
STATUTORY INSTRUMENTS

2016 No. 190

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

Signed by authority of the Secretary of State for Health.

Department of Health

George Freeman
Parliamentary Under-Secretary of State,

Simon Hamilton
Minister for Health, Social Services and Public
Safety

John Penrose
George Hollingbery
Two of the Lords Commissioners of Her
Majesty's Treasury

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. 1 para. 1 words inserted by [S.I. 2023/314 reg. 23](#)
- Sch. 2 para. 38 omitted by [S.I. 2019/775 Sch. 1 para. 7\(9\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(9) substituted immediately before IP completion day by [S.I. 2020/1488, reg. 1, Sch. 2 para. 188\(g\)\(vii\)](#))
- Sch. 2 para. 38(4) substituted by [S.I. 2019/775 Sch. 1 para. 7\(9\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(9) substituted immediately before IP completion day by [S.I. 2020/1488, reg. 1, Sch. 2 para. 188\(g\)\(vii\)](#))
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(a\)\(i\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(a\)\(ii\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(a\)\(iii\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(a\)\(iv\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(a\)\(v\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(a\)\(vi\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(b\)\(i\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(b\)\(ii\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(b\)\(iii\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(b\)\(iv\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(b\)\(v\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(c\)\(i\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(c\)\(ii\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(c\)\(iii\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(c\)\(iv\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(c\)\(v\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(d\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(e\)\(i\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(e\)\(ii\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(e\)\(iii\)](#)
- Sch. 2 para. 24(5) sum substituted by [S.I. 2023/314 reg. 24\(3\)\(f\)](#)
- Sch. 2 para. 25(1)(a) sum substituted by [S.I. 2023/314 reg. 24\(4\)\(a\)](#)
- Sch. 2 para. 25(1)(b) sum substituted by [S.I. 2023/314 reg. 24\(4\)\(b\)](#)
- Sch. 2 para. 28(4)(b) sum substituted by [S.I. 2023/314 reg. 24\(6\)\(c\)](#)
- Sch. 2 para. 30(1)(a) sum substituted by [S.I. 2023/314 reg. 24\(8\)\(a\)](#)
- Sch. 2 para. 30(1)(b) sum substituted by [S.I. 2023/314 reg. 24\(8\)\(b\)](#)
- Sch. 2 para. 30(1)(c) sum substituted by [S.I. 2023/314 reg. 24\(8\)\(c\)](#)
- Sch. 2 para. 31(1) sum substituted by [S.I. 2023/314 reg. 24\(9\)\(a\)](#)
- Sch. 2 para. 31(2) sum substituted by [S.I. 2023/314 reg. 24\(9\)\(b\)](#)
- Sch. 2 para. 31(5) sum substituted by [S.I. 2023/314 reg. 24\(9\)\(c\)](#)
- Sch. 2 para. 32(1) sum substituted by [S.I. 2023/314 reg. 24\(10\)\(a\)](#)
- Sch. 2 para. 32(2) sum substituted by [S.I. 2023/314 reg. 24\(10\)\(b\)](#)
- Sch. 2 para. 33(1)(a) sum substituted by [S.I. 2023/314 reg. 24\(11\)\(a\)\(i\)](#)
- Sch. 2 para. 33(1)(b) sum substituted by [S.I. 2023/314 reg. 24\(11\)\(a\)\(ii\)](#)
- Sch. 2 para. 33(2) sum substituted by [S.I. 2023/314 reg. 24\(11\)\(b\)](#)
- Sch. 2 para. 34(a) sum substituted by [S.I. 2023/314 reg. 24\(12\)\(a\)](#)
- Sch. 2 para. 34(b) sum substituted by [S.I. 2023/314 reg. 24\(12\)\(b\)](#)
- Sch. 2 para. 35(1) sum substituted by [S.I. 2023/314 reg. 24\(13\)](#)
- Sch. 2 para. 38 Table 1 sum substituted by [S.I. 2023/314 reg. 24\(15\)\(a\)\(i\)](#)
- Sch. 2 para. 38 Table 1 sum substituted by [S.I. 2023/314 reg. 24\(15\)\(a\)\(ii\)](#)
- Sch. 2 para. 38 Table 1 sum substituted by [S.I. 2023/314 reg. 24\(15\)\(a\)\(iii\)](#)
- Sch. 2 para. 38 Table 1 sum substituted by [S.I. 2023/314 reg. 24\(15\)\(a\)\(iv\)](#)
- Sch. 2 para. 38 Table 1 sum substituted by [S.I. 2023/314 reg. 24\(15\)\(a\)\(v\)](#)

- Sch. 2 para. 38 Table 1 sum substituted by S.I. 2023/314 reg. 24(15)(a)(vi)
- Sch. 2 para. 38 Table 1 sum substituted by S.I. 2023/314 reg. 24(15)(a)(vii)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(i)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(ii)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(iii)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(iv)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(v)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(vi)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(vii)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(viii)
- Sch. 2 para. 40(1) sum substituted by S.I. 2023/314 reg. 24(16)
- Sch. 2 para. 42(1)(a) sum substituted by S.I. 2023/314 reg. 24(17)(a)
- Sch. 2 para. 42(1)(b) sum substituted by S.I. 2023/314 reg. 24(17)(b)
- Sch. 2 para. 42(1)(c) sum substituted by S.I. 2023/314 reg. 24(17)(c)
- Sch. 2 para. 43(a) sum substituted by S.I. 2023/314 reg. 24(18)(a)
- Sch. 2 para. 43(b) sum substituted by S.I. 2023/314 reg. 24(18)(b)
- Sch. 2 para. 44 sum substituted by S.I. 2023/314 reg. 24(19)
- Sch. 2 para. 45 sum substituted by S.I. 2023/314 reg. 24(20)
- Sch. 2 para. 46 sum substituted by S.I. 2023/314 reg. 24(21)
- Sch. 2 para. 47 sum substituted by S.I. 2023/314 reg. 24(22)
- Sch. 2 para. 48 sum substituted by S.I. 2023/314 reg. 24(23)
- Sch. 2 para. 49(1) sum substituted by S.I. 2023/314 reg. 24(24)
- Sch. 2 para. 53(a)(ii) sum substituted by S.I. 2023/314 reg. 24(25)
- Sch. 2 para. 54(1)(a) sum substituted by S.I. 2023/314 reg. 24(26)(a)(i)
- Sch. 2 para. 54(1)(b) sum substituted by S.I. 2023/314 reg. 24(26)(a)(ii)
- Sch. 2 para. 54(2) sum substituted by S.I. 2023/314 reg. 24(26)(b)
- Sch. 2 para. 56(a) sum substituted by S.I. 2023/314 reg. 24(27)(a)
- Sch. 2 para. 56(b) sum substituted by S.I. 2023/314 reg. 24(27)(a)
- Sch. 2 para. 57(2)(a)(i) sum substituted by S.I. 2023/314 reg. 24(28)(a)
- Sch. 2 para. 57(2)(a)(ii) sum substituted by S.I. 2023/314 reg. 24(28)(a)
- Sch. 2 para. 57(2)(b)(i) sum substituted by S.I. 2023/314 reg. 24(28)(b)
- Sch. 2 para. 57(2)(b)(ii) sum substituted by S.I. 2023/314 reg. 24(28)(c)
- Sch. 2 para. 1 words inserted by S.I. 2023/314 reg. 24(2)(a)
- Sch. 2 para. 1 words inserted by S.I. 2023/314 reg. 24(2)(b)
- Sch. 2 para. 4(a) words substituted by S.I. 2019/775 Sch. 1 para. 7(2) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(2) substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(g) (i))
- Sch. 2 para. 22(1) words substituted by S.I. 2019/775 Sch. 1 para. 7(3)(a) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(3)(a) amended immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(g) (ii)(aa))
- Sch. 2 para. 22(2)(f) words substituted by S.I. 2019/775 Sch. 1 para. 7(3)(b) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(3)(b) amended immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(g) (ii)(bb))
- Sch. 2 para. 22(3) words substituted by S.I. 2019/775 Sch. 1 para. 7(3)(c) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(3)(c) amended immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(g) (ii)(cc))
- 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))
- Sch. 3 para. 2(1)(a) sum substituted by S.I. 2023/314 reg. 25(2)(a)
- Sch. 3 para. 2(1)(b) sum substituted by S.I. 2023/314 reg. 25(2)(b)
- Sch. 3 para. 5(a) sum substituted by S.I. 2023/314 reg. 25(3)(a)
- Sch. 3 para. 5(b) sum substituted by S.I. 2023/314 reg. 25(3)(a)

- Sch. 3 para. 5(b) sum substituted by S.I. 2023/314 reg. 25(3)(b)
- Sch. 3 para. 6(2)(a) sum substituted by S.I. 2023/314 reg. 25(4)(a)
- Sch. 3 para. 6(2)(b) sum substituted by S.I. 2023/314 reg. 25(4)(b)
- Sch. 3 para. 6(2)(c) sum substituted by S.I. 2023/314 reg. 25(4)(b)
- Sch. 3 para. 7(3) sum substituted by S.I. 2023/314 reg. 25(5)
- Sch. 3 para. 8(1)(a) sum substituted by S.I. 2023/314 reg. 25(6)(a)(i)
- Sch. 3 para. 8(1)(b) sum substituted by S.I. 2023/314 reg. 25(6)(a)(i)
- Sch. 3 para. 8(1)(b) sum substituted by S.I. 2023/314 reg. 25(6)(a)(ii)
- Sch. 3 para. 8(3) sum substituted by S.I. 2023/314 reg. 25(6)(b)
- Sch. 3 para. 9(1)(a)(i) sum substituted by S.I. 2023/314 reg. 25(7)(a)(i)
- Sch. 3 para. 9(1)(a)(ii) sum substituted by S.I. 2023/314 reg. 25(7)(a)(i)
- Sch. 3 para. 9(1)(a)(ii) sum substituted by S.I. 2023/314 reg. 25(7)(a)(ii)
- Sch. 3 para. 9(1)(b)(i) sum substituted by S.I. 2023/314 reg. 25(7)(b)(i)
- Sch. 3 para. 9(1)(b)(ii) sum substituted by S.I. 2023/314 reg. 25(7)(b)(i)
- Sch. 3 para. 9(1)(b)(ii) sum substituted by S.I. 2023/314 reg. 25(7)(b)(ii)
- Sch. 3 para. 9(3)(a) sum substituted by S.I. 2023/314 reg. 25(7)(c)(i)
- Sch. 3 para. 9(3)(b) sum substituted by S.I. 2023/314 reg. 25(7)(c)(ii)
- Sch. 3 para. 10(a) sum substituted by S.I. 2023/314 reg. 25(8)(a)
- Sch. 3 para. 10(b) sum substituted by S.I. 2023/314 reg. 25(8)(b)
- Sch. 4 para. 15(1) substituted by S.I. 2023/314 reg. 26(7)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(a)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(b)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(c)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(d)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(e)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(f)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(g)
- Sch. 4 para. 6 sum substituted by S.I. 2023/314 reg. 26(3)
- Sch. 4 para. 7(a) sum substituted by S.I. 2023/314 reg. 26(4)(a)
- Sch. 4 para. 7(b) sum substituted by S.I. 2023/314 reg. 26(4)(b)
- Sch. 4 para. 11(1) sum substituted by S.I. 2023/314 reg. 26(5)
- Sch. 4 para. 11(2) sum substituted by S.I. 2023/314 reg. 26(5)
- Sch. 4 para. 12(1) sum substituted by S.I. 2023/314 reg. 26(6)(a)
- Sch. 4 para. 12(2) sum substituted by S.I. 2023/314 reg. 26(6)(b)
- Sch. 4 para. 16 sum substituted by S.I. 2023/314 reg. 26(9)
- reg. 4(a) sum substituted by S.I. 2023/314 reg. 3(a)
- reg. 4(b) sum substituted by S.I. 2023/314 reg. 3(b)
- reg. 4(c) sum substituted by S.I. 2023/314 reg. 3(c)
- reg. 4(d) sum substituted by S.I. 2023/314 reg. 3(d)
- reg. 4(e) sum substituted by S.I. 2023/314 reg. 3(e)
- reg. 5(1)(a) sum substituted by S.I. 2023/314 reg. 4(a)
- reg. 5(1)(b) sum substituted by S.I. 2023/314 reg. 4(b)
- reg. 6 sum substituted by S.I. 2023/314 reg. 5
- reg. 7(1)(a) sum substituted by S.I. 2023/314 reg. 6(a)
- reg. 7(1)(b) sum substituted by S.I. 2023/314 reg. 6(b)
- reg. 8 sum substituted by S.I. 2023/314 reg. 7
- reg. 9 sum substituted by S.I. 2023/314 reg. 8
- reg. 10(1) sum substituted by S.I. 2023/314 reg. 9
- reg. 12(1) words inserted by S.I. 2023/314 reg. 10
- reg. 14 sum substituted by S.I. 2023/314 reg. 11
- reg. 15(1)(a) sum substituted by S.I. 2023/314 reg. 12(a)
- reg. 15(1)(b) sum substituted by S.I. 2023/314 reg. 12(b)
- reg. 15(3) sum substituted by S.I. 2023/314 reg. 12(c)
- reg. 21(1) sum substituted by S.I. 2023/314 reg. 18
- reg. 22(1) sum substituted by S.I. 2023/314 reg. 19
- reg. 23(3)(b)(i) substituted by S.I. 2019/775 Sch. 1 para. 3(2) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 3(2)-(4) substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(d))

- reg. 27(1) sum substituted by S.I. 2023/314 reg. 20(a)
- reg. 27(3) sum substituted by S.I. 2023/314 reg. 20(b)
- reg. 41(1) sum substituted by S.I. 2023/314 reg. 21(a)
- reg. 41(2) sum substituted by S.I. 2023/314 reg. 21(b)
- reg. 42(1) sum substituted by S.I. 2023/314 reg. 22

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