Title: Amendments to the fees charged by the MHRA in relation to the regulation of medicines for human use **IA No:** **RPC Reference No:** **Lead department or agency:** Medicines and Healthcare products Regulatory Agency	**Impact Assessment (IA)** **Date:** 23 February 2023 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary Legislation **Contact for enquiries:** maham.masood@mhra.gov.uk

Summary: Intervention and Options

RPC Opinion: N/A out of scope

Cost of Preferred Option (in 2019 prices, 2020 present value base year)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
£0m	£66.2m	£7.7m	Not a qualifying provision

What is the problem under consideration? Why is government action or intervention necessary?

The MHRA has recently undertaken a review of its statutory fees. The review found that numerous areas of the MHRA's work are under-recovering costs. Adjustments therefore need to be made to the MHRA's statutory fees to ensure all costs involved in delivering the regulatory activities associated with each fee are recovered. This is essential for ensuring the MHRA works within the principles of HM Treasury's Managing Public Money guidance, and also to ensure the MHRA is self-sufficient and financially sustainable in the long-term.

What are the policy objectives of the action or intervention and the intended effects?

The objective of this policy is to ensure full cost recovery of regulatory work done by the MHRA in accordance with Managing Public Money principles. This is essential for ensuring the MHRA is self-sufficient and financially sustainable in the long-term.

This approach is simply intended to make sure that the government neither profits at the expense of consumers or industry, nor makes a loss for taxpayers to subsidise.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option one: Do nothing. In the do nothing option we maintain fees at the current level. This would mean the MHRA continues to under recover the costs of its regulatory activities.

Option two: Increase statutory fees to ensure cost recovery. Increase fees to ensure all costs involved in delivering the regulatory activities associated with each fee are recovered.

Option two is the preferred option as this best meets the policy objective.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 2024

Is this measure likely to impact on international trade and investment?		No		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** N/A	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Chief Finance Officer Rose Braithwaite Date: 23/02/23

Summary: Analysis & Evidence

Policy Option 1

Description: Do nothing: maintain current statutory fee levels

FULL ECONOMIC ASSESSMENT

Price Base Year 2023	PV Base Year 2023	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 0	**High:** 0	**Best Estimate:** 0

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	0			
High	0			
Best Estimate	0			

Description and scale of key monetised costs by 'main affected groups'

As this is the baseline, the costs and benefits are zero.

Other key non-monetised costs by 'main affected groups'

Under this option, the MHRA is not able to fully recover the costs of its regulatory activities, which would jeopardise its ability to be self-sufficient and financially sustainable in the long-term.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	0		0	**0**
High	0		0	**0**
Best Estimate	0		0	**0**

Description and scale of key monetised benefits by 'main affected groups'

As this is the baseline, the costs and benefits are zero.

Other key non-monetised benefits by 'main affected groups'

Under this option organisations which use the MHRA's services would continue to pay lower fees, which do not reflect the full cost of the services provided to them.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5

The key risk of this option is that the MHRA would not be self-sufficient and financially sustainable in the long-term. This would risk the quality of the delivery of the regulatory service it provides. Underfunded services would need to be subsidised, which does not align with Managing Public Money principles.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 0	**Benefits:** 0	**Net:** 0	

Summary: Analysis & Evidence Policy Option 2 (Recommended)

Description: Increase statutory fees to ensure cost recovery

FULL ECONOMIC ASSESSMENT

Price Base Year 2023	PV Base Year 2023	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 0	**High:** 0	**Best Estimate:** 0

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	0		£8.9m	**£76.8m**
High	0		£10.9m	**£93.6m**
Best Estimate	0		£9.8m	**£84.4m**

Description and scale of key monetised costs by 'main affected groups'

The cost of this policy is the additional fees paid by organisations which use the MHRA's services. Assuming the volumes of business remain constant to previous years, we expect this to cost £9.8m per year.

This is an economic transfer, as it is not a new use of resources, rather a transfer of payment from industry to the MHRA.

Other key non-monetised costs by 'main affected groups'

There are no non-monetised costs of this option.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	0		£8.9m	**£76.8m**
High	0		£10.9m	**£93.6m**
Best Estimate	0		£9.8m	**£84.4m**

Description and scale of key monetised benefits by 'main affected groups'

The benefit of this policy is the additional income gained by the MHRA. Assuming the volumes remain constant, we expect the income for MHRA to increase by £9.8m per year.

This is an economic transfer, as it is not a new use of resources, rather a transfer of payment from industry to the MHRA.

Other key non-monetised benefits by 'main affected groups'

This option means that the MHRA's funding will be in accordance with Managing Public Money guidance, and it will allow the MHRA to maintain the quality of the delivery of the regulatory service it provides.

This will secure the long-term financial sustainability of the MHRA and enable the delivery of a responsive, innovative, and efficient regulatory service that protects and improves patient and public health by facilitating access to high-quality, safe, effective and innovative medical products.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5%

We have made an assumption in the analysis that the volume of business the MHRA receives will remain constant. It is likely the actual volume forecasts will fluctuate. To account for this sensitivity, we have provided a high and low estimate of the costs, based on the volumes fluctuating 9% lower and 10.9% higher than our best estimate. These high and low range scenarios are based on analysis of historical fluctuations.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 9.8	**Benefits:** 0	**Net:** 9.8	n/a

Evidence Base

Background

1. The MHRA regulates medicines, medical devices and blood components for transfusion in the United Kingdom, carrying out regulatory functions on behalf of the Secretary of State. Generally, whenever the MHRA provides a direct service for medicines, medical devices or blood components for transfusion regulatory work, a fee is charged to recover the costs. Although medical devices work is primarily funded through grant-in-aid from the Department of Health and Social Care, there are aspects of the MHRA's medical devices work that are also fee dependent. As the fees are set in secondary legislation, legislative change is required to amend them.

2. 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.

3. In setting the cost of fees, the MHRA has taken numerous factors into account to ensure costs are recovered, 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.

4. The MHRA's statutory fees have been adjusted several times in the past to ensure they remain accurate; this is standard practice for government bodies that charge fees. However, the fees have not been updated since financial year 2016/17 for medicines regulatory services. This means that there have been fee decreases in real terms (i.e. accounting for the effects of inflation).

5. Decisions to not adjust fees in recent years were made to provide certainty and stability for the health and social care sector and industry throughout the EU Exit period, and while the MHRA and wider healthcare system responded to the COVID-19 pandemic. However, it is not sustainable for the MHRA to continue charging fees at their current level as they do not adequately recover costs. In addition, the MHRA has been operating as a Trading Fund since 2003. However, in 2019 the Office for National Statistics reviewed the sector classification of the MHRA and reclassified it from a Trading Fund to a Market Regulatory Agency. This reclassification, which came into force in April 2022, means that the MHRA is not able to retain and rely on cash reserves to manage areas of under-recovery as it has done previously. This means that cost-recovery across all services is essential to ensure the financial sustainability of the MHRA moving forwards.

6. This impact assessment, and the accompanying statutory instrument, cover the fee increases in relation to the medicines regulatory services that the MHRA provides. The MHRA is also implementing fee increases for medical devices and blood components for transfusion regulatory services, in a separate statutory instrument. The medical devices and blood components for transfusion services fee increases are out of scope of this impact assessment, as they are not part of the statutory instrument this impact assessment is supporting.

Problem under consideration and rationale for intervention

7. The MHRA has recently undertaken a review of its statutory fees. The review identified numerous areas of the MHRA's work that are under-recovering. Adjustments therefore need to be made to the MHRA's statutory fees to ensure all costs involved in delivering the activity associated with each fee are recovered.

8. This approach is simply intended to make sure that the government neither profits at the expense of consumers or industry, nor makes a loss for taxpayers to subsidise.

9. This is essential for ensuring the MHRA works within the principles of HM Treasury's Managing Public Money[1], and also to ensure the MHRA is self-sufficient and financially sustainable in the long-term.

Policy objective

10. The objective of this policy is to ensure full cost recovery of work done by MHRA in line with Managing Public Money principles. They are necessary to ensure the MHRA's long-term financial sustainability and enable the Agency to deliver a responsive, innovative and efficient regulatory service that protects and improves patient and public health by facilitating access to high-quality, safe, effective and innovative medical products.

Description of options considered

Option one: Do nothing.

11. In the 'do nothing 'option we maintain fees at the current level. This would mean the MHRA continues to under recover the costs of its regulatory activities.

Option two: Increase medicines statutory fees to ensure cost recovery (preferred option).

12. Increase medicines fees to ensure all costs involved in delivering the regulatory activities associated with each fee are recovered.

Summary and preferred option with description of implementation plan

13. The fee increases will be implemented from April 2023. There are three fee increase categories that we are taking forward.

14. Annex B contains the list of fee changes contained within these three categories.

Category 1

15. The first category is to apply a 10% indexation uplift across the MHRA's statutory fees. The indexation is linked to staff costs which, in line with the Civil Service pay award, have risen by 10% since the last medicines fees review in 2016. Staff costs account for over half of the MHRA's total expenditure and therefore have a significant impact on the fees charged.

16. The remaining expenditure include items such as IT, laboratories and accommodation, the costs of which have risen in line with inflation. At the point the revised fees were calculated, the Consumer Prices Index (CPI) was up 21% since 2016, however Agency

[1] Managing public money - GOV.UK (www.gov.uk)

cost reduction programmes mean the MHRA is able to cover most increases within the 10% uplift.

Category 2

17. Through a review of its fees, the MHRA identified fees which are under-recovering so significantly that the 10% indexation uplift would mean they still do not achieve cost recovery. The MHRA is therefore uplifting these fees on top of the indexation increase in order to achieve full cost recovery. Each specific fee uplift varies as it reflects the cost of the activity, tasks and workload involved in delivering the service and is set solely to achieve cost recovery.

Category 3

18. The third category is to introduce new fees, to ensure that the MHRA appropriately recovers the cost of the regulatory activity across all its services, in accordance with HM Treasury's principles on Managing Public Money.

19. The fees have been set according to estimates of the cost of the activity, workload and tasks involved in delivering the service. The fees for these services will be kept under review over the next 12-month period and will be adjusted in April 2024, if required, to ensure they are as close to cost recovery as possible.

Monetised and non-monetised costs and benefits of each option

20. This impact assessment is only seeking to set appropriate fees for services the MHRA already provides. The impact assessment is not discussing the provision of any new services.
21. As this impact assessment only deals with where the funding for the services already being provided will come from, all of the costs and benefits are economic transfers, therefore the net present value will be zero.

Option one: do nothing.

22. Option one is our baseline, therefore the costs and benefits are zero.

Costs

23. Under this option, the MHRA is not able to fully recover the costs of its fees, which would jeopardise its ability to be self-sufficient and financially sustainable in the long-term. This would risk the quality of the delivery of the regulatory service it provides. Underfunded services would need to be subsidised, which does not align with Managing Public Money principles.

Benefits

24. Under this option organisations which use the MHRA's services would continue to pay lower fees, which do not reflect the full cost of the services provided to them.

Option two: Increase fees

Costs

25. The cost of this policy falls on the organisations who use the MHRA's services. These are direct costs and are included in the business net present value, net cost to business per year and equivalent annual direct impact on business calculations.
26. We have estimated the total cost of the fee rise to businesses is between £8.9m per year to £10.9m per year, with a best estimate of £9.8m per year. This calculation is based on the fee increases outlined in Annex B, and we have taken previous years' volumes and assumed they will be consistent.
27. It is likely the actual volume forecasts will fluctuate. To account for this sensitivity we have also provided a high and low estimate of the costs, based on the volumes fluctuating 9% lower and 10.9% higher than our best estimate. Please see the 'Risks and assumptions' section for information on this sensitivity analysis.
28. As businesses already have processes for checking and paying fees, we do not expect there to be any additional transitional or familiarisation costs from this option.

Benefits

29. The direct benefits of this policy fall on the MHRA, who will receive additional income as a result of the increase in fees. The benefits to the MHRA will be equal to the costs to industry, therefore the benefits of this policy between £8.9m per year to £10.9m per year, with a best estimate of £9.8m per year.
30. This option means that the MHRA's funding will be in accordance with Managing Public Money guidance, and it will allow the MHRA to maintain the quality of the delivery of the regulatory service it provides. 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.
31. This will secure the long-term financial sustainability of the MHRA and enable the delivery of a responsive, innovative, and efficient regulatory service that protects and improves patient and public health by facilitating access to high-quality, safe, effective and innovative medical products.

Risks and assumptions

32. The key assumption in this analysis is the volume forecasts for the MHRA's activities. To account for this, we have conducted sensitivity analysis around this assumption.

33. To examine how much the income may fluctuate, we have analysed the fluctuation in the MHRA's income in the relevant categories over an eleven-year period, from 2011/12 to 2021/22. The analysis showed that:

    a. The lowest the income deviated below our best estimate was 9 percent.
    b. The highest the income deviated above our best estimate was 10.9 percent.
    c. The mean deviation was -1.3 percent.
    d. The standard deviation was 5.6 percent.

34. This analysis gives us reasonable confidence in our best estimate. However, to account for the fluctuation in volumes, we have provided a range of the costs and benefits based on volumes reducing 9% lower than or increasing 10.9% higher than our best estimate.

Rationale and evidence to justify the level of analysis used in the IA (proportionality approach)

35. This is a standard fee increase being done in line with Managing Public Money guidance. We have provided estimations of the cost to business of the fee increase in line with the Better Regulation Framework[2], and conducted relevant sensitivity analysis.

Wider impacts

Consultation

36. The MHRA and the Department of Health Northern Ireland launched a public consultation on 31 August 2022 to seek the views of stakeholders on proposals to amend the statutory fees charged for regulatory services. The consultation closed on 23 November 2022. The MHRA received a total of 99 formal responses to the consultation.

37. There was a general acceptance of the need to ensure cost recovery for regulatory activities, and that this was important for ensuring a consistent level of service. One of the main themes raised by respondents was the need for more consistent and improved services, and that any increase in fees should be met with improvements in MHRA performance. By ensuring the MHRA is sufficiently resourced and operating a sustainable cost recovery fee model, this will help the MHRA deliver the required service standards more consistently.

38. The MHRA has analysed all responses and considered the feedback received alongside the necessity of actions that must be taken to operate on a cost recovery basis. A summary of the consultation responses and the Government's response can be found online: https://www.gov.uk/government/consultations/consultation-on-proposals-for-changes-to-the-medicines-and-healthcare-products-regulatory-agencys-statutory-fees

Impact on micro, small and medium businesses

39. Data from the MHRA systems shows that of the 6227 organisations in our customer base, between 24 to 43 of them are micro, small or medium enterprises. This means micro, small or medium enterprises make up between 0.4% to 0.7% of our customer base.

40. The MHRA is obliged to recover the costs of the regulatory work it does from industry, so excluding micro, small and medium businesses from this legislation is not a viable option. We recognise that there will be a burden on micro, small and medium businesses from the increase in fees.

41. The MHRA has established payment easement measures in place to reduce the burden on smaller businesses, and another payment easement measure for medium businesses. An outline of the payment easement offer to small businesses can be seen in Annex A.

Equality assessment

42. Evidence gathered from the consultation suggested that increasing fees may have an adverse impact on development and access to medical products for rare conditions or minority groups with smaller patient populations. The UK is a recognised leader in research, treatment, and care for rare diseases and has made important strides in the treatments made available for rare disease patients. The MHRA is committed to

[2] Better regulation framework - GOV.UK (www.gov.uk)

improving development and access to medicinal products for rare conditions and has a number of initiatives designed to support patient access to medical products, and in particular for rare conditions, we offer a number of important services in this regard:

a. The MHRA introduced the Early Access to Medicines Scheme (EAMS) in 2014 to give people across the UK early access to new medicines that do not yet have a marketing authorisation, when there is a clear unmet clinical need. Since its launch, rare disease patients living with Duchenne muscular dystrophy and haemophilia have benefited from the scheme with earlier access to life-changing treatments.

b. In 2021, the MHRA launched the Innovative Licensing and Access Pathway (ILAP), which aims to accelerate the time to market, facilitating patient access to medicines. By supporting expedited, efficient and innovative approaches to product development and patient access, ILAP allows the MHRA and its partner agencies to support the path to market of innovative and novel treatments, while ensuring there are no compromises in assessing the safety and efficacy of the treatments.

c. ILAP's 'innovation passport' designation is the gateway to the pathway and includes a rare disease and/or other special population component among the criteria. The decision on whether to issue an innovation passport is made between the partners and includes input from the ILAP Patient and Public Reference Group, which includes rare disease representation.

d. The MHRA also offers significant incentives in the form of market exclusivity and full or partial refunds for marketing authorisation fees to encourage development of medicines in rare diseases. Waivers from scientific advice fees are also available for UK based SMEs.

43. The fee changes will not impact on these incentives and waivers, which continue to be available. More information can be found in Annex A and on the MHRA's website.

Environment assessment

44. The proposals are not thought to impact the environment.

Monitoring and Evaluation

45. The MHRA has a finance group who have well established reporting systems in place to closely monitor the impact of this policy. They will continue to use those financial accounting systems to assess whether the cost of MHRA fees accurately reflects the cost to MHRA of delivering those activities.

46. The MHRA's Chief Finance Officer will provide governance over the fees policy, to ensure the MHRA continues to adhere to Managing Public Money principles, and that it has the funding to provide a fit for purpose regulatory service.

Annex A: Payment easement policy for small companies

1. The following is a brief overview of MHRA's payment easement policy for small companies. It should not be used as legal guidance for the policy. The full details of MHRA's payment easement offer for small and medium companies can be seen online[3].

Payment Easements Available for Small Companies

2. The MHRA's fees legislation currently has provision for some payment easements for small companies in relation to a number of capital fees.

    a. Major applications: 25% of the application fee for a new active substance at the time of the application with the remaining 75% payable within 30 days of the major application being determined.

    b. Complex applications: 50% of the application fee for a new active substance at the time of the application with the remaining 50% payable within 30 days of the MA being determined.

    c. Applications for Manufacturers' or Wholesale Dealer's licences: 50% at time of application with 50% payable 12 months after that time.

    d. The "50% rule" at time of application then 50% payable 12 months after also applies to the payment of applications for traditional herbal medicines registrations and applications for complex variations to traditional herbal registrations.

    e. In respect to inspection fees in connection with applications for a marketing authorisation, traditional herbal registration, manufacturer's licence, manufacturer's authorisation or wholesale dealer's licence, the fee payable is 50% within 14 days following receipt of written notice requiring those fees, with 50% payable 12 months after that date.

Payment Waivers Available for Small and Medium Companies

3. The MHRA's fees legislation currently has provision for some payment waivers for small and medium companies.

    a. Fees payable in connection with a meeting mentioned in any of regulations 4 to 10, as set out in the Human Medicines (Amendment etc.) (EU Exit) Regulations 2020.

    b. 100% of initial application fee where the licensing authority grants an orphan marketing authorisation.

    c. 100% of application for variation of orphan marketing authorisation made within first 12 months of the date of grant.

    d. This does not apply to an application to authorise use of the medicinal product in a new therapeutic area which does not meet the orphan criteria listed in regulation 50G(2) of the Human Medicines Regulations.

[3] Payment easements and waivers for Small and Medium Companies - GOV.UK (www.gov.uk)

Annex B: MHRA statutory fee changes

Table 1: 10% Indexation Increase					
Level 1 Descriptor	**Level 2 Descriptor**	**Level 3 Descriptor**	**Fee Name**	**Current Fee (£)**	**Revised Fee (£)**
1. Active pharmaceutical ingredients manufacturers and importers registration: fees	Fees for registration of active substance importer or distributor	New applications	Additional fee if the risk assessment of the initial application triggers an inspection	582	640
1. Active pharmaceutical ingredients manufacturers and importers registration: fees	Fees for registration of active substance importer or distributor	Variations	Notification of changes (variation)	257	283
1. Active pharmaceutical ingredients manufacturers and importers registration: fees	Fees for registration of active substance importer or distributor	Annual compliance report	Assessment of the annual compliance report	257	283
1. Active pharmaceutical ingredients manufacturers and importers registration: fees	Fees for registration of active substance importer or distributor	Annual compliance report	Annual compliance report where a variation is required	514	565
2. Active substance importers or distributors: fees			Application for registration	1,803	1,983
2. Active substance importers or distributors: fees			Additional fee for the first day of inspection if triggered following risk-assessment of the application	582	640
2. Active substance importers or distributors: fees			Persons appointed appeals procedure fee	10,000	11,000
3. Active substance manufacturers: fees			Application for registration	3,143	3,457
3. Active substance manufacturers: fees			Additional fee for the first day of an inspection if triggered following risk-	792	871

			assessment of the application		
7. Broker registration fees	Broker registration fees	New Applications	Additional fee if the risk assessment of the initial application triggers an inspection	582	640
7. Broker registration fees	Broker registration fees	Annual Compliance Report	Annual Compliance where a variation is required	514	565
8. Clinical trials: application fees		Applications with an IMP dossier	Higher fee (Phase 1, Full and Simplified IMPD)	3,060	3,366
8. Clinical trials: application fees		Applications without an IMP dossier	Lower fee (Phase IV, Cross referral, Additional protocol)	225	248
8. Clinical trials: application fees		CT variations/amendments		225	248
14. Licence applications: marketing authorisations (including extension applications) fees	Major		Major Orphan (reduced in exceptional circumstances)	29,732	32,705
14. Licence applications: marketing authorisations (including extension applications) fees	Major		Incoming mutual recognition procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	62,421	68,663
14. Licence applications: marketing authorisations (including extension applications) fees	Major		European reference product application for sale or supply in Northern Ireland	62,421	68,663

14. Licence applications: marketing authorisations (including extension applications) fees	Major		Decentralised procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	62,421	68,663
14. Licence applications: marketing authorisations (including extension applications) fees	Major		Major: (Previously granted by EU) - unfettered access route to GB	18,437	20,281
14. Licence applications: marketing authorisations (including extension applications) fees	Major		Major: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	62,421	68,663
14. Licence applications: marketing authorisations (including extension applications) fees	Major		Major: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	18,437	20,281
14. Licence applications: marketing authorisations (including extension applications) fees	Major		National fee (any other case including hybrid applications)	92,753	102,028
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged complex		Incoming mutual recognition procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	17,330	19,063

14. Licence applications: marketing authorisations (including extension applications) fees	Abridged complex		European reference product application for sale or supply in Northern Ireland	17,330	19,063
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged complex		Decentralised procedure for the sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	17,330	19,063
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged complex		Complex: (Previously granted by EU) - unfettered access route to GB	10,443	11,487
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged complex		Complex: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	17,330	19,063
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged complex		Complex: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	10,443	11,487
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged complex		National fee (any other case including hybrid applications)	25,643	28,207
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged standard		Incoming mutual recognition procedure for sale or supply in Northern Ireland and any	6,350	6,985

			subsequent Unfettered access route for a UKMA(GB)		
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged standard		European reference product application for sale or supply in Northern Ireland	6,350	6,985
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged standard		Decentralised procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	6,350	6,985
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged standard		Standard: (Previously granted by EU) - unfettered access route to GB	5,783	6,361
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged standard		Standard: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	6,350	6,985
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged standard		Standard: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	5,783	6,361
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged standard		National fee (all other cases)	9,402	10,342

14. Licence applications: marketing authorisations (including extension applications) fees	Abridged simple		Incoming mutual recognition procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	2,564	2,820
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged simple		Decentralised procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	2,564	2,820
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged simple		Simple: (Previously granted by EU) - unfettered access route to GB	2,564	2,820
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged simple		Simple: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	2,564	2,820
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged simple		Simple: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	2,564	2,820
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged simple		National fee (all other cases)	2,564	2,820

14. Licence applications: marketing authorisations (including extension applications) fees	Extension application group		Incoming mutual recognition (UK CMS)	17,330	19,063
14. Licence applications: marketing authorisations (including extension applications) fees	Extension application group bulk		Incoming mutual recognition (UK CMS)	6,350	6,985
15. Licence applications: manufacturers licence (including THMPD and homeopathic medicinal products)* fees			Standard	3,143	3,457
15. Licence applications: manufacturers licence (including THMPD and homeopathic medicinal products)* fees			Non-orthodox practitioner (NOP)	183	201
15. Licence applications: manufacturers licence (including THMPD and homeopathic medicinal products)* fees			Change of ownership	344	378
16. Licence applications: parallel imports fees			Complex application*	18,180	19,998
16. Licence applications: parallel imports fees			Simple application	1,792	1,971
16. Licence applications: parallel imports fees			Change of ownership (including THMPD registrations)	442	486
17. Licence applications: Phase 1 Accreditation Scheme fees		Phase I Accreditation Scheme	Accreditation of Phase 1 units	117	129
17. Licence applications: Phase 1 Accreditation Scheme fees		Phase I Accreditation Scheme	Certificate of accreditation	62	68
18. Medicines export certificates: fees		Urgent request: two working days per set	Original and two copies	152	167

18. Medicines export certificates: fees		Standard request: ten working days per set	Original and two copies	68	75
18. Medicines export certificates: fees		Standard request: ten working days per set	Each additional copy	34	37
19. Periodic fees for holding a marketing authorisation			New active substance (1)	9,710	10,681
19. Periodic fees for holding a marketing authorisation			Derivatives with a different route of administration (1) or complex abridged (2)	9,710	10,681
19. Periodic fees for holding a marketing authorisation			Other derivatives (1)	6,554	7,209
19. Periodic fees for holding a marketing authorisation		Prescription only medicine	Standard fee*	2,428	2,671
19. Periodic fees for holding a marketing authorisation		Prescription only medicine	Reduced rate fee	1,211	1,332
19. Periodic fees for holding a marketing authorisation		Prescription only medicine	'Maintenance' fee	307	338
19. Periodic fees for holding a marketing authorisation		Prescription only medicine	All others (P, GSL, PLPI and None)	307	338
19. Periodic fees for holding a marketing authorisation			Herbal	76	84
19. Periodic fees for holding a marketing authorisation			Homeopathic and Anthroposophic PLRs (per PLR)	76	84
19. Periodic fees for holding a marketing authorisation			National Rules Homeopathic Authorisation	76	84
19. Periodic fees for holding a marketing authorisation			Manufacturer's licence	468	515
19. Periodic fees for holding a marketing authorisation			Wholesale dealer's licence	288	317
19. Periodic fees for holding a marketing authorisation			Wholesale dealer's licence (reduced rate or GSL) (4)	172	189
19. Periodic fees for holding a marketing authorisation			THMPD registration	76	84

20. Licence renewals, reclassifications and assessment of labels and leaflets: fees		Licence Renewal Applications	Manufacturers' licences Non-orthodox practitioner (NOP)	178	196
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	747	822
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)	747	822
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	9,682	10,650
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 (3), (4)	8,162	8,978
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees		Reclassification	Reclassification variation application P to GSL	8,162	8,978
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees		Assessment of labels and leaflets	Single or first application (5)	518	570
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees		Assessment of labels and leaflets	National (BROMI) - Article 61 (3) Notification (6)	186	205
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees		Assessment of labels and leaflets	Parallel imports	328	361
21. Orphan Marketing Products: fees			Orphan Major (Full fee)	92,753	102,028
21. Orphan Marketing Products: fees			Orphan Major (exceptional circumstances in which point 6 pf Part II of Annex 1 in the 2001 Directive applies)	29,732	32,705

21. Orphan Marketing Products: fees			Orphan Complex (Full Fee)	25,643	28,207
21. Orphan Marketing Products: fees			Orphan Standard (Full Fee)	9,402	10,342
22. Pharmacovigilance (PV) Safety Review: fees			PV Major Safety Review (1-2 active ingredients)	51,286	56,415
22. Pharmacovigilance (PV) Safety Review: fees			PV Major Safety Review (3 active ingredients)	59,595	65,555
22. Pharmacovigilance (PV) Safety Review: fees			PV Major Safety Review (4 active ingredients)	67,904	74,694
22. Pharmacovigilance (PV) Safety Review: fees			PV Major Safety Review (5 or more active ingredients)	76,213	83,834
22. Pharmacovigilance (PV) Safety Review: fees			PV Periodic Safety Update Report (PSUR) single assessment: Full Fee	890	979
22. Pharmacovigilance (PV) Safety Review: fees			PV Periodic Safety Update Report (PSUR) single assessment: Half Fee	445	490
22. Pharmacovigilance (PV) Safety Review: fees			PV Post Authorisation Safety Study (PASS) protocol	8,309	9,140
22. Pharmacovigilance (PV) Safety Review: fees			Assessment of PASS Results	8,309	9,140
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	9,140
23. Plasma Master File (PMF) & Vaccine Antigen Master File certification or certified annual update work: fees			Vaccine Antigen Master File (VAMF) certification	8,309	9,140

24. Pre-Assessment (Rolling Review): fees			Application by pre-assessment (NAS) - Module 3 (chemical, pharmaceutical and biological information)	23,188	25,507
24. Pre-Assessment (Rolling Review): fees			Application by pre-assessment (NAS) - Module 4 (non-clinical reports)	23,188	25,507
24. Pre-Assessment (Rolling Review): fees			Application by pre-assessment (NAS) - Module 5 (clinical study reports)	23,188	25,507
24. Pre-Assessment (Rolling Review): fees			Application by pre-assessment (Biosimilar) - Module 3 (chemical, pharmaceutical and biological information)	4,333	4,766
24. Pre-Assessment (Rolling Review): fees			Application by pre-assessment (Biosimilar) - Module 4 (non-clinical reports)	4,333	4,766
24. Pre-Assessment (Rolling Review): fees			Application by pre-assessment (Biosimilar) - Module 5 (clinical study reports)	4,333	4,766
26. Scientific advice meetings: fees			Quality development only	2,201	2,421
26. Scientific advice meetings: fees			Safety development only	2,201	2,421
26. Scientific advice meetings: fees			Quality and safety development	3,061	3,367
26. Scientific advice meetings: fees			Clinical development only	2,763	3,039
26. Scientific advice meetings: fees			Quality and clinical development	3,624	3,986
26. Scientific advice meetings: fees			Safety and clinical development	3,624	3,986

26. Scientific advice meetings: fees			Quality, safety and clinical development	4,487	4,936
26. Scientific advice meetings: fees	Pre-consultation application meetings on devices incorporating an ancillary medicinal substance*		Broader scope meetings	4,451	4,896
26. Scientific advice meetings: fees	Pharmacovigilance advice meetings		Standard meeting	3,061	3,367
26. Scientific advice meetings: fees	Pharmacovigilance advice meetings		Major meeting	3,624	3,986
26. Scientific advice meetings: fees	Pharmacovigilance advice meetings		Post-authorisation regulatory advice meetings	2,763	3,039
26. Scientific advice meetings: fees	Pharmacovigilance advice meetings		Advertising advice	2,201	2,421
26. Scientific advice meetings: fees	Pharmacovigilance advice meetings		Advice on labels and leaflets	2,201	2,421
26. Scientific advice meetings: fees	Reclassification advice meetings		Pharmacy to General Sales List switch	2,763	3,039
26. Scientific advice meetings: fees	Reclassification advice meetings		Prescription Only Medicine to Pharmacy switch	3,624	3,986
30. Testing of samples: fees		Plasma pools which require three or fewer tests	Fee payable where the licensing authority carries out a full assessment	180	198
30. Testing of samples: fees		Plasma pools which require three or fewer tests	Fee payable where the licensing authority carries out a paper-based assessment	90	99
30. Testing of samples: fees		Plasma pools which require four or five tests	Fee payable where the licensing authority carries out a full assessment	215	237
30. Testing of samples: fees		Plasma pools which require four or five tests	Fee payable where the licensing authority carries out a paper-	90	99

			based assessment		
30. Testing of samples: fees		Plasma pools which require six or more tests	Fee payable where the licensing authority carries out a full assessment	230	253
30. Testing of samples: fees		Plasma pools which require six or more tests	Fee payable where the licensing authority carries out a paper-based assessment	90	99
30. Testing of samples: fees		Band A – single component product, other than Botulinum toxin. requiring five or fewer in vitro tests	Fee payable where the licensing authority carries out a full assessment	1,660	1,826
30. Testing of samples: fees		Band B – Factor VIII, Factor VIX or intravenous Immunoglobin	Fee payable where the licensing authority carries out a full assessment	1,910	2,101
30. Testing of samples: fees		Band C – Multi-component product, or Botulinum toxin, requiring five or fewer in vitro tests	Fee payable where the licensing authority carries out a full assessment	2,340	2,574
30. Testing of samples: fees		Band D – product requiring six to nine in vitro tests	Fee payable where the licensing authority carries out a full assessment	3,690	4,059
30. Testing of samples: fees		Band E – product requiring (a) ten or more in vitro tests, or (b) one or more in vivo tests	Fee payable where the licensing authority carries out a full assessment	6,410	7,051

30. Testing of samples: fees		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 tissue cells as part of testing	Fee payable where the licensing authority carries out a full assessment	10,350	11,385
34. Variations: licence variations application fees		Type II complex	National	8,309	9,140
34. Variations: licence variations application fees		Chapter II of Commission Regulation (EC) /1234/2008 (as amended for CMS). In addition, variations submitted under the relevant National reliance/recognition routes.	Single kind variation - Type II Complex Variation	2,493	2,742
34. Variations: licence variations application fees		Chapter II of Commission Regulation (EC) /1234/2008 (as amended for CMS). In addition, variations submitted under the relevant National reliance/recognition routes.	Single kind variation - Extended Type II Complex Variation	7,693	8,462
35. Variations: licence variations applications groups fees			Minor variation (Type IB) group fee (national)	622	684
35. Variations: licence variations applications groups fees			Major variation (Type II) group fee (national)	1,652	1,817
35. Variations: licence variations applications groups fees			Major variation (Type II) complex group fee (national)	9,010	9,911
35. Variations: licence variations applications groups fees			Major variation (Type II) extended complex group fee (national)	26,276	28,904

35. Variations: licence variations applications groups fees		Chapter II of Commission Regulation (EC) /1234/2008 (as amended for CMS). In addition, variations submitted under the relevant National reliance/recognition routes.	Major Variation (Type II) Complex Group Application	2,703	2,973
35. Variations: licence variations applications groups fees		Chapter II of Commission Regulation (EC) /1234/2008 (as amended for CMS). In addition, variations submitted under the relevant National reliance/recognition routes.	Major Variation (Type II) Extended Complex Group Application	7,883	8,671
36. Variations: other licence variations applications fees		Parallel import (PI)	Standard	357	393
36. Variations: other licence variations applications fees		Manufacturer's licences (including traditional herbal medicines)	Standard	514	565
36. Variations: other licence variations applications fees		Manufacturer's licences (including traditional herbal medicines)	Administrative	257	283
36. Variations: other licence variations applications fees		Wholesale dealers' licences (includes Traditional Herbal Medicinal Products)	Standard	486	535
36. Variations: other licence variations applications fees		Wholesale dealers' licences (includes Traditional Herbal Medicinal Products)	Administrative	257	283
36. Variations: other licence variations applications fees		Clinical trial authorisations	Amendments to 1 part of dossier	225	248
36. Variations: other licence variations applications fees		Clinical trial authorisations	Amendments to 2 parts of dossier	225	248
36. Variations: other licence variations applications fees		Clinical trial authorisations	Amendments to 3 parts of dossier	225	248
36. Variations: other licence variations applications fees		Clinical trial authorisations	Protocol	225	248
38. Wholesale distribution authorisations: fees		New Applications	Change of ownership	399	439
38. Wholesale distribution authorisations: fees		New Applications	Standard variation	486	535

38. Wholesale distribution authorisations: fees		New Applications	Administrative variation	257	283
38. Wholesale distribution authorisations: fees		Inspections	Issue of Good Distribution Practice Certificates	68	75

Table 2: Cost Recovery		
Fee Name	**Current Fee (£)**	**Revised Fee (£)**
Inspection - Full day rate (Good Manufacturing Practice, Good Clinical Practice and Pharmacovigilance)	2,655	3,651
Inspection - Full day rate (Good Distribution Practice)	1,936	2,662
Inspection - Half day rate (Good Manufacturing Practice, Good Clinical Practice and Pharmacovigilance)	1,328	1,825
Inspection - Half day rate (Good Distribution Practice)	968	1,331
Inspection - Office based evaluation and risk assessments (Good Manufacturing Practice, Good Clinical Practice and Pharmacovigilance)	1,863	2,562
Inspection - Office based risk assessments (Wholesale distribution authorisations)	1,354	1,862
Inspection – Traditional Herbal Medicinal Product/Homeopathic only (Wholesale distribution authorisations)	1,367	1,880
Inspection - reduced rate Traditional Herbal Medicinal Product/Homeopathic only (Wholesale distribution authorisations)	744	1,023
Variation - Extended application group (National fee)	25,643	33,003
Variation - Single kind variation - Type IB (Falling under scope of Chapter II Commission Regulation 1234/2008)	277	344

Variation - Single kind variation - Type II (Falling under scope of Chapter II Commission Regulation 1234/2008)	277	344
Variation - Type IB National	277	344
Variation - Reclassification Type IB	277	344
Variation - Minor Variation (Type IB) Group Application (Falling under scope of Chapter II Commission Regulation 1234/2008)	277	344
Certified Annual Update of a Plasma Master File (PMF)	277	344
Variation - Major (Type II) Group Application (Falling under scope of Chapter II Commission Regulation 1234/2008)	496	1,255
Variation - Type II Standard National	734	1,308
Variation - Reclassification variation application (MA) (analogous product)	734	1,308
Certified Annual Update of a Plasma Master File (PMF) - significant changes to safety information	734	1,308
Parallel imports fees - standard application	6,663	8,722
Reclassification – Prescription Only Medicine to Pharmacy (Additional for MA or PI application)	11,992	33,003
Reclassification – Prescription Only Medicine to Pharmacy (variation application)	11,992	33,003

Safety and quality vetting of unlicensed imported medicines fees:		
Number of annual notifications: 1 - 20	130	70
Number of annual notifications: 21 - 100	519	350
Number of annual notifications: 101 - 1,000	2,077	2,400
Number of annual notifications: 1,001 - 5,000	10,383	12,000
Number of annual notifications: 5,001 - 20,000	25,957	30,000
Number of annual notifications: 20,001 - 50,000	51,914	60,000
Number of annual notifications: 50,001 - 100,000	103,828	120,000
Number of annual notifications: 100,001 +	155,742	200,000
The below six lines relate to Control Testing fees 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	305	367

Band B – Factor VIII, Factor VIX or intravenous Immunoglobin	305	367
Band C – Multi-component product, or Botulinum toxin, requiring five or fewer in vitro tests	305	992
Band D – product requiring six to nine in vitro tests	677	992
Band E – product requiring (a) ten or more in vitro tests, or (b) one or more in vivo tests	677	1,849
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	677	1,849

Table 3: New Fees

Fee Name	Fee (£)
Early Access to Medicines Scheme (EAMS) – Promising Innovative Medicine (PIM) designation	3,986
EAMS - fee for the assessment of the scientific opinion for new chemical or biological medicinal products	25,643
EAMS renewal fee for new chemical or biological medicinal products (if applicable)	12,821
EAMS - fee for the assessment of the scientific opinion for new indications	8,309
EAMS renewal fee for new indications (if applicable)	4,154

Safety and quality vetting of unlicensed imported medicines fees:	
Number of annual product codes: 1-5	100
Number of annual product codes: 6-10	200
Number of annual product codes: 11-20	400
Number of annual product codes: 21-50	1,000
Number of annual product codes: 51-100	2,000
Number of annual product codes: 101-200	4,000
Number of annual product codes: per additional 100 product codes above 200	2,000
Clinical Trials - Assessment of annual safety reports	248