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STATUTORY INSTRUMENTS

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**2016 No. 190**

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

**PART 6**

Capital Fees for Assessment of Labels and Leaflets

**Meaning of “set of proposed changes”**

**24.** For the purposes of this Part and Part 5 of Schedule 2, a “set of proposed changes” means a number of proposed changes to the labelling or package leaflet of a medicinal product, where—

- (a) if there is more than one version of the labelling or package leaflet for that product, those changes all relate to the same version; and
- (b) those changes are submitted to the licensing authority at the same time.

### **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