Medicines & Healthcare products
Regulatory Agency

MHRA consultation on statutory fees

Proposals to recover costs

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Consultation description

The aim of this consultation is to seek the views of stakeholders on proposals for changes to the Medicines and Healthcare products Regulatory Agency's statutory fees. The consultation will run from Wednesday 31st August 2022 and close on Wednesday 23rd November 2022. The proposed implementation date for these changes is 1 April 2023.

1. Executive summary

1.1 The aim of this consultation is to seek the views of stakeholders on proposals to amend statutory fees from the Medicines and Healthcare products Regulatory Agency (MHRA). The proposed adjustments fall into 3 categories:

a) A 10% indexation uplift across statutory fees

b) A further uplift for 61 significantly under recovering fees to achieve cost recovery

c) The introduction of 22 new fees for services that require cost-recovery since the last fee changes in 2016/2017 for medicines and 2017/2018 for medical devices

1.2 The fee proposals set out in this consultation are designed to ensure the MHRA is resourced to provide the high-quality service that patients, the public and industry want and expect, and to achieve full cost recovery in line with HM Treasury's principles on Managing Public Money. This will ensure the MHRA is financially sustainable in the long-term, enabling 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.

2. Introduction

2.1 Background

2.1.1 Generally, wherever the MHRA provides a direct service for medicines, medical devices or blood components for transfusion regulatory work, a fee is charged to recover the cost of the work involved, in line with HM Treasury guidance **Managing Public Money**1. Although medical devices are primarily funded through a grant from the Department of Health and Social Care, there are aspects of the MHRA's devices work that are fee dependent.

2.1.2 The cost of a fee takes into account numerous factors, including identifying the various activities involved in delivering the fee (this can involve anything from processing and registration to technical assessment and evaluation of data), the time these activities take, and the staff level, grade and seniority required to complete the task. In addition, in line with HM Treasury's **Managing Public Money**, the Agency is also required to factor in corporate overhead costs and system investments[2].

2.1.3 The MHRA's statutory fees are set out in legislation such as **The Medicines (Products for Human Use) (Fees) Regulations 2016**[3]. The fees charged in relation to medicines and medical devices can be amended through secondary legislation using the powers in the Medicines and Medical Devices Act 2021[4].

2.1.4 The MHRA's statutory fees have not been increased since financial year 2016/17 for medicines, financial year 2017/18 for devices, and financial year 2010/11 for blood components for transfusion. Decisions to not adjust fees were made following 2016 and 2017 in order to (1) ensure as much certainty and stability for industry throughout the EU Exit period and (2) while the Agency responded to the unprecedented challenge of COVID-19.

2.1.5 The principles for charging fees are set by HM Treasury in **Managing Public Money**. The basic principle states that '**the standard approach is to set charges to recover full costs**'[5]. This full cost-recovery approach means that the regulated bear the cost of regulation, as well as ensuring the MHRA does not profit from fees or make a loss

[1] HMT, 2022, Managing public money - GOV.UK (www.gov.uk)

[2] HMT, 2022, *Managing Public Money*, section 6.2.1, p.46.

[3] The Medicines (Products for Human Use) (Fees) Regulations 2016 (legislation.gov.uk)

[4] Medicines and Medical Devices Act 2021 (legislation.gov.uk)

[5] HMT, *Managing Public Money*, 2022, p.46.

which must then be subsidised by the Department of Health and Social Care or wider Government.

2.1.6 This is important because 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. The removal of Trading Fund status was given legal effect by the Medicines and Healthcare products Regulatory Agency Trading Fund (Revocation) Order 2022 which came into force on 1 April 2022.This reclassification 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 any over or under spend will directly impact the financial position of the Department of Health and Social Care, HM Treasury, and have implications for other Government Departments.

2.1.7 The MHRA has recently undertaken a review of its statutory fees. A summary of the review's purpose, aim and scope can be found at Annex A.

2.1.8 The review found that numerous areas of the MHRA's work 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. This is essential for ensuring the MHRA works within the principles of HM Treasury's **Managing Public Money**, and also to ensure the Agency is self-sufficient and financially sustainable in the long-term.

2.1.9 Informal consultation with industry, for example in the Medicines Industry Group and Medical Devices Industry Liaison Group meetings, indicates that primary and overarching concerns among industry stakeholders are the quality and stability of the MHRA's services and ensuring any increase in fees is met with an increase in performance. This is a valid concern, and one of the driving factors for amending the MHRA's statutory fees is that by ensuring the MHRA is sufficiently funded and resourced, this will ensure the MHRA is equipped to provide industry with the high-quality service they expect.

2.2 Policy objectives

2.2.1 The fee proposals set out in this document are designed to ensure the MHRA is resourced to provide the service that patients, the public and industry want and expect. They have been designed with the specific aim of achieving cost recovery, in line with HM Treasury's principles on **Managing Public Money**. This will ensure that the MHRA is financially sustainable in the long-term, enabling a responsive and efficient regulatory service that protects and improves patient and public health by facilitating access to high-quality, safe, effective and innovative medical products.

Without amending statutory fees, the MHRA will not recover its costs and will not be able to provide the services industry require to enable them to market their products in the UK.

3. The proposals

The MHRA is proposing to prepare secondary legislation to implement the following proposals, which would apply from 1 April 2023.

Proposal 1

The first proposal is to apply a 10% indexation uplift across Agency 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 fees review in 2016. Staff costs account for over half of the MHRA's total expenditure and the Agency has no control over the pay award.

The remaining expenditure include items such as IT, laboratories and accommodation. These costs should have risen in line with inflation, CPI is 21% since 2016, however Agency cost reduction programmes mean the MHRA is able to cover any increases within the 10% price rise.

The proposed list of fees reflecting the 10% indexation uplift can be found in Annex B – MHRA statutory fee proposals (Table 1).

Proposal 2

The second proposal is to apply a further, cost-based uplift, for 61 significantly under recovering fees, on top of the indexation uplift, to achieve full cost recovery.

Through a review of its fees, the MHRA has identified 61 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 proposing to uplift these 61 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.

For example, in recent years there has been substantial technological progress in the field of medical devices and increased rigour is required in order to accommodate the growing complexity of modern devices. This requires the MHRA to extend scrutiny of these devices, which is more resource intensive and time consuming.

In addition, as the MHRA changes its approach to be a more responsive, enabling and supportive regulator, it requires additional time to help applicants to prepare more effectively for assessment. The MHRA's new approach to clinical investigations is an example, where the MHRA spends more time supporting applicants, and as a result carrying out these activities is more resource intensive but better prepares applicants for successful

applications. The cost of the additional time invested into supporting applicants has to be recovered, and this is reflected in the additional increase to some of these fees.

Finally, the MHRA now has improved operational experience and a greater understanding of resources required to carry out the activities related to these fees, meaning the Agency can more accurately understand the real costs and more appropriately match these to fees.

The proposed list of fees reflecting this cost-based uplift can be found in Annex B – MHRA statutory fee proposals (Table 2).

Proposal 3

The MHRA's statutory fees have not been changed since 2016/17 for medicines and 2017/18 for medical devices. The third proposal is to introduce 22 new fees, to ensure that the Agency appropriately recovers the cost of the regulatory activity across its services, in line with HM Treasury's principles on **Managing Public Money**.

For example, the introduction of a fee for a clinical trial complex amendment reflects modern innovative investigational medicinal products and the use of innovative trial designs, where amendments may require significant assessment activity not covered by the existing standard amendment fee. For instance, an example of this could be adding a new unlicensed medicine into an arm of the clinical trial or substantial changes to the manufacture of a biological product.

The MHRA has also introduced new services for which statutory fees are required. For example, in 2021 the MHRA introduced the Innovative Licensing and Access Pathway (ILAP), a new pathway supporting innovative approaches to the safe, timely and efficient development of medicines to improve patient access. The MHRA is proposing to include new fees for the ILAP, specifically for the scientific advice.

The fees proposed 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.

The list of the proposed 22 new fees can be found in Annex B – MHRA statutory fee proposals (Table 3).

4. Consultation Questions

Question 1

Do you support proposal 1, to apply a 10% indexation uplift across Agency statutory fees to match the increased pay costs national average since the last MHRA fees review? Yes/No. If you have any concerns about this proposal, please provide them below.

Question 2

Do you support proposal 2, to place a cost-based uplift for 61 significantly under recovering fees to achieve full cost recovery? Yes/No. If you have any concerns about this proposal, please provide them below.

Question 3

Do you support proposal 3 to introduce 22 new fees for services offered by the MHRA? Yes/No. If you have any concerns about this proposal, please provide them below.

Question 4

Would you consider these proposals to impact certain types of business disproportionately? e.g. small businesses? Yes/No. If yes, in what ways? e.g. costs/time etc. Please provide more detail below.

Question 5

Do you think any of the proposals in this consultation could have an impact on the development and access to medicines or devices for (1) rare conditions or (2) minority groups with smaller patient populations? Yes/No. If yes, please provide more detail below.

Question 6

Do you think any of the proposals in this consultation pose a risk to existing products being withdrawn from the UK market? Yes/No. If yes, please provide more detail below.

Question 7

Do you think any of the proposals in this consultation could have an impact on research, clinical trials or clinical investigations in the UK? Yes/No. If yes, what could be the impact? Please provide further detail below.

Question 8

With reference to the protected characteristics covered by the Public Sector Equality Duty set out in section 149 of the Equality Act 2010 or by section 75 of the Northern Ireland Act 1998, **we do not consider that our proposals risk impacting different people differently with reference to their protected characteristics. Do you agree? Yes/No. If no, please provide more detail below.**

[Public Sector Equality Duty set out in section 149 of the Equality Act 2010
https://www.legislation.gov.uk/ukpga/2010/15/section/149

Section 75 of the Northern Ireland Act 1998
https://www.legislation.gov.uk/ukpga/1998/47/section/75

Question 9

In Northern Ireland new policies must be screened under Section 75 of the Northern Ireland Act 1998, https://www.legislation.gov.uk/ukpga/1998/47/section/75 which places a statutory duty on public authorities, to mainstream equality in all its functions – so that equality of opportunity and good relations are central to policy making and service delivery. In addition, new or revised policies must be rural proofed in line with the Rural Needs Act (NI) 2016 https://www.legislation.gov.uk/nia/2016/19/contents which requires public authorities to have due regard to rural needs.

We do not consider that our proposals risk impacting different people differently with reference to their protected characteristics or where they live in Northern Ireland. Do you agree? Yes/No. If no, please provide more detail below.

Annex A – MHRA fees review

Agency fees review overview

Aim

The aim of the fees review was to make sure all Agency activities are identified, accounted for, linked to specific lines of revenue in the Agency general ledger and that the fees charged are accurate and recover full costs in line with the requirements of HM Treasury's **Managing Public Money**.

The review aimed to deliver an evidence base for the Agency which could tell us:

- The entire list of activities the Agency carries out
- The number of staff (in FTE) it requires to deliver these activities
- How much this will cost
- Whether the fees we are currently charging are accurate
- How much we will need to adjust our fees to achieve cost recovery, including corporate overhead costs and systems investments

Reason for the review

A review of the Agency's fee structure was essential for a number of reasons:

- The Agency Transformation and restructure – our Agency fees must reflect and be able to fund our new structure as a key element of financial sustainability
- The loss of the Agency Trading Fund status and the inability to build and use reserves means cost recovery is essential
- To ensure the way the Agency operates (fee charging) is in accordance with HMT guidelines set out in **Managing Public Money** (on a cost recovery basis)
- The Agency's fees have not been reviewed or adjusted since leaving the EU (even in light of changing work volumes)
- The Agency needs to maintain an up-to-date evidence base of our Agency costs to justify any future fee changes (including fee increases)
- Recent changes in legislation have required increased scrutiny on multiple areas of the Agency's work – this has increased resourcing requirements and therefore costs, and

this must be reflected in Agency fees if the Agency is to remain financially sustainable and in accordance with **Managing Public Money**

Project key deliverables

The key deliverables for the project were:

- The total cost of the regulatory activity associated with each individual fee
- The associated gross profit or loss per fee
- The % increase/decrease to achieve cost recovery

Annex B - MHRA Statutory fee proposals

Proposed statutory fees from 1 April 2023

Table 1 – 10% Indexation increase in line with increased pay costs

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
1.Active pharmaceutical ingredients manufacturers and importers registration: fees	Fees for registration of active substance manufacturers	New applications	New application for registration as a manufacturer of active substances	5,006	**5,507**
1. Active pharmaceutical ingredients manufacturers and importers registration: fees	Fees for registration of active substance importer or distributor	New applications	New application for registration as an importer or distributor of active substances	3,157	**3,473**
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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			Assessment of initial application: active substance importer / distributor	1,354	**1,489**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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			Assessment of Initial Application	1,863	**2,049**
3. Active substance manufacturers: fees			Additional fee for the first day of an inspection if triggered following risk-assessment of the application	792	**871**
4. Blood banks: application fees for a Review Panel hearing			Fee	10,000	**11,000**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
5. Blood banks and other blood establishments: fees	Blood Establishments	New Applications	Standard application	3,074	**3,381**
5. Blood banks and other blood establishments: fees	Blood Establishments	Variations	Standard variation	518	**570**
5. Blood banks and other blood establishments: fees	Blood Establishments	Periodic Fee	Annual fee	463	**509**
5. Blood banks and other blood establishments: fees	Hospital Blood Banks and facilities	Compliance	Annual fee	683	**751**
7. Broker registration fees	Broker registration fees	New Applications	New application for registration as a broker	3,157	**3,473**
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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**
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	**4,550**
10. Drug-device combination products: fees			Further consultation of a Device which incorporates one or more known medicinal substances from an approved manufacturer of that substance	818	**900**
10. Drug-device combination products: fees			Initial Consultation for a Device which incorporates one or more known medicinal substances from a new source	9,640	**10,604**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
10. Drug-device combination products: fees			Further consultation of a Device which incorporates one or more known medicinal substances from a new source	2,228	**2,451**
10. Drug-device combination products: fees			Initial consultation for a Device which incorporates a new active substance	42,296	**46,526**
10. Drug-device combination products: fees			Further consultation of a Device which incorporates a new active substance	10,501	**11,551**
12. Homeopathic National Rules Scheme: fees for inspections			GDP (wholesale dealers including homeopathic wholesalers)	1,328	**1,461**
14. Licence applications: marketing authorisations (including extension applications) fees	Major		Major Orphan (reduced in exceptional circumstances)	29,732	**32,705**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged standard		Incoming mutual recognition procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for a UKMA(GB)	6,350	**6,985**
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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		Decentralised procedure where the UK is CMS	9,078	**9,986**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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		Reclassification	Reclassification variation application (PI) (analogous product)	176	**194**
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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	23,188	**25,507**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
			reports)		
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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		Quality development only	749	**824**
26. Scientific advice meetings: fees	Pre-consultation application meetings on devices incorporating an ancillary medicinal substance		Safety development only	749	**824**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
26. Scientific advice meetings: fees	Pre-consultation application meetings on devices incorporating an ancillary medicinal substance		Quality and safety development	949	**1,044**
26. Scientific advice meetings: fees	Pre-consultation application meetings on devices incorporating an ancillary medicinal substance		Clinical development only	949	**1,044**
26. Scientific advice meetings: fees	Pre-consultation application meetings on devices incorporating an ancillary medicinal substance		Quality and clinical development	1,299	**1,429**
26. Scientific advice meetings: fees	Pre-consultation application meetings on devices incorporating an ancillary medicinal substance		Safety and clinical development	1,299	**1,429**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
26. Scientific advice meetings: fees	Pre-consultation application meetings on devices incorporating an ancillary medicinal substance		Quality, safety and clinical development	1,648	**1,813**
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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-based assessment	90	**99**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
34. Variations: licence variations application fees		Type II complex	National	8,309	**9,140**
34. Variations: licence variations application fees		Extended type II complex	National	25,643	**28,207**
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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	Major Variation (Type II) Extended Complex Group Application	7,883	**8,671**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
		routes.			
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	Standard	486	**535**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
		Medicinal Products)			
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**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	Proposed Fee (£)
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 – Fees that increase above indexation to achieve cost-based recovery

Fee Name	Current Fee (£)	Proposed 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 - Full day rate (Blood banks and other blood establishments)	2,583	**3,552**
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 - Half day rate (Blood banks and other blood establishments)	1,292	**1,776**
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**
Inspection - Standard application plus full inspection fee (Wholesale	3,739	**4,645**

Fee Name	Current Fee (£)	Proposed Fee (£)
distribution authorisations)		
Inspection - Reduced application plus full inspection fee (Wholesale distribution authorisations)	2,838	**3,654**
Inspection - Reduced application plus reduced Inspection fee - General Sales List (GSL) only (Wholesale distribution authorisations)	1,870	**2,323**
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**

Fee Name		Current Fee (£)	Proposed Fee (£)
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 -	103,828	**120,000**

Fee Name		Current Fee (£)	Proposed Fee (£)
	100,000		
	Number of annual notifications: 100,001 +	155,742	**200,000**
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**
Initial application for designation (covers both Approved Body and Notified Body)		8,252	**35,672**
Re-application to address ground for rejection of a previous application		2,063	**8,918**
Initial designation audit		15,904	**58,341**

Fee Name		Current Fee (£)	Proposed Fee (£)
Surveillance		10,160	**45,675**
Witnessed Audit		4,404	**10,072**
Re-designation application fee		8,252	**35,672**
Re-designation audit		15,904	**58,341**
Follow up Audit - Major Closure		3,876	**22,789**
Follow up Audit - Special Clinical		2,586	**18,583**
Follow up Audit - Process Specific		3,876	**22,789**
TSE Applications UK Conformity Assessment Bodies		532	**1,297**
In addition to each of the above, these two fees are for time spent on audit and travel:	Half day rate for auditing	361	**631**
	Hourly rate for travel	90	**171**
Class I, IIa, or IIb other than implantable or long-term invasive devices: Notification		3,820	**7,472**
Class I, IIa, or IIb other than implantable or long-term invasive devices: Notification - re-notification in the event of an objection		2,920	**5,711**
Class IIb implantable or long-term invasive, Class III, and active implantable devices: Notification		5,040	**15,627**

Fee Name	Current Fee (£)	Proposed Fee (£)
Class IIb implantable or long-term invasive, Class III, and active implantable devices: Notification - re-notification in the event of an objection	3,570	**11,069**
Devices Registration	100	**240**
Devices Registration amendment	100	**240**
Devices Blood bank annual fee	492	**967**

Table 3 – New Fees

Fee Name	Proposed Fee (£)
Conformity Assessment Body Designation Applications – Extension to scope, new UKCA codes or Annex (covers both Approved Body and Notified Body)	**18,212**
Conformity Assessment Body Designation Applications – Extension to scope, where codes are limited (covers both Approved Body and Notified Body)	**12,571**
Conformity Assessment Body Audits – Subsidiary audit subject to additional fees calculated by hourly rate and travel rates (covers both Approved Body and Notified Body)	**22,789**
Clinical investigations consultation fee (optional) – Device Regulatory Advice meeting	**906**
Clinical Investigations consultation fee optional service – Clinical Investigations statistical review	**782**
In Vitro Diagnostic (IVD) Performance Report (also known as IVD performance evaluation report)	**7,472**
Scientific Advice - aligned to the Innovative Licensing and Access Pathway (ILAP) Innovation Passport	**9,895**
Scientific Advice - aligned to the ILAP Target Development Profile	**23,948**
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**

Fee Name		Proposed Fee (£)
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**
Clinical Trials - Complex amendments		**1,800**

Annex C - Legal basis and assessment of the matters set out in sections 2 and 15 of the Medicines and Medical Devices Act 2021

The Medicines and Medical Devices Act 2021 (the Act) received Royal Assent on 11 February 2021. We propose to make the legislative changes for fees relating to medicines and medical devices under consultation in this document using powers in Part 2 of the Act, which provides powers to make regulations about human medicines and Part 4 in relation to medical devices.

This consultation is conducted pursuant to the consultation requirement in section 45(1) of the Act.

Sections 2 (in relation to medicines) and 15 (in relation to medical devices) of the Act state that safeguarding public health must be the overarching objective of the appropriate authority when making regulations. These sections require that when assessing whether regulations would contribute to that objective, the appropriate authority must have regard to three factors:

(a) The safety of human medicines and medical devices, and that the benefits of doing so outweigh any risks

(b) The availability of human medicines and medical devices

(c) The likelihood of the relevant part of the United Kingdom being seen as a favourable place in which to –

  (i) Carry out research relating to human medicines and medical devices

  (ii) Conduct clinical trials of medicines,

  (iii) Develop medical devices, or

  (iii) Manufacture or supply human medicines and medical devices

For medicines, the appropriate authority is the Secretary of State in relation to Great Britain and the Department of Health in Northern Ireland in relation to Northern Ireland. For medical devices, the appropriate authority is the Secretary of State.

Below we have assessed the proposals against each of the factors set out in the Act.

Safety

While all decisions relating to the safety of human medicines and medical devices are made objectively and independently of the price paid for the service, in ensuring that the MHRA statutory fees reflect the cost of the activity and work involved in delivering them, the aim is to ensure the MHRA is sufficiently funded and resourced to carry out the necessary and required work relating to safety in a timely manner.

Availability

There is a risk that increasing fees may deter companies from submitting applications to the MHRA, which would have an impact on the availability of medicines and medical devices. However, the MHRA believe this risk to be low given that annual fee increases across regulators is a standard approach and we would expect this to be built into company budgeting as a standard practice. As set out earlier in this consultation, it is important that the MHRA is properly resourced to deliver the service that industry wants and expects, and therefore, on balance, the MHRA has made the decision to put forward these proposals

Favourability

The purpose of adjusting MHRA statutory fees is intended to have a positive effect on the UK Life Sciences industry. By ensuring the MHRA is accurately recovering the costs involved in delivering services for industry, the MHRA will be in a better position to deliver the level of service that industry wants and expects. Through informal consultation industry have told us that MHRA performance and ability to deliver is paramount, and by adjusting the fees to ensure the Agency is accurately recovering costs, rather than under recovering, the Agency will be able to provide a greater service for industry.

Additionally, these fee proposals are not expected to impact the MHRA's favourability in the market globally. It is standard practice for regulator fees to be reviewed annually. As an example, the EMA have consistently increased their fees year on year, and in April 2022 the EMA announced an inflationary increase to fees, compounded across 2020 and 2021. The proposed adjustments to MHRA statutory fees are akin to the year-on-year increases by the EMA and other regulators.

Conclusion

Based on our assessment of the statutory fee proposals against each of the factors set out in the Act, we consider the requirements of the Act to be fulfilled as the proposals will ensure the MHRA is sufficiently funded and resourced to deliver a responsive and efficient regulatory service that safeguards and improves public health by facilitating access to high-quality, safe, effective and innovative medical products.

Annex D – Consultation questions and how to respond

How to respond

Responses are invited on the specific questions raised. The questions can be found through the document and are also listed in full in below.

This consultation will close on **Wednesday 23 November 2022.**

Please respond through our online consultation survey, on SurveyOptic - SocialOptic (mhra.gov.uk)

When responding please say if you are a business, individual or representative body. In the case of representative bodies, please provide information on the number and nature of individuals or firms you represent.

Consultation questions

Question 1

Do you support proposal 1, to apply a 10% indexation uplift across Agency statutory fees to match the increased pay costs national average since the last MHRA fees review? Yes/No. If you have any concerns about this proposal, please provide them below.

Question 2

Do you support proposal 2, to place a cost-based uplift for 61 significantly under recovering fees to achieve full cost recovery? Yes/No. If you have any concerns about this proposal, please provide them below.

Question 3

Do you support proposal 3 to introduce 22 new fees for services offered by the MHRA? Yes/No. If you have any concerns about this proposal, please provide them below.

Question 4

Would you consider these proposals to impact certain types of business disproportionately? e.g. small businesses? Yes/No. If yes, in what ways? e.g. costs/time etc. Please provide more detail below.

Question 5

Do you think any of the proposals in this consultation could have an impact on the development and access to medicines or devices for (1) rare conditions or (2) minority groups with smaller patient populations? Yes/No. If yes, please provide more detail below.

Question 6

Do you think any of the proposals in this consultation pose a risk to existing products being withdrawn from the UK market? Yes/No. If yes, please provide more detail below.

Question 7

Do you think any of the proposals in this consultation could have an impact on research, clinical trials or clinical investigations in the UK? Yes/No. If yes, what could be the impact? Please provide further detail below.

Question 8

With reference to the protected characteristics covered by the Public Sector Equality Duty set out in section 149 of the Equality Act 2010 or by section 75 of the Northern Ireland Act 1998, **we do not consider that our proposals risk impacting different people differently with reference to their protected characteristics. Do you agree? Yes/No. If no, please provide more detail below.**

Public Sector Equality Duty set out in section 149 of the Equality Act 2010
https://www.legislation.gov.uk/ukpga/2010/15/section/149

Section 75 of the Northern Ireland Act 1998
https://www.legislation.gov.uk/ukpga/1998/47/section/75

Question 9

In Northern Ireland new policies must be screened under Section 75 of the Northern Ireland Act 1998, https://www.legislation.gov.uk/ukpga/1998/47/section/75 which places a statutory duty on public authorities, to mainstream equality in all its functions – so that equality of opportunity and good relations are central to policy making and service delivery. In addition, new or revised policies must be rural proofed in line with the Rural Needs Act (NI) 2016 https://www.legislation.gov.uk/nia/2016/19/contents which requires public authorities to have due regard to rural needs.

We do not consider that our proposals risk impacting different people differently with reference to their protected characteristics or where they live in Northern Ireland. Do you agree? Yes/No. If no, please provide more detail below.

9. Confidentiality of Information

Information published in response to this consultation, including personal information may be published or disclosed in accordance with the access to information regimes. These are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 2018 (DPA), UK General Data Protection Regulation (UK GDPR) and the Environmental Information Regulations 2004.

If you want the information that you provide to be treated as confidential it would be helpful if you could explain to us why you regard the information you have provided as confidential. Any information not published, including personal information, may still be subject to disclosure in accordance with the Freedom of Information Act. If we receive a request for disclosure of such unpublished information, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. We will not take a standard confidentiality statement included in an email message as a specific request for non-disclosure.

The MHRA will process your personal data in accordance with the DPA and UK GDPR and in the majority of circumstances this will mean that your personal data will not be disclosed to third parties. However, the information you send us may need to be published in a summary of responses to this consultation.