
STATUTORY INSTRUMENTS

2023 No. 314

**The Medicines (Products for Human Use)
(Fees) (Amendment) Regulations 2023**

Amendment of Schedule 2

24.—(1) Schedule 2 (capital fees for applications for, and variations to, marketing authorisations, licences, registrations and certificates) is amended as follows.

(2) In paragraph 1(1) (interpretation)—

(a) after the definition of “active ingredient from a new source”, insert—

““*EAMS scientific opinion*” has the meaning given in regulation 8(1) of the Human Medicines Regulations;”, and

(b) after the definition of “Phase IV trial”, insert—

““*Promising Innovative Medicines designation*” means a designation issued by the licensing authority under the Early Access to Medicines Scheme in accordance with regulation 167C(2)(a) of the Human Medicines Regulations;”.

(3) In paragraph 24(5)(2) (marketing authorisations), in the second column (fee payable) of the table (fees for marketing authorisation applications)—

(a) in item 1 (major application)—

- (i) in entry (a), for “£29,732” substitute “£32,705”,
- (ii) in entries (b) to (d), for “£62,421” substitute “£68,663”,
- (iii) in entry (e), for “£18,437” substitute “£20,281”,
- (iv) in entry (f), for “£62,421” substitute “£68,663”,
- (v) in entry (g), for “£18,437” substitute “£20,281”,
- (vi) in entry (h), for “£92,753” substitute “£102,028”,

(b) in item 2 (complex application)—

- (i) in entries (a) to (c), for “£17,330” substitute “£19,063”,
- (ii) in entry (d), for “£10,443” substitute “£11,487”,
- (iii) in entry (e), for “£17,330” substitute “£19,063”,
- (iv) in entry (f), for “£10,443” substitute “£11,487”,
- (v) in entry (g), for “£25,643” substitute “£28,207”,

(c) in item 3 (standard application)—

- (i) in entries (a) to (c), for “£6,350” substitute “£6,985”,
- (ii) in entry (d), for “£5,783” substitute “£6,361”,
- (iii) in entry (e), for “£6,350” substitute “£6,985”,

(1) Paragraph 1 of Schedule 2 was amended but the amendment is not relevant to these Regulations.
(2) Table inserted by [S.I. 2019/775](#) and amended by [S.I. 2020/1488](#).

- (iv) in entry (f), for “£5,783” substitute “£6,361”,
- (v) in entry (g), for “£9,402” substitute “£10,342”,
- (d) in item 4 (simple application), in entries (a) to (f), for “£2,564” substitute “£2,820”,
- (e) in item 5 (parallel import licence applications)—
 - (i) in entry (a), for “£1,792” substitute “£1,971”,
 - (ii) in entry (b), for “£6,663” substitute “£8,722”,
 - (iii) in entry (c), for “£18,180” substitute “£19,998”, and
- (f) in item 6 (change of ownership application), for “£442” substitute “£486”.
- (4) In paragraph 25(1) (fees where application includes reclassification)—
 - (a) in sub-paragraph (a), for “£11,992” substitute “£33,003”, and
 - (b) in sub-paragraph (b), for “£8,162” substitute “£8,978”.
- (5) In paragraph 27(3) (joint development)—
 - (a) in sub-paragraph (2)—
 - (i) in paragraph (a)(i), for “£17,330” substitute “£19,063”,
 - (ii) in paragraph (b)(i), for “£6,350” substitute “£6,985”,
 - (iii) in paragraph (c)(i), for “£17,330” substitute “£19,063”,
 - (iv) in paragraph (d)(i), for “£6,350” substitute “£6,985”, and
 - (b) in sub-paragraph (3)(a)(i), for “£6,350” substitute “£6,985”.
- (6) In paragraph 28(4) (application for multiple authorisations)—
 - (a) in sub-paragraph (2)—
 - (i) in paragraph (a)(i), for “£17,330” substitute “£19,063”,
 - (ii) in paragraphs (b)(i) and (c)(i), for “£6,350” substitute “£6,985”,
 - (b) in sub-paragraph (3), in paragraphs (b)(i) and (c)(i), for “£6,350” substitute “£6,985”, and
 - (c) in sub-paragraph (4)(b), for “£734” substitute “£1,308”.
- (7) In paragraph 28A(5) (application by pre-assessment of modules)—
 - (a) in sub-paragraphs (1)(a) to (c), for each “£23,188.25” substitute “£25,507”, and
 - (b) in sub-paragraphs (2)(a) to (c), for each “£4,332.50” substitute “£4,766”.
- (8) In paragraph 30(1) (manufacturer’s licences and authorisations)—
 - (a) in paragraph (a), for “£183” substitute “£201”,
 - (b) in paragraph (b), for “£344” substitute “£378”, and
 - (c) in paragraph (c), for “£3,143” substitute “£3,457”.
- (9) In paragraph 31 (wholesale dealer’s licences)—
 - (a) in sub-paragraph (1), for “£1,803” substitute “£1,983”,
 - (b) in sub-paragraph (2), for “£902” substitute “£992”, and
 - (c) in sub-paragraph (5), for “£399” substitute “£439”.
- (10) In paragraph 32 (broker’s registrations)—
 - (a) in sub-paragraph (1), for “£1,803” substitute “£1,983”, and

(3) Amended by [S.I. 2019/775](#)(as amended by [S.I. 2020/1488](#)).

(4) Amended by [S.I. 2019/775](#)(as amended by [S.I. 2020/1488](#)).

(5) Inserted by [S.I. 2019/775](#) (as amended by [S.I. 2020/1488](#)).

- (b) in sub-paragraph (2), for “£399” substitute “£439”.
- (11) In paragraph 33 (active substance registrations)—
- (a) in sub-paragraph (1)—
- (i) in paragraph (a), for “£3,143” substitute “£3,457”,
- (ii) in paragraph (b), for “£1,803” substitute “£1,983”, and
- (b) in sub-paragraph (2), for “£399” substitute “£439”.
- (12) In paragraph 34 (clinical trial authorisations)—
- (a) in sub-paragraph (a), for “£3,060” substitute “£3,366”, and
- (b) in sub-paragraph (b), for “£225” substitute “£248”.
- (13) In paragraph 35(1) (traditional herbal registrations), in the second column (fee payable) of the table (fee for application for traditional herbal registration), in entry 5 (change of ownership application), for “£442” substitute “£486”.
- (14) After paragraph 35, insert—

“Early Access to Medicines Scheme fees

35A. The fee payable under regulation 12(1)(a) in connection with an application submitted under the Early Access to Medicines Scheme of a kind described in column 1 of the following table is the fee specified in the corresponding entry in column 2 of that table.

Fees for Early Access to Medicines Scheme applications

<i>Column 1</i>	<i>Column 2</i>
<i>Kind of Application</i>	<i>Fee payable</i>
1. Promising Innovative Medicine (PIM) designation	£3,986
2. EAMS scientific opinion for new medicinal products	£25,643
3. Renewal of an EAMS scientific opinion for new chemical or biological medicinal products	£12,821
4. EAMS scientific opinion for new indications	£8,309
5. Renewal of an EAMS scientific opinion for new indications	£4,154”

- (15) In paragraph 38 (marketing authorisations)—
- (a) in the second column (fee payable) of Table 1(6) (fees for applications for variations of marketing authorisations falling within the scope of Chapter II of [Commission Regulation \(EC\) No 1234/2008](#))—
- (i) in entries 1(a) and 1(b), for “£277” substitute “£344”,
- (ii) in entry 1(c), for “£2,493” substitute “£2,742”,
- (iii) in entry 1(d), for “£7,693” substitute “£8,462”,
- (iv) in entry 2(a), for “£277” substitute “£344”,
- (v) in entry 2(b), for “£496” substitute “£1,255”,
- (vi) in entry 2(c), for “£2,703” substitute “£2,973”,
- (vii) in entry 2(d), for “£7,883” substitute “£8,671”,

(6) Table substituted by [S.I. 2019/775](#)(as amended by [S.I. 2020/1488](#)).

- (b) in the second column (fee payable) in Table 2 (fees for applications for variations of marketing authorisations falling within the scope of Chapter IIa of [Commission Regulation \(EC\) No 1234/2008](#) and of marketing authorisations in force in Great Britain)—
- (i) in entry 1, for “£277” substitute “£344”,
 - (ii) in entry 2, for “£734” substitute “£1,308”,
 - (iii) in entry 3, for “£8,309” substitute “£9,140”,
 - (iv) in entry 4, for “£25,643” substitute “£33,003”,
 - (v) in entry 5, for “£622” substitute “£684”,
 - (vi) in entry 6, for “£1,652” substitute “£1,817”,
 - (vii) in entry 7, for “£9,010” substitute “£9,911”,
 - (viii) in entry 8, for “£26,276” substitute “£28,904”, and
- (c) in the second column (fee payable) in Table 3 (fees for reclassification variation applications)—
- (i) in entry (a), for “£11,992” substitute “£33,003”,
 - (ii) in entry (b), for “£8,162” substitute “£8,978”.
- (16) In paragraph 40(1) (reclassification of marketing authorisations), for “£734” substitute “£1,308”.
- (17) In paragraph 42(1) (variation of parallel import licence)—
- (a) in paragraph (a), for “£11,992” substitute “£33,003”,
 - (b) in paragraph (b), for “£8,162” substitute “£8,978”, and
 - (c) in paragraph (c), for “£357” substitute “£393”.
- (18) In paragraph 43 (manufacturer’s authorisations and licences)—
- (a) in sub-paragraph (a), for “£257” substitute “£283”, and
 - (b) in sub-paragraph (b), for “£514” substitute “£565”.
- (19) In paragraph 44 (variation of manufacturer’s authorisations and licences), for “£257” substitute “£283”.
- (20) In paragraph 45 (wholesale dealer’s licences), for “£486” substitute “£535”.
- (21) In paragraph 46 (variation of wholesale dealer’s licence), for “£257” substitute “£283”.
- (22) In paragraph 47 (variation of a broker’s registration), for “£257” substitute “£283”.
- (23) In paragraph 48 (variation of an active substance registration), for “£257” substitute “£283”.
- (24) In paragraph 49(1) (clinical trial authorisations) for “£225” substitute “£248”.
- (25) In paragraph 53(a)(ii) (multiple reclassification variation applications), for “£734” substitute “£1,308”.
- (26) In paragraph 54 (a set of changes)—
- (a) in sub-paragraph (1)—
 - (i) in paragraph (a), for “£518” substitute “£570”,
 - (ii) in paragraph (b), for “£328” substitute “£361”, and
 - (b) in sub-paragraph (2), for “£186” substitute “£205”.
- (27) In paragraph 56(7) (renewal of a marketing authorisation)—
- (a) in sub-paragraphs (a) and (b), for “£747” substitute “£822”, and

- (b) in sub-paragraph (c), for “£9,682” substitute “£10,650”.
- (28) In paragraph 57(2)(8) (renewal of multiple marketing authorisations)—
- (a) in sub-paragraphs (a)(i) and (a)(ii), for “£747” substitute “£822”,
 - (b) in sub-paragraph (b)(i), for “£9,682” substitute “£10,650”, and
 - (c) in sub-paragraph (b)(ii), for “£747” substitute “£822”.
- (29) In paragraph 57A(9) (capital fee for conducting a major safety review)—
- (a) in sub-paragraph (a), for “£51,286” substitute “£56,415”,
 - (b) in sub-paragraph (b), for “£59,595” substitute “£65,555”,
 - (c) in sub-paragraph (c), for “£67,904” substitute “£74,694”, and
 - (d) in sub-paragraph (d), for “£76,213” substitute “£83,834”.
- (30) In paragraph 57B(4)(10)—
- (a) in the second column (fee payable where the licensing authority carries out a full assessment) of the table (fees for testing of samples)—
 - (i) in entry 1(a), for “£180” substitute “£198”,
 - (ii) in entry 1(b), for “£215” substitute “£237”,
 - (iii) in entry 1(c), for “£230” substitute “£253”,
 - (iv) in entry 2, for “£1,660” substitute “£1,826”,
 - (v) in entry 3, for “£1,910” substitute “£2,101”,
 - (vi) in entry 4, for “£2,340” substitute “£2,574”,
 - (vii) in entry 5, for “£3,690” substitute “£4,059”,
 - (viii) in entry 6, for “£6,410” substitute “£7,051”,
 - (ix) in entry 7, for “£10,350” substitute “£11,385”, and
 - (b) in the third column (fee payable where the licensing authority carries out a paper-based assessment) of the table—
 - (i) in entries 1(a), (b) and (c), for “£90” substitute “£99”,
 - (ii) in entries 2 and 3, for “£305” substitute “£367”,
 - (iii) in entry 4, for “£305” substitute “£992”,
 - (iv) in entry 5, for “£677” substitute “£992”,
 - (v) in entries 6 and 7, for “£677” substitute “£1,849”.

(8) Amended by [S.I. 2019/775](#)(as amended by [S.I. 2020/1488](#)).

(9) Inserted by [S.I. 2019/775](#) (as amended by [S.I. 2020/1488](#)).

(10) Amended by [S.I. 2019/775](#) (as amended by [S.I. 2020/1488](#)).