product's preservative system; or

(iii) a change in that product's excipients which significantly affects the pharmaceutical or the therapeutic properties of that product; or

(b) which is considered a "major variation of type II" within the meaning of **[**F2in the case of a UKMA(NI) or UKMA(UK), Article 2(3) of Commission Regulation (EC) No 1234/2008 or, in the case of a UKMA(GB), paragraph 1 of Schedule 10A to the Human Medicines Regulations**]** and which is—

(i) supported by data which comprises or includes the results of clinical trials or physicochemical, biological, microbiological or pharmacological and toxicological tests; or

(ii) accompanied by evidence relating to post-marketing experience which is information of any type described in paragraph 5.2.6 of Part I of Annex I to the 2001 Directive (clinical documentation); or

(c) in the composition, manufacture or use of a medicinal product to which—

(i) sub-paragraph (c), (e), (g), (h), (j) or (n) of the definition of complex application in paragraph 5 of this Schedule would apply where an application for a marketing authorisation is made in respect of a medicinal product; or

(ii) sub-paragraph (i) of that definition would so apply and the change is not a minor variation of type IA or a minor variation of type IB within the meaning of **[**F3in the case of a UKMA(NI) or UKMA(UK), Commission Regulation (EC) No 1234/2008 or, in the case of a UKMA(GB), paragraph 1 of Schedule 10A to the Human Medicines Regulations**]** .

Textual Amendments

F1 Words in Sch. 2 para. 23(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 7(4)(a)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(g)(iii)(aa)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F2 Words in Sch. 2 para. 23(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 7(4)(b)** (with Sch. 1 para. 11) (as amended byThe Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(g)(iii)(bb)**); 2020 c. 1, Sch. 5 para. 1(1)

F3 Words in Sch. 2 para. 23(c) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 7(4)(c)** (with Sch. 1 para. 11) (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(g)(iii)(cc)**); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Medicines (Products for Human Use) (Fees) Regulations 2016. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Sch. 2 para. 23(a) words substituted by S.I. 2019/775 Sch. 1 para. 7(4)(a) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(4)(a) amended immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(g)(iii)(aa))

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:
Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- Sch. 2 para. 35A inserted by S.I. 2023/314 reg. 24(14)
- Sch. 2 para. 27(2)(a)(i) sum substituted by S.I. 2023/314 reg. 24(5)(a)(i)
- Sch. 2 para. 27(2)(b)(i) sum substituted by S.I. 2023/314 reg. 24(5)(a)(ii)
- Sch. 2 para. 27(2)(c)(i) sum substituted by S.I. 2023/314 reg. 24(5)(a)(iii)
- Sch. 2 para. 27(2)(d)(i) sum substituted by S.I. 2023/314 reg. 24(5)(a)(iv)
- Sch. 2 para. 27(3)(a)(i) sum substituted by S.I. 2023/314 reg. 24(5)(b)
- Sch. 2 para. 28(2)(a)(i) sum substituted by S.I. 2023/314 reg. 24(6)(a)(i)
- Sch. 2 para. 28(2)(b)(i) sum substituted by S.I. 2023/314 reg. 24(6)(a)(ii)
- Sch. 2 para. 28(2)(c)(i) sum substituted by S.I. 2023/314 reg. 24(6)(a)(ii)
- Sch. 2 para. 28(3)(b)(i) sum substituted by S.I. 2023/314 reg. 24(6)(b)
- Sch. 2 para. 28(3)(c)(i) sum substituted by S.I. 2023/314 reg. 24(6)(b)
- Sch. 2 para. 28A(1)(a)-(c) sum substituted by S.I. 2023/314 reg. 24(7)(a)
- Sch. 2 para. 28A(2)(a)-(c) sum substituted by S.I. 2023/314 reg. 24(7)(b)
- Sch. 2 para. 56(c) sum substituted by S.I. 2023/314 reg. 24(27)(b)
- Sch. 2 para. 57A(a) sum substituted by S.I. 2023/314 reg. 24(29)(a)
- Sch. 2 para. 57A(b) sum substituted by S.I. 2023/314 reg. 24(29)(b)
- Sch. 2 para. 57A(c) sum substituted by S.I. 2023/314 reg. 24(29)(c)
- Sch. 2 para. 57A(d) sum substituted by S.I. 2023/314 reg. 24(29)(d)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(i)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(ii)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(iii)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(iv)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(v)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(vii)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(viii)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(ix)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(b)(i)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(b)(ii)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(b)(iii)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(b)(iv)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(b)(v)
- Sch. 4 para. 15(3) inserted by S.I. 2023/314 reg. 26(8)
- reg. 19A(1) sum substituted by S.I. 2023/314 reg. 13(a)
- reg. 19A(2)(a) sum substituted by S.I. 2023/314 reg. 13(b)
- reg. 19A(2)(b) sum substituted by S.I. 2023/314 reg. 13(c)
- reg. 19B sum substituted by S.I. 2023/314 reg. 14
- reg. 19C(2)(a) sum substituted by S.I. 2023/314 reg. 15(a)(i)
- reg. 19C(2)(b) sum substituted by S.I. 2023/314 reg. 15(a)(ii)
- reg. 19C(2)(c) sum substituted by S.I. 2023/314 reg. 15(a)(iii)

- reg. 19C(3)(a) sum substituted by S.I. 2023/314 reg. 15(b)(i)
- reg. 19C(3)(b) sum substituted by S.I. 2023/314 reg. 15(b)(ii)
- reg. 19C(3)(c) sum substituted by S.I. 2023/314 reg. 15(b)(iii)
- reg. 19E(2)(a) sum substituted by S.I. 2023/314 reg. 16(a)
- reg. 19E(2)(b) sum substituted by S.I. 2023/314 reg. 16(b)
- reg. 19EA inserted by S.I. 2023/314 reg. 17