
STATUTORY INSTRUMENTS

2016 No. 190

**The Medicines (Products for Human
Use) (Fees) Regulations 2016**

PART 3

**Capital Fees for Applications for Authorisations, Registrations,
Licences or Certificates and for Associated Inspections**

Fees for applications for authorisations, registrations, licences or certificates etc.

12.—(1) Unless Part 16 of these Regulations (revocations and savings) applies, the application fee for a marketing authorisation (other than a European Union marketing authorisation), a parallel import licence, a traditional herbal registration, a manufacturer's licence, a manufacturing authorisation, a wholesale dealer's licence, a clinical trial authorisation, a broker's registration or an active substance registration is—

- (a) the fee prescribed for that application in Part 2 of Schedule 2; and
 - (b) in respect of an inspection of a site made in connection with that application, the fee payable in accordance with regulations 30 and 32 to 37.
- (2) Unless regulation 32 applies, the fee in paragraph (1) is payable by the applicant.

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 :

- reg. 12(1) words inserted by [S.I. 2023/314 reg. 10](#)

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](#)