Medicines & Healthcare products
Regulatory Agency

MHRA consultation on statutory fees

Proposals on ongoing cost recovery

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Version control

Version	Date	Changes
1.0	29/08/24	Final version published
1.2	10/09/24	Following early feedback from customers and stakeholders, we have clarified some terms in the consultation document relating to Priority 2: The MHRA proposes to amend its existing Medical Device Registration fee to include the costs for medical device post-market work. In this section we have replaced the term ‘category’ with ‘code’ and the term ‘supplier’ with ‘manufacturer’.

Executive summary

This is a consultation document lead by the Medicines and Healthcare products Regulatory Agency (MHRA). The consultation will run from 29 August 2024 and close on 24 October 2024. The aim of this consultation is to seek views on proposals to update the statutory fees charged by the MHRA to ensure it continues to recover its costs. The MHRA's fees are updated on a regular basis to ensure they continue to achieve full cost-recovery in line with HM Treasury guidance "*Managing Public Money*"[1]. This is necessary for long-term financial sustainability and the ongoing delivery of the MHRA's services. The implementation date for these proposed changes is April 2025.

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

Introduction

The MHRA regulates medicines, medical devices and blood components for transfusion in the UK. They use science and data to inform their decisions, enable innovation and make sure that the medicines and healthcare products available in the UK are safe and effective.

The MHRA gets most of its income from charging statutory fees for its services. Generally, wherever the MHRA provides a service for regulatory work a statutory fee is set to recover the cost of the work involved. This is in line with the HM Treasury guidance "*Managing Public Money*" which states that *'the standard approach is to set charges to recover full costs'*. Medical devices work is primarily funded through a grant from the Department for Health and Social Care (DHSC). However, some elements of the MHRA's medical devices work, for example clinical investigations and auditing approved bodies, are funded by fees.

This full cost-recovery approach ensures the agency's financial sustainability and the ongoing delivery of services. It also means the regulated bear the cost of regulation, and Government bodies do not profit from statutory fees or make a loss which must be subsidised by wider Government and ultimately the taxpayer, including patients themselves.

Fees are set by taking into account numerous factors to reflect the cost of the regulatory activity, for example the activities involved in delivering a service, the time taken, the number and grade of staff involved. In addition, and also in line with the HM Treasury guidance "*Managing Public Money",* the MHRA includes the costs of necessary corporate overheads and system investments.[2] More detail on this is provided below.

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

The majority of MHRA's fees are statutory and set out in legislation such as "*The Medicines (Products for Human Use) (Fees) Regulations 2016"*[3]. As such, legislation is needed to add new fees or changing existing fees relating to medicines and medical devices. We intend to take forward secondary legislation using the powers in the Medicines and Medical Devices Act 2021.[4] This consultation is conducted pursuant to the consultation requirement in section 45(1) of the Act – more details on this can be found in Annex A.

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[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)

The proposals here cover the whole of the UK and the consultation is being carried out jointly by the Department of Health in Northern Ireland and the UK Secretary of State for Health and Social Care.

The MHRA recognises its customers have a right to expect a quality and consistent service. The major focus of its current 2024/25 Business Plan is the optimisation of service delivery and the MHRA is delivering a programme of work to ensure efficient performance and build reliable and predictable services in the short and long term. They are working to increase confidence in all stakeholders in the agency's service delivery.

The MHRA also recognises that increasing its fees will impact Small and Medium Enterprises (SMEs) more than larger companies. The MHRA's fees legislation has some provisions for certain payment easements for small companies and payment waivers for SMEs. More information on the financial support offered and how to apply can be found on our website.

The proposals

The MHRA is proposing to prepare secondary legislation to implement the following proposals, which we aim to be in force from April 2025.

Proposal 1

The MHRA proposes to increase the statutory fees shown in Annex B to ensure continued cost-recovery.

The proposed increase for each fee has been calculated to ensure it covers all associated costs for the period between April 2025 (when the fees come into effect) to March 2027 (the month before the next fee uplift is planned).

In line with the HM Treasury guidance "*Managing Public Money*", costs are based on staff costs (including annual pay rises, which are determined elsewhere in government) and corporate overheads, including maintenance and system investments.

Staff costs have been informed by the use of employee activity recording data. Employee activity recording is the practice of monitoring and recording certain activities performed by employees to establish how long they take and so how much they cost. The MHRA does not yet carry our employee activity recording all year round so, for the first time, this data was collected for a range of fee earning areas during a 3-month sampling period in 2024 and then the resulting figures were adjusted using volume assumptions. This produced more accurate cost data to underpin the modelling.

Corporate overheads were calculated by using management accounts, which set out the MRHA's expected future costs, and distributing these costs between the fees based on staff costs as allocated by the employee activity recording data.

To ensure fees cover costs until 2027, an indexation of 8.85% was also then added to all fees. This was calculated based on half of the 2023/24 civil service pay award of 4.5% plus an assumed 2.2% (which is an average for last 5 years) pay award in years 24/25, 25/26 and 26/27.

The full list of fees and their current and proposed amounts can be found in Annex B.

Proposal 2

The MHRA proposes to amend its existing Medical Device Registration fee to include the costs for medical device post-market work.

The MHRA regulation of medical devices from the point at which a product is placed on the market to the end of its life cycle (also known as post-market) is currently funded by a grant from the DHSC. The MHRA wishes to replace this funding with a charge to manufacturers who benefit from the post-market work. The proposal is intended to distribute the cost of providing a stable and supportive regulatory environment more equitably across market participants and therefore to support competition.

Manufacturers must already register their medical device products with the MHRA. The proposal is to modify the current Medical Device Registration Fee so that it covers the cost to the MHRA of its post-market activities. The MHRA post-market activities start when a product is registered. The modified Medical Device Registration Fee will be calculated by relating staff costs for post-market work to the number of Global Medical Device Nomenclature (GMDN) codes registered to each manufacturer. The GMDN is a comprehensive set of terms that name and group all medical device products. There will be an annual fee for each of the GMDN codes under which a manufacturer registers.

We propose that the new Medical Device Registration Fee will be **£210 per GMDN registration**. On this basis 44% of the manufactures currently registered with the MHRA would only need to register for one GMDN code. This is based on analysis of the products and GMDN codes registered with the MHRA. The table below is the current view of the spread of GMDNs across manufacturers and the size of fee this would generate by manufacturer.

This table illustrates that a manufacturer with higher GMDN registration may pay as much as estimated £280,000 annually. Whereas a manufacturer with a single GMDN registration will only pay £210 on an annual basis. We have evaluated this to be a fair and equitable method.

GMDN Combined Registrations Band	Fees collected by band	Manufacturers count	Average fee per manufacturer per band	Fees collected cumulative descending	no. manufacturer cumulative descending	Fees collected cumulative descending	% manufacturers cumulative descending
£280k to <£290k	£280,140	1	£280,140	£280,140	1	1.7%	0.01%
£270k to <£280k							
£260k to <£270k							
£250k to <£260k							
£240k to <£250k							
£230k to <£240k							
£220k to <£230k							
£210k to <£220k							
£200k to <£210k							
£190k to <£200k	£191,100	1	£191,100	£471,240	2	2.9%	0.02%
£180k to <£190k	£369,390	2	£184,695	£840,630	4	5.1%	0.05%
£170k to <£180k	£347,340	2	£173,670	£1,187,970	6	7.2%	0.07%
£160k to <£170k							
£150k to <£160k							

GMDN Combined Registrations Band	Fees collected by band	Manufacturers count	Average fee per manufacturer per band	Fees collected cumulative descending	no. manufacturer cumulative descending	Fees collected cumulative descending	% manufacturers cumulative descending
£140k to <£150k							
£130k to <£140k	£135,240	1	£135,240	£1,323,210	7	8.0%	0.08%
£120k to <£130k	£129,780	1	£129,780	£1,452,990	8	8.8%	0.10%
£110k to <£120k							
£100k to <£110k							
£90k to <100k	£93,660	1	£93,660	£1,546,650	9	9.4%	0.11%
£80k to <£90k	£259,980	3	£86,660	£1,806,630	12	10.9%	0.14%
£70k to <£80k	£366,030	5	£73,206	£2,172,660	17	13.1%	0.20%
£60k to <£70k	£392,490	6	£65,415	£2,565,150	23	15.5%	0.28%
£50k to <£60k	£646,170	12	£53,848	£3,211,320	35	19.4%	0.42%
£40k to <£50k	£618,030	14	£44,145	£3,829,350	49	23.2%	0.59%
£30k to <£40k	£979,020	28	£34,965	£4,808,370	77	29.1%	0.92%
£20k to <£30k	£849,450	34	£24,984	£5,657,820	111	34.2%	1.33%
£10k to <£20k	£2,362,710	166	£14,233	£8,020,530	277	48.5%	3.31%

GMDN Combined Registrations Band	Fees collected by band	Manufacturers count	Average fee per manufacturer per band	Fees collected cumulative descending	no. manufacturer cumulative descending	Fees collected cumulative descending	% manufacturers cumulative descending
£5k to <£10k	£2,523,780	360	£7,011	£10,544,310	637	63.8%	7.62%
£4k to <£5k	£555,450	124	£4,479	£11,099,760	761	67.2%	9.11%
£3k to <£4k	£844,410	240	£3,518	£11,944,170	1001	72.3%	11.98%
£2k to <£3k	£1,138,410	459	£2,480	£13,082,580	1460	79.2%	17.47%
£1k to <£2k	£1,433,040	1040	£1,378	£14,515,620	2500	87.8%	29.92%
£500 to <£1k	£768,390	1074	£715	£15,284,010	3574	92.5%	42.77%
£400 to <£500	£474,180	1129	£420	£15,758,190	4703	95.4%	56.28%
£300 to <£400							
£200 to <£300	£767,130	3653	£210	£16,525,320	8356	100.0%	100.00%

The analysis shows the equitable distribution of MHRA costs across GMDN categories with one exception. There is a disproportionate number of GMDN codes to MHRA workload for custom made dental appliance manufacturers. A single GMDN fee will be charged in these cases, and this has been taken into account in the figure of £210 and in the table above.

It is intended that the MHRA registration system, with some modification, will automate the initial registration charge and its annual renewal.

Proposal 3

The MHRA proposes to create a new service providing regulatory advice meetings for medical devices.

The MHRA's approach to the regulation of medical devices is to ensure that UK patients can quickly and safely access the medical devices that they need, whilst ensuring that the UK is seen as an attractive market for the innovation and development, manufacture, and launch of medical devices.

Central to this approach is the provision of expert regulatory advice to medical device manufacturers. In addition to publishing guidance and addressing written enquiries, the MHRA proposes to further support manufacturers by creating a new service of regulatory advice meetings to support understanding of the application of UK's regulatory framework to their product/s.

We will aim to target this service in particular to those developing novel and/or complex products with the potential to significantly improve patient outcomes, where the application of the Regulations is not straightforward and easily understood.

The new service will facilitate an earlier and better understanding of regulatory requirements for the manufacturers of medical devices, and in doing so, support manufacturers' interpretation of the relevant regulatory requirements for their product approvals. We already receive regular requests for such advice, however under current rules we are not able to charge for the service we give, which limits the resource we can devote to it. This service would be for complex queries rather than those that might be readily answered by applicants consulting the relevant online guidance.

The MHRA proposes that this service be charged at £987 for a one hour meeting. This is based on the cost of internal MHRA discussions, meeting preparation, the meeting and any post meeting feedback.

Proposal 4

The MHRA proposes to amend the fee model for three existing services, as well as increasing the fees to ensure continued cost-recovery, and also to remove 51 fees that are no longer in use.

A summary of the proposed amendments for the three existing services is summarised below. In each case the amendment aims to improve or simplify the fee structure. The fees have also been increased to ensure continue cost-recovery as summarised above. The MHRA also proposes to remove 51 fees that are no longer in use as they have been superseded by the changes in the proposals here or because the services have become redundant since the UK left the EU. These fees are shown in Annex B.

A) Scientific Advice Meetings

Customers can seek scientific advice from the MHRA at any stage of the initial development of a medicine before an application for a product licence has been submitted or during the pre-submission period for a variation to an existing product licence. The MHRA proposes to change the current model of a flat fee per a type of specialist needed at the meeting to a model based on simple, low, medium and high complexity (based on the number of MHRA specialists needed to provide the advice). This approach is best practice and aligns with other fees models across Government. It will make it easier for customers to understand the pricing and for the MHRA to assign the right fee based on complexity and extent of the questions raised.

B) Control Testing

The MHRA charges for performing independent batch release testing and certification of biological medicines for the UK. Control testing is the process of confirming every batch of vaccine or blood product has the correct composition and meets the product specifications from the relevant marketing authorisation. Control testing is performed by the MHRA's National Institute for Biological Standards and Control (NIBSC). It helps to ensure that patients get medicines that are of appropriate quality and have the desired effect. The MHRA proposes to change the current price bands for Control testing to a single time-based fee that enables cost to be more precisely reflected. This is simpler for customers and allows more flexibility for novel medicines and laboratory methods.

C) Unlicenced Medicines Importation

The MHRA is proposing to change the fees it charges annually for the vetting of notifications to import unlicenced medicines. Importers must currently comply with certain obligations in relation to the importation of unlicensed medicinal products, and this includes submitting a notification of intent to import the unlicensed medicine prior to the importation taking place. The fees for this service are set based on bands of the number of notifications processed by

the MHRA per importer per financial year. The MHRA proposes to keep to this approach but to increase the number of pay bands from 8 to 13. This means individual fees should better reflect the actual costs of the service, and it should reduce the difference in cost between the extremes and enable savings for people importing at smaller scales.

Proposal 5

The MHRA proposes to update and clarify the legal definition of a "standard variation" application for homeopathic products. The "standard variation" application statutory fee for homeopathic products will be unchanged.

Before a homoeopathic product can be marketed in the UK, it must be granted either a national homoeopathic product marketing authorisation or a certificate of registration by the MHRA.

Homoeopathic product authorisation/registration holders may apply to the MHRA to make changes to their product authorisation/registration via variation applications.

There are different types of variation applications and the different types of changes that can be applied for are defined in the Medicines (Products for Human Use) (Fees) Regulations 2016. These regulations define the changes that fall within a "standard variation" application for homoeopathic products with a certificate of registration or a national homoeopathic product marketing authorisation.

Changes to product packaging that are consequential to other variation applications are dealt with as part of that variation application. For example, where there is a change to the shape of a product's container, there might be a consequential change to the product's outer packaging. In this case the variation for that packaging change is included in the variation application for the change to the product's container.

Currently, variation applications that are submitted to change the labelling of the immediate packaging (e.g. the physical container of the product itself) that are not due to the consequential impact of another variation are dealt with under the definition of "standard variation".

However, the wording of the definition for "standard variation" does not explicitly cover variation applications to change the secondary packaging (i.e. the outer label and/or patient information leaflet) that are not due to the consequential impact of another variation.

The MHRA proposes to update the definition of "standard variation" to make it clear that "standard variation" applications would cover changes to both immediate (e.g. the physical container of the product itself) and secondary packaging (i.e. the outer label and/or patient information leaflet) that are not due to the consequential impact of another variation.

Consultation questions

Our online survey is available at the following link:
https://www.surveys.mhra.gov.uk/66c5b1cac08298bd15040d1b

Question 1

Do you support proposal 1? Yes/No/Don't know/No opinion – please explain why.

Question 2

Do you support proposal 2? Yes/No/Don't know/No opinion – please explain why.

Question 3

Do you support proposal 3? Yes/No/Don't know/No opinion – please explain why.

Question 4

Do you support proposal 4? Yes/No/Don't know/No opinion – please explain why.

Question 5

Do you support proposal 6? Yes/No/Don't know/No opinion – please explain why.

Question 6

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, the MHRA does not consider that these proposals risk impacting different people differently with reference to their protected characteristics. Do you agree? Yes/No/Don't know – please explain why.

Question 7

In Northern Ireland new policies must be screened under Section 75 of the Northern Ireland Act 1998, 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 which requires public authorities to have due regard to rural needs. The MHRA does not consider that these proposals risk impacting different people differently with reference to their protected characteristics or where they live in Northern Ireland. Do you agree? Yes/No/Don't know – please explain why.

Annex A: legal basis and assessment of the matters set out in sections 2 and 15 of the Medicines and Medical Devices Act 2021

We propose to make the legislative changes under consultation in this document using powers in Part 2 of the Medicines and Medical Devices Act 2021 (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 public health must be the overarching objective of the appropriate authority when making regulations. 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. 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

   iv. Manufacture or supply human medicines and medical devices

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

Safety

The MHRA's mission is to protect and promote public health by ensuring that healthcare products, used every day by millions of people in the UK, work and are acceptably safe. In order to do this the agency must be able to charge fees that recover its costs.

While all decisions relating to the safety of medicines and medical devices are made objectively and independently of the price paid for the service**,** in ensuring the MHRA's fees reflect the full cost of the activity involved in delivering them, the aim is to ensure the MHRA is sufficiently resourced to carry out the work relating to patient safety, in a timely manner.

The MHRA will continue to protect patient safety by maintaining four pieces of assimilated tertiary EU law until we transition to the Great Britain regulatory framework for medical devices, ensuring that there are appropriate regulatory controls for medical devices on our market.

Availability

The MHRA has considered whether there is a risk that increasing fees might deter customers from submitting applications, which would have an impact on the availability of medical products. However, the MHRA consider this risk to be low. Regular fee increases are standard across all regulators; this fact should be built into company budgeting as standard. The MHRA must be properly resourced to provide the service that industry, patients and the public want and expect, and therefore, the MHRA has made the decision to put forward these proposals.

The availability of medicines and medical devices will not be affected by maintaining the tertiary law mentioned above, since this is the status quo.

Favourability

By ensuring the MHRA is fully recovering costs, it will be in a better position to deliver the level of service that industry, patients and the public want and expect. These fee proposals are not expected to impact the MHRA's favourability in the global market. Regular fee increases are standard across all regulators.

The favourability of the UK will not be affected by maintaining the tertiary law mentioned above, since this is the status quo.

Annex B: MHRA statutory fees proposals

A list of fees for proposal 1

Fee name	Current	Proposed
1. Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or distributor - Annual compliance report - Annual compliance report where a variation is required	£565	£688
1. Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or distributor - Annual compliance report - Assessment of the annual compliance report	£283	£345
1. Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or distributor - New applications - Additional fee if the risk assessment of the initial application triggers an inspection	£640	£697
1. Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or distributor - New applications - Inspection fee (per site if required)	£2,662	£2,898
1. Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or distributor - New applications - New application for registration as an importer or distributor of active substances	£3,845	£4,186
1. Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or distributor - Variations - Inspection fee (per site if required)	£2,662	£2,898
1. Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or distributor - Variations - Notification of changes (variation)	£283	£309
1. Active pharmaceutical ingredients manufacturers and importers registration: fees - Manufacturer - New applications - New application for registration as a manufacturer of active substances	£6,019	£6,552

Fee name	Current	Proposed
2. Active substance importers or distributors: fees - Additional fee for the first day of inspection if triggered following risk-assessment of the application	£640	£697
2. Active substance importers or distributors: fees - Application for registration	£1,983	£2,159
2. Active substance importers or distributors: fees - Assessment of initial application: active substance importer / distributor	£1,862	£2,027
2. Active substance importers or distributors: fees - Assessment of the Annual Compliance Report: Active Substance Importer / Distributor	£283	£309
2. Active substance importers or distributors: fees - Notification of changes	£283	£309
2. Active substance importers or distributors: fees - Persons appointed appeals procedure fee	£11,000	£11,974
2. Active substance importers or distributors: fees - Standard daily rate for Inspection	£2,662	£2,898
3. Active substance manufacturers: fees - Additional fee for the first day of an inspection if triggered following risk-assessment of the application	£871	£949
3. Active substance manufacturers: fees - Application for registration	£3,457	£3,763
3. Active substance manufacturers: fees - Assessment of Initial Application	£2,562	£2,789
3. Active substance manufacturers: fees - Assessment of the Annual Compliance Report	£283	£309
3. Active substance manufacturers: fees - Inspection days	£3,651	£3,975
3. Active substance manufacturers: fees - Notification of Changes	£283	£309

Fee name	Current	Proposed
4. Blood banks: application fees for a Review Panel hearing - Fee	£11,000	£11,974
5. Blood banks and other blood establishments: fees - Blood Establishments - Haemovigilance - Annual fee	£967	£1,053
5. Blood banks and other blood establishments: fees - Blood Establishments - Inspections - Standard Inspection Fee: daily rate	£3,552	£5,324
5. Blood banks and other blood establishments: fees - Blood Establishments - New Applications - Inspection fee (per additional site if required)	£3,552	£3,867
5. Blood banks and other blood establishments: fees - Blood Establishments - New Applications - Standard application plus full inspection fee	£6,933	£7,547
5. Blood banks and other blood establishments: fees - Blood Establishments - Periodic Fee - Annual fee	£509	£555
5. Blood banks and other blood establishments: fees - Blood Establishments - Variations - Standard variation	£570	£621
5. Blood banks and other blood establishments: fees - Hospital Blood Banks and facilities - Compliance - Annual fee	£751	£818
5. Blood banks and other blood establishments: fees - Hospital Blood Banks and facilities - Haemovigilance - Annual fee	£967	£1,053
5. Blood banks and other blood establishments: fees - Hospital Blood Banks and facilities - Inspections - Inspection fee (per additional site if required)	£3,552	£5,324
6. Blood facilities: contract laboratories fees - Inspections - Inspection fee* (per additional site if required)	£3,552	£5,324
7. Broker registration fees - Annual Compliance Report - Annual Compliance where a variation is required	£565	£688

Fee name	Current	Proposed
7. Broker registration fees - Annual Compliance Report - Assessment of the Annual Compliance Report	£283	£345
7. Broker registration fees - New Applications - Additional fee if the risk assessment of the initial application triggers an inspection	£640	£780
7. Broker registration fees - New Applications - Inspection Fee (per site if required)	£2,662	£3,241
7. Broker registration fees - New Applications - New application for registration as a broker	£3,845	£4,681
7. Broker registration fees - Variations - Notification of Changes (Variation)	£283	£345
8. Clinical trials: application fees - Applications with an IMP dossier - Higher fee (Phase 1, Full and Simplified IMPD)	£3,366	£4,656
8. Clinical trials: application fees - Applications without an IMP dossier - Lower fee (Phase IV, Cross referral, Additional protocol)	£248	£343
8. Clinical trials: application fees - Assessment of annual safety reports	£248	£343
8. Clinical trials: application fees - CT variations/amendments	£248	£343
9. Clinical investigations for devices: fees - Amendment fees - High risk device amendment	£331	£361
9. Clinical investigations for devices: fees - Amendment fees - Low risk device amendment	£207	£226
9. Clinical investigations for devices: fees - Consultation - Clinical Investigations statistical review	£782	£852
9. Clinical investigations for devices: fees - Consultation - Device Regulatory Advice meeting	£906	£987
9. Clinical investigations for devices: fees - Notification of a clinical investigation - Class I, IIa, or IIb other than	£5,711	£11,701

Fee name	Current	Proposed
implantable or long-term invasive devices (Resubmission)		
9. Clinical investigations for devices: fees - Notification of a clinical investigation - Class I, IIa, or IIb other than implantable or long-term invasive devices (Initial submission)	£7,472	£15,309
9. Clinical investigations for devices: fees - Notification of a clinical investigation - Class IIb implantable or long-term invasive, Class III, and active implantable devices (Resubmission)	£11,069	£22,678
9. Clinical investigations for devices: fees - Notification of a clinical investigation - Class IIb implantable or long-term invasive, Class III, and active implantable devices (Initial submission)	£15,627	£32,016
10. Drug-device combination products: fees - Conformity Assessment Body Designation Applications - Extension to scope, to carry out tasks under Part 2, Part 3 or Part 4, which extends the body's designation in relation to a Part under which they have already been designated.	£12,571	£13,684
10. Drug-device combination products: fees - Conformity Assessment Body Designation Applications - Extension to scope, which extends the body's designation to carry out certain tasks that were not previously within the scope of the body's designation and where the Secretary of State considers that an additional assessment of the body's procedures is required.	£18,212	£19,824
10. Drug-device combination products: fees - Conformity Assessment Body Designation Applications - Subsidiary audit* subject to additional fees calculated by hourly rate and travel rates (covers both Approved Body and Notified Body)	£22,789	£24,806
10. Drug-device combination products: fees - Further consultation of a Device which incorporates a new active substance	£11,551	£12,574
10. Drug-device combination products: fees - Further consultation of a Device which incorporates one or more known medicinal substances from a new source	£2,451	£2,668

Fee name	Current	Proposed
10. Drug-device combination products: fees - Further consultation of a Device which incorporates one or more known medicinal substances from an approved manufacturer of that substance	£900	£980
10. Drug-device combination products: fees - Initial consultation for a Device which incorporates a new active substance	£46,526	£50,644
10. Drug-device combination products: fees - Initial consultation for a Device which incorporates one or more known medicinal substances from a new source	£10,604	£11,543
10. Drug-device combination products: fees - Initial consultation for a Device which incorporates one or more known medicinal substances from an approved manufacturer of that substance	£4,550	£4,953
11. Homoeopathic National Rules Scheme: fees - Both stock and formulation already assessed - 5 stocks or fewer	£517	£630
11. Homoeopathic National Rules Scheme: fees - Both stock and formulation already assessed - more than 5 stocks	£732	£892
11. Homoeopathic National Rules Scheme: fees - Formulation already assessed - 5 stocks or fewer	£808	£984
11. Homoeopathic National Rules Scheme: fees - Formulation already assessed - more than 5 stocks	£1,014	£1,235
11. Homoeopathic National Rules Scheme: fees - Reduced - stock already assessed - 5 stocks or fewer	£808	£984
11. Homoeopathic National Rules Scheme: fees - Reduced - stock already assessed - more than 5 stocks	£1,014	£1,235
11. Homoeopathic National Rules Scheme: fees - Standard - 5 stocks or fewer	£1,088	£1,325
11. Homoeopathic National Rules Scheme: fees - Standard - more than 5 stocks	£1,312	£1,598

Fee name	Current	Proposed
11. Homoeopathic National Rules Scheme: fees - Supplementary fees - New excipients	£7,185	£8,746
11. Homoeopathic National Rules Scheme: fees - Supplementary fees - New method of sterilisation (non-pharmacopoeial)	£2,154	£2,622
11. Homoeopathic National Rules Scheme: fees - Supplementary fees - New sources TSE risk actives/excipients (non-CEP)	£635	£773
12. Homeopathic National Rules Scheme: fees for inspections - All GMP, GCP and pharmacovigilance inspections	£3,651	£5,251
12. Homeopathic National Rules Scheme: fees for inspections - Full day rate	£2,662	£4,136
12. Homeopathic National Rules Scheme: fees for inspections - Office based risk assessments (see notes below)	£1,862	£3,810
12. Homeopathic National Rules Scheme: fees for inspections - Office-based risk assessments	£2,562	£4,924
12. Homeopathic National Rules Scheme: fees for inspections - Reduced rate (see notes below)	£1,331	£2,068
13. Inspection: fees - All GMP, GCP and Pharmacovigilance inspections including (this is not an exhaustive list): intermediate biological sites, manufacturers of active pharmaceutical ingredients (API), sterile, non-sterile and assembly sites, non-routine inspections, pharmacovigilance inspection, clinical trials, contract laboratories, homeopathic manufacturers	£3,651	£5,251
13. Inspection: fees - GDP (wholesale dealers including homeopathic wholesalers) - Full day rate	£2,662	£4,136
13. Inspection: fees - GDP (wholesale dealers including homeopathic wholesalers) - Reduced rate (see notes below)	£1,331	£2,068

Fee name	Current	Proposed
13. Inspection: fees - Office based evaluation and risk assessments (see notes below)	£2,562	£4,924
14. Licence applications: marketing authorisation fees - Abridged complex - Complex International Recognition Type A application for GB or UK	£11,487	£13,983
14. Licence applications: marketing authorisation fees - Abridged complex - Complex International Recognition Type B application for GB or UK	£19,063	£23,205
14. Licence applications: marketing authorisation fees - Abridged complex - Complex: (Previously granted by EU) - unfettered access route to GB	£11,487	£13,983
14. Licence applications: marketing authorisation fees - Abridged complex - Decentralised procedure for the sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	£19,063	£23,205
14. Licence applications: marketing authorisation fees - Abridged complex - European reference product application for sale or supply in Northern Ireland	£19,063	£23,205
14. Licence applications: marketing authorisation fees - Abridged complex - Incoming mutual recognition procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	£19,063	£23,205
14. Licence applications: marketing authorisation fees - Abridged complex - National fee (any other case including hybrid applications)	£28,207	£34,335
14. Licence applications: marketing authorisation fees - Abridged simple - Decentralised procedure for sale or supply in Northern Ireland and Unfettered access route for UKMA(GB)	£2,820	£3,433
14. Licence applications: marketing authorisation fees - Abridged simple - Incoming mutual recognition procedure for sale or supply in Northern Ireland and Unfettered access route for UKMA(GB)	£2,820	£3,433

Fee name	Current	Proposed
14. Licence applications: marketing authorisation fees - Abridged simple - National fee (all other cases)	£2,820	£3,433
14. Licence applications: marketing authorisation fees - Abridged simple - Simple: (Previously granted by EU) - unfettered access route to GB	£2,820	£3,433
14. Licence applications: marketing authorisation fees - Abridged standard - Decentralised procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	£6,985	£8,503
14. Licence applications: marketing authorisation fees - Abridged standard - European reference product application for sale or supply in Northern Ireland	£6,985	£8,503
14. Licence applications: marketing authorisation fees - Abridged standard - Incoming mutual recognition procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for a UKMA(GB)	£6,985	£8,503
14. Licence applications: marketing authorisation fees - Abridged standard - National fee (all other cases)	£10,342	£12,589
14. Licence applications: marketing authorisation fees - Abridged standard - Standard International Recognition Type A application for GB or UK	£6,361	£7,743
14. Licence applications: marketing authorisation fees - Abridged standard - Standard International Recognition Type B application for GB or UK	£6,985	£8,503
14. Licence applications: marketing authorisation fees - Abridged standard - Standard: (Previously granted by EU) - unfettered access route to GB	£6,361	£7,743
14. Licence applications: marketing authorisation fees - Major - Decentralised procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	£68,663	£83,580
14. Licence applications: marketing authorisation fees - Major - European reference product application for	£68,663	£83,580

Fee name	Current	Proposed
sale or supply in Northern Ireland		
14. Licence applications: marketing authorisation fees - Major - Incoming mutual recognition procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	£68,663	£83,580
14. Licence applications: marketing authorisation fees - Major - Major International Recognition Type A application for GB or UK	£20,281	£24,688
14. Licence applications: marketing authorisation fees - Major - Major International Recognition Type B application for GB or UK	£68,663	£83,580
14. Licence applications: marketing authorisation fees - Major - Major Orphan (reduced in exceptional circumstances)	£32,705	£39,811
14. Licence applications: marketing authorisation fees - Major - Major: (Previously granted by EU) - unfettered access route to GB	£20,281	£24,688
14. Licence applications: marketing authorisation fees - Major - National fee (any other case including hybrid applications)	£102,028	£124,194
15. Licence applications: manufacturers licence (including THMPD and homeopathic medicinal products)* fees - Change of ownership	£378	£461
15. Licence applications: manufacturers licence (including THMPD and homeopathic medicinal products)* fees - Non-orthodox practitioner (NOP)	£201	£245
15. Licence applications: manufacturers licence (including THMPD and homeopathic medicinal products)* fees - Standard	£3,457	£4,209
16. Licence applications: parallel imports fees - Change of ownership (including THMPD registrations)	£486	£592

Fee name	Current	Proposed
16. Licence applications: parallel imports fees - Complex application*	£19,998	£24,343
16. Licence applications: parallel imports fees - Simple application	£1,971	£2,400
16. Licence applications: parallel imports fees - Standard application*	£8,722	£10,617
17. Licence applications: Phase 1 Accreditation Scheme fees - Phase I Accreditation Scheme - Accreditation of Phase 1 units	£129	£141
17. Licence applications: Phase 1 Accreditation Scheme fees - Phase I Accreditation Scheme - Certificate of accreditation	£68	£75
18. Medicines export certificates: fees - Standard request: ten working days - Electronic copy	£75	£82
18. Medicines export certificates: fees - Urgent request: two working days - Electronic copy	£167	£182
19. Periodic fees for holding a marketing authorisation - Derivatives with a different route of administration[footnote 4] or complex abridged[footnote 5]	£10,681	£11,627
19. Periodic fees for holding a marketing authorisation - Herbal	£84	£92
19. Periodic fees for holding a marketing authorisation - Homeopathic and Anthroposophic PLRs (per PLR)	£84	£92
19. Periodic fees for holding a marketing authorisation - Manufacturer’s licence	£515	£561
19. Periodic fees for holding a marketing authorisation - National Rules Homeopathic Authorisation	£84	£92
19. Periodic fees for holding a marketing authorisation - New active substance[footnote 4]	£10,681	£11,627
19. Periodic fees for holding a marketing authorisation - Other derivatives[footnote 4]	£7,209	£7,847

Fee name	Current	Proposed
19. Periodic fees for holding a marketing authorisation - Prescription Only Medicine (POM) - ‘Maintenance’ fee	£338	£368
19. Periodic fees for holding a marketing authorisation - Prescription Only Medicine (POM) - All others (P, GSL, PLPI and None)	£338	£368
19. Periodic fees for holding a marketing authorisation - Prescription Only Medicine (POM) - Reduced rate fee	£1,332	£1,450
19. Periodic fees for holding a marketing authorisation - Prescription Only Medicine (POM) - Standard fee[footnote 6]	£2,671	£2,908
19. Periodic fees for holding a marketing authorisation - THMPD registration	£84	£92
19. Periodic fees for holding a marketing authorisation - Wholesale dealer’s licence	£317	£346
19. Periodic fees for holding a marketing authorisation - Wholesale dealer’s licence (reduced rate or GSL) [footnote 7]	£189	£206
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Assessment of labels and leaflets - National (BROMI) notification/self-certification[footnote 13]	£205	£224
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Assessment of labels and leaflets - Parallel imports	£361	£440
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Assessment of labels and leaflets - Single or first application[footnote 12]	£570	£992
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - First renewal of a market authorisation granted with a new active substance - All other cases	£10,650	£16,042

Fee name	Current	Proposed
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - First renewal of a market authorisation granted with a new active substance - UKMA(GB) granted under the unfettered access route	£822	£1,239
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - First renewal of a market authorisation granted with a new active substance - UKMA(GB) previously granted by EU (automatic recognition)	£822	£1,239
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - First renewal of a market authorisation granted with a new active substance - UKMA(GB) previously granted by International Recognition	£822	£1,239
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Licence Renewal Applications - Manufacturers' licences Non-orthodox practitioner (NOP)	£196	£214
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Reclassification - P to GSL - Additional fee for MA or PI application with reclassification element from P to GSL[footnote 10],[footnote 11]	£8,978	£10,929
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Reclassification - POM to P - Additional for MA or PI application with reclassification element from POM to P[footnote 10], [footnote 11]	£33,003	£40,173
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Reclassification - Reclassification Type IB variation application (MA) (analogous product) [footnote 11]	£344	£419
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Reclassification - Reclassification variation application (MA) (analogous product) [footnote 11]	£1,308	£1,593
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Reclassification - Reclassification variation application P to GSL	£8,978	£10,929

Fee name	Current	Proposed
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees - Reclassification - Reclassification variation application POM to P[footnote 10],[footnote 11]	£33,003	£40,173
21. Orphan Marketing Products: fees - Orphan Complex (Full Fee)	£28,207	£34,335
21. Orphan Marketing Products: fees - Orphan Major (exceptional circumstances in which point G of Part IV of Annex 1 in the 2001 Directive applies)	£32,705	£39,811
21. Orphan Marketing Products: fees - Orphan Major (Full fee)	£102,028	£124,194
21. Orphan Marketing Products: fees - Orphan Standard (Full Fee)	£10,342	£12,589
22. Pharmacovigilance (PV) Safety Review: fees - Assessment of PASS Results	£9,140	£9,949
22. Pharmacovigilance (PV) Safety Review: fees - PV Major Safety Review (1-2 active ingredients)	£56,415	£61,408
22. Pharmacovigilance (PV) Safety Review: fees - PV Major Safety Review (3 active ingredients)	£65,555	£71,357
22. Pharmacovigilance (PV) Safety Review: fees - PV Major Safety Review (4 active ingredients)	£74,694	£81,305
22. Pharmacovigilance (PV) Safety Review: fees - PV Major Safety Review (5 or more active ingredients)	£83,834	£91,254
22. Pharmacovigilance (PV) Safety Review: fees - PV Periodic Safety Update Report (PSUR) single assessment: Full Fee	£979	£1,066
22. Pharmacovigilance (PV) Safety Review: fees - PV Periodic Safety Update Report (PSUR) single assessment: Half Fee	£490	£534
22. Pharmacovigilance (PV) Safety Review: fees - PV Post Authorisation Safety Study (PASS) protocol	£9,140	£9,949

Fee name	Current	Proposed
23. Plasma Master File (PMF) & Vaccine Antigen Master File certification or certified annual update work: fees - Certification of new PMF (for scientific & technical evaluation)	£9,140	£11,126
23. Plasma Master File (PMF) & Vaccine Antigen Master File certification or certified annual update work: fees - Certified Annual Update of a PMF (epidemiology update only)	£344	£419
23. Plasma Master File (PMF) & Vaccine Antigen Master File certification or certified annual update work: fees - Certified Annual Update of a PMF (significant changes to safety information)	£1,308	£1,593
23. Plasma Master File (PMF) & Vaccine Antigen Master File certification or certified annual update work: fees - Vaccine Antigen Master File (VAMF) certification	£9,140	£11,126
24. Pre-Assessment (Rolling Review): fees - Application by pre-assessment (Biosimilar) - Module 3 (chemical, pharmaceutical and biological information)	£4,766	£5,802
24. Pre-Assessment (Rolling Review): fees - Application by pre-assessment (Biosimilar) - Module 4 (non-clinical reports)	£4,766	£5,802
24. Pre-Assessment (Rolling Review): fees - Application by pre-assessment (Biosimilar) - Module 5 (clinical study reports)	£4,766	£5,802
24. Pre-Assessment (Rolling Review): fees - Application by pre-assessment (NAS) - Module 3 (chemical, pharmaceutical and biological information)	£25,507	£31,049
24. Pre-Assessment (Rolling Review): fees - Application by pre-assessment (NAS) - Module 4 (non-clinical reports)	£25,507	£31,049
24. Pre-Assessment (Rolling Review): fees - Application by pre-assessment (NAS) - Module 5 (clinical study reports)	£25,507	£31,049

Fee name	Current	Proposed
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 1 – 20	£70	£86
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 21 – 100	£350	£427
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - 1 – 5	£100	£122
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - 101 – 200	£4,000	£4,869
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - 11– 20	£400	£487
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - 21 – 50	£1,000	£1,218
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - 51 – 100	£2,000	£2,435
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - 6 – 10	£200	£244
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - Per additional 100 codes above 200	£2,000	£2,435
26. Scientific advice meetings: fees - Pharmacovigilance advice meetings - Advice on labels and leaflets	£2,421	£3,757
26. Scientific advice meetings: fees - Reclassification advice meetings - Pharmacy to General Sales List	£3,039	£8,758

Fee name	Current	Proposed
switch		
26. Scientific advice meetings: fees - Reclassification advice meetings - Prescription Only Medicine to Pharmacy switch	£3,986	£8,758
27. Simplified Homeopathic Registration Scheme: fees - Both stock and formulation already assessed - 5 stocks or fewer	£159	£194
27. Simplified Homeopathic Registration Scheme: fees - Both stock and formulation already assessed - more than 5 stocks	£393	£479
27. Simplified Homeopathic Registration Scheme: fees - Formulation already assessed - 5 stocks or fewer	£478	£582
27. Simplified Homeopathic Registration Scheme: fees - Formulation already assessed - more than 5 stocks	£704	£857
27. Simplified Homeopathic Registration Scheme: fees - Reduced - 5 stocks or fewer	£478	£582
27. Simplified Homeopathic Registration Scheme: fees - Reduced - more than 5 stocks	£704	£857
27. Simplified Homeopathic Registration Scheme: fees - Standard - 5 stocks or fewer	£790	£962
27. Simplified Homeopathic Registration Scheme: fees - Standard - more than 5 stocks	£1,034	£1,259
28. Simplified Homeopathic Registration Scheme: Decentralised Procedure applications: fees - Decentralised Procedure for sale or supply in Northern Ireland and Unfettered access route for UKHR(GB) - 5 stocks or fewer	£430	£524
28. Simplified Homeopathic Registration Scheme: Decentralised Procedure applications: fees - Decentralised Procedure for sale or supply in Northern Ireland and Unfettered access route for UKHR(GB) - more than 5 stocks	£563	£686

Fee name	Current	Proposed
29. Simplified Homoeopathic Registration Scheme: Mutual Recognition Procedures: fees - Incoming Mutual Recognition for sale or supply in Northern Ireland and Unfettered access route for UKHR(GB) - 5 stocks or fewer	£501	£610
29. Simplified Homoeopathic Registration Scheme: Mutual Recognition Procedures: fees - Incoming Mutual Recognition for sale or supply in Northern Ireland and Unfettered access route for UKHR(GB) - more than 5 stocks	£638	£777
31. Traditional Herbal Registration Scheme: fees - Complex - 2 or more new herbal active ingredients	£7,269	£8,849
31. Traditional Herbal Registration Scheme: fees - Complex - single new herbal active ingredient	£4,846	£5,899
31. Traditional Herbal Registration Scheme: fees - Reduced - Category I - 3 or fewer existing herbal active ingredients	£539	£657
31. Traditional Herbal Registration Scheme: fees - Reduced - Category I - more than 3 existing herbal active ingredients	£807	£983
31. Traditional Herbal Registration Scheme: fees - Reduced - Category II - 3 or fewer existing herbal active ingredients	£807	£983
31. Traditional Herbal Registration Scheme: fees - Reduced - Category II - more than 3 existing herbal active ingredients	£1,212	£1,476
31. Traditional Herbal Registration Scheme: fees - Standard - 3 or fewer existing herbal active ingredients	£2,423	£2,950
31. Traditional Herbal Registration Scheme: fees - Standard - more than 3 existing herbal active ingredients	£3,634	£4,424
31. Traditional Herbal Registration Scheme: fees - Traditional Herbal Registration Scheme: supplementary	£1,077	£1,311

Fee name	Current	Proposed
fees - Ancillary vitamins / minerals - Existing Sources plus CEP		
31. Traditional Herbal Registration Scheme: fees - Traditional Herbal Registration Scheme: supplementary fees - Ancillary vitamins / minerals - New excipients	£7,186	£8,748
31. Traditional Herbal Registration Scheme: fees - Traditional Herbal Registration Scheme: supplementary fees - Ancillary vitamins / minerals - New sources (non-CEP)	£2,154	£2,622
31. Traditional Herbal Registration Scheme: fees - Traditional Herbal Registration Scheme: supplementary fees - Ancillary vitamins / minerals - New sources TSE risk excipients (non-CEP)	£638	£777
31. Traditional Herbal Registration Scheme: fees - Traditional Herbal Registration Scheme: supplementary fees - Ancillary vitamins / minerals - Sterile products	£2,154	£2,622
32. Variation: Homeopathic National Rules Scheme fees - Indication	£374	£456
32. Variation: Homeopathic National Rules Scheme fees - Other applications (for any subsequent variations where no further medical, technical or scientific assessment is required)	£61	£75
32. Variation: Homeopathic National Rules Scheme fees - Other applications (for up to 30 variations where no further medical, technical or scientific assessment is required)	£122	£149
32. Variation: Homeopathic National Rules Scheme fees - Standard variation application	£243	£296
33. Variations: Homeopathic Simplified Scheme fees - New technical	£243	£296
33. Variations: Homeopathic Simplified Scheme fees - Other applications (for any subsequent variations where no further medical, technical or scientific assessment is required)	£61	£75
33. Variations: Homeopathic Simplified Scheme fees - Other applications (for up to 30 variations where no	£122	£149

Fee name	Current	Proposed
further medical, technical or scientific assessment is required)		
33. Variations: Homeopathic Simplified Scheme fees - Other applications (where further medical, technical or scientific assessment is required)	£243	£296
34. Variations: licence variations application fees - Applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008. - Single kind variation - Extended Type II Complex Variation	£8,462	£10,301
34. Variations: licence variations application fees - Applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008. - Single kind variation - Type IB	£344	£419
34. Variations: licence variations application fees - Applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008. - Single kind variation - Type II	£344	£419
34. Variations: licence variations application fees - Applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008. - Single kind variation - Type II Complex Variation	£2,742	£3,338
34. Variations: licence variations application fees - Applications for variations of marketing authorisations falling within the scope of Chapter IIa of Commission Regulation (EC) No 1234/2008 and of marketing authorisations in force in Great Britain. - National Type 1B Variation	£344	£419
34. Variations: licence variations application fees - Applications for variations of marketing authorisations falling within the scope of Chapter IIa of Commission Regulation (EC) No 1234/2008 and of marketing authorisations in force in Great Britain. - National Type II Variation	£1,308	£1,593
34. Variations: licence variations application fees - Applications for variations of marketing authorisations	£9,140	£11,126

Fee name	Current	Proposed
falling within the scope of Chapter IIa of Commission Regulation (EC) No 1234/2008 and of marketing authorisations in force in Great Britain. - National Type II Complex Variation		
34. Variations: licence variations application fees - Applications for variations of marketing authorisations falling within the scope of Chapter IIa of Commission Regulation (EC) No 1234/2008 and of marketing authorisations in force in Great Britain. - National Type II Extended Complex Variation	£33,003	£40,173
35. Variations: licence variations applications groups fees - Applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008. - Major Variation (Type II) Complex Group	£2,973	£3,619
35. Variations: licence variations applications groups fees - Applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008. - Major Variation (Type II) Extended Complex Group	£8,671	£10,555
35. Variations: licence variations applications groups fees - Applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008. - Major Variation (Type II) Group	£1,255	£1,528
35. Variations: licence variations applications groups fees - Applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008. - Minor variation (Type IB) Group	£344	£419
35. Variations: licence variations applications groups fees - Applications for variations of marketing authorisations falling within the scope of Chapter IIa of Commission Regulation (EC) No 1234/2008 and of marketing authorisations in force in Great Britain. - National Type IB Minor Variation Group	£684	£833
35. Variations: licence variations applications groups fees - Applications for variations of marketing authorisations falling within the scope of Chapter IIa of Commission Regulation (EC) No 1234/2008 and of marketing authorisations in force in Great Britain. - National Type II Major Variation Group	£1,817	£2,212

Fee name	Current	Proposed
35. Variations: licence variations applications groups fees - Applications for variations of marketing authorisations falling within the scope of Chapter IIa of Commission Regulation (EC) No 1234/2008 and of marketing authorisations in force in Great Britain. - National Type II Major Variation Complex Group	£9,911	£12,065
35. Variations: licence variations applications groups fees - Applications for variations of marketing authorisations falling within the scope of Chapter IIa of Commission Regulation (EC) No 1234/2008 and of marketing authorisations in force in Great Britain. - National Type II Major Variation Extended Complex Group	£28,904	£35,184
36. Variations: other licence variations applications fees - Clinical trial authorisations - Amendments to 1 part of dossier	£248	£302
36. Variations: other licence variations applications fees - Clinical trial authorisations - Amendments to 2 parts of dossier	£248	£302
36. Variations: other licence variations applications fees - Clinical trial authorisations - Amendments to 3 parts of dossier	£248	£302
36. Variations: other licence variations applications fees - Clinical trial authorisations - Protocol	£248	£302
36. Variations: other licence variations applications fees - Manufacturer’s licences (including traditional herbal medicines) - Administrative	£283	£345
36. Variations: other licence variations applications fees - Manufacturer’s licences (including traditional herbal medicines) - Standard	£565	£688
36. Variations: other licence variations applications fees - Parallel import (PI) - Standard	£393	£479
36. Variations: other licence variations applications fees - Wholesale dealers’ licences (includes THMPD) - Administrative	£283	£345

Fee name	Current	Proposed
36. Variations: other licence variations applications fees - Wholesale dealers' licences (includes THMPD) - Standard	£535	£652
37. Variations: Traditional Herbal Registration Scheme fees - Administrative	£152	£186
37. Variations: Traditional Herbal Registration Scheme fees - Complex	£635	£773
37. Variations: Traditional Herbal Registration Scheme fees - New excipient	£7,186	£8,748
37. Variations: Traditional Herbal Registration Scheme fees - Standard	£240	£293
38. Wholesale distribution authorisations: fees - Inspections - Inspection fee reduced rate THMP/Homeopathic only	£1,023	£1,114
38. Wholesale distribution authorisations: fees - Inspections - Inspection fee THMP/Homeopathic only	£1,880	£2,047
38. Wholesale distribution authorisations: fees - Inspections - Issue of GDP Certificates	£75	£82
38. Wholesale distribution authorisations: fees - Inspections - Office Based Risk Assessments	£1,862	£3,810
38. Wholesale distribution authorisations: fees - Inspections - Reduced rate Inspection fee	£1,331	£2,068
38. Wholesale distribution authorisations: fees - Inspections - Standard Inspection Fee (per site)	£2,662	£4,136
38. Wholesale distribution authorisations: fees - New Applications - Change of ownership	£439	£478
38. Wholesale distribution authorisations: fees - New Applications - Inspection Fee (per additional site if required)	£2,662	£2,898
38. Wholesale distribution authorisations: fees - New Applications - Reduced application plus reduced	£2,323	£2,529

Fee name	Current	Proposed
Inspection fee - General Sales List (GSL) only		
38. Wholesale distribution authorisations: fees - New Applications - Reduced application* plus full inspection fee	£3,654	£3,978
38. Wholesale distribution authorisations: fees - New Applications - Standard application plus full inspection fee	£1,880	£2,047
38. Wholesale distribution authorisations: fees - Variations - Administrative variation	£283	£309
38. Wholesale distribution authorisations: fees - Variations - Standard variation	£535	£583
39. Early Access to Medicines Scheme (EAMS) - Promising Innovative Medicine (PIM) designation	£3,986	£4,852
39. Early Access to Medicines Scheme (EAMS) - Renewal fee for new indications	£4,154	£5,057
39. Early Access to Medicines Scheme (EAMS) - Renewal fee for new medicinal products	£12,821	£15,607
39. Early Access to Medicines Scheme (EAMS) - Scientific opinion for new indications	£8,309	£10,115
39. Early Access to Medicines Scheme (EAMS) - Scientific opinion for new medicinal products	£25,643	£31,214
40. Devices - Day rate for auditing	£1,262	£1,463
40. Devices - Extension to scope - Extension to scope, where codes are limited	£12,571	£14,568
40. Devices - Extension to scope - new UKCA codes or Annex	£18,212	£21,105
40. Devices - Follow up Audit - Major Closure	£22,789	£26,408

Fee name	Current	Proposed
40. Devices - Follow up Audit - Process Specific	£22,789	£26,408
40. Devices - Follow up Audit - Special Clinical	£18,583	£21,535
40. Devices - Initial application for designation	£35,672	£41,337
40. Devices - Initial designation audit	£58,341	£67,606
40. Devices - Re-application	£8,918	£10,335
40. Devices - Re-designation application fee	£35,672	£41,337
40. Devices - Re-designation audit	£58,341	£67,606
40. Devices - Subsidiary audit	£22,789	£26,408
40. Devices - Surveillance	£45,675	£52,929
40. Devices - TSE Applications UK Conformity Assessment Bodies	£1,297	£1,503
40. Devices - Witnessed Audit	£10,072	£11,672
41. ILAP – Innovation Passport	£3,624	£3,945
41.ILAP – Target Development Profile	£4,451	£4,845

A list of fees for proposal 3 – regulatory advice meetings for medical devices

New fee name	Proposed
Regulatory advice meeting for medical devices	£987

A list of fees for proposal 4 – amended fees for Scientific Advice Meetings

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

A list of fees for proposal 4 – amended fees for Control Testing

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

A list of fees for proposal 4 – amended fees for Unlicenced Medicines Importation

New fee name (see final table for the old fees)	Proposed
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 101 to 500	£2,131
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 501 to 1000	£4,261
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 1,001-2,000	£8,521
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 2,001-5,000	£17,042
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - Per additional bracket of 5,000 notifications above 50,000	£17,042
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 10,001-15,000	£51,125
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 20,001-25,000	£85,208
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 35,001-40,000	£119,291
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 5,001-10,000	£34,083
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 15,001-20,000	£68,166
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 25,001-30,000	£102,249
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 30,001-35,000	£119,291
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 35,001-40,000	£136,333

New fee name (see final table for the old fees)	Proposed
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 40,001-45,000	£153,375
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 45,001-50,000	£170,417

A list of fees for proposal 4 – fees replaced by proposed changes above or obsolete fees

Old fee name	Fee
14. Licence applications: marketing authorisation fees - Abridged complex - Complex: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	£19,063
14. Licence applications: marketing authorisation fees - Abridged complex - Complex: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	£11,487
14. Licence applications: marketing authorisation fees - Abridged standard - Standard: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	£6,985
14. Licence applications: marketing authorisation fees - Abridged standard - Standard: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	£6,361
14. Licence applications: marketing authorisation fees - Abridged simple - Simple: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	£2,820
14. Licence applications: marketing authorisation fees - Abridged simple - Simple: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	£2,820
14. Licence applications: marketing authorisation fees - Major - Major: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	£68,663
14. Licence applications: marketing authorisation fees - Major - Major: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	£20,281
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 101 – 1,000	£2,400

Old fee name	Fee
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 1,001 – 5,000	£12,000
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 5,001 – 20,000	£30,000
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 20,001 – 50,000	£60,000
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 50,001 – 100,000	£120,000
25. Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 100,001 +	£200,000
26. Scientific advice meetings: fees - Quality development only	£2,421
26. Scientific advice meetings: fees - Pre-consultation application meetings on devices incorporating an ancillary medicinal substance* - Safety development only	£824
26. Scientific advice meetings: fees - Pre-consultation application meetings on devices incorporating an ancillary medicinal substance* - Quality and safety development	£1,044
26. Scientific advice meetings: fees - Pre-consultation application meetings on devices incorporating an ancillary medicinal substance* - Clinical development only	£1,044
26. Scientific advice meetings: fees - Pre-consultation application meetings on devices incorporating an ancillary medicinal substance* - Quality and clinical development	£1,429
26. Scientific advice meetings: fees - Pre-consultation application meetings on devices incorporating an ancillary medicinal substance* - Safety and clinical development	£1,429
26. Scientific advice meetings: fees - Pre-consultation application meetings on devices incorporating an ancillary medicinal substance* - Quality, safety and clinical development	£1,813

Old fee name	Fee
26. Scientific advice meetings: fees - Pre-consultation application meetings on devices incorporating an ancillary medicinal substance* - Broader scope meetings	£4,896
26. Scientific advice meetings: fees - Pharmacovigilance advice meetings - Standard meeting	£3,367
26. Scientific advice meetings: fees - Pharmacovigilance advice meetings - Major meeting	£3,986
26. Scientific advice meetings: fees - Pharmacovigilance advice meetings - Post-authorisation regulatory advice meetings	£3,039
26. Scientific advice meetings: fees - Safety development only	£2,421
26. Scientific advice meetings: fees - Pharmacovigilance advice meetings - Advertising advice	£2,421
26. Scientific advice meetings: fees - Quality and safety development	£3,367
26. Scientific advice meetings: fees - Clinical development only	£3,039
26. Scientific advice meetings: fees - Quality and clinical development	£3,986
26. Scientific advice meetings: fees - Safety and clinical development	£3,986
26. Scientific advice meetings: fees - Quality, safety and clinical development	£4,936
26. Scientific advice meetings: fees - Pre-consultation application meetings on devices incorporating an ancillary medicinal substance* - Quality development only	£824
30. Testing of samples: fees - Fee payable where the licensing authority carries out a full assessment - Plasma pools which require three or fewer tests	£198
30. Testing of samples: fees - Fee payable where the licensing authority carries out a paper-based assessment - Plasma	£99

Old fee name	Fee
pools which require three or fewer tests	
30. Testing of samples: fees - Fee payable where the licensing authority carries out a paper-based assessment - Plasma pools which require four or five tests	£99
30. Testing of samples: fees - Fee payable where the licensing authority carries out a paper-based assessment - Plasma pools which require six or more tests	£99
30. Testing of samples: fees - Fee payable where the licensing authority carries out a paper-based assessment - Band A – single component product, other than Botulinum toxin. requiring five or fewer in vitro tests	£367
30. Testing of samples: fees - Fee payable where the licensing authority carries out a paper-based assessment - Band B – Factor VIII, Factor VIX or intravenous Immunoglobin	£367
30. Testing of samples: fees - Fee payable where the licensing authority carries out a paper-based assessment - Band C – Multi-component product, or Botulinum toxin, requiring five or fewer in vitro tests	£992
30. Testing of samples: fees - Fee payable where the licensing authority carries out a paper-based assessment - Band D – product requiring six to nine in vitro tests	£992
30. Testing of samples: fees - Fee payable where the licensing authority carries out a paper-based assessment - Band E – product requiring (a) ten or more in vitro tests, or (b) one or more in vivo tests	£1,849
30. Testing of samples: fees - Fee payable where the licensing authority carries out a paper-based assessment - Band F – one or more tests that must be carried out under containment measures applicable to hazard Group 3 or 4 biological agents under Control of Substances Hazardous to Health Regulations 2002 (123) or requires use of human tissues or cells as part of testing	£1,849
30. Testing of samples: fees - Fee payable where the licensing authority carries out a full assessment - Plasma pools which require four or five tests	£237

Old fee name	Fee
30. Testing of samples: fees - Fee payable where the licensing authority carries out a full assessment - Plasma pools which require six or more tests	£253
30. Testing of samples: fees - Fee payable where the licensing authority carries out a full assessment - Band A – single component product, other than Botulinum toxin. requiring five or fewer in vitro tests	£1,826
30. Testing of samples: fees - Fee payable where the licensing authority carries out a full assessment - Band B – Factor VIII, Factor VIX or intravenous Immunoglobin	£2,101
30. Testing of samples: fees - Fee payable where the licensing authority carries out a full assessment - Band C – Multi-component product, or Botulinum toxin, requiring five or fewer in vitro tests	£2,574
30. Testing of samples: fees - Fee payable where the licensing authority carries out a full assessment - Band D – product requiring six to nine in vitro tests	£4,059
30. Testing of samples: fees - Fee payable where the licensing authority carries out a full assessment - Band E – product requiring (a) ten or more in vitro tests, or (b) one or more in vivo tests	£7,051
30. Testing of samples: fees - Fee payable where the licensing authority carries out a full assessment - Band F – one or more tests that must be carried out under containment measures applicable to hazard Group 3 or 4 biological agents under Control of Substances Hazardous to Health Regulations 2002 (123) or requires use of human tissues or cells as part of testing	£11,385

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.