STATUTORY INSTRUMENTS

2025 No. 317

MEDICINES

FEES AND CHARGES

The Medicines (Products for Human Use) (Fees) (Amendment) Regulations 2025

Made - - - - at 10:02 a.m. on 11th March 2025

Laid before Parliament at 4:00 p.m. on 11th March 2025

Laid before the Northern Ireland Assembly at 4:00 p.m. on 11th March 2025

Coming into force - - 1st April 2025

The Secretary of State in relation to England and Wales and Scotland, and the Department of Health in Northern Ireland and the Secretary of State acting jointly in relation to Northern Ireland, make these Regulations in exercise of the powers conferred by section 2(1), 6(1)(a) and 43(2) of the Medicines and Medical Devices Act 2021(**a**).

The Secretary of State and the Department of Health in Northern Ireland have carried out a public consultation in accordance with section 45(1) of that Act.

In accordance with section 2(2) to (4) of that Act, the Secretary of State's and the Department of Health in Northern Ireland's overarching objective in making these Regulations is safeguarding public health, and the Secretary of State and the Department of Health in Northern Ireland have had regard to the matters specified in section 2(3) of that Act and consider that, where these Regulations may have an impact on the safety of human medicines, the benefits of making these Regulations outweigh the risks.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Medicines (Products for Human Use) (Fees) (Amendment) Regulations 2025.

(2) These Regulations come into force on 1st April 2025.

(3) These Regulations extend to England and Wales, Scotland and Northern Ireland.

(**a**) 2021 c. 3. The powers in section 2(1) of the Medicines and Medical Devices Act 2021, and in the provisions that relate to it, are exerciseable by the "appropriate authority". See section 2(6) of that Act, which contains the definition of "appropriate authority" that is relevant to the powers being exercised. See section 9 of that Act for the definition of "law relating to human medicines" for the purposes of section 2(1) of that Act, and section 6(4) of that Act for the definition of "human medicines provision" for the purposes of section 6(1)(a) of that Act.

Amendment of the Medicines (Products for Human Use) (Fees) Regulations 2016

2. The Medicines (Products for Human Use) (Fees) Regulations 2016(**a**) are amended in accordance with regulations 3 to 31.

New regulation 3A

3. After regulation 3 (interpretation of Part 2), insert—

"Fee for scientific or other advice

3A.—(1) Unless regulation 5 applies, the fee specified in paragraph (2) is payable by a person with whom the licensing authority holds a meeting in order to provide scientific or other advice relating to a medicinal product.

(2) The fee payable by a person in relation to a meeting referred to in paragraph (1) is—

(a) £17,516, if the advice provided at that meeting is on a matter of high complexity;

(b) £13,137, if the advice provided at that meeting is on a matter of medium complexity;

(c) £8,758, if the advice provided at that meeting is on a matter of low complexity;

(d) £986, if the advice provided at that meeting is on a matter of simple complexity.

(3) In paragraph (2), a matter is of—

(a) high complexity if it requires more than twelve assessor days;

(b) medium complexity if it requires more than seven, but not more than twelve, assessor days;

(c) low complexity if it requires more than three, but not more than seven, assessor days;

(d) simple complexity if it requires not more than three assessor days.

(4) If the person paying the fee in accordance with paragraph (1) consents, the licensing authority may provide any advice in writing instead of at a meeting.

(5) In this regulation—

"*assessor day*" means—

(a) in the case of an assessor who is a member of the senior civil service, one assessor working for one day;

(b) in the case of an assessor who is not a member of the senior civil service, one assessor working for two days.

"*medicinal product*", in paragraph (e) of the definition of scientific or other advice in this regulation, includes a substance incorporated in a device which, if used separately, may be considered to be a medicinal product as defined in Article 1(2) of the 2001 Directive;

"*scientific or other advice*" includes—

(a) scientific advice on an application for an EU marketing authorisation, or an application for the variation of an EU marketing authorisation, in relation to a medicinal product;

(b) advice before the publication of advertising of a medicinal product by the holder of a marketing authorisation for that product on whether that

(**a**) S.I. 2016/190; relevant amending instruments are S.I. 2019/775 (as amended by S.I. 2020/1448) and S.I. 2023/314.

advertising conforms to the requirements of the Human Medicines Regulations;

(c) pharmacovigilance advice;

(d) regulatory advice;

(e) advice in relation to—

(i) scientific or regulatory issues relating to the development of a medicinal product or a type of medicinal product;

(ii) the design of pharmaceutical or pre-clinical tests, or clinical trials, for a medicinal product or a type of medicinal product;

(iii) the management of risk in relation to a medicinal product or a type of medicinal product which is under development, or is being marketed;

(iv) other scientific or regulatory issues relating to a medicinal product or a type of medicinal product after an EU marketing authorisation has been granted for that product or a product of that type.".

Omission of regulation 4

4. Omit regulation 4 (fee for scientific advice: application for, or variation to, EU marketing authorisation)(**a**).

Amendment of regulation 5

5. In regulation 5(1) (fee for scientific advice: classification of a medicinal product)(**b**)—

(a) in sub-paragraph (a), for "£3,039" substitute "£8,758";

(b) in sub-paragraph (b), for "£3,986" substitute "£8,758".

Omission of regulation 6

6. Omit regulation 6 (fee for advertising advice)(**c**).

Omission of regulation 7

7. Omit regulation 7 (fee for pharmacovigilance advice)(**d**).

Amendment of regulation 8

8. In regulation 8 (fee for advice on labelling or leaflets)(**e**), for "£2,421" substitute "£3,757".

Omission of regulation 9

9. Omit regulation 9 (fee for regulatory advice)(**f**).

(**a**) Amended by S.I. 2023/314.
(**b**) Amended by S.I. 2023/314.
(**c**) Amended by S.I. 2023/314.
(**d**) Amended by S.I. 2023/314.
(**e**) Amended by S.I. 2023/314.
(**f**) Amended by S.I. 2023/314.

Omission of regulation 10

10. Omit regulation 10 (fee for advice for other purposes)(**a**).

Amendment of regulation 10A

11. In regulation 10A(1) (waiver for advice given to small and medium companies)(**b**), for "4 to 10" substitute "3A to 8".

Amendment of regulation 11

12. In regulation 11 (time for payment of fees under regulations 4 to 10), for "4 to 10", in each place it occurs (including the heading to the regulation), substitute "3A to 8".

Amendment of regulation 14

13. In regulation 14 (fee for applications for additional copy certificates)(**c**), for "£75" substitute "£82".

Amendment of regulation 15

14. In regulation 15 (fees for applications for certificates and copy certificates by exporters of medicinal products)(**d**)—

(a) in paragraph (1)(a), for "£167" substitute "£182";

(b) in paragraph (1)(b), for "£75" substitute "£82".

Amendment of regulation 19A

15. In regulation 19A (fees for certification of plasma master files)(**e**)—

(a) in paragraph (1), for "£9,140" substitute "£11,126";

(b) in paragraph (2)(a), for "£344" substitute "£419";

(c) in paragraph (2)(b), for "£1,308" substitute "£1,593".

Amendment of regulation 19B

16. In regulation 19B (fee for certification of vaccine antigen master files)(**f**), for "£9,140" substitute "£11,126".

Amendment of regulation 19C

17. In regulation 19C (fees for assessment of post-authorisation safety studies)(**g**) for "£9,140", in both places it occurs, substitute "£9,949".

Amendment of regulation 19E

18. In regulation 19E(2) (fee for assessment of periodic safety update reports)(**h**)—

(a) in sub-paragraph (a), for "£979" substitute "£1,066";

(**a**) Amended by S.I. 2021/905 and 2023/314.
(**b**) Inserted by S.I. 2019/775 (as amended by S.I. 2020/1488).
(**c**) Amended by S.I. 2023/314.
(**d**) Amended by S.I. 2023/314.
(**e**) Inserted by S.I. 2019/775 and amended by S.I. 2023/314.
(**f**) Inserted by S.I. 2019/775 and amended by S.I. 2023/314.
(**g**) Inserted by S.I. 2019/775 (as amended by S.I. 2020/1488) and amended by S.I. 2023/314.
(**h**) Inserted by S.I. 2019/775 and amended by S.I. 2023/314.

(b) in sub-paragraph (b), for "£490" substitute "£534".

Amendment of regulation 19EA

19. In regulation 19EA (fee for assessment of clinical trial annual safety reports)(**a**), for "£248" substitute "£343".

Amendment of regulation 21

20. In regulation 21(1) (fees for notification of changes and reports for broker's registrations)(**b**), for "£283" substitute "£345".

Amendment of regulation 22

21. In regulation 22(1) (fees for notification of changes and compliance reports for active substance registrations)(**c**), for "£283" substitute "£309".

Amendment of regulation 27

22. In regulation 27(1) (fees for renewals of certain manufacturer's licences)(**d**), for "£196" substitute "£214".

Amendment of regulation 41

23. In regulation 41 (fees for applications for membership and certificates)(**e**)—

(a) in paragraph (1), for "£129" substitute "£141";

(b) in paragraph (2), for "£68" substitute "£75".

Amendment of regulation 42

24. In regulation 42(1) (fee for a review upon oral representations or a person appointed hearing)(**f**), for "£11,000" substitute "£11,974".

Amendment of regulation 44

25. In regulation 44(1) (interpretation), in the definition of "standard variation"—

(a) in sub-paragraph (o), at the end, omit "or";

(b) in sub-paragraph (p), for "authorisation." substitute "authorisation; or";

(c) after sub-paragraph (p), insert—

"(q) a change to any packaging of the product, including the container or other form of packaging immediately in contact with the medicinal product, any packaging into which the container or other form of packaging immediately in contact with the product is placed, or to a leaflet that accompanies the product and contains information for the user of the product.".

(**a**) Inserted by S.I. 2023/314.
(**b**) Amended by S.I. 2023/314.
(**c**) Amended by S.I. 2023/314.
(**d**) Amended by S.I. 2023/314.
(**e**) Amended by S.I. 2023/314.
(**f**) Amended by S.I. 2023/314.

Amendment of regulation 47

26. In regulation 47 (fees for variations of certificates)—

(a) in paragraph (1)(a)—

(i) in paragraph (i), for "£123" substitute "£149";

(ii) in paragraph (ii), for "£62" substitute "£75";

(b) in paragraph (1)(b), for "£123" substitute "£149";

(c) in paragraph (2)(a)—

(i) in paragraph (i), for "£243" substitute "£296";

(ii) in paragraph (ii), for "£243" substitute "£296";

(iii) in paragraph (iii), for "£123" substitute "£149";

(iv) in paragraph (iv), for "£62" substitute "£75";

(d) in paragraph (2)(b), for "£243" substitute "£296".

Amendment of Schedule 2

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

(2) In paragraph 21 (standard variation application for a homoeopathic medicinal product)—

(a) in sub-paragraph (o), at the end, omit "or";

(b) in sub-paragraph (p), for "Directive." substitute "Directive; or";

(c) after sub-paragraph (p), insert—

"(q) a change to any packaging of the product, including the container or other form of packaging immediately in contact with the medicinal product, any packaging into which the container or other form of packaging immediately in contact with the product is placed, or to a leaflet that accompanies the product and contains information for the user of the product.".

(3) In paragraph 24(5) (marketing authorisations)(**a**), in the table (fees for marketing authorisation applications)—

(a) in item 1 (major application)—

(i) in entry (a), for "£32,705" substitute "£39,811";

(ii) in entries (b) to (d), for "£68,663", in each place it occurs, substitute "£83,580";

(iii) in entry (e), for "£20,281" substitute "£24,688";

(iv) omit entry (f);

(v) omit entry (g);

(vi) in entry (h), for "£102,028" substitute "£124,194";

(b) in item 2 (complex application)—

(i) in entries (a) to (c), for "£19,063", in each place it occurs, substitute "£23,205";

(ii) in entry (d), for "£11,487" substitute "£13,983";

(iii) omit entry (e);

(iv) omit entry (f);

(v) in entry (g), for "£28,207" substitute "£34,335";

(**a**) Table inserted by S.I. 2019/775 and amended by S.I. 2020/1488 and S.I. 2023/314.

(c) in item 3 (standard application)—

(i) in entries (a) to (c), for "£6,985", in each place it occurs, substitute "£8,503";

(ii) in entry (d), for "£6,361" substitute "£7,743";

(iii) omit entry (e);

(iv) omit entry (f);

(v) in entry (g), for "£10,342" substitute "£12,589";

(d) in item 4 (simple application)—

(i) in entries (a) to (c), for "£2,820", in each place it occurs, substitute "£3,433";

(ii) omit entry (d);

(iii) omit entry (e);

(iv) in entry (f), for "£2,820" substitute "£3,433";

(e) in item 5 (parallel import licence applications)—

(i) in entry (a), for "£1,971" substitute "£2,400";

(ii) in entry (b), for "£8,722" substitute "£10,617";

(iii) in entry (c), for "£19,998" substitute "£24,343";

(f) in item 6 (change of ownership application), for "£486" substitute "£592".

(4) In paragraph 25(1) (fees where application includes reclassification)(**a**)—

(a) in sub-paragraph (a), for "£33,003" substitute "£40,173";

(b) in sub-paragraph (b), for "£8,978" substitute "£10,929".

(5) In paragraph 28(4)(b) (application for multiple authorisations)(**b**), for "£1,308" substitute "£1,593".

(6) In paragraph 28A (application by pre-assessment of modules)(**c**)—

(a) in sub-paragraphs (1)(a) to (c), for "£25,507", in each place it occurs, substitute "£31,049";

(b) in sub-paragraphs (2)(a) to (c), for "£4,766", in each place it occurs, substitute "£5,802".

(7) In paragraph 29 (authorisation for a national homoeopathic product)—

(a) in sub-paragraph (4), in the table (fees for homoeopathic marketing authorisation applications)—

(i) in the second column (fee for applications in respect of products prepared from not more than 5 homoeopathic stocks)—

(aa) in entry 1, for "£517" substitute "£630";

(bb) in entry 2, for "£808" substitute "£984";

(cc) in entry 3, for "£1,088" substitute "£1,325";

(ii) in the third column (fee for other applications)—

(aa) in entry 1, for "£732" substitute "£892";

(bb) in entry 2, for "£1,014" substitute "£1,235";

(cc) in entry 3, for "£1,312" substitute "£1,598";

(b) in sub-paragraph (6), for "£2,154" substitute "£2,622";

(**a**) Amended by S.I. 2023/314.
(**b**) Amended by S.I. 2023/314.
(**c**) Inserted by S.I. 2019/775 (as amended by S.I. 2020/1488) and amended by S.I. 2023/314.

(c) in sub-paragraph (7), for "£7,185" substitute "£8,746";

(d) in sub-paragraph (8), for "£635" substitute "£773".

(8) In paragraph 30(1) (manufacturer's licences and authorisations)(**a**)—

(a) in sub-paragraph (a), for "£201" substitute "£245";

(b) in sub-paragraph (b), for "£378" substitute "£461";

(c) in sub-paragraph (c), for "£3,457" substitute "£4,209".

(9) In paragraph 31 (wholesale dealer's licences)(**b**)—

(a) in sub-paragraph (1), for "£1,983" substitute "£2,159";

(b) in sub-paragraph (5), for "£439" substitute "£478".

(10) In paragraph 33(1) (active substance registrations)(**c**)—

(a) in paragraph (a), for "£3,457" substitute "£3,763";

(b) in paragraph (b), for "£1,983" substitute "£2,159".

(11) In paragraph 34 (clinical trial authorisations)(**d**)—

(a) in sub-paragraph (a), for "£3,366" substitute "£4,656";

(b) in sub-paragraph (b), for "£248" substitute "£343".

(12) In paragraph 35 (traditional herbal registrations)(**e**)—

(a) in sub-paragraph (1), in the second column (fee payable) of the table (fee for application for traditional herbal registration)—

(i) in entry 1 (complex registration application)—

(aa) in entry (a), for "£4,846" substitute "£5,899";

(bb) in entry (b), for "£7,269" substitute "£8,848";

(ii) in entry 2 (standard registration application)—

(aa) in entry (a), for "£2,423" substitute "£2,950";

(bb) in entry (b), for "£3,634" substitute "£4,424";

(iii) in entry 3 (reduced registration application category II)—

(aa) in entry (a), for "£807" substitute "£983";

(bb) in entry (b), for "£1,212" substitute "£1,476";

(iv) in entry 4 (reduced registration application category I)—

(aa) in entry (a), for "£539" substitute "£657";

(bb) in entry (b), for "£807" substitute "£983";

(v) in entry 5 (change of ownership application), for "£486" substitute "£592".

(b) in sub-paragraph (3)—

(i) in paragraph (a), for "£1,077" substitute "£1,311";

(ii) in paragraph (b), for "£2,154" substitute "£2,622";

(c) in sub-paragraph (4), for "£7,186" substitute "£8,748";

(d) in sub-paragraph (5), for "£638" substitute "£777";

(e) in sub-paragraph (6), for "£2,154" substitute "£2,622".

(**a**) Amended by S.I. 2023/314.
(**b**) Amended by S.I. 2023/314.
(**c**) Amended by S.I. 2023/314.
(**d**) Amended by S.I. 2023/314.
(**e**) Amended by S.I. 2023/314.

(13) In paragraph 35A (early access to medicines scheme fees), in the second column (fee payable) of the table (fees for early access to medicines scheme applications)(**a**)—

(a) in entry 1, for "£3,986" substitute "£4,852";

(b) in entry 2, for "£25,643" substitute "£31,214";

(c) in entry 3, for "£12,821" substitute "£15,607";

(d) in entry 4, for "£8,309" substitute "£10,115";

(e) in entry 5, for "£4,154" substitute "£5,057".

(14) In paragraph 38(6) (marketing authorisations)—

(a) in the second column (column 2 fee payable) of Table 1 (fees for applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008)(**b**)—

(i) in item 1 (application for a single kind variation)—

(aa) in entries (a) and (b), for "£344", in both places it occurs, substitute "£419";

(bb) in entry (c), for "£2,742" substitute "£3,338";

(cc) in entry (d), for "£8,462" substitute "£10,301";

(ii) in item 2 (applications for a group)—

(aa) in entry (a), for "£344" substitute "£419";

(bb) in entry (b), for "£1,255" substitute "£1,528";

(cc) in entry (c), for "£2,973" substitute "£3,619";

(dd) in entry (d), for "£8,671" substitute "£10,555";

(b) in the second column (fee payable) of 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)(**c**)—

(i) in item 1, for "£344" substitute "£419";

(ii) in item 2, for "£1,308" substitute "£1,593";

(iii) in item 3, for "£9,140" substitute "£11,126";

(iv) in item 4, for "£33,003" substitute "£40,173";

(v) in item 5, for "£684" substitute "£833";

(vi) in item 6, for "£1,817" substitute "£2,212";

(vii) in item 7, for "£9,911" substitute "£12,065";

(viii) in item 8, for "£28,904" substitute "£35,184";

(c) in the second column (fee payable) of Table 3 (fees for reclassification variation applications)(**d**)—

(i) in entry (a), for "£33,003" substitute "£40,173";

(ii) in entry (b), for "£8,978" substitute "£10,929".

(15) In paragraph 40(1) (reclassification of marketing authorisations)(**e**), for "£1,308" substitute "£1,593".

(**a**) Inserted by S.I. 2023/314.
(**b**) Substituted by S.I. 2019/775 (as amended by S.I. 2020/1488) and amended by S.I. 2023/314.
(**c**) Amended by S.I. 2019/775 (as amended by S.I. 2020/1488) and 2023/314.
(**d**) Amended by S.I. 2023/314.
(**e**) Amended by S.I. 2023/314.

(16) In paragraph 41 (variation of marketing authorisation: national homoeopathic products)—

(a) in sub-paragraph (a), for "£243" substitute "£296";

(b) in sub-paragraph (b), for "£374" substitute "£456";

(c) in sub-paragraph (c), for "£123" substitute "£149".

(17) In paragraph 42(1) (variation of parallel import licence)(**a**)—

(a) in paragraph (a), for "£33,003" substitute "£40,173";

(b) in paragraph (b), for "£8,978" substitute "£10,929";

(c) in paragraph (c), for "£393" substitute "£479".

(18) In paragraph 43 (manufacturer's authorisations and licences)(**b**)—

(a) in sub-paragraph (a), for "£283" substitute "£345";

(b) in sub-paragraph (b), for "£565" substitute "£688".

(19) In paragraph 44 (variation of manufacturer's authorisations and licences)(**c**), for "£283" substitute "£345".

(20) In paragraph 45 (wholesale dealer's licences)(**d**), for "£535" substitute "£652".

(21) In paragraph 46 (variation of wholesale dealer's licence)(**e**), for "£283" substitute "£345".

(22) In paragraph 47 (variation of a broker's registration)(**f**), for "£283" substitute "£345".

(23) In paragraph 48 (variation of an active substance registration)(**g**), for "£283" substitute "£309".

(24) In paragraph 49(1) (clinical trial authorisations)(**h**), for "£248" substitute "£302".

(25) In paragraph 50 (traditional herbal registrations)—

(a) in sub-paragraph (a), for "£240" substitute "£293";

(b) in sub-paragraph (b), for "£635" substitute "£773";

(c) in sub-paragraph (c), for "£7,186" substitute "£8,748";

(d) in sub-paragraph (d), for "£152" substitute "£186".

(26) In paragraph 54 (a set of changes)(**i**)—

(a) in sub-paragraph (1)—

(i) in paragraph (a), for "£570" substitute "£992";

(ii) in paragraph (b), for "£361" substitute "£440";

(b) in sub-paragraph (2), for "£205" substitute "£224".

(27) In paragraph 56 (renewal of a marketing authorisation)(**j**)—

(a) in sub-paragraphs (a) and (b), for "£822", in both places it occurs, substitute "£1,239";

(b) in sub-paragraph (c), for "£10,650" substitute "£16,042".

(28) In paragraph 57(2) (renewal of multiple marketing authorisations)(**k**)—

(a) in paragraphs (a)(i) and (a)(ii), for "£822", in both places it occurs, substitute "£1,239";

(**a**) Amended by S.I. 2023/314.
(**b**) Amended by S.I. 2023/314.
(**c**) Amended by S.I. 2023/314.
(**d**) Amended by S.I. 2023/314.
(**e**) Amended by S.I. 2023/314.
(**f**) Amended by S.I. 2023/314.
(**g**) Amended by S.I. 2023/314.
(**h**) Amended by S.I. 2023/314.
(**i**) Amended by S.I. 2023/314.
(**j**) Substituted by S.I. 2019/775 (as amended by S.I. 2020/1488) and amended by S.I. 2023/314.
(**k**) Substituted by S.I. 2019/775 (as amended by S.I. 2020/1488) and amended by S.I. 2023/314.

(b) in paragraph (b)(i), for "£10,650" substitute "£16,042".

(29) In paragraph 57A (capital fee for conducting a major safety review)(**a**)—

(a) in sub-paragraph (a), for "£56,415" substitute "£61,408";

(b) in sub-paragraph (b), for "£65,555" substitute "£71,357";

(c) in sub-paragraph (c), for "£74,694" substitute "£81,305";

(d) in sub-paragraph (d), for "£83,834" substitute "£91,254".

(30) For paragraph 57B (capital fee for testing of samples by the appropriate authority)(**b**) substitute—

> **"57B.**—(1) The fee payable under regulation 19F(1) in connection with the submission of a sample of a batch of a medicinal product is £5,093 for each day taken to examine the sample for testing, the appropriate documentation (as defined in regulation 60A of the Human Medicines Regulations) or both (as the case may be), and the fee payable is to be adjusted pro rata for each period taken of less than 1 day.
>
> (2) In this paragraph, a "day" means a period of 8 hours and 30 minutes.".

Amendment of Schedule 3

28.—(1) Schedule 3 (fees for inspections) is amended as follows.

(2) In paragraph 2(1) (fees: general)(**c**)—

(a) in paragraph (1)(a), for "£3,651" substitute "£5,251";

(b) in paragraph (1)(b), for "£1,825" substitute "£2,625".

(3) In paragraph 5 (wholesale dealer's licence: general)(**d**)—

(a) in sub-paragraphs (a) and (b), for "£2,662", in both places it occurs, substitute "£4,136";

(b) in sub-paragraph (b), for "£1,331" substitute "£2,068".

(4) In paragraph 6(2) (wholesale dealer's licence: traditional herbal medicinal products)(**e**)—

(a) in paragraph (a), for "£1,023" substitute "£1,114";

(b) in paragraphs (b) and (c), for "£1,880", in both places it occurs, substitute "£2,047".

(5) In paragraph 7(3) (wholesale dealer's licences: inspection of short duration)(**f**), for "£1,331" substitute "£2,068".

(6) In paragraph 8 (broker's registrations)(**g**)—

(a) in sub-paragraph (1)—

(i) in paragraphs (a) and (b), for "£2,662", in both places it occurs, substitute "£3,241";

(ii) in paragraph (b), for "£1,331" substitute "£1,621";

(b) in sub-paragraph (3), for "£640" substitute "£780".

(7) In paragraph 9 (active substance registrations)(**h**)—

(a) in sub-paragraph (1)(a)—

(**a**) Inserted by S.I. 2019/775 and amended by S.I. 2023/314.
(**b**) Inserted by S.I. 2019/775 and amended by S.I. 2023/314.
(**c**) Amended by S.I. 2023/314.
(**d**) Amended by S.I. 2023/314.
(**e**) Amended by S.I. 2023/314.
(**f**) Amended by S.I. 2023/314.
(**g**) Amended by S.I. 2023/314.
(**h**) Amended by S.I. 2023/314.

(i) in sub-paragraphs (i) and (ii), for "£3,651", in both places it occurs, substitute "£3,975";

(ii) in sub-paragraph (ii), for "£1,825" substitute "£1,988";

(b) in sub-paragraph (1)(b)—

(i) in sub-paragraphs (i) and (ii), for "£2,662", in both places it occurs, substitute "£2,898";

(ii) in sub-paragraph (ii), for "£1,331" substitute "£1,449";

(c) in sub-paragraph (3)—

(i) in paragraph (a), for "£871" substitute "£949";

(ii) in paragraph (b), for "£640" substitute "£697".

(8) In paragraph 10 (office-based inspections)(**a**)—

(a) in sub-paragraph (a), for "£2,562" substitute "£4,924";

(b) in sub-paragraph (b), for "£1,862" substitute "£3,810".

Amendment of Schedule 4

29.—(1) Schedule 4 (Periodic fees for licences) is amended as follows.

(2) In paragraph 5 (marketing authorisations)(**b**), in column 2 (fee payable) of the table (periodic fees for holding a marketing authorisation)—

(a) in entry 1, for "£10,681" substitute "£11,627";

(b) in entry 2, for "£338" substitute "£368";

(c) in entry 3(a), for "£10,681" substitute "£11,627";

(d) in entry 3(b)(i), for "£2,671" substitute "£2,908";

(e) in entry 3(b)(ii), for "£1,332" substitute "£1,450";

(f) in entries 3(b)(iii), (c) and (d), for "£338", in each place it occurs, substitute "£368";

(g) in entries 3(e) to (h), for "£84", in each place it occurs, substitute "£92".

(3) In paragraph 6 (marketing authorisation: where Part 2 of the Act applies)(**c**), for "£338" substitute "£368".

(4) In paragraph 7 (marketing authorisation: derivatives)(**d**)—

(a) in sub-paragraph (a), for "£10,681" substitute "£11,627";

(b) in sub-paragraph (b), for "£7,209" substitute "£7,847".

(5) In paragraph 11(1) and (2) (manufacturer's licences or manufacturing authorisations)(**e**), for "£515", in both places it occurs, substitute "£561".

(6) In paragraph 12 (wholesale dealer's licences)(**f**)—

(a) in sub-paragraph (1), for "£317" substitute "£346";

(b) in sub-paragraph (2), for "£189" substitute "£206".

(7) In paragraph 15(1)(b)(**g**) (additional amount for manufacturer's licences and wholesale dealer's licences which relate to special medicinal products)—

(**a**) Amended by S.I. 2023/314.
(**b**) Amended by S.I. 2023/314.
(**c**) Amended by S.I. 2023/314.
(**d**) Amended by S.I. 2023/314.
(**e**) Amended by S.I. 2023/314.
(**f**) Amended by S.I. 2023/314.
(**g**) Amended by S.I. 2023/314.

(a) for Table 1 (additional periodic fee in connection with notices for imported special medicinal products) substitute—

"Table 1

Additional periodic fee in connection with notices for imported special medicinal products

Column 1	***Column 2***
Number of special import notices	*Additional amount*
1 to 20	£86
21 to 100	£427
101 to 500	£2,131
501 to 1,000	£4,261
1,001 to 2,000	£8,521
2,001 to 5,000	£17,042
5,001 to 10,000	£34,083
10,001 to 15,000	£51,125
15,001 to 20,000	£68,166
20,001 to 25,000	£85,208
25,001 to 30,000	£102,249
30,001 to 35,000	£119,291
35,001 to 40,000	£136,333
40,001 to 45,000	£153,375
45,001 to 50,000	£170,417
Each additional 5,000 above 50,000	£170,417 plus £17,042 for each additional 5,000 special import notices";

(b) in the second column (additional amount) of Table 2 (Additional periodic fee in connection with the number of different special medicinal products notified for import)—

(i) in the entry "1 to 5", for "£100" substitute "£122";

(ii) in the entry "6 to 10", for "200" substitute "£244";

(iii) in the entry "11 to 20", for "£400" substitute "£487";

(iv) in the entry "21 to 50", for "£1,000" substitute "£1,218";

(v) in the entry "51 to 100, for "£2,000" substitute "£2,435";

(vi) in the entry "101 to 200", for "£4,000" substitute "£,4,869";

(vii) in the entry "For each additional 100 special medicinal products notified for import above 200", for "£2,000" substitute "£4,869 plus £2,435 for each additional 100 special medicinal products notified for import".

(8) In paragraph 16 (traditional herbal registrations)(**a**), for "£84" substitute "£92".

Amendment of Schedule 5

30.—(1) Schedule 5 (fees for certificates of registration) is amended as follows.

(2) In the table—

(a) in the second column (fees for applications in respect of products prepared from not more than 5 homoeopathic stocks)—

(i) in item 1, for "£159" substitute "£194";

(ii) in item 2, for "£478" substitute "£582";

(iii) in item 3, for "£501" substitute "£610";

(iv) in item 5, for "£430" substitute "£524";

(v) in item 7, for "£790" substitute "£962";

(b) in the third column (fees for other applications)—

(i) in item 1, for "£393" substitute "£479";

(ii) in item 2, for "£704" substitute "£857";

(iii) in item 3, for "£638" substitute "£777";

(iv) in item 5, for "£563" substitute "£686";

(v) in item 7 for "£1,034" substitute "£1,259".

Amendment of Schedule 7

31.—(1) Schedule 7 (waiver, reduction or refund of capital fees) is amended as follows.

(2) In paragraph 11(1) (scientific advice: paediatric indications), for "regulation 4" substitute "regulation 3A".

Signed by authority of the Secretary of State for Health and Social Care

Karin Smyth
Minister of State
Department of Health and Social Care

At 10.02 a.m. on 11th March 2025

Sealed with the Official Seal of the Department of Health in Northern Ireland

L.S.

Cathy Harrison
A senior officer of the Department of Health in Northern Ireland

(**a**) Amended by S.I. 2023/314.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to the Medicines (Products for Human Use) (Fees) Regulations 2016 (S.I. 2016/190).

The Medicines (Products for Human Use) (Fees) Regulations 2016 make provision for the fees payable in relation to authorisations, licences, certificates and registrations in respect of medicinal products for human use, including those under the Human Medicines Regulations 2012 and the Medicines for Human Use (Clinical Trials) Regulations 2004.

The fee amounts specified in these Regulations represent increases in the majority of existing fees of between 9% and 22%, with around 10% of fees rising by more than this, the highest rises being for scientific advice meetings and inspections, and are set in line with a consultation document issued by the Medicines and Healthcare products Regulatory Agency ("MHRA") on 29 August 2024 . A summary of the consultation responses and the Government's response to the consultation are published on the MHRA's website (www.mhra.gov.uk).

Regulation 3 introduces an amended fee structure for the optional service provided by the licensing authority in relation to scientific, regulatory, pharmacovigilance, or advertising advice, based on the complexity of the matter on which advice is given. Regulations 4, 6, 7, 9, and 10 omit the fees which are replaced by the amended fee structure. Regulation 27(30) introduces an amended fee structure for batch testing, so that it would be based on the time taken. Regulation 29(7) increases the number of payment bands for fees in connection with notices for imported special medicinal products. Regulations 25 and 27(2) amend the definition of "standard variation" in relation to homoeopathic medicinal products to explicitly include changes to outer packaging, inner packaging, and package leaflets.

A full impact assessment of the effect that this instrument will have on the cost of business and the voluntary sector is available from the Medicines and Healthcare products Regulatory Agency, 10 South Colonnade, Canary Wharf, London, E14 4PU and is published with the Explanatory Memorandum alongside the instrument on www.legislation.gov.uk.

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