EXPLANATORY MEMORANDUM TO

THE MEDICINES (PRODUCTS FOR HUMAN USE) (FEES) (AMENDMENT) REGULATIONS 2025

2025 No. 317

1. Introduction

1.1 This explanatory memorandum has been prepared by The Medicines and Healthcare products Regulatory Agency ("MHRA"), an executive agency of the Department of Health and Social Care ("DHSC") and is laid before Parliament by Command of His Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments and the Northern Ireland Assembly.

2. Declaration

2.1 Karin Smyth MP, Minister of State for Health (Secondary Care) at the DHSC confirms that this Explanatory Memorandum meets the required standard.

2.2 Rose Braithwaite, Chief Finance Officer at the MHRA confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Maham Masood at the MHRA: info@mhra.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 This instrument amends the Medicines (Products for Human Use) (Fees) Regulations 2016 (S.I. 2016/190) ("the 2016 Regulations"), to update the fees payable to the MHRA in relation to the regulation of medicinal products for human use.

4.2 The instrument amends a range of fees in line with the increased costs of providing these services, ensuring that MHRA recovers the costs of its activity in accordance with HM Treasury Managing Public Money principles. This is necessary to ensure the MHRA's long-term financial sustainability and enable the MHRA to deliver a responsive, innovative and efficient regulatory service that protects and improves patient and public health.

4.3 Given the different legal positions in relation to the powers to make regulations about fees relating to human medicines, medical devices and blood components for transfusion, the MHRA are using two instruments to update its fees: this one for human medicines fees and laid before the UK Parliament and Northern Ireland Assembly and subject to the negative procedure; and a separate one, due to be laid in April, for medical devices and blood components for transfusion fees laid before the UK Parliament only and subject to the affirmative procedure.

Where does the legislation extend to, and apply?

4.4 The extent of this instrument is the whole of the United Kingdom ("UK").

4.5 The territorial application of this instrument is the whole of the UK.

5. Policy Context

What is being done and why?

5.1 The MHRA regulates medicines, medical devices and blood components for transfusion in the UK. Generally, whenever the MHRA provides a direct service for regulatory work, a fee is charged to recover the costs. As the fees are set in secondary legislation, legislative change is required to amend them.

5.2 This instrument amends the medicines fees currently set out in the 2016 Regulations to ensure the MHRA recovers the cost of regulatory activities in relation to the regulation of medicinal products for human use.

5.3 The principles for how the MHRA charges fees are set by HM Treasury in Managing Public Money. The basic principle is to set statutory fees and charges to recover full costs. This means that the regulated bear the cost of regulation and the MHRA does not profit from fees or make a loss which must then be subsidised by Government departments or the UK taxpayer.

5.4 In setting the cost of fees, the MHRA has taken numerous factors into account to ensure costs are covered, including identifying activities involved in delivering a service, the time these activities take, and the staff grade and seniority required to complete the task. In addition, the MHRA is required to factor in corporate overhead costs and system investments.

5.5 To ensure ongoing cost-recovery, the MHRA updates its fees on an ongoing basis. This is standard practice for government bodies that charge fees. The MHRA's fees were last updated in April 2023 and the implementation date for these proposed changes is April 2025. The MHRA aims to update its fees every two years as regularity provides more certainty to customers and enables financial planning.

5.6 This instrument increases the statutory fees shown in the Annex to ensure continued cost-recovery until 2027. The proposed increase for each fee has been calculated to ensure it covers all associated costs for the period between April 2025 (when the fees come into effect) to March 2027 (the month before the next fees uplift is planned).

5.7 This instrument updates the fee model for three existing services, simplifying the fee structure as well as increasing fees in the same way as mentioned above to ensure continued cost-recovery until 2027.

5.8 This instrument removes 51 fees that are no longer in use as they have been superseded by the changes above or because the services have become redundant since the UK left the EU.

5.9 This instrument updates the legal definition of a "standard variation" application for homeopathic products. This is for the purposes of clarity and the "standard variation" application statutory fee is unchanged. Homoeopathic product authorisation or registration holders may apply to the MHRA to make changes to their product authorisation or registration via variation applications. The instrument updates the definition of "standard variation" to make it clear that "standard variation" applications cover changes to both immediate (e.g. the physical container of the

product itself) and secondary packaging (i.e. the outer label and/or patient information leaflet) that are not due to the consequential impact of another variation.

What was the previous policy, how is this different?

5.10 This instrument amends the medicines fees currently set out in the 2016 Regulations as these are out of date. This is to ensure the MHRA recovers the cost of regulatory activities in relation to the regulation of medicinal products for human use.

6. Legislative and Legal Context

How has the law changed?

6.1 The Human Medicines Regulations 2012 (S.I. 2012/1916) ("the HMRs") govern the arrangements across the United Kingdom for the licensing, manufacture, wholesale dealing, sale or supply, advertising and post-marketing monitoring of medicines for human use.

6.2 The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031) ("the 2004 Regulations") govern the conduct of clinical trials of medicinal products for human use.

6.3 Together, these regulations set the essential framework, alongside the surviving provisions of the Medicines Act 1968, the Medicines Act 1971 and the 2016 Regulations, for the regulation of medicines for human use in the United Kingdom.

6.4 The MHRA carries out the functions of the licensing authority, relating to medicines for human use, under the HMRs and the 2004 Regulations on behalf of the Secretary of State and the Minister of Health in Northern Ireland.

6.5 The 2016 Regulations make provision for the fees payable to the MHRA in relation to the regulatory functions it carries out under the HMRs and 2004 Regulations.

6.6 Section 2(1) of the Medicines and Medical Devices Act 2021 ("MMDA") provides the power to amend the 2016 Regulations and section 6(1)(a) MMDA provides that regulations made under s2 MMDA can make provision for charging fees.

6.7 This instrument uses those MMDA powers to amend the 2016 Regulations, updating the statutory fees charged by the MHRA in relation to the regulation of medicines for human use, to ensure the MHRA recovers the costs of its regulatory activities.

6.8 In making regulations under the MMDA, the overriding objective of the Secretary of State and the Department of Health in Northern Ireland must be safeguarding public health.

6.9 Accordingly, in making this instrument, the Secretary of State and the Department of Health in Northern Ireland have given regard to (1) the safety of medicines; (2) the availability of medicines; and (3) the likelihood of the UK being seen as a favourable place to conduct clinical trials, carry out research related to medicines, or manufacture or supply medicines.

6.10 The Secretary of State and the Department of Health in Northern Ireland, having had regard to these factors, consider that this instrument contributes to the overarching objective of safeguarding public health because the fee amendments will help ensure that the MHRA is sufficiently funded and resourced to deliver an efficient regulatory service which facilitates access to high-quality, safe, effective and innovative medicinal products.

6.11 Information on how these factors have been considered can be found in the Government's response to the consultation on gov.uk at: https://www.gov.uk/government/consultations/mhra-consultation-on-statutory-fees-proposals-on-ongoing-cost-recovery

Why was this approach taken to change the law?

6.12 This is the only possible approach to make the necessary changes to the legislation.

7. Consultation

Summary of consultation outcome and methodology

7.1 The MHRA carried out a joint public consultation on proposed amendments to its statutory fees with the Department of Health in Northern Ireland.

7.2 The consultation ran from 29 August 2024 to 24 October 2024 and was promoted and accompanied by a webinar to engage with small and medium enterprises (SMEs).

7.3 The MHRA has analysed all responses and published the Government's response to the public consultation on gov.uk. In response to feedback, the MHRA is proceeding with its overall fee uplift but is reconsidering the proposal to introduce a new registration free for medical devices and is introducing a new payment easement for SMEs for some of its medical device clinical investigation fees. The MHRA will be laying a second instrument to update fees payable to the MHRA in relation to the regulation of medical devices and blood components for transfusion bloods so details on these changes are not covered in this memorandum.

7.4 This instrument is being made jointly by the Secretary of State and the Department of Health in Northern Ireland on a UK wide basis. The Scottish and Welsh Devolved Administrations were also consulted. Colleagues in all Devolved Governments are supportive of this change.

8. Applicable Guidance

8.1 Guidance and information regarding fees payable to the MHRA can be found on the MHRA website at: https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees. Updated guidance and information on the new fees will be published in advance of this instrument coming into force.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment is submitted with this memorandum and published alongside the Explanatory Memorandum on the legislation.gov.uk website.

Impact on businesses, charities and voluntary bodies

9.2 The overall impact on business, charities or voluntary bodies is £14.5 million per year after inflation. This cost is the additional fees payable by organisations which use the MHRA's medicines services. The published full impact assessment shows a higher cost than this (£15.2 million per year) as it covers the entire MHRA fees uplift and therefore also the cost of the uplift to medical devices and blood components for transfusion services fees and there is a separate instrument for these.

9.3 The legislation does impact small and micro businesses.

9.4 The 2016 Regulations already have provision for certain payment easements for small companies and payment waivers for small and medium sized businesses.

9.5 The fee changes here will not affect these easements/waivers, and they continue to be available. More information on financial support offered to small and medium businesses can be found on the MHRA's website: https://www.gov.uk/government/publications/mhra-fees/payment-easements-and-waivers-for-small-and-medium-companies

9.6 The impact on the public sector is minimal. Some public sector bodies use the MHRA's services and will pay the increased fees. In 2023, the MHRA's total trading income was approximately £150m and approximately £2.5m of that came from public bodies. This indicates the impact on the public sector will be minimal. There is also a public sector benefit as the fee increases will ensure the MHRA is financially sustainable and will not require the DHSC to subsidise its costs.

9.7 To minimise burden on businesses generally, the MHRA will continue to review its fees periodically to ensure they are set appropriately to neither profit at the expense of those paying them, nor make a loss for taxpayers to subsidise.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring of this legislation is for the MHRA to monitor fees on an ongoing basis to ensure all fees are set at a level to recover full costs incurred. The MHRA also monitors and takes action on customer service feedback.

10.2 The instrument does not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015 Minister Karin Smyth MP has made the following statement:

"Regulations setting out the fees payable in relation to services provided, and regulatory functions carried out, by the MHRA in relation to medicines for human use are periodically reviewed. There is also already a requirement in section 46 of the Medicines and Medical Devices Act 2021 to review the operation of these Regulations every 24 months".

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments and the Northern Ireland Assembly

11.1 Given the different legal positions in relation to the powers to make regulations about fees relating to human medicines, medical devices and blood components for transfusion, the MHRA are using two instruments: one for human medicines fees and laid before the UK Parliament and Northern Ireland Assembly and subject to the negative procedure; and one for medical devices and blood components for transfusion fees laid before the UK Parliament only and subject to the affirmative procedure.

11.2 All MHRA fees are set to recover their costs, as per HM Treasury Managing Public Money principles. All fees have had an 8.85% indexation added to ensure they cover staff costs until 2027, the date of our next planned uplift. This is calculated based on

half of the 2023/24 Civil Service pay award of 4.5% plus an assumed 2.2% (which is an average for last 5 years) pay award in years 24/25, 25/26 and 26/27.

11.3 This instrument also imposes some fees increases above the rate of indexation. This is because some fees were under-recovering. This was shown via real-time cost recovery modelling, informed by newly available employee activity recording data. Employee activity recording is the practice of monitoring and recording certain activities performed by employees to establish how long they take and so how much they cost. The MHRA does not yet have the capability to carry out employee activity recording all year round so, for the first time, these data were collected for a range of fee earning areas during a 3-month sampling period in 2024 and then the resulting figures were adjusted using volume assumptions. This produced more accurate cost data to underpin the modelling and meant some fees needed to be adjusted.

11.4 The majority of fees (~90%) have increased by between 8.85-22%. Around 10% of fees are rising by more than this, with the highest rises for scientific advice meeting and Inspections fees. Our scientific advice service has been historically under recovering and its fees are also considerably lower than other benchmarks and our inspections had been under recovering as their fees did not fully account for the costs of the services.

Matters of special interest to the Northern Ireland Assembly

11.5 Section 2(6)(b)(ii) of the MMDA provides that in relation to Northern Ireland, regulations under section 2 can be made by the Secretary of State and the Department of Health in Northern Ireland acting jointly. This instrument will apply to the whole of the United Kingdom and accordingly is made jointly.

11.6 Section 47(5)(c) of the MMDA provides that in the case of the regulations being made jointly under the negative procedure, the regulations are subject to annulment in pursuance of a resolution of either House of Parliament and a negative resolution within the meaning of s41(6) of the Interpretation Act (Northern Ireland) 1954.

12. European Convention on Human Rights

12.1 As the instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 (“relevant European Union Acts”).

Annex

The list of fees and the changes to each

Fee name	Current	Proposed
1. Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or distributor - Annual compliance report - Annual compliance report where a variation is required	£565	£688
1. Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or distributor - Annual compliance report - Assessment of the annual compliance report	£283	£345
1. Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or distributor - New applications - Additional fee if the risk assessment of the initial application triggers an inspection	£640	£697
1. Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or distributor - New applications - Inspection fee (per site if required)	£2,662	£2,898
1. Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or distributor - New applications - New application for registration as an importer or distributor of active substances	£3,845	£4,186
1. Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or distributor - Variations - Inspection fee (per site if required)	£2,662	£2,898
1. Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or distributor - Variations - Notification of changes (variation)	£283	£309
1. Active pharmaceutical ingredients manufacturers and importers registration: fees - Manufacturer - New applications - New application for registration as a manufacturer of active substances	£6,019	£6,552
2. Active substance importers or distributors: fees - Additional fee for the first day of inspection if triggered following risk-assessment of the application	£640	£697
2. Active substance importers or distributors: fees - Application for registration	£1,983	£2,159
2. Active substance importers or distributors: fees - Assessment of initial application: active substance importer / distributor	£1,862	£2,027
2. Active substance importers or distributors: fees - Assessment of the Annual Compliance Report: Active Substance Importer / Distributor	£283	£309
2. Active substance importers or distributors: fees - Notification of changes	£283	£309
2. Active substance importers or distributors: fees - Persons appointed appeals procedure fee	£11,000	£11,974
2. Active substance importers or distributors: fees - Standard daily rate for Inspection	£2,662	£2,898
3. Active substance manufacturers: fees - Additional fee for the first day of an inspection if triggered following risk-assessment of the application	£871	£949
3. Active substance manufacturers: fees - Application for registration	£3,457	£3,763
3. Active substance manufacturers: fees - Assessment of Initial Application	£2,562	£2,789
3. Active substance manufacturers: fees - Assessment of the Annual Compliance Report	£283	£309
3. Active substance manufacturers: fees - Inspection days	£3,651	£3,975
3. Active substance manufacturers: fees - Notification of Changes	£283	£309
7. Broker registration fees - Annual Compliance Report - Annual Compliance where a variation is required	£565	£688
7. Broker registration fees - Annual Compliance Report - Assessment of the Annual Compliance Report	£283	£345
7. Broker registration fees - New Applications - Additional fee if the risk assessment of the initial application triggers an inspection	£640	£780
7. Broker registration fees - New Applications - Inspection Fee (per site if required)	£2,662	£3,241
7. Broker registration fees - New Applications - New application for registration as a broker	£3,845	£4,681
7. Broker registration fees - Variations - Notification of Changes (Variation)	£283	£345
8. Clinical trials: application fees - Applications with an IMP dossier - Higher fee (Phase 1, Full and Simplified IMPD)	£3,366	£4,656
8. Clinical trials: application fees - Applications without an IMP dossier - Lower fee (Phase IV, Cross referral, Additional protocol)	£248	£343
8. Clinical trials: application fees - Assessment of annual safety reports	£248	£343
8. Clinical trials: application fees - CT variations/amendments	£248	£343
10. Drug-device combination products: fees - Conformity Assessment Body Designation Applications - Extension to scope, to carry out tasks under Part 2, Part 3 or Part 4, which extends the body's designation in relation to a Part under which they have already been designated.	£12,571	£13,684
10. Drug-device combination products: fees - Conformity Assessment Body Designation Applications - Extension to scope, which extends the body's designation to carry out certain tasks that were not previously within the scope of the body's designation and where the Secretary of State considers that an additional assessment of the body's procedures is required.	£18,212	£19,824
10. Drug-device combination products: fees - Conformity Assessment Body Designation Applications - Subsidiary audit* subject to additional fees calculated by hourly rate and travel rates (covers both Approved Body and Notified Body)	£22,789	£24,806

10. Drug-device combination products: fees - Further consultation of a Device which incorporates a new active substance	£11,551	£12,574
10. Drug-device combination products: fees - Further consultation of a Device which incorporates one or more known medicinal substances from a new source	£2,451	£2,668
10. Drug-device combination products: fees - Further consultation of a Device which incorporates one or more known medicinal substances from an approved manufacturer of that substance	£900	£980
10. Drug-device combination products: fees - Initial consultation for a Device which incorporates a new active substance	£46,526	£50,644
10. Drug-device combination products: fees - Initial consultation for a Device which incorporates one or more known medicinal substances from a new source	£10,604	£11,543
10. Drug-device combination products: fees - Initial consultation for a Device which incorporates one or more known medicinal substances from an approved manufacturer of that substance	£4,550	£4,953
11. Homoeopathic National Rules Scheme: fees - Both stock and formulation already assessed - 5 stocks or fewer	£517	£630
11. Homoeopathic National Rules Scheme: fees - Both stock and formulation already assessed - more than 5 stocks	£732	£892
11. Homoeopathic National Rules Scheme: fees - Formulation already assessed - 5 stocks or fewer	£808	£984
11. Homoeopathic National Rules Scheme: fees - Formulation already assessed - more than 5 stocks	£1,014	£1,235
11. Homoeopathic National Rules Scheme: fees - Reduced - stock already assessed - 5 stocks or fewer	£808	£984
11. Homoeopathic National Rules Scheme: fees - Reduced - stock already assessed - more than 5 stocks	£1,014	£1,235
11. Homoeopathic National Rules Scheme: fees - Standard - 5 stocks or fewer	£1,088	£1,325
11. Homoeopathic National Rules Scheme: fees - Standard - more than 5 stocks	£1,312	£1,598
11. Homoeopathic National Rules Scheme: fees - Supplementary fees - New excipients	£7,185	£8,746
11. Homoeopathic National Rules Scheme: fees - Supplementary fees - New method of sterilisation (non-pharmacopoeial)	£2,154	£2,622
11. Homoeopathic National Rules Scheme: fees - Supplementary fees - New sources TSE risk actives/excipients (non-CEP)	£635	£773
12. Homeopathic National Rules Scheme: fees for inspections - All GMP, GCP and pharmacovigilance inspections	£3,651	£5,251
12. Homeopathic National Rules Scheme: fees for inspections - Full day rate	£2,662	£4,136
12. Homeopathic National Rules Scheme: fees for inspections - Office based risk assessments (see notes below)	£1,862	£3,810
12. Homeopathic National Rules Scheme: fees for inspections - Office-based risk assessments	£2,562	£4,924
12. Homeopathic National Rules Scheme: fees for inspections - Reduced rate (see notes below)	£1,331	£2,068
13. Inspection: fees - All GMP, GCP and Pharmacovigilance inspections including (this is not an exhaustive list): intermediate biological sites, manufacturers of active pharmaceutical ingredients (API), sterile, non-sterile and assembly sites, non-routine inspections, pharmacovigilance inspection, clinical trials, contract laboratories, homeopathic manufacturers	£3,651	£5,251
13. Inspection: fees - GDP (wholesale dealers including homeopathic wholesalers) - Full day rate	£2,662	£4,136
13. Inspection: fees - GDP (wholesale dealers including homeopathic wholesalers) - Reduced rate (see notes below)	£1,331	£2,068
13. Inspection: fees - Office based evaluation and risk assessments (see notes below)	£2,562	£4,924
14. Licence applications: marketing authorisation fees - Abridged complex - Complex International Recognition Type A application for GB or UK	£11,487	£13,983
14. Licence applications: marketing authorisation fees - Abridged complex - Complex International Recognition Type B application for GB or UK	£19,063	£23,205
14. Licence applications: marketing authorisation fees - Abridged complex - Complex: (Previously granted by EU) - unfettered access route to GB	£11,487	£13,983
14. Licence applications: marketing authorisation fees - Abridged complex - Decentralised procedure for the sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	£19,063	£23,205
14. Licence applications: marketing authorisation fees - Abridged complex - European reference product application for sale or supply in Northern Ireland	£19,063	£23,205
14. Licence applications: marketing authorisation fees - Abridged complex - Incoming mutual recognition procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	£19,063	£23,205
14. Licence applications: marketing authorisation fees - Abridged complex - National fee (any other case including hybrid applications)	£28,207	£34,335
14. Licence applications: marketing authorisation fees - Abridged simple - Decentralised procedure for sale or supply in Northern Ireland and Unfettered access route for UKMA(GB)	£2,820	£3,433
14. Licence applications: marketing authorisation fees - Abridged simple - Incoming mutual recognition procedure for sale or supply in Northern Ireland and Unfettered access route for UKMA(GB)	£2,820	£3,433
14. Licence applications: marketing authorisation fees - Abridged simple - National fee (all other cases)	£2,820	£3,433
14. Licence applications: marketing authorisation fees - Abridged simple - Simple: (Previously granted by EU) - unfettered access route to GB	£2,820	£3,433
14. Licence applications: marketing authorisation fees - Abridged standard - Decentralised procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	£6,985	£8,503

14. Licence applications: marketing authorisation fees - Abridged standard - European reference product application for sale or supply in Northern Ireland	£6,985	£8,503
14. Licence applications: marketing authorisation fees - Abridged standard - Incoming mutual recognition procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for a UKMA(GB)	£6,985	£8,503
14. Licence applications: marketing authorisation fees - Abridged standard - National fee (all other cases)	£10,342	£12,589
14. Licence applications: marketing authorisation fees - Abridged standard - Standard International Recognition Type A application for GB or UK	£6,361	£7,743
14. Licence applications: marketing authorisation fees - Abridged standard - Standard International Recognition Type B application for GB or UK	£6,985	£8,503
14. Licence applications: marketing authorisation fees - Abridged standard - Standard: (Previously granted by EU) - unfettered access route to GB	£6,361	£7,743
14. Licence applications: marketing authorisation fees - Major - Decentralised procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	£68,663	£83,580
14. Licence applications: marketing authorisation fees - Major - European reference product application for sale or supply in Northern Ireland	£68,663	£83,580
14. Licence applications: marketing authorisation fees - Major - Incoming mutual recognition procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	£68,663	£83,580
14. Licence applications: marketing authorisation fees - Major - Major International Recognition Type A application for GB or UK	£20,281	£24,688
14. Licence applications: marketing authorisation fees - Major - Major International Recognition Type B application for GB or UK	£68,663	£83,580
14. Licence applications: marketing authorisation fees - Major - Major Orphan (reduced in exceptional circumstances)	£32,705	£39,811
14. Licence applications: marketing authorisation fees - Major - Major: (Previously granted by EU) - unfettered access route to GB	£20,281	£24,688
14. Licence applications: marketing authorisation fees - Major - National fee (any other case including hybrid applications)	£102,028	£124,194
15. Licence applications: manufacturers licence (including THMPD and homeopathic medicinal products)* fees - Change of ownership	£378	£461
15. Licence applications: manufacturers licence (including THMPD and homeopathic medicinal products)* fees - Non-orthodox practitioner (NOP)	£201	£245
15. Licence applications: manufacturers licence (including THMPD and homeopathic medicinal products)* fees - Standard	£3,457	£4,209
16. Licence applications: parallel imports fees - Change of ownership (including THMPD registrations)	£486	£592
16. Licence applications: parallel imports fees - Complex application*	£19,998	£24,343
16. Licence applications: parallel imports fees - Simple application	£1,971	£2,400
16. Licence applications: parallel imports fees - Standard application*	£8,722	£10,617
17. Licence applications: Phase 1 Accreditation Scheme fees - Phase I Accreditation Scheme - Accreditation of Phase 1 units	£129	£141
17. Licence applications: Phase 1 Accreditation Scheme fees - Phase I Accreditation Scheme - Certificate of accreditation	£68	£75
18. Medicines export certificates: fees - Standard request: ten working days - Electronic copy	£75	£82
18. Medicines export certificates: fees - Urgent request: two working days - Electronic copy	£167	£182
19. Periodic fees for holding a marketing authorisation - Derivatives with a different route of administration[footnote 4] or complex abridged[footnote 5]	£10,681	£11,627
19. Periodic fees for holding a marketing authorisation - Herbal	£84	£92
19. Periodic fees for holding a marketing authorisation - Homeopathic and Anthroposophic PLRs (per PLR)	£84	£92
19. Periodic fees for holding a marketing authorisation - Manufacturer's licence	£515	£561
19. Periodic fees for holding a marketing authorisation - National Rules Homeopathic Authorisation	£84	£92
19. Periodic fees for holding a marketing authorisation - New active substance[footnote 4]	£10,681	£11,627
19. Periodic fees for holding a marketing authorisation - Other derivatives[footnote 4]	£7,209	£7,847
19. Periodic fees for holding a marketing authorisation - Prescription Only Medicine (POM) - 'Maintenance' fee	£338	£368
19. Periodic fees for holding a marketing authorisation - Prescription Only Medicine (POM) - All others (P, GSL, PLPI and None)	£338	£368
19. Periodic fees for holding a marketing authorisation - Prescription Only Medicine (POM) - Reduced rate fee	£1,332	£1,450
19. Periodic fees for holding a marketing authorisation - Prescription Only Medicine (POM) - Standard fee[footnote 6]	£2,671	£2,908
19. Periodic fees for holding a marketing authorisation - THMPD registration	£84	£92
19. Periodic fees for holding a marketing authorisation - Wholesale dealer's licence	£317	£346
19. Periodic fees for holding a marketing authorisation - Wholesale dealer's licence (reduced rate or GSL) [footnote 7]	£189	£206

20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Assessment of labels and leaflets - National (BROMI) notification/self-certification[footnote 13]	£205	£224
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Assessment of labels and leaflets - Parallel imports	£361	£440
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Assessment of labels and leaflets - Single or first application[footnote 12]	£570	£992
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - First renewal of a market authorisation granted with a new active substance - All other cases	£10,650	£16,042
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - First renewal of a market authorisation granted with a new active substance - UKMA(GB) granted under the unfettered access route	£822	£1,239
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - First renewal of a market authorisation granted with a new active substance - UKMA(GB) previously granted by EU (automatic recognition)	£822	£1,239
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - First renewal of a market authorisation granted with a new active substance - UKMA(GB) previously granted by International Recognition	£822	£1,239
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Licence Renewal Applications - Manufacturers' licences Non-orthodox practitioner (NOP)	£196	£214
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Reclassification - P to GSL - Additional fee for MA or PI application with reclassification element from P to GSL[footnote 10],[footnote 11]	£8,978	£10,929
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Reclassification - POM to P - Additional for MA or PI application with reclassification element from POM to P[footnote 10], [footnote 11]	£33,003	£40,173
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Reclassification - Reclassification Type IB variation application (MA) (analogous product) [footnote 11]	£344	£419
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Reclassification - Reclassification variation application (MA) (analogous product) [footnote 11]	£1,308	£1,593
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Reclassification - Reclassification variation application P to GSL	£8,978	£10,929
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Reclassification - Reclassification variation application POM to P[footnote 10],[footnote 11]	£33,003	£40,173
21. Orphan Marketing Products: fees - Orphan Complex (Full Fee)	£28,207	£34,335
21. Orphan Marketing Products: fees - Orphan Major (exceptional circumstances in which point G of Part IV of Annex 1 in the 2001 Directive applies)	£32,705	£39,811
21. Orphan Marketing Products: fees - Orphan Major (Full fee)	£102,028	£124,194
21. Orphan Marketing Products: fees - Orphan Standard (Full Fee)	£10,342	£12,589
22. Pharmacovigilance (PV) Safety Review: fees - Assessment of PASS Results	£9,140	£9,949
22. Pharmacovigilance (PV) Safety Review: fees - PV Major Safety Review (1-2 active ingredients)	£56,415	£61,408
22. Pharmacovigilance (PV) Safety Review: fees - PV Major Safety Review (3 active ingredients)	£65,555	£71,357
22. Pharmacovigilance (PV) Safety Review: fees - PV Major Safety Review (4 active ingredients)	£74,694	£81,305
22. Pharmacovigilance (PV) Safety Review: fees - PV Major Safety Review (5 or more active ingredients)	£83,834	£91,254
22. Pharmacovigilance (PV) Safety Review: fees - PV Periodic Safety Update Report (PSUR) single assessment: Full Fee	£979	£1,066
22. Pharmacovigilance (PV) Safety Review: fees - PV Periodic Safety Update Report (PSUR) single assessment: Half Fee	£490	£534
22. Pharmacovigilance (PV) Safety Review: fees - PV Post Authorisation Safety Study (PASS) protocol	£9,140	£9,949
23. Plasma Master File (PMF) & Vaccine Antigen Master File certification or certified annual update work: fees - Certification of new PMF (for scientific & technical evaluation)	£9,140	£11,126
23. Plasma Master File (PMF) & Vaccine Antigen Master File certification or certified annual update work: fees - Certified Annual Update of a PMF (epidemiology update only)	£344	£419
23. Plasma Master File (PMF) & Vaccine Antigen Master File certification or certified annual update work: fees - Certified Annual Update of a PMF (significant changes to safety information)	£1,308	£1,593
23. Plasma Master File (PMF) & Vaccine Antigen Master File certification or certified annual update work: fees - Vaccine Antigen Master File (VAMF) certification	£9,140	£11,126
24. Pre-Assessment (Rolling Review): fees - Application by pre-assessment (Biosimilar) - Module 3 (chemical, pharmaceutical and biological information)	£4,766	£5,802
24. Pre-Assessment (Rolling Review): fees - Application by pre-assessment (Biosimilar) - Module 4 (non-clinical reports)	£4,766	£5,802
24. Pre-Assessment (Rolling Review): fees - Application by pre-assessment (Biosimilar) - Module 5 (clinical study reports)	£4,766	£5,802
24. Pre-Assessment (Rolling Review): fees - Application by pre-assessment (NAS) - Module 3 (chemical, pharmaceutical and biological information)	£25,507	£31,049
24. Pre-Assessment (Rolling Review): fees - Application by pre-assessment (NAS) - Module 4 (non-clinical reports)	£25,507	£31,049
24. Pre-Assessment (Rolling Review): fees - Application by pre-assessment (NAS) - Module 5 (clinical study reports)	£25,507	£31,049
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 1 – 20	£70	£86
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 21 – 100	£350	£427

25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - 1 – 5	£100	£122
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - 101 – 200	£4,000	£4,869
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - 11– 20	£400	£487
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - 21 – 50	£1,000	£1,218
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - 51 – 100	£2,000	£2,435
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - 6 – 10	£200	£244
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - Per additional 100 codes above 200	£2,000	£2,435
26. Scientific advice meetings: fees - Pharmacovigilance advice meetings - Advice on labels and leaflets	£2,421	£3,757
26. Scientific advice meetings: fees - Reclassification advice meetings - Pharmacy to General Sales List switch	£3,039	£8,758
26. Scientific advice meetings: fees - Reclassification advice meetings - Prescription Only Medicine to Pharmacy switch	£3,986	£8,758
27. Simplified Homeopathic Registration Scheme: fees - Both stock and formulation already assessed - 5 stocks or fewer	£159	£194
27. Simplified Homeopathic Registration Scheme: fees - Both stock and formulation already assessed - more than 5 stocks	£393	£479
27. Simplified Homeopathic Registration Scheme: fees - Formulation already assessed - 5 stocks or fewer	£478	£582
27. Simplified Homeopathic Registration Scheme: fees - Formulation already assessed - more than 5 stocks	£704	£857
27. Simplified Homeopathic Registration Scheme: fees - Reduced - 5 stocks or fewer	£478	£582
27. Simplified Homeopathic Registration Scheme: fees - Reduced - more than 5 stocks	£704	£857
27. Simplified Homeopathic Registration Scheme: fees - Standard - 5 stocks or fewer	£790	£962
27. Simplified Homeopathic Registration Scheme: fees - Standard - more than 5 stocks	£1,034	£1,259
28. Simplified Homeopathic Registration Scheme: Decentralised Procedure applications: fees - Decentralised Procedure for sale or supply in Northern Ireland and Unfettered access route for UKHR(GB) - 5 stocks or fewer	£430	£524
28. Simplified Homeopathic Registration Scheme: Decentralised Procedure applications: fees - Decentralised Procedure for sale or supply in Northern Ireland and Unfettered access route for UKHR(GB) - more than 5 stocks	£563	£686
29. Simplified Homoeopathic Registration Scheme: Mutual Recognition Procedures: fees - Incoming Mutual Recognition for sale or supply in Northern Ireland and Unfettered access route for UKHR(GB) - 5 stocks or fewer	£501	£610
29. Simplified Homoeopathic Registration Scheme: Mutual Recognition Procedures: fees - Incoming Mutual Recognition for sale or supply in Northern Ireland and Unfettered access route for UKHR(GB) - more than 5 stocks	£638	£777
31. Traditional Herbal Registration Scheme: fees - Complex - 2 or more new herbal active ingredients	£7,269	£8,849
31. Traditional Herbal Registration Scheme: fees - Complex - single new herbal active ingredient	£4,846	£5,899
31. Traditional Herbal Registration Scheme: fees - Reduced - Category I - 3 or fewer existing herbal active ingredients	£539	£657
31. Traditional Herbal Registration Scheme: fees - Reduced - Category I - more than 3 existing herbal active ingredients	£807	£983
31. Traditional Herbal Registration Scheme: fees - Reduced - Category II - 3 or fewer existing herbal active ingredients	£807	£983
31. Traditional Herbal Registration Scheme: fees - Reduced - Category II - more than 3 existing herbal active ingredients	£1,212	£1,476
31. Traditional Herbal Registration Scheme: fees - Standard - 3 or fewer existing herbal active ingredients	£2,423	£2,950
31. Traditional Herbal Registration Scheme: fees - Standard - more than 3 existing herbal active ingredients	£3,634	£4,424
31. Traditional Herbal Registration Scheme: fees - Traditional Herbal Registration Scheme: supplementary fees - Ancillary vitamins / minerals - Existing Sources plus CEP	£1,077	£1,311
31. Traditional Herbal Registration Scheme: fees - Traditional Herbal Registration Scheme: supplementary fees - Ancillary vitamins / minerals - New excipients	£7,186	£8,748
31. Traditional Herbal Registration Scheme: fees - Traditional Herbal Registration Scheme: supplementary fees - Ancillary vitamins / minerals - New sources (non-CEP)	£2,154	£2,622
31. Traditional Herbal Registration Scheme: fees - Traditional Herbal Registration Scheme: supplementary fees - Ancillary vitamins / minerals - New sources TSE risk excipients (non-CEP)	£638	£777
31. Traditional Herbal Registration Scheme: fees - Traditional Herbal Registration Scheme: supplementary fees - Ancillary vitamins / minerals - Sterile products	£2,154	£2,622
32. Variation: Homeopathic National Rules Scheme fees - Indication	£374	£456
32. Variation: Homeopathic National Rules Scheme fees - Other applications (for any subsequent variations where no further medical, technical or scientific assessment is required)	£61	£75
32. Variation: Homeopathic National Rules Scheme fees - Other applications (for up to 30 variations where no further medical, technical or scientific assessment is required)	£122	£149
32. Variation: Homeopathic National Rules Scheme fees - Standard variation application	£243	£296
33. Variations: Homeopathic Simplified Scheme fees - New technical	£243	£296

33. Variations: Homeopathic Simplified Scheme fees - Other applications (for any subsequent variations where no further medical, technical or scientific assessment is required)	£61	£75
33. Variations: Homeopathic Simplified Scheme fees - Other applications (for up to 30 variations where no further medical, technical or scientific assessment is required)	£122	£149
33. Variations: Homeopathic Simplified Scheme fees - Other applications (where further medical, technical or scientific assessment is required)	£243	£296
34. Variations: licence variations application fees - Applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008. - Single kind variation - Extended Type II Complex Variation	£8,462	£10,301
34. Variations: licence variations application fees - Applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008. - Single kind variation - Type IB	£344	£419
34. Variations: licence variations application fees - Applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008. - Single kind variation - Type II	£344	£419
34. Variations: licence variations application fees - Applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008. - Single kind variation - Type II Complex Variation	£2,742	£3,338
34. Variations: licence variations application fees - 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. - National Type 1B Variation	£344	£419
34. Variations: licence variations application fees - 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 orce in Great Britain. - National Type II Variation	£1,308	£1,593
34. Variations: licence variations application fees - 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. - National Type II Complex Variation	£9,140	£11,126
34. Variations: licence variations application fees - 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. - National Type II Extended Complex Variation	£33,003	£40,173
35. Variations: licence variations applications groups fees - Applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008. - Major Variation (Type II) Complex Group	£2,973	£3,619
35. Variations: licence variations applications groups fees - Applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008. - Major Variation (Type II) Extended Complex Group	£8,671	£10,555
35. Variations: licence variations applications groups fees - Applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008. - Major Variation (Type II) Group	£1,255	£1,528
35. Variations: licence variations applications groups fees - Applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008. - Minor variation (Type IB) Group	£344	£419
35. Variations: licence variations applications groups fees - 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. - National Type IB Minor Variation Group	£684	£833
35. Variations: licence variations applications groups fees - 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. - National Type II Major Variation Group	£1,817	£2,212
35. Variations: licence variations applications groups fees - 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. - National Type II Major Variation Complex Group	£9,911	£12,065
35. Variations: licence variations applications groups fees - 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. - National Type II Major Variation Extended Complex Group	£28,904	£35,184
36. Variations: other licence variations applications fees - Clinical trial authorisations - Amendments to 1 part of dossier	£248	£302
36. Variations: other licence variations applications fees - Clinical trial authorisations - Amendments to 2 parts of dossier	£248	£302
36. Variations: other licence variations applications fees - Clinical trial authorisations - Amendments to 3 parts of dossier	£248	£302
36. Variations: other licence variations applications fees - Clinical trial authorisations - Protocol	£248	£302
36. Variations: other licence variations applications fees - Manufacturer's licences (including traditional herbal medicines) - Administrative	£283	£345
36. Variations: other licence variations applications fees - Manufacturer's licences (including traditional herbal medicines) - Standard	£565	£688
36. Variations: other licence variations applications fees - Parallel import (PI) - Standard	£393	£479
36. Variations: other licence variations applications fees - Wholesale dealers' licences (includes THMPD) - Administrative	£283	£345
36. Variations: other licence variations applications fees - Wholesale dealers' licences (includes THMPD) - Standard	£535	£652
37. Variations: Traditional Herbal Registration Scheme fees - Administrative	£152	£186
37. Variations: Traditional Herbal Registration Scheme fees - Complex	£635	£773

37. Variations: Traditional Herbal Registration Scheme fees - New excipient	£7,186	£8,748
37. Variations: Traditional Herbal Registration Scheme fees - Standard	£240	£293
38. Wholesale distribution authorisations: fees - Inspections - Inspection fee reduced rate THMP/Homeopathic only	£1,023	£1,114
38. Wholesale distribution authorisations: fees - Inspections - Inspection fee THMP/Homeopathic only	£1,880	£2,047
38. Wholesale distribution authorisations: fees - Inspections - Issue of GDP Certificates	£75	£82
38. Wholesale distribution authorisations: fees - Inspections - Office Based Risk Assessments	£1,862	£3,810
38. Wholesale distribution authorisations: fees - Inspections - Reduced rate Inspection fee	£1,331	£2,068
38. Wholesale distribution authorisations: fees - Inspections - Standard Inspection Fee (per site)	£2,662	£4,136
38. Wholesale distribution authorisations: fees - New Applications - Change of ownership	£439	£478
38. Wholesale distribution authorisations: fees - New Applications - Inspection Fee (per additional site if required)	£2,662	£2,898
38. Wholesale distribution authorisations: fees - New Applications - Reduced application plus reduced Inspection fee - General Sales List (GSL) only	£2,323	£2,529
38. Wholesale distribution authorisations: fees - New Applications - Reduced application* plus full inspection fee	£3,654	£3,978
38. Wholesale distribution authorisations: fees - New Applications - Standard application plus full inspection fee	£1,880	£2,047
38. Wholesale distribution authorisations: fees - Variations - Administrative variation	£283	£309
38. Wholesale distribution authorisations: fees - Variations - Standard variation	£535	£583
39. Early Access to Medicines Scheme (EAMS) - Promising Innovative Medicine (PIM) designation	£3,986	£4,852
39. Early Access to Medicines Scheme (EAMS) - Renewal fee for new indications	£4,154	£5,057
39. Early Access to Medicines Scheme (EAMS) - Renewal fee for new medicinal products	£12,821	£15,607
39. Early Access to Medicines Scheme (EAMS) - Scientific opinion for new indications	£8,309	£10,115
39. Early Access to Medicines Scheme (EAMS) - Scientific opinion for new medicinal products	£25,643	£31,214
41. ILAP – Innovation Passport	£3,624	£3,945
41.ILAP – Target Development Profile	£4,451	£4,845

Amended fees for Scientific Advice Meetings

New fee name (see final table for the old fees)	Proposed
Scientific Advice Meeting - High complexity	£17,516
Scientific Advice Meeting - Medium complexity	£13,137
Scientific Advice Meeting - Low complexity	£8,758
Scientific Advice Meeting – Simple complexity	£986

Amended fees for Control Testing

New fee name (see final table for the old fees)	Proposed
Control Testing - Daily rate	£5,093

Amended fees for Unlicenced Medicines Importation

New fee name (see final table for the old fees)	Proposed
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 101 to 500	£2,131
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 501 to 1000	£4,261
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 1,001-2,000	£8,521
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 2,001-5,000	£17,042
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - Per additional bracket of 5,000 notifications above 50,000	£17,042
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 10,001-15,000	£51,125

25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 20,001-25,000	£85,208
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 35,001-40,000	£119,291
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 5,001-10,000	£34,083
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 15,001-20,000	£68,166
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 25,001-30,000	£102,249
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 30,001-35,000	£119,291
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 35,001-40,000	£136,333
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 40,001-45,000	£153,375
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 45,001-50,000	£170,417

Fees replaced by proposed changes above or obsolete fees

Old fee name	Fee
14. Licence applications: marketing authorisation fees - Abridged complex - Complex: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	£19,063
14. Licence applications: marketing authorisation fees - Abridged complex - Complex: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	£11,487
14. Licence applications: marketing authorisation fees - Abridged standard - Standard: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	£6,985
14. Licence applications: marketing authorisation fees - Abridged standard - Standard: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	£6,361
14. Licence applications: marketing authorisation fees - Abridged simple - Simple: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	£2,820
14. Licence applications: marketing authorisation fees - Abridged simple - Simple: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	£2,820
14. Licence applications: marketing authorisation fees - Major - Major: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	£68,663
14. Licence applications: marketing authorisation fees - Major - Major: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	£20,281
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 101 – 1,000	£2,400
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 1,001 – 5,000	£12,000
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 5,001 – 20,000	£30,000
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 20,001 – 50,000	£60,000
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 50,001 – 100,000	£120,000
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 100,001 +	£200,000
26. Scientific advice meetings: fees - Quality development only	£2,421
26. Scientific advice meetings: fees - Pre-consultation application meetings on devices incorporating an ancillary medicinal substance* - Safety development only	£824
26. Scientific advice meetings: fees - Pre-consultation application meetings on devices incorporating an ancillary medicinal substance* - Quality and safety development	£1,044
26. Scientific advice meetings: fees - Pre-consultation application meetings on devices incorporating an ancillary medicinal substance* - Clinical development only	£1,044
26. Scientific advice meetings: fees - Pre-consultation application meetings on devices incorporating an ancillary medicinal substance* - Quality and clinical development	£1,429
26. Scientific advice meetings: fees - Pre-consultation application meetings on devices incorporating an ancillary medicinal substance* - Safety and clinical development	£1,429
26. Scientific advice meetings: fees - Pre-consultation application meetings on devices incorporating an ancillary medicinal substance* - Quality, safety and clinical development	£1,813
26. Scientific advice meetings: fees - Pre-consultation application meetings on devices incorporating an ancillary medicinal substance* - Broader scope meetings	£4,896
26. Scientific advice meetings: fees - Pharmacovigilance advice meetings - Standard meeting	£3,367
26. Scientific advice meetings: fees - Pharmacovigilance advice meetings - Major meeting	£3,986
26. Scientific advice meetings: fees - Pharmacovigilance advice meetings - Post-authorisation regulatory advice meetings	£3,039

26. Scientific advice meetings: fees - Safety development only	£2,421
26. Scientific advice meetings: fees - Pharmacovigilance advice meetings - Advertising advice	£2,421
26. Scientific advice meetings: fees - Quality and safety development	£3,367
26. Scientific advice meetings: fees - Clinical development only	£3,039
26. Scientific advice meetings: fees - Quality and clinical development	£3,986
26. Scientific advice meetings: fees - Safety and clinical development	£3,986
26. Scientific advice meetings: fees - Quality, safety and clinical development	£4,936
26. Scientific advice meetings: fees - Pre-consultation application meetings on devices incorporating an ancillary medicinal substance* - Quality development only	£824
30. Testing of samples: fees - Fee payable where the licensing authority carries out a full assessment - Plasma pools which require three or fewer tests	£198
30. Testing of samples: fees - Fee payable where the licensing authority carries out a paper-based assessment - Plasma pools which require three or fewer tests	£99
30. Testing of samples: fees - Fee payable where the licensing authority carries out a paper-based assessment - Plasma pools which require four or five tests	£99
30. Testing of samples: fees - Fee payable where the licensing authority carries out a paper-based assessment - Plasma pools which require six or more tests	£99
30. Testing of samples: fees - Fee payable where the licensing authority carries out a paper-based assessment - Band A – single component product, other than Botulinum toxin. requiring five or fewer in vitro tests	£367
30. Testing of samples: fees - Fee payable where the licensing authority carries out a paper-based assessment - Band B – Factor VIII, Factor VIX or intravenous Immunoglobin	£367
30. Testing of samples: fees - Fee payable where the licensing authority carries out a paper-based assessment - Band C – Multi-component product, or Botulinum toxin, requiring five or fewer in vitro tests	£992
30. Testing of samples: fees - Fee payable where the licensing authority carries out a paper-based assessment - Band D – product requiring six to nine in vitro tests	£992
30. Testing of samples: fees - Fee payable where the licensing authority carries out a paper-based assessment - Band E – product requiring (a) ten or more in vitro tests, or (b) one or more in vivo tests	£1,849
30. Testing of samples: fees - Fee payable where the licensing authority carries out a paper-based assessment - Band F – one or more tests that must be carried out under containment measures applicable to hazard Group 3 or 4 biological agents under Control of Substances Hazardous to Health Regulations 2002 (123) or requires use of human tissues or cells as part of testing	£1,849
30. Testing of samples: fees - Fee payable where the licensing authority carries out a full assessment - Plasma pools which require four or five tests	£237
30. Testing of samples: fees - Fee payable where the licensing authority carries out a full assessment - Plasma pools which require six or more tests	£253
30. Testing of samples: fees - Fee payable where the licensing authority carries out a full assessment - Band A – single component product, other than Botulinum toxin. requiring five or fewer in vitro tests	£1,826
30. Testing of samples: fees - Fee payable where the licensing authority carries out a full assessment - Band B – Factor VIII, Factor VIX or intravenous Immunoglobin	£2,101
30. Testing of samples: fees - Fee payable where the licensing authority carries out a full assessment - Band C – Multi-component product, or Botulinum toxin, requiring five or fewer in vitro tests	£2,574
30. Testing of samples: fees - Fee payable where the licensing authority carries out a full assessment - Band D – product requiring six to nine in vitro tests	£4,059
30. Testing of samples: fees - Fee payable where the licensing authority carries out a full assessment - Band E – product requiring (a) ten or more in vitro tests, or (b) one or more in vivo tests	£7,051
30. Testing of samples: fees - Fee payable where the licensing authority carries out a full assessment - Band F – one or more tests that must be carried out under containment measures applicable to hazard Group 3 or 4 biological agents under Control of Substances Hazardous to Health Regulations 2002 (123) or requires use of human tissues or cells as part of testing	£11,385