SCHEDULES

SCHEDULE 2

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

PART 2

Capital Fees for Applications for Authorisations, Licences, Registrations and Certificates

Joint development

27.—(1) In this paragraph—

"joint development" means the development by two or more applicants for marketing authorisations relating to medicinal products—

(a) each of which contains the same new active ingredient or combination of new active ingredients but with different proprietary names and which does not require separate consideration by the Commission on Human Medicines, the Herbal Medicines Advisory Committee or the Advisory Board on the Registration of Homoeopathic Products;

(b) the development of which has been notified to the licensing authority at or before the time the application is submitted, as being a joint development undertaken by those applicants; and

(c) in respect of which applications for marketing authorisations have been received by the licensing authority within one month of each other;

"primary applicant" means—

(a) that party to a joint development who first makes an application for a marketing authorisation relating to a new active ingredient which was the subject of that joint development; or

(b) that party to a joint development who first makes an application for a marketing authorisation relating to a different dosage form or strength of that new active ingredient;

"secondary applicant" means any party to a joint development, other than the primary applicant, who makes an application for a marketing authorisation relating to the same new active ingredient as that which was the subject of the application made by the primary applicant.

(2) Unless sub-paragraph (3) applies, where a joint development relates to a medicinal product and two or more applications for marketing authorisations are submitted to the licensing authority by parties to the joint development, the fee payable under regulation 12(1)(a) is the amount payable in respect of a major application under paragraph 24 plus—

[F1(a) in respect of the first or only marketing authorisation applied for by that secondary applicant—

(i) in the case of an application relating to a medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £17,330; or

(ii) in any other case, the amount payable in respect of a complex application under paragraph 24;

(b) in respect of each additional marketing authorisation applied for by that secondary applicant which relates to a medicinal product of the same dosage form—

(i) in the case of an application relating to a medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £6,350; or

(ii) in any other case, the amount payable in respect of a standard application under paragraph 24;

(c) in respect of the first additional marketing authorisation applied for by that secondary applicant relating to that medicinal product which is of a different dosage form—

(i) in the case of an application relating to a medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £17,330; or

(ii) in any other case, the amount payable in respect of a complex application under paragraph 24;

(d) in respect of any other additional marketing authorisation applied for by that secondary applicant relating to that medicinal product which is of a different dosage form—

(i) in the case of an application relating to a medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £6,350; or

(ii) in any other case, the amount payable in respect of a standard application under paragraph 24.**]**

(3) Where a joint development relates to a medicinal product and an application for an additional marketing authorisation is submitted by both the primary applicant and the secondary applicant, both or all of which applications relate to identical dosage forms and strengths of the product—

[F2(a) where the amount payable by the primary applicant is that in respect of a complex application, the fee payable under regulation 12(1)(a) by the secondary applicant is—

(i) in the case of an application relating to a biological medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £6,350; or

(ii) in any other case, the amount payable in respect of a standard application under paragraph 24;**]**

(b) where the amount payable by the primary applicant is that in respect of a standard application, the fee payable under regulation 12(1)(a) by the secondary applicant is that in respect of a simple application under paragraph 24.

Textual Amendments

F1 Sch. 2 para. 27(2)(a)-(d) substituted for Sch. 2 para. 27(2)(a)-(c) (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 7(7)(a)** (with Sch. 1 para. 11); 2020 c. 1, Sch. 5 para. 1(1)

F2 Sch. 2 para. 27(3)(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(7)(b)** (with Sch. 1 para. 11); 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 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