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Medicines & Healthcare products Regulatory Agency (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency)

Statutory guidance

Current MHRA fees

Updated 5 September 2022

Contents

This publication is available at https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees

MHRA fees for 2022 - 2023 are remaining the same as 2021 - 2022.

How to make a payment to the MHRA (https://www.gov.uk/guidance/make-a-payment-to-mhra).

For further information regarding EU Exit fees seeThe Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (https://www.legislation.gov.uk/ukdsi/2020/9780348213980/schedule/2/part/18?view=plain)

1. Active pharmaceutical ingredients manufacturers and importers registration: fees

Fees for registration of active substance manufacturers	Fees	Notes
New applications		
New application for registration as a manufacturer of active substances	£5006	£3143 application fee plus £1863 assessment fee

Fees for registration of active substance importer or distributor	Fees	Notes
New applications		
New application for registration as an importer or distributor of active substances	£3157	£1803 application fee plus £1354 assessment fee
Additional fee if the risk assessment of the initial application triggers an inspection	£582	£1936 Inspection fee less £1354 assessment fee
Inspection fee (per site if required)	£1936	Charged for inspections conducted post registration
Variations		

Fees for registration of active substance importer or distributor	Fees	Notes
Notification of changes (variation)	£257	
Inspection fee (per site if required)	£1936	
Annual compliance report		
Assessment of the annual compliance report	£257	Subsequent to 2013, 30 April of each reporting year
Annual compliance report where a variation is required	£514	When there have been changes during the year which need to be updated. £257 Notification of changes fee + £257 annual compliance report assessment fee.

2. Active substance importers or distributors: fees

Application for registration	£1,803
Assessment of initial application: active substance importer / distributor	£1,354
Additional fee for the first day of inspection if triggered following risk-assessment of the application	£582
Assessment of the Annual Compliance Report: Active Substance Importer / Distributor	£257
Notification of changes	£257
Standard daily rate for Inspection	£1,936
Persons appointed appeals procedure fee	£10,000

3. Active substance manufacturers: fees

Application for registration	£3,143
Assessment of Initial Application	£1,863
Additional fee for the first day of an inspection if triggered following risk-assessment of the application	£792
Assessment of the Annual Compliance Report	£257
Notification of Changes	£257
Inspection days	£2,655

4. Blood banks: application fees for a Review Panel hearing

Fee	£10,000

Notes: This fee will be payable on application for a Review Panel hearing and applies to all Review Panel proceedings related to an applicant who disagrees with a decision of the licensing authority and who has made an application to be heard pursuant to the relevant sections of the Human Medicines Regulations 2012 and subordinate legislation. A fee will be payable in respect of requests for hearings relating to marketing authorisations, manufacturer's licences and authorisations, clinical trials applications, herbal and homeopathic registration and blood establishments and blood banks.

If the outcome of the hearing is positive for the company and the original advice is overturned, the fee will be refunded. If an application is made and subsequently withdrawn before a panel has been appointed to consider the case, a partial refund (60%) will be made. If the application is withdrawn after the panel has been appointed, no refund will be applicable

5. Blood banks and other blood establishments: fees

Blood Establishments	Fee	Notes
New Applications		

Standard application plus full inspection fee	£5,657	£3074 application fee plus £2583 inspection fee
Inspection fee (per additional site if required)	£2,583	
Variations		
Standard variation	£518	
Periodic Fee		
Annual fee	£463	
Inspections		
Standard Inspection Fee: daily rate	£2,583	
Haemovigilance		
Annual fee	£492	Cost to the MHRA of operating the system for receiving and assessing reports of serious adverse events and reactions

Hospital Blood Banks and facilities	Fee	Notes
Inspections		
Inspection fee (per additional site if required)	£2,583	
Haemovigilance		
Annual fee	£492	In respect of cost to the MHRA of operating the system for receiving and assessing reports of serious adverse events and reactions(2)
Compliance		

Annual fee	£683	In respect of receipt and assessment of annual compliance reports submitted by hospital blood banks to the MHRA(3)
1. ‘Facility’ is defined in SI 2006/2013 as: “a hospital, any other facility or service owned or managed by a health service body, a care home, an independent clinic, a manufacturer, or a biomedical research institute”		
2. SI 2006/2013 exempts from payment of the annual haemovigilance fee a facility that has entered into an arrangement with a hospital blood bank for that hospital blood bank to report serious adverse events or reactions on the facility’s behalf		
3. The annual compliance fee is only payable by hospital blood banks, not by facilities. It is charged in addition to any inspection fee that may be payable		

6. Blood facilities: contract laboratories fees

Inspections	
Inspection fee* (per additional site if required)	£2,583
*For contract laboratories that test blood components on behalf of blood establishments or hospital blood banks	

7. Broker registration fees

Broker registration fees	**Fees**	**Notes**
New Applications		

Broker registration fees	Fees	Notes
New application for registration as a broker	£3157	(£1803 application fee + £1354 assessment fee)
Additional fee if the risk assessment of the initial application triggers an inspection	£582	(£1936 Inspection fee less £1354 assessment fee)
Inspection Fee (per site if required)	£1936	Charged for inspections conducted post registration
Variations		
Notification of Changes (Variation)	£257	
Annual Compliance Report		
Assessment of the Annual Compliance Report	£257	Subsequent to 2013, 30 April of each reporting year
Annual Compliance where a variation is required	£514	When there have been changes during the year which need to be updated. £257 Notification of Changes fee + £257 Annual Compliance Report assessment fee.

8. Clinical trials: application fees

Fee description	Type of fee	Fee
Applications with an IMP dossier	Higher fee (Phase 1, Full and Simplified IMPD)	£ 3060
Applications without an IMP dossier	Lower fee (Phase IV, Cross referral, Additional protocol)	£225
CT variations/amendments		£225

Notes:

There is no annual Clinical Trials fee and no fee for Phase IV notifications. For a cross-referral or additional protocol submission, no new Investigational Medical Product Dossier (IMPD) or IB data should be provided; however, copies of the relevant manufacturer's authorisation(s) and QP declaration (if applicable) should be provided since these are study specific.

9. Clinical investigations for devices: fees

The fee depends on the class of your device. The figure in brackets is the fee for re-notification in the event of an objection.

9.1 Class I, IIa, or IIb other than implantable or long-term invasive devices

Notification	Fee
Notification of a clinical investigation	£3,820 (£2,920)
Notification of a clinical investigation amendment	£207

9.2 Class IIb implantable or long-term invasive, Class III, and active implantable devices

Notification	Fee
Notification of a clinical investigation	£5,040 (£3,570)
Notification of a clinical investigation amendment	£331

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	£4,136
Further consultation of a Device which incorporates one or more known medicinal substances from an approved manufacturer of that substance	£818
Initial consultation for a Device which incorporates one or more known medicinal substances from a new source	£9,640

Further consultation of a Device which incorporates one or more known medicinal substances from a new source	£2,228
Initial consultation for a Device which incorporates a new active substance	£42,296
Further consultation of a Device which incorporates a new active substance	£10,501

Notes:

- if a device incorporates two or more medicinal substances the fee will be for the higher priced substance.
- the same fee applies regardless of the strength or concentration of the medicinal substance.
- one fee will apply to multiple applications made at the same time for a range of similar devices (e.g. a range of catheters made of the same material) incorporating the same medicinal substance at the same level.

11. Homoeopathic National Rules Scheme: fees

Standard	
5 stocks or fewer	£1,088
more than 5 stocks	£1,312

Reduced	
Stock already assessed	
5 stocks or fewer	£808
more than 5 stocks	£1,014

Formulation already assessed	
5 stocks or fewer	£808

Formulation already assessed	
more than 5 stocks	£1,014

Both stock and formulation already assessed	
5 stocks or fewer	£517
more than 5 stocks	£732

Supplementary fees	
New method of sterilisation (non-pharmacopoeial)	£2,154
New excipients	£7,185
New sources TSE risk actives/excipients (non-CEP)	£635

12. Homeopathic National Rules Scheme: fees for inspections

Inspections are charged at a daily rate	
Type of inspection	
All GMP, GCP and pharmacovigilance inspections	£2,655 (daily rate)

These include the following (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 inspections, including those of service providers
- clinical trials
- contract laboratories
- homoeopathic manufacturers

- blood banks
- blood establishments

Office-based risk assessments	£1,863	(see notes below)
GDP (wholesale dealers* including homeopathic wholesalers)		
*A reduced rate fee for a wholesale dealer inspection will be payable by wholesale dealers who handle GSL products only and for registered retail pharmacies and small wholesale dealers where wholesaling of licensed products does not exceed 15% or £35,000 of total turnover ONLY where an inspector spends less than 3.5 hours on site. This fee will be £1,328		
Full day rate £1,936		
Reduced rate (see notes below)	£968	
Office based risk assessments (see notes below) 1,354		

Before applying for an office-based risk assessment, please read the following:

1. Minimum fee of one day (with the exception of the GDP inspections)
2. Inspection daily rate is calculated against a standard 7 hour working day (excluding lunch breaks). Number of days spent on site for fees purposes will be calculated by dividing the number of hours on site by 7. Additional part days of less than 3.5 hours will be charged at half the daily rate and part days in excess of 3.5 hours will be charged at the full daily rate.
3. Daily rate fee includes pre-inspection preparation, travelling time, reporting of inspections and resolving issues. It also incorporates activities such as evaluation of compliance assessment report and other support functions and directly related overheads.
4. A reduced rate fee for a wholesale dealer inspection will be payable by wholesale dealers who handle GSL products only and for registered retail pharmacies and small wholesale dealers where wholesaling of licensed products does not exceed 15% or £35,000 of total turnover ONLY where an inspector spends less than 3.5 hours on site. This fee will be £1,328.

5. For inspections where two (or more) fully qualified inspectors undertake the inspection, the time on site for fees purposes will be the aggregated time for both inspectors.
6. For inspections attended by two or more inspectors, one or more of who is in training, only the cost of one inspector will be charged. The status of the inspectors will be made clear to the company at the start of the inspection.
7. The office based risk assessment fee will be charged where a risk assessment is conducted which does not lead to an inspection

13. Inspection: fees

Please note: Where a half fee is applicable, the sum will always need to be rounded up, e.g if the fee is £599, then the half fee is £300.

From 1 April 2015 fees for inspections will continue to be charged at a daily rate as follows:

Type of inspection	**Daily rate £**
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	2,655
Office based evaluation and risk assessments (see notes below)	1,863
GDP (wholesale dealers including homeopathic wholesalers):	
Full day rate	1,936
Reduced rate (see notes below)	968
Office based risk assessments (see notes below)	

Notes:

1. There is a minimum fee of 1 day (with the exception of the GDP inspections).
2. The inspection daily rate is calculated against a standard 7 hour working day (excluding lunch breaks). Therefore the number of days spent on site for fees

purposes will be calculated by dividing the number of hours on site by 7. Additional part days of less than 3.5 hours will be charged at half the daily rate and part days in excess of 3.5 hours will be charged at the full daily rate.

3. The daily rate fee includes pre-inspection preparation, reporting of inspections, resolving issues and may include travel time. It also incorporates activities such as evaluation of compliance assessment report and other support functions and directly related overheads.
4. A reduced rate fee for a wholesale dealer inspection will be payable by wholesale dealers who handle GSL products only and for registered retail pharmacies and small wholesale dealers where wholesaling of licensed products does not exceed £35,000 of total turnover only where an inspector spends less than 3.5 hours on site.
5. The MHRA Inspectorate charge a daily fee for each accredited inspector that conducts the inspection. If an inspector is undergoing accreditation and is only qualified to perform specific aspects of the inspection, a partial fee will be charged.
6. The office based inspection evaluation and risk assessment fee will be charged where a risk assessment of documentation not involving an inspection of a site is conducted which is in connection with the monitoring of GMP, GDP, GCP or GPvP. It can also be used in conjunction with or instead of an on-site inspection as notified to the site prior to the start of the inspection.

14. Licence applications: marketing authorisation fees

Major	
Major Orphan (reduced in exceptional circumstances)	£29,732
Incoming mutual recognition procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	£62,421
European reference product application for sale or supply in Northern Ireland	£62,421
Decentralised procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	£62,421

Major	
Major: (Previously granted by EU) - unfettered access route to GB	£18,437
Major: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	£62,421
Major: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	£18,437
National fee (any other case including hybrid applications)	£92,753

Abridged complex	
Incoming mutual recognition procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	£17,330
European reference product application for sale or supply in Northern Ireland	£17,330
Decentralised procedure for the sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	£17,330
Complex: (Previously granted by EU) - unfettered access route to GB	£10,443
Complex: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	£17,330
Complex: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	£10,443
National fee (any other case including hybrid applications)	£25,643

Abridged standard	
Incoming mutual recognition procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for a UKMA(GB)	£6,350
European reference product application for sale or supply in Northern Ireland	£6,350
Decentralised procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	£6,350
Standard: (Previously granted by EU) - unfettered access route to GB	£5,783

Abridged standard	
Standard: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	£6,350
Standard: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	£5,783
National fee (all other cases)	£9,402

Abridged simple	
Incoming mutual recognition procedure for sale or supply in Northern Ireland and Unfettered access route for UKMA(GB)	£2,564
Decentralised procedure for sale or supply in Northern Ireland and Unfettered access route for UKMA(GB)	£2,564
Simple: (Previously granted by EU) - unfettered access route to GB	£2,564
Simple: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	£2,564
Simple: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	£2,564
National fee (all other cases)	£2,564

15. Licence applications: manufacturers licence (including THMPD and homeopathic medicinal products)* fees

*To which section G of part IV of the Annex to Council Directive 75/318/EEC refers

Standard	£3,143
Non-orthodox practitioner (NOP)	£183
Change of ownership	£344

16. Licence applications: parallel imports fees

Complex application*	£18,180
Standard application*	£6,663
Simple application	£1,792
Change of ownership (including THMPD registrations)	£442
*An application for a Parallel Import licence for a product where there is no common origin between the imported and UK reference product. Similar definitions for incoming Mutual Complex and Standard applications apply	

17. Licence applications: Phase 1 Accreditation Scheme fees

Phase I Accreditation Scheme	Fee
Accreditation of Phase 1 units	£117
Certificate of accreditation	£62

18. Medicines export certificates: fees

Urgent request: two working days per set	
Original and two copies	£152
Standard request: ten working days per set	
Original and two copies	£68
Each additional copy	£34

19. Periodic fees for holding a marketing authorisation

Type of licence	Fee
New active substance (1)	£9,710
Derivatives with a different route of administration (1) or complex abridged (2)	£9,710
Other derivatives (1)	£6,554
Legal status/sale category	Fee type - see note 3
Prescription Only Medicine (POM)	
Standard fee*	£2,428
Reduced rate fee	£1,211
‘Maintenance’ fee	£307
All others (P, GSL, PLPI and None)	£307

Type of licence	Fee
Herbal	£76
Homeopathic and Anthroposophic PLRs (per PLR)	£76
Simplified Homeopathic Registration	No fee
National Rules Homeopathic Authorisation	£76
Manufacturer’s licence	£468
Wholesale dealer’s licence	£288
Wholesale dealer’s licence (reduced rate or GSL) (4)	£172
THMPD registration	£76

Notes:

1. Payable for first five complete fee periods following the year of grant. Includes Reduced Major Drugs with turnover greater than £200,000 - otherwise treat as prescription-only medicine.
2. Payable for first three complete fee periods following the year of grant.
3. Standard fee - This fee relates to prescription only medicine (POM) products only and means the periodic fee payable where the value of the product sold or supplied does exceed £35,000 in the relevant fee period. Reduced fee - This fee related to POM products only and means the periodic fee payable where the value of the product sold or supplied does not exceed £35,000 in the relevant fee period. Maintenance fee - This fee means the periodic fee payable relating to a POM is not expected to be manufactured, or imported into the United Kingdom during the relevant fee period and: (a) that the medicinal product has not been manufactured or imported into the UK during the period of 12 months preceding the commencement of the relevant fee period; OR (b) where the medicinal product had been manufactured or imported into the UK during the period referred to in (a) above that the value of that product sold or supplied did not exceed £1,000 during that period
4. Wholesale dealer's licence (reduced rate or GSL) The reduced fee payable under regulation 37(3) is applicable where the wholesale dealer's licence— (a) relates to anything done in a registered pharmacy by or under the supervision of a pharmacist and amounts to wholesale dealing, where such dealing constitutes no more than 15% of the total value of the sale of authorised medicinal products carried on at that pharmacy; (b) does not relate to anything done in a registered pharmacy, where the total value of the sale by way of wholesale dealing in authorised medicinal products does not exceed £35,000; or (c) relates to general sale list medicines only.

All other legal status medicinal products

Lower fee - This fee is payable relating to pharmacy medicines, general sale list medicines or 'none' status medicines regardless of turnover.

> If you no longer require your licence and do not want to be charged a periodic fee in April 2023, you are required to formally cancel your licence before 31 December 2022.

Holders of Manufacturers and Wholesale Dealer's licences are required to notify the MHRA at pcl@mhra.gov.uk by 31 December 2022. If you do not formally cancel your licence by this date, you will be charged a periodic fee for the period 1 April 2023 to 31 March 2024.

20. Licence renewals, reclassifications and assessment of labels and leaflets: fees

Where a half fee is applicable, the sum will always need to be rounded up e.g. if the fee is £599 the half fee is £300

Licence Renewal Applications	Fee
Manufacturers' licences Non-orthodox practitioner (NOP)	£178

First renewal of a market authorisation granted with a new active substance	Fee
UKMA(GB) granted under the unfettered access route	£747 (1), (2)
UKMA(GB) previously granted by EU (automatic recognition)	£747 (1), (2)
All other cases	£9,682 (1), (2)

Reclassification	Fee
POM to P - Additional for MA or PI application with reclassification element from POM to P (3), (4)	£11,992
Reclassification variation application POM to P (3),(4)	£11,992
P to GSL - Additional fee for MA or PI application with reclassification element from P to GSL (3), (4)	£8,162
Reclassification variation application P to GSL	£8,162
Reclassification variation application (MA) (analogous product) (4)	£734
Reclassification Type IB variation application (MA) (analogous product) (4)	£277
Reclassification variation application (PI) (analogous product)	£176

Assessment of labels and leaflets	

Assessment of labels and leaflets	
Single or first application (5)	£518
National (BROMI) - Article 61 (3) Notification (6)	£186
Parallel imports	£328

Notes:

1. Where the application:
   - relates to a medicinal product which, at the time the marketing authorisation was granted, contained a new active ingredient; and
   - is the first renewal in relation to that product.
2. If a number of such renewal applications are made at the same time and in relation to products with the same active ingredient, dosage form, indications, Periodic Safety Update Report (PSUR) and renewal date, the full fee is charged for the first application, but a fee of £747 will be payable in respect of each of the other applications.
3. Where the Agency is of the view that a major reclassification application does not require consideration by a medicines advisory committee a 50% reduction of the fee applies.
4. If multiple MA applications with reclassification elements are made at the same time and in relation to products with the same active ingredient, the full additional fee is charged for one application but only £734 for each other application. If multiple reclassification variation applications are made at the same time and in relation to products with the same active ingredient, the full fee is charged for the one application but in relation to each other application the fee is only £734, or £367 for PLPI variations in the case of other applications where there is an analogous product already with the same legal status.
5. For all label and leaflet applications, a bulk “discount” applies where a number of simultaneous applications are made for identical changes covering a range of strengths of the same dosage form. The first application is charged at the full rate shown and second and subsequent applications are charged at 50%.
6. See more on national leaflets and labels (https://www.gov.uk/medicines-packaging-labelling-and-patient-information-leaflets).

21. Orphan Marketing Products: fees

Orphan Major (Full fee)	£92,753

Orphan Major (exceptional circumstances in which point 6 pf Part II of Annex 1 in the 2001 Directive applies)	£29,732
Orphan Complex (Full Fee)	£25,643
Orphan Standard (Full Fee)	£9,402

Notes:

Where the licensing authority grants an orphan marketing authorisation, the following percentage of the fee otherwise payable under regulation 12(1)(a) in connection with the application for that authorisation shall be refunded, if it has not yet paid, shall be waived

(a) Small and medium (SME) company: 100%

(b) Applications not made on behalf of SME but which paragraph 6 of Part II of Annex 1 to the 2001 Directive applies: 50%

(c) Any other case: 10%

22. Pharmacovigilance (PV) Safety Review: fees

PV Major Safety Review (1-2 active ingredients)	£51,286
PV Major Safety Review (3 active ingredients)	£59,595
PV Major Safety Review (4 active ingredients)	£67,904
PV Major Safety Review (5 or more active ingredients)	£76,213
PV Periodic Safety Update Report (PSUR) single assessment: Full Fee	£890
PV Periodic Safety Update Report (PSUR) single assessment: Half Fee	£445
PV Post Authorisation Safety Study (PASS) protocol	£8,309
Assessment of PASS Results	£8,309

23. Plasma Master File (PMF) & Vaccine Antigen Master File certification or certified annual update work: fees

Certification of new PMF (for scientific & technical evaluation)	£8,309
Certified Annual Update of a PMF (epidemiology update only)	£277
Certified Annual Update of a PMF (significant changes to safety information)	£734
Vaccine Antigen Master File (VAMF) certification	£8,309

24. Pre-Assessment (Rolling Review): fees

Application by pre-assessment (NAS) - Module 3 (chemical, pharmaceutical and biological information)	£23,188
Application by pre-assessment (NAS) - Module 4 (non-clinical reports)	£23,188
Application by pre-assessment (NAS) - Module 5 (clinical study reports)	£23,188
Application by pre-assessment (Biosimilar) - Module 3 (chemical, pharmaceutical and biological information)	£4,333
Application by pre-assessment (Biosimilar) - Module 4 (non-clinical reports)	£4,333
Application by pre-assessment (Biosimilar) - Module 5 (clinical study reports)	£4,333

25. Safety and quality vetting of unlicenced imported medicines fees

Number of notifications estimated for coming year	**Additional sum to be paid***
1 – 20	£130
21 – 100	£519
101 – 1,000	£2,077
1,001 – 5,000	£10,383
5,001 – 20,000	£25,957

Number of notifications estimated for coming year	Additional sum to be paid*
20,001 – 50,000	£51,914
50,001 – 100,000	£103,828
100,001 +	£155,742

*Additional sum to be paid with annual periodic fee for Manufacturers Licence holders and wholesale dealer licence holders

26. Scientific advice meetings: fees

Quality development only	£2,201
Safety development only	£2,201
Quality and safety development	£3,061
Clinical development only	£2,763
Quality and clinical development	£3,624
Safety and clinical development	£3,624
Quality, safety and clinical development	£4,487
Discussion on development of paediatric forms and uses meeting criteria for waiver set down in schedule 5 paragraph 10 of SI 2008 No.552	No fee
Pre-consultation application meetings on devices incorporating an ancillary medicinal substance*	
Quality development only	£749
Safety development only	£749
Quality and safety development	£949
Clinical development only	£949
Quality and clinical development	£1,299
Safety and clinical development	£1,299

Quality, safety and clinical development	£1,648
Broader scope meetings	£4,451
Pharmacovigilance advice meetings	
Standard meeting	£3,061
Major meeting	£3,624
Post-authorisation regulatory advice meetings	£2,763
Advertising advice	£2,201
Advice on labels and leaflets	£2,201
Reclassification advice meetings	
Pharmacy to General Sales List switch	£2,763
Prescription Only Medicine to Pharmacy switch	£3,624

*Scientific advice on the medicinal substance aspects of the device product.

27. Simplified Homeopathic Registration Scheme: fees

Standard			
5 stocks or fewer	£790	more than 5 stocks	£1,034
Reduced			
Stock already assessed			
5 stocks or fewer	£478	more than 5 stocks	£704
Formulation already assessed			
5 stocks or fewer	£ 478	more than 5 stocks	£704
Both stock and formulation already			

assessed			
5 stocks or fewer	£159	more than 5 stocks	£393

28. Simplified Homeopathic Registration Scheme: Decentralised Procedure applications: fees

Where the UK is CMS	5 stocks or fewer	£430	more than 5 stocks	£563

29. Simplified Homoeopathic Registration Scheme: Mutual Recognition Procedures: fees

Mutual recognition outgoing	
5 stocks or fewer	£287
more than 5 stocks	£374
Mutual recognition incoming	
5 stocks or fewer	£501
more than 5 stocks	£638

30. Testing of samples: fees

Product Type	Fee payable where the licensing authority carries out a full assessment	Fee payable where the licensing authority carries out a paper-based assessment

Plasma pools which require three or fewer tests	£180	£90
Plasma pools which require four or five tests	£215	£90
Plasma pools which require six or more tests	£230	£90
Band A – single component product, other than Botulinum toxin. requiring five or fewer in vitro tests	£1,660	£305
Band B – Factor VIII, Factor VIX or intravenous Immunoglobin	£1,910	£305
Band C – Multi-component product, or Botulinum toxin, requiring five or fewer in vitro tests	£2,340	£305
Band D – product requiring six to nine in vitro tests	£3,690	£677
Band E – product requiring (a) ten or more in vitro tests, or (b) one or more in vivo tests	£6,410	£677
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	£10,350	£677

31. Traditional Herbal Registration Scheme: fees

Standard	
3 or fewer existing herbal active ingredient	£2,423
more than 3 existing herbal active ingredients	£3,634

Reduced	
Category I	
3 or fewer existing herbal active ingredients	£539

Reduced	
more than 3 existing herbal active ingredients	£807
Category II	
3 or fewer existing herbal active ingredients	£807
more than 3 existing herbal active ingredients	£1,212

Complex	
single new herbal active ingredient	£4,846
2 or more new herbal active ingredients	£7,269

Traditional Herbal Registration Scheme: supplementary fees	
Ancillary vitamins / minerals	
Existing Sources plus CEP	£1,077
New sources (non-CEP)	£2,154
New excipients	£7,186
New sources TSE risk excipients (non-CEP)	£638
Sterile products	£2,154
Inspection of Manufacturers	
Full day	£1,615
Half day	£994
Inspection of Wholesale Dealers	
Full day	£1,367
Half day	£744
Inspection of non-orthodox practitioners	£295

*Reduced registration application category I" means an application, other than a complex registration application, for a traditional herbal registration relating to a medicinal product which is presented in the form of a herbal tea; "reduced registration application category II" means an application, other than a complex registration application, for a traditional herbal registration where the application falls within one of the descriptions specified in sub-paragraphs (a) to (d) as follows:

(a) the application relates to a medicinal product which is presented in the form of a herbal tincture

(b) the application relates to a medicinal product which is presented in the form of an essential oil

(c) the application relates to a medicinal product which is presented in the form of a fatty oil or

(d) the application relates to a medicinal product which contains only "herbal substances in a capsule"

32. Variation: Homeopathic National Rules Scheme fees

Standard variation application	£243
Indication	£374
Other applications (for up to 30 variations where no further medical, technical or scientific assessment is required)	£122
Other applications (for any subsequent variations where no further medical, technical or scientific assessment is required)	£61

33. Variations: Homeopathic Simplified Scheme fees

New technical	**£243**
Other applications (where further medical, technical or scientific assessment is required)	£243
Other applications (for up to 30 variations where no further medical, technical or scientific assessment is required)	£122

New technical	**£243**
Other applications (for any subsequent variations where no further medical, technical or scientific assessment is required)	£61

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	£277
Single kind variation - Type II	£277
Single kind variation - Type II Complex Variation	£2,493
Single kind variation - Extended Type II Complex Variation	£7,693

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 1A Variation	No fee
National Type 1B Variation	£277
National Type II Variation	£734
National Type II Complex Variation	£8,309
National Type II Extended Complex Variation	£25,643

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	£277

Major Variation (Type II) Group	£496
Major Variation (Type II) Complex Group	£2,703
Major Variation (Type II) Extended Complex Group	£7,883

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	£622
National Type II Major Variation Group	£1,652
National Type II Major Variation Complex Group	£9,010
National Type II Major Variation Extended Complex Group	£26,276

36. Variations: other licence variations applications fees

Parallel import (PI)	
Standard	£357
Administrative	No fee

Manufacturer’s licences (including traditional herbal medicines)	
Standard	£514
Administrative	£257

Wholesale dealers’ licences (includes THMPD)	
Standard	£486
Administrative	£257

Clinical trial authorisations	
Amendments to 1 part of dossier	£225
Amendments to 2 parts of dossier	£225
Amendments to 3 parts of dossier	£225
Protocol	£225

Where a half fee is applicable, the sum will always need to be rounded up, eg if the fee is £599, the half fee is £300

37. Variations: Traditional Herbal Registration Scheme fees

Standard	£240
Complex	£635
New excipient	£7,186
Administrative	£152

Notes: 1. Reductions for ‘bulks’ of single or group variations (ie same changes different authorisations belonging to the same company) are available. Further guidance for bulk variations is available at the end of this page

- Standard fees will be charged where the application is concerned with the introduction of new suppliers of defined simple Active Pharmaceutical Ingredients (APIs) only. Further information: Fees for New Suppliers of Defined Simple Active Pharmaceutical Ingredients (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/425024/Fees_for_new_suppliers_of_defined_simple_active_pharmaceutical_ingredients__APIs_.pdf).

37.1 Bulk fee reductions

Terminology

- Lead Case: the first Licence listed on the application form of a specific variation

- Bulk Case: each additional licence included in the application form of a specific variation

Reductions for ‘bulks’ of single or group variations are available. You must meet the following criteria:

- the changes are to authorisations registered under the same company number
- the changes are identical across the lead and bulk members, and rely on the same supporting data. (QRD updates to the SPC do not need to meet this requirement)
- the authorisations included are not a combination of Mutual Recognition and National licences

Complex variations are subject to different bulk fee reductions

Each bulk case included in the variation carries a 50% reduced fee of the full specified fee for the lead case. The fee type for the lead case is dependent upon the type of submission (grouping/single), the category of variation (Type 1A/1B/2) and procedure type of MA (National/MRP or CMS).

IMPORTANT: Type IB or Type II variations that include any Type IA changes require a grouped fee according the highest classification of change. Variations in this format supported by a proof of payment for a single fee (or other lesser fee) will be invalidated.

Example 1: National Procedures

Type IB National - lead case - £277, each bulk case - £139 Minor variation (type IB) grouped - lead case - £622, each bulk case £311

Example 2: Mutual Recognition Procedure.

CMS major variation (type II) Grouped lead case – £496, each bulk case - £298

Complex Variations

The lead case incurs a type II complex or extended complex fee, each bulk member is charged at the relevant single type II fee (national or CMS).

Grouped Complex Variations

The lead case incurs a ‘type II grouped complex’ or ‘extended grouped complex fee’ and each bulk member is charged at the type II group major bulk fee (national or CMS).

38. Wholesale distribution authorisations: fees

New Applications		
Standard application plus full inspection fee	£3739 (£1803 application fee plus £1936 inspection fee)	
Inspection Fee (per additional site if required)	£1936	
Reduced application* plus full inspection fee	£2838	£902 application fee plus £1936 inspection fee
Reduced application plus reduced Inspection fee - General Sales List (GSL) only	£1870	£902 application fee plus £968 inspection fee
Change of ownership	£399	
Variations		
Standard variation	£486	
Administrative variation	£257	

Inspections		
Standard Inspection Fee (per site)	£1936	(See: fees for Inspection)
Reduced rate Inspection fee	£968	
Inspection fee THMP/Homeopathic only	£1367	
Inspection fee reduced rate THMP/Homeopathic only	£744	
Office Based Risk Assessments	£1354	
Issue of GDP Certificates	£68 + 1 additional copy	

Notes:

Special reduced rates to apply to:

1) Wholesale dealers handling GSL products only.

2) Registered retail pharmacies where wholesaling of licensed products does not exceed 15% of total turnover in licensed products.

3) Small wholesale dealers where wholesaling of licensed products does not exceed £35,000 of total turnover in licensed products.

4) See also fees for registration of Active Pharmaceutical Ingredient Manufacturers

39. Fees: additional information

The medicines (products for human use) (fees) regulations 2016 (http://www.legislation.gov.uk/uksi/2016/190/contents/made)

See information on fees for new suppliers of defined simple active pharmaceutical ingredients (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/419433/New_suppliers_of_defined_simple_active_pharmaceutical_ingredients__APIs__-_fees.pdf).

1. Definitions of different types of marketing authorisation applications: one of the most common questions we are asked is about the definitions of the different types of marketing authorisation applications. We are therefore publishing an extract from the MHRA fees legislation the The Medicines (Products for Human Use)(Fees) Regulations 2010 S.I No 551 which defines each of the different types of application: See MHRA fees definitions (https://www.gov.uk/government/publications/mhra-fees) for information.
2. Clarification of terminology relating to periodic fees: you might find it useful to refer to the terminology relating to periodic fees (https://www.gov.uk/government/publications/mhra-fees) from the The Medicines (Products for Human Use)(Fees) Regulations 2010 S.I No 551. They will help you determine how to calculate turnover and whether you can claim reduced or maintenance rates for any of your products.
3. The Agency's fees legislation currently has provision for some payment easements for small companies and payment waivers for small and medium companies (SME) (https://www.gov.uk/government/publications/mhra-fees/payment-easements-and-waivers-for-small-and-medium-companies).

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