ANNEX A

Medicines & Healthcare products Regulatory Agency

MHRA consultation on statutory fees (2026)

Proposals for ongoing cost-recovery and to fund higher-value services

Published 17 August 2026

Contents

Executive summary

The purpose of this consultation is to seek views on proposals to update the statutory fees charged by the Medicines and Healthcare products Regulatory Agency (MHRA) from 1 April 2027. The consultation will run from 17 August to 25 September.

The UK is competing globally for life sciences activity and investment. Industry feedback indicates that applicants increasingly value speed, reliability and predictability in regulatory services, alongside scientific quality and independence. These proposals are designed to help the MHRA continue to recover the cost of delivering its regulatory services while investing to enable faster, more reliable and predictable services to support a more competitive UK regulatory offer.

The MHRA reviews its fees regularly to reflect the costs of delivering its regulatory functions. This is in line with HM Treasury guidance, Managing Public Money, which requires that public bodies should set charges to recover the full cost of the service provided.

Since the last fee update, the MHRA has made significant progress improving its service performance. Industry engagement has consistently highlighted the importance of reliability, predictability and timely decisions. These proposals are intended to help sustain recent improvements and support further service enhancements.

The MHRA is proposing that most fees will increase by indexation only. A small number of fees will change by more and in a targeted way. For these fees, there is demand for higher-value services and the expected cost of delivering those services is higher, including the cost of specialist staff, training, systems and other support needed. The MHRA is also proposing adjustments to some existing fees. For selected services, the MHRA is proposing clearer service standards, a rebate mechanism where guaranteed timelines are not met, and enhanced support for eligible small and medium-sized enterprises (SMEs). Finally, the MHRA is proposing improvements to its scientific advice service.

As part of the wider government drive to minimise administrative burden, the MHRA will ensure that new processes are simple and fast, with information requirements that are proportionate, easy for applicants to provide and practical for the MHRA to process.

The proposals cover the whole of the UK. This 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.

Introduction

The MHRA regulates medicines, medical devices and blood components for transfusion in the UK. It uses science and data to make decisions, support innovation and help make sure that the medicines and healthcare products available in the UK are safe and effective.

The MHRA receives around 80% of its income from statutory fees charged for services. Fees are set to recover the cost of the work involved and all increases are intended to recover costs only and are not intended to generate profit or recover unrelated costs, or make a shortfall, which would have to be subsidised by the taxpayer. This is in line with HM Treasury guidance, *Managing Public Money*[1], which states that the standard approach is to set charges to recover full costs.

Full cost-recovery helps make sure that the MHRA can continue to deliver its services in a financially sustainable way. Fees are set by considering the cost of delivering each service. This includes the activities involved, the time taken, the number and grade of staff needed, and the necessary corporate costs and systems that support delivery.

For the 2027 fee update, the MHRA is proposing to recover the expected cost of delivering services over the period from 1 April 2027 to 31 March 2029. This includes expected costs such as building specialist capacity, training staff and improving systems to ensure reliable and predictable service delivery.

Overall, the proposals are intended to support a more competitive UK life sciences environment, by enabling investment in specialist capacity, training and digital infrastructure that supports reliable and predictable delivery. They build on recent improvements in service performance and are intended to help make those improvements sustainable, while supporting further gains in speed, reliability and predictability.

Most fees will increase by indexation only to ensure the MHRA continues to recover its costs, while a smaller number of higher-value fees will receive a larger uplift to fund additional capacity and the remaining fees are being adjusted as the current level does not reflect the cost of delivering the service. By supporting faster, more reliable services, the proposals are intended to help make the UK a more attractive place to develop, test and bring new products to market.

The MHRA intends to take forward secondary legislation using the powers in the Medicines and Medical Devices Act 2021 to change its fees. More information on the legal basis for these proposals is set out in Annex A. The proposed changes in this consultation are intended to come into force on 1 April 2027.

[1] https://www.gov.uk/government/publications/managing-public-money

The proposals

The proposals cover six areas:

1. Increase most fees by indexation only.
2. Targeted increases for a small number of higher-value services.
3. Enhanced service standards, guaranteed timelines and rebates for selected services.
4. Enhanced support for eligible small and medium-sized enterprises.
5. Improvements to the MHRA’s scientific advice service.
6. A phased update to the medical devices post-market surveillance fee.
7. Adjustments to some existing fees.

The full list of current and proposed fees is set out in Annex B.

Proposal 1

Increase most fees by indexation only

The MHRA proposes to increase most statutory fees by indexation only from 1 April 2027. This is the MHRA's standard approach to keeping fees aligned with changes in the cost of delivering services.

Indexation means increasing fees to reflect changes in the cost of delivering services. This helps make sure that fees continue to recover the cost of the work involved.

For this fee update, the proposed indexation increase is 8.93%. This will apply to 180 fees, which represents 62% of MHRA's statutory fees. It reflects expected changes in staff pay and employer costs over the period from 1 April 2027 to 31 March 2029.

The 8.93% figure is based on three main factors: 1.76% from the 2025 Employer National Insurance contribution increase, a 0.9% adjustment to reflect the higher than previously assumed 2026/27 Civil Service pay award (3.5% rather than the 2.6% previously assumed), and an assumed 3% Civil Service pay award for 2027/28 and 2028/29.

These fees are not changing because the nature of the service is changing. They are changing so that the fee continues to reflect the cost of delivering the same service. However, the MHRA will continue to improve its performance across all services.

The MHRA reviews advertising submitted for pre-publication vetting to check compliance with the legislation. This work has previously been undertaken without charge. We propose to introduce a fee to recover the cost of this activity. Advertising complaint investigations remain outside the new proposed fees.

The full list of fees affected by this proposal is set out in Annex B.

Proposal 2

Targeted increases for a small number of higher-value services

The MHRA proposes to apply a larger increase to a small number of fees where there is demand for higher-value, time-sensitive services and where the expected cost of delivering that service is higher.

This will apply to 25 fees, which represents 9% of MHRA's statutory fees. These fees will increase by around 27%, including the 8.93% indexation increase in Proposal 1.

The targeted increase is intended to recover the expected cost of delivering the selected services to a more reliable, predictable and timely standard. This includes investment in additional scientific assessor capacity, training and capability building, and digital infrastructure.

The added value is not only speed but also greater reliability and predictability, better engagement and improved transparency, whilst maintaining standards.

The MHRA has carried out initial research with industry stakeholders to understand what applicants value most from its services. The proposals have also been informed by independent assurance of the cost modelling, industry interviews and international benchmarking.

Feedback has shown that applicants place particular value on reliable, predictable and timely services, and that targeted fee increases will be acceptable where they are linked to faster, more predictable service performance. Industry has also indicated that "burn rate" is an important issue, especially for smaller companies. This means that delays and uncertainty can increase the wider cost of developing a product before it generates income. Benchmarking against other regulators also indicates that the proposed fees will remain broadly competitive internationally.

The MHRA will develop clear plans to ensure the additional funding results in strengthened staff capability and digital infrastructure. In addition, the MHRA will continue with its work improving coordination in the health and social care system to ensure that the benefits of faster regulatory decisions can be fully realised by industry.

The MHRA will publish further detail on planned improvements, including timelines, industry involvement and performance reporting arrangements. This will help applicants understand how the targeted uplift will translate into practical service improvements and provide assurance that enhanced services will be delivered without compromising standard services.

The full list of fees affected by this proposal is set out in Annex B.

Proposal 3

Enhanced service standards, guaranteed timelines and rebates for selected services

The MHRA proposes to introduce clearer service standards for selected high-value, time-sensitive services where applicants need a more reliable, predictable and timely service.

The proposed performance guarantees will apply to:

- New Active Substance (NAS) licensing assessment: 90-day first assessment, covering dossier review and CHM examination; enabling early certainty of decision timelines through the national process;

- NAS Priority Pathway: initially up to 10 slots a year (this figure will be kept under review) with an additional £100,000 fee per slot on top of the standard NAS fee, reducing the overall timeline from the current 210 days to 180 calendar days; enabling earlier MHRA decisions for high-value, novel applications;

- Phase I first-in-human clinical trials: 14-day initial assessment to deliver faster approvals, greater predictability, maintained safety standards, and improved UK attractiveness for early phase R&D investment; and

- Scientific advice: a 90-working day standard service and a 45-working day accelerated route with a performance rebate, giving companies or sponsors clearer choices about the advice they need based on complexity, urgency and type of advice (see Proposal 5).

For these selected services, the MHRA will set out the expected timeline for delivery and how performance against that timeline will be measured. This will help applicants understand what they can expect from the service, see how the MHRA is performing, and plan with greater confidence.

Where a guaranteed timeline applies, the MHRA is also proposing to introduce a rebate mechanism. This means that if the MHRA does not meet the guaranteed timeline, the performance-related part of the targeted fee increase will be returned to the applicant. Applicants will still pay the original fee and the indexation increase, because these reflect the underlying cost of delivering the service. The MHRA intends to introduce a new general wavier power in relation to its medicines fees to help deliver this proposal.

Initial research indicates that rebates would be welcomed, but that companies place greater value on predictable and reliable timelines than on compensation. However, the MHRA believes that rebates signal a clear commitment to delivery and accountability.

The purpose of the rebate mechanism is to support accountability and confidence in the service. The MHRA’s aim is to meet the guaranteed timelines, rather than to pay rebates.

The MHRA will seek to ensure that enhanced service standards for selected services do not reduce the quality or reliability of standard services.

The MHRA will ensure that the application and rebate processes are simple and fast, with information requirements that are proportionate, easy for applicants to provide and practical for the MHRA to process.

The MHRA recognises that service standards and key performance indicators (KPIs) need to be meaningful for applicants. The agency has already improved its KPIs and reporting arrangements specifically on scientific advice, and further work will be done to ensure metrics are focused on applicant experience and transparency, including both end-to-end and internal process measures. Ahead of implementation, the MHRA will develop an external reporting plan setting out meaningful service standards, how performance will be measured, and how this information will be reported publicly. This will help applicants understand what they can expect from each route and provide greater assurance that the proposed uplift is linked to meaningful improvements in service delivery.

This consultation sets out the proposed framework for the guarantee and rebate mechanism. The detailed design of the scheme will be developed further following consultation, informed by stakeholder feedback and further operational planning, and published in due course.

Proposal 4

Enhanced support for eligible small and medium-sized enterprises

The MHRA proposes to introduce enhanced financial support for eligible small and medium-sized enterprises (SMEs). SMEs play an important role in developing innovative medicines and healthcare products. However, they may be more affected by increased regulatory costs, delays and uncertainty.

The MHRA is therefore proposing targeted support for smaller UK-based companies developing innovative products to help eligible SMEs access MHRA services at key points in product development, while ensuring the scheme remains targeted, affordable and consistent with the principle of cost-recovery overall. The support is proposed to operate via a waiver/voucher mechanism covering the full cost of the relevant fee. The proposed eligibility criteria are:

- standard UK SME size criteria, assessed at group level;
- a substantive UK economic presence proportional to the overall entity size (that is proportionate for UK SMEs with small but genuine UK operations), including UK registration, active operations, and substantive research and development or manufacturing activity;
- use of the support for services associated with innovative or early-stage product development, namely NAS applications, scientific advice and clinical trials; and
- non-transferable support, with a cap per applicant.

The criteria are designed to ensure the support reaches eligible SMEs and prevents larger companies or company groups from accessing the support via subsidiary companies.

The new SME support scheme is in addition to the current SME offering and it will be subject to an annual cap of £2 million in this scheme. This cap reflects an estimate of likely the demand and will be kept under review. The cap will help ensure that support remains targeted and affordable, while allowing the MHRA to continue operating on a full cost-recovery basis. The MHRA expect the cost of the scheme to be offset through efficiencies generated by improvements to their operating model, including investment in capability, process improvements and digital systems.

This consultation sets out the proposed framework for enhanced support for eligible SMEs. The detailed design of the scheme will be developed further following consultation, informed by stakeholder feedback and further operational planning, and published in due course. The MHRA will ensure the verification process is simple and fast, with proportionate evidence requirements that are easy for applicants to provide and the MHRA to verify.

The MHRA will design and deliver this support in accordance with applicable legal requirements, including any subsidy control requirements. The MHRA intends to introduce a new general wavier power in relation to its medicines fees to deliver this scheme.

Proposal 5

Improvements to the MHRA's scientific advice service

The MHRA proposes to improve its scientific advice service, so companies or sponsors have clearer choices about the advice they need based on complexity, urgency and type of advice.

Scientific advice helps applicants understand regulatory expectations during the development of medicines and healthcare products. It can support better-quality applications and help applicants make informed decisions earlier in development.

This will include:

- clearer guidance on the current tiered scientific advice options;
- an accelerated route (45-working day rather than 90-working day) for high- and medium-complexity advice, with defined eligibility criteria;
- clearer service standards and rebates on the accelerated route (see Proposal 3);
- a new route for non-scientific regulatory queries to provide a more flexible way to ask simpler regulatory questions rather than waiting for a formal advice meeting; and
- exploring a Scientific Advice and Customer Relationship Service to give better access and transparency to customers.

The refreshed service is intended to provide value through the quality, relevance and predictability of MHRA advice, not only through faster timelines. By directing different questions to the right route and making better use of specialist expertise, the MHRA aims to provide advice that is proportionate to the complexity of the issue, clear about regulatory expectations, and useful to applicants' development planning.

This consultation sets out the proposed framework for improving the scientific advice service. The detailed design of the refreshed service will be developed further following consultation, informed by stakeholder feedback and further operational planning. Further guidance will provide detail on eligibility criteria, service routes, timelines, improved reporting, and how applicants should choose the route that best matches the complexity and urgency of the advice they need.

The MHRA is also developing a new Scientific Opinion service, which will provide early MHRA decisions to reduce uncertainty and de-risk product development. This service is expected to be delivered via a separate piece of secondary legislation.

The proposed fees for scientific advice services are set out in Annex B.

Proposal 6

A phased approach to the medical devices post-market surveillance registration fee

The MHRA proposes to update its medical devices annual post-market surveillance (PMS) registration fee from 1 April 2027.

PMS is the work the MHRA carries out to collect and act on safety and performance information about medical devices once they are on the UK market. It includes reviewing adverse incident reports, field safety corrective actions and other vigilance data, and taking action to protect patients and the public.

The PMS fee supports the strengthened medical devices PMS system introduced following the Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024, which came into force on 16 June 2025. A stronger PMS system supports patient safety, market confidence and a more risk-proportionate, pro-innovation approach to medical devices regulation.

The current fee was introduced in April 2026 on a part-subsidised basis, following the MHRA's previous commitment to phase in the PMS registration fee. In the previous government response[2], the MHRA explained that there would be a phased roll out to make it easier for companies to adapt, that the 2026/27 fee would be part subsidised, and that the MHRA proposed to move to full cost recovery in 2027/28.

The MHRA is now proposing not to move to full cost recovery next financial year but to continue with the phased approach for 2027/28 and 2028/29 and maintain some partial government subsidy during this period. This will reduce the impact on the sector, including small and medium-sized enterprises.

The proposed fee from 1 April 2027 is an increase from £300 to £511 per chargeable Global Medical Device Nomenclature (GMDN) level 2 category. The proposed fee includes the 8.93% indexation increase described in Proposal 1 and reflects a continued partial government subsidy of £8.45m for 2027/28 and 2028/29.

The MHRA recognises that the medical devices sector includes a significant number of smaller businesses and that fee increase can have a greater impact on SMEs. The proposed approach will reduce the immediate impact on manufacturers while maintaining the funding needed for strengthened PMS activity.

[2] Fees-Consultation-Devices-Government-Response_september2025.pdf

The previous government response estimated that around 60% of manufacturers would pay a single charge and that SMEs are likely to fall into that category, as they are likely to have a more limited range of products compared with larger companies. The MHRA will keep the impact of the fee under review as more data becomes available on payment levels, product registrations and de-registrations.

The MHRA will keep this fee under review and explore longer-term options for PMS funding based on consultation feedback.

Proposal 7

Adjustments to some existing fees

The MHRA proposes to make adjustments to some existing fees where the current fee modelling shows the current fee level no longer reflects the cost of delivering the service.

This will apply to 73 fees, which represents 24% of MHRA's statutory fees.

These adjustments all include the indexation increase described in Proposal 1 but go beyond that as, upon review, some fees were lower than the cost of delivering the service.

Since the last fee update, the MHRA has made significant progress improving its service performance. The fee increases are intended to help sustain recent improvements and support further service enhancements.

The MHRA is proposing these adjustments so that its fees remain fair, transparent and consistent with the principle of full cost-recovery.

The full list of fees affected by this proposal is set out in Annex B.

Consultation questions

An online survey is available at the following link:
https://www.surveys.mhra.gov.uk/6a6a19cc506b2f7654014f9d

Question 1

Do you agree with Proposal 1: increasing most fees by indexation only?

Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view – please explain why.

Question 2

Do you agree with Proposal 2: targeted increases for higher-value services?

Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

Please explain why, including whether the proposed fee lines are the right services to include in this category.

Question 3

Do you agree with Proposal 3: introducing enhanced service standards, guaranteed timelines and rebates for selected services?

Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

Please explain why, including: (a) whether the proposed offer would provide value to your organisation, (b) how performance should be measured and reported, (c) what information should be included in the detailed guidance we provide, and (d) any issues, risks, or points that would need to be clarified before implementation.

Question 4

Do you agree with Proposal 4: enhanced support for eligible small and medium-sized enterprises?

Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

Please explain why, including (a) whether the proposed eligibility criteria and overall design of the scheme would target support appropriately and (b) what information should be included in the detailed guidance for this proposal, including any points that would need to be clarified before implementation.

Question 5

Do you agree with Proposal 5: improvements to the MHRA's scientific advice service?

Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

Please explain why, including (a). whether the proposed changes would meet your needs or if additional elements could be added to improve them, and (b) what information and clarifications should be included in the subsequent detailed guidance.

Question 6

Do you agree with Proposal 6: a phased approach to the medical devices post-market surveillance registration fee?

Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

Please explain why, including what you see as the most beneficial activities for post-market surveillance and if you have any feedback on how the fee is currently operating? (optional)

Question 7

Do you agree with Proposal 7: adjustments to some existing fees?

Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

Please explain why, including whether you have concerns about any specific fees.

Question 8

We expect that the proposed increases in fees will not have a significant negative impact on market activity, innovation, or production. To what extent do you agree or disagree?

Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

Please share any evidence to support your view.

Question 9

The MHRA's services should be funded at a level that supports effective and efficient regulation and avoids a decline in service performance. To what extent do you agree or disagree?

Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

Please share any evidence to support your view.

Question 10

The MHRA does not consider that these proposals risk impacting different people differently with reference to their protected characteristics as covered by the Public Sector Equality Duty set out in section 149 of the Equality Act 2010 and by section 75 of the Northern Ireland Act 1998. To what extent do you agree or disagree?

Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

Please share any evidence to support your view.

Question 11

The MHRA does not consider that these proposals risk impacting people differently with reference to their protected characteristics or where they live in Northern Ireland. 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. To what extent do you agree or disagree?

Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

Please share any evidence to support your view.

Annex A

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

It is proposed that the legislative changes under consultation be made 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 safeguarding 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, or that department and the Secretary of State acting jointly, 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.

b) The availability of human medicines and medical devices.

c) The likelihood of the relevant part of the UK 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.

Where regulations may have an impact on safety, the appropriate authority may only make them if they consider the benefits of doing so outweigh the risks.

An assessment of the proposals against each of the factors set out in the Act as follows:

Safety

The MHRA's mission is to protect public health and to do this, the MHRA must have the right specialist capacity, systems and support in place to carry out its regulatory work effectively.

The proposals are intended to make sure that the MHRA continues to recover the full cost of delivering its services, including the necessary future costs of maintaining specialist expertise, training staff and supporting reliable service delivery. This will help the MHRA continue to assess applications rigorously and in a timely way.

The MHRA therefore considers that the proposals will not change regulatory standards or the basis on which regulatory decisions are made. Decisions about safety, quality and effectiveness will continue to be made objectively and independently.

Availability

The MHRA has considered whether increases to fees could discourage applicants from using MHRA services, which could in turn affect the availability of medicines and medical devices. The MHRA considers this risk to be low overall but recognises that fee increases can have a greater impact on smaller companies.

The proposals include enhanced support for eligible small and medium-sized enterprises. This is intended to help smaller UK-based companies developing innovative products access MHRA services, while making sure that support is targeted and affordable.

The MHRA also considers that more reliable and predictable services support availability. Clearer timelines, improved scientific advice and services will help applicants plan more effectively, reduce uncertainty and make product development more efficient.

The MHRA therefore considers that the proposals will support, rather than reduce, product availability.

Favourability

The MHRA has considered the likely impact of the proposals on the UK being seen as a favourable place to develop, manufacture and supply medicines and medical devices.

The MHRA recognises that fees are one factor applicants consider. However, research with industry indicates that applicants also place significant value on reliable, predictable and timely regulatory services. For many companies, delays and uncertainty can create wider costs during product development.

The proposed changes are designed to deliver improvements that are expected to support and improve the UK's favourability. This includes clearer service standards, more predictable timelines, improvements to scientific advice, and targeted support for eligible SMEs.

By recovering the cost of these improvements, the MHRA can provide services that better meet the needs of applicants, while continuing to maintain high standards. This should help make the UK a more attractive place to do business. Benchmarking also indicates that the proposed fees will remain broadly competitive internationally.

The MHRA therefore considers that the proposals will support, rather than reduce, UK favourability.

Annex B:

MHRA statutory fees proposals

Proposal 1 - Increase most fees by indexation only

Fee	Current fee (£)	Proposed fee (£)	% change
Blood banks and other blood establishments: fees - Hospital Blood Banks and facilities - Haemovigilance - Annual fee	1,053	0	Obsolete - delete fee
Blood facilities: contract laboratories fees - Inspections - Inspection fee (per additional site if required)	3,552	0	Obsolete - delete fee
Blood banks and other blood establishments: fees - Blood Establishments - Haemovigilance - Annual fee	1,053	1,147	8.93%
Blood banks and other blood establishments: fees - Blood Establishments - New Applications - Inspection fee (per additional site if required)	5,324	5,799	8.93%
Blood banks and other blood establishments: fees - Blood Establishments - New Applications - Standard application plus full inspection fee	8,705	9,482	8.93%
Blood banks and other blood establishments: fees - Blood Establishments - Periodic Fee - Annual fee	555	605	8.93%
Blood banks and other blood establishments: fees - Blood Establishments - Variations - Standard variation	621	676	8.93%
Blood banks and other blood establishments: fees - Hospital Blood Banks and facilities - Compliance - Annual fee	818	891	8.93%

Fee	Current fee (£)	Proposed fee (£)	% change
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.	13,684	14,906	8.93%
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.	19,824	21,594	8.93%
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)	24,806	27,021	8.93%
Drug-device combination products: fees - Further consultation of a Device which incorporates a new active substance	12,574	13,697	8.93%
Drug-device combination products: fees - Further consultation of a Device which incorporates one or more known medicinal substances from a new source	2,668	2,906	8.93%
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	980	1,068	8.93%
Drug-device combination products: fees - Initial consultation for a Device which incorporates a new active substance	50,644	55,167	8.93%
Drug-device combination products: fees - Initial consultation for a Device which incorporates one or more known medicinal substances from a new source	11,543	12,574	8.93%
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	4,953	5,395	8.93%

Fee	Current fee (£)	Proposed fee (£)	% change
Clinical investigations for devices: fees - Consultation - Clinical Investigations statistical review	852	928	8.93%
Clinical investigations for devices: fees - Notification of a clinical investigation - Class I, IIa, or IIb other than implantable or long-term invasive devices (Resubmission)	11,701	12,746	8.93%
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)	32,016	34,875	8.93%
Clinical investigations for devices: fees - Notification of a clinical investigation - Class IIb implantable or long-term invasive, Class III, and active implantable devices (Resubmission)	22,678	24,703	8.93%
Clinical investigations for medical devices: fees - Notification of a clinical investigation - Class I, IIa, or IIb other than implantable or long-term invasive devices (Initial submission)	15,309	16,676	8.93%
Clinical investigations for devices: fees - Amendment fees - High risk device amendment	361	0	Obsolete - delete fee
Clinical investigations for devices: fees - Amendment fees - Low risk device amendment	226	0	Obsolete - delete fee
Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or distributor - Annual compliance report - Annual compliance report where a variation is required	688	752	8.93%
Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or distributor - Annual compliance report - Assessment of the annual compliance report	345	376	8.93%
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	697	759	8.93%
Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or	439	478	8.93%

Fee	Current fee (£)	Proposed fee (£)	% change
distributor - New applications - Change of ownership			
Active substance importers or distributors: fees - Additional fee for the first day of inspection if triggered following risk-assessment of the application	697	759	8.93%
Active substance importers or distributors: fees - Application for registration	2,159	2,352	8.93%
Active substance manufacturers: fees - Additional fee for the first day of an inspection if triggered following risk-assessment of the application	949	1,034	8.93%
Active substance manufacturers: fees - Application for registration	3,763	4,099	8.93%
Broker registration fees - Annual Compliance Report - Annual Compliance where a variation is required	688	752	8.93%
Broker registration fees - Annual Compliance Report - Assessment of the Annual Compliance Report	345	376	8.93%
Broker registration fees - New Applications - Additional fee if the risk assessment of the initial application triggers an inspection	780	850	8.93%
Broker registration fees - New Applications - Change of ownership	439	478	8.93%
Broker registration fees - Variations - Notification of Changes (Variation)	345	376	8.93%
ILAP – Innovation Passport	3,945	4,297	8.93%
ILAP – Target Development Profile	4,845	5,278	8.93%
Homoeopathic National Rules Scheme: fees - Both stock and formulation already assessed - 5 stocks or fewer	630	686	8.93%

Fee	Current fee (£)	Proposed fee (£)	% change
Homoeopathic National Rules Scheme: fees - Both stock and formulation already assessed - more than 5 stocks	892	972	8.93%
Homoeopathic National Rules Scheme: fees - Formulation already assessed - 5 stocks or fewer	984	1,072	8.93%
Homoeopathic National Rules Scheme: fees - Formulation already assessed - more than 5 stocks	1,235	1,345	8.93%
Homoeopathic National Rules Scheme: fees - Reduced - stock already assessed - 5 stocks or fewer	984	1,072	8.93%
Homoeopathic National Rules Scheme: fees - Reduced - stock already assessed - more than 5 stocks	1,235	1,345	8.93%
Homoeopathic National Rules Scheme: fees - Standard - 5 stocks or fewer	1,325	1,443	8.93%
Homoeopathic National Rules Scheme: fees - Standard - more than 5 stocks	1,598	1,741	8.93%
Homoeopathic National Rules Scheme: fees - Supplementary fees - New excipients	8,746	9,527	8.93%
Homoeopathic National Rules Scheme: fees - Supplementary fees - New method of sterilisation (non-pharmacopoeial)	2,622	2,856	8.93%
Homoeopathic National Rules Scheme: fees - Supplementary fees - New sources TSE risk actives/excipients (non-CEP)	773	842	8.93%
Licence applications: marketing authorisation fees - Abridged complex - Complex: (Previously granted by EU) - unfettered access route to GB	13,983	15,232	8.93%
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)	23,205	25,277	8.93%

Fee	Current fee (£)	Proposed fee (£)	% change
Licence applications: marketing authorisation fees - Abridged complex - European reference product application for sale or supply in Northern Ireland	23,205	25,277	8.93%
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)	23,205	25,277	8.93%
Licence applications: marketing authorisation fees - Abridged simple - Decentralised procedure for sale or supply in Northern Ireland and Unfettered access route for UKMA(GB)	3,433	3,740	8.93%
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)	3,433	3,740	8.93%
Licence applications: marketing authorisation fees - Abridged simple - Simple: (Previously granted by EU) - unfettered access route to GB	3,433	3,740	8.93%
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)	8,503	9,262	8.93%
Licence applications: marketing authorisation fees - Abridged standard - European reference product application for sale or supply in Northern Ireland	8,503	9,262	8.93%
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)	8,503	9,262	8.93%
Licence applications: marketing authorisation fees - Major - Decentralised procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	83,580	91,044	8.93%
Licence applications: marketing authorisation fees - Major - European reference product	83,580	91,044	8.93%

Fee	Current fee (£)	Proposed fee (£)	% change
application for sale or supply in Northern Ireland			
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)	83,580	91,044	8.93%
Licence applications: marketing authorisation fees - Major - Major Orphan (reduced in exceptional circumstances)	39,811	43,366	8.93%
Licence applications: marketing authorisation fees - Major - Major: (Previously granted by EU) - unfettered access route to GB	24,688	26,893	8.93%
Licence applications: manufacturers licence (including THMPD and homeopathic medicinal products) fees - Change of ownership	461	502	8.93%
Licence applications: manufacturers licence (including THMPD and homeopathic medicinal products) fees - Non-orthodox practitioner (NOP)	245	267	8.93%
Licence applications: manufacturers licence (including THMPD and homeopathic medicinal products) fees - Standard	4,209	4,585	8.93%
Licence applications: parallel imports fees - Complex application	24,343	26,517	8.93%
Licence applications: parallel imports fees - Standard application	10,617	11,565	8.93%
Licence applications: Phase 1 Accreditation Scheme fees - Phase I Accreditation Scheme - Accreditation of Phase 1 units	141	154	8.93%
Periodic fees for holding a marketing authorisation - Derivatives with a different route of administration or complex abridged*	11,627	12,665	8.93%
Periodic fees for holding a marketing authorisation - Herbal	92	100	8.93%

Fee	Current fee (£)	Proposed fee (£)	% change
Periodic fees for holding a marketing authorisation - Homeopathic and Anthroposophic PLRs (per PLR)	92	100	8.93%
Periodic fees for holding a marketing authorisation - Manufacturer’s licence	561	611	8.93%
Periodic fees for holding a marketing authorisation - National Rules Homeopathic Authorisation	92	100	8.93%
Periodic fees for holding a marketing authorisation - New active substance	11,627	12,665	8.93%
Periodic fees for holding a marketing authorisation - Other derivatives	7,847	8,548	8.93%
Periodic fees for holding a marketing authorisation - Prescription Only Medicine (POM) - ‘Maintenance’ fee	368	401	8.93%
Periodic fees for holding a marketing authorisation - Prescription Only Medicine (POM) - All others (P, GSL, PLPI and None)	368	401	8.93%
Periodic fees for holding a marketing authorisation - Prescription Only Medicine (POM) - Reduced rate fee	1,450	1,579	8.93%
Periodic fees for holding a marketing authorisation - Prescription Only Medicine (POM) - Standard fee	2,908	3,168	8.93%
Periodic fees for holding a marketing authorisation - THMPD registration	92	100	8.93%
Periodic fees for holding a marketing authorisation - Wholesale dealer’s licence	346	377	8.93%
Periodic fees for holding a marketing authorisation - Wholesale dealer’s licence (reduced rate or GSL)	206	224	8.93%
Licence renewals, reclassifications and assessment of labels and leaflets: fees - Assessment of labels and leaflets - Labelling Exemptions	0	558	New

Fee	Current fee (£)	Proposed fee (£)	% change
Licence renewals, reclassifications and assessment of labels, leaflets and advertising – Pre-publication assessment of medicinal product advertising – Simple**	0	965	New
Licence renewals, reclassifications and assessment of labels, leaflets and advertising – Pre-publication assessment of medicinal product advertising – Complex**	0	1,163	New
Licence renewals, reclassifications and assessment of labels and leaflets: fees - Assessment of labels and leaflets - National (BROMI) notification/self-certification	224	244	8.93%
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	16,042	17,475	8.93%
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	1,239	1,350	8.93%
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)	1,239	1,350	8.93%
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	1,239	1,350	8.93%
Licence renewals, reclassifications and assessment of labels and leaflets: fees - Licence Renewal Applications - Manufacturers' licences Non-orthodox practitioner (NOP)	214	233	8.93%
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	10,929	11,905	8.93%
Licence renewals, reclassifications and assessment of labels and leaflets: fees - Reclassification -	40,173	43,760	8.93%

Fee	Current fee (£)	Proposed fee (£)	% change
POM to P - Additional for MA or PI application with reclassification element from POM to P			
Licence renewals, reclassifications and assessment of labels and leaflets: fees - Reclassification - Reclassification Type IB variation application (MA) (analogous product)	419	456	8.93%
Licence renewals, reclassifications and assessment of labels and leaflets: fees - Reclassification - Reclassification variation application (MA) (analogous product)	1,593	1,735	8.93%
Licence renewals, reclassifications and assessment of labels and leaflets: fees - Reclassification - Reclassification variation application P to GSL	10,929	11,905	8.93%
Licence renewals, reclassifications and assessment of labels and leaflets: fees - Reclassification - Reclassification variation application POM to P	40,173	43,760	8.93%
Orphan Marketing Products: fees - Orphan Complex (Full Fee)	34,335	37,401	8.93%
Orphan Marketing Products: fees - Orphan Major (exceptional circumstances in which point G of Part IV of Annex 1 in the 2001 Directive applies)	39,811	43,366	8.93%
Orphan Marketing Products: fees - Orphan Major (Full fee)	124,194	135,285	8.93%
Orphan Marketing Products: fees - Orphan Standard (Full Fee)	12,589	13,713	8.93%
Pharmacovigilance (PV) Safety Review: fees - Assessment of PASS Results	9,949	10,837	8.93%
Pharmacovigilance (PV) Safety Review: fees - PV Major Safety Review (1-2 active ingredients)	61,408	66,892	8.93%
Pharmacovigilance (PV) Safety Review: fees - PV Major Safety Review (3 active ingredients)	71,357	77,729	8.93%
Pharmacovigilance (PV) Safety Review: fees - PV Major Safety Review (4 active ingredients)	81,305	88,566	8.93%
Pharmacovigilance (PV) Safety Review: fees - PV Major Safety Review (5 or more active ingredients)	91,254	99,403	8.93%

Fee	Current fee (£)	Proposed fee (£)	% change
Pharmacovigilance (PV) Safety Review: fees - PV Post Authorisation Safety Study (PASS) protocol	9,949	10,837	8.93%
Plasma Master File (PMF) & Vaccine Antigen Master File certification or certified annual update work: fees - Certification of new PMF (for scientific & technical evaluation)	11,126	12,120	8.93%
Plasma Master File (PMF) & Vaccine Antigen Master File certification or certified annual update work: fees - Certified Annual Update of a PMF (epidemiology update only)	419	456	8.93%
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)	1,593	1,735	8.93%
Plasma Master File (PMF) & Vaccine Antigen Master File certification or certified annual update work: fees - Vaccine Antigen Master File (VAMF) certification	11,126	12,120	8.93%
Pre-Assessment (Rolling Review): fees - Application by pre-assessment (Biosimilar) - Module 3 (chemical, pharmaceutical and biological information)	5,802	6,320	8.93%
Pre-Assessment (Rolling Review): fees - Application by pre-assessment (Biosimilar) - Module 4 (non-clinical reports)	5,802	6,320	8.93%
Pre-Assessment (Rolling Review): fees - Application by pre-assessment (Biosimilar) - Module 5 (clinical study reports)	5,802	6,320	8.93%
Pre-Assessment (Rolling Review): fees - Application by pre-assessment (NAS) - Module 3 (chemical, pharmaceutical and biological information)	31,049	33,822	8.93%
Pre-Assessment (Rolling Review): fees - Application by pre-assessment (NAS) - Module 4 (non-clinical reports)	31,049	33,822	8.93%
Pre-Assessment (Rolling Review): fees - Application by pre-assessment (NAS) - Module 5	31,049	33,822	8.93%

Fee	Current fee (£)	Proposed fee (£)	% change
(clinical study reports)			
Scientific advice meetings: fees - Reclassification advice meetings - Pharmacy to General Sales List switch	8,758	9,540	8.93%
Scientific advice meetings: fees - Reclassification advice meetings - Prescription Only Medicine to Pharmacy switch	8,758	9,540	8.93%
Simplified Homeopathic Registration Scheme: fees - Both stock and formulation already assessed - 5 stocks or fewer	194	211	8.93%
Simplified Homeopathic Registration Scheme: fees - Both stock and formulation already assessed - more than 5 stocks	479	522	8.93%
Simplified Homeopathic Registration Scheme: fees - Formulation already assessed - 5 stocks or fewer	582	634	8.93%
Simplified Homeopathic Registration Scheme: fees - Formulation already assessed - more than 5 stocks	857	934	8.93%
Simplified Homeopathic Registration Scheme: fees - Reduced - 5 stocks or fewer	582	634	8.93%
Simplified Homeopathic Registration Scheme: fees - Reduced - more than 5 stocks	857	934	8.93%
Simplified Homeopathic Registration Scheme: fees - Standard - 5 stocks or fewer	962	1,048	8.93%
Simplified Homeopathic Registration Scheme: fees - Standard - more than 5 stocks	1,259	1,371	8.93%
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	524	571	8.93%

Fee	Current fee (£)	Proposed fee (£)	% change
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	686	747	8.93%
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	610	664	8.93%
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	777	846	8.93%
Traditional Herbal Registration Scheme: fees - Complex - 2 or more new herbal active ingredients	8,849	9,639	8.93%
Traditional Herbal Registration Scheme: fees - Complex - single new herbal active ingredient	5,899	6,426	8.93%
Traditional Herbal Registration Scheme: fees - Reduced - Category I - 3 or fewer existing herbal active ingredients	657	716	8.93%
Traditional Herbal Registration Scheme: fees - Reduced - Category I - more than 3 existing herbal active ingredients	983	1,071	8.93%
Traditional Herbal Registration Scheme: fees - Reduced - Category II - 3 or fewer existing herbal active ingredients	983	1,071	8.93%
Traditional Herbal Registration Scheme: fees - Reduced - Category II - more than 3 existing herbal active ingredients	1,476	1,608	8.93%
Traditional Herbal Registration Scheme: fees - Standard - 3 or fewer existing herbal active ingredients	2,950	3,213	8.93%

Fee	Current fee (£)	Proposed fee (£)	% change
Traditional Herbal Registration Scheme: fees - Standard - more than 3 existing herbal active ingredients	4,424	4,819	8.93%
Traditional Herbal Registration Scheme: fees - Traditional Herbal Registration Scheme: supplementary fees - Ancillary vitamins / minerals - Existing Sources plus CEP	1,311	1,428	8.93%
Traditional Herbal Registration Scheme: fees - Traditional Herbal Registration Scheme: supplementary fees - Ancillary vitamins / minerals - New excipients	8,748	9,529	8.93%
Traditional Herbal Registration Scheme: fees - Traditional Herbal Registration Scheme: supplementary fees - Ancillary vitamins / minerals - New sources (non-CEP)	2,622	2,856	8.93%
Traditional Herbal Registration Scheme: fees - Traditional Herbal Registration Scheme: supplementary fees - Ancillary vitamins / minerals - New sources TSE risk excipients (non-CEP)	777	846	8.93%
Traditional Herbal Registration Scheme: fees - Traditional Herbal Registration Scheme: supplementary fees - Ancillary vitamins / minerals - Sterile products	2,622	2,856	8.93%
Variation: Homeopathic National Rules Scheme fees - Indication	456	497	8.93%
Variation: Homeopathic National Rules Scheme fees - Other applications (for any subsequent variations where no further medical, technical or scientific assessment is required)	75	82	8.93%
Variation: Homeopathic National Rules Scheme fees - Other applications (for up to 30 variations where no further medical, technical or scientific assessment is required)	149	162	8.93%
Variation: Homeopathic National Rules Scheme fees - Standard variation application	296	322	8.93%
Variations: Homeopathic Simplified Scheme fees - New technical	296	322	8.93%
Variations: Homeopathic Simplified Scheme fees - Other applications (for any subsequent variations where no further medical, technical or scientific assessment is required)	75	82	8.93%

Fee	Current fee (£)	Proposed fee (£)	% change
Variations: Homeopathic Simplified Scheme fees - Other applications (for up to 30 variations where no further medical, technical or scientific assessment is required)	149	162	8.93%
Variations: Homeopathic Simplified Scheme fees - Other applications (where further medical, technical or scientific assessment is required)	296	322	8.93%
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	10,301	11,221	8.93%
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	419	456	8.93%
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	3,338	3,636	8.93%
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	3,619	3,942	8.93%
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	10,555	11,498	8.93%
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	419	456	8.93%
Variations: licence variations applications groups fees - Applications for variations of marketing authorisations falling within the scope of Chapter IIa of Commission Regulation (EC) No	12,065	13,142	8.93%

Fee	Current fee (£)	Proposed fee (£)	% change
1234/2008 and of marketing authorisations in force in Great Britain. - National Type II Major Variation Complex Group			
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	35,184	38,326	8.93%
Variations: other licence variations applications fees - Clinical trial authorisations - Amendments to 1 part of dossier	302	329	8.93%
Variations: other licence variations applications fees - Clinical trial authorisations - Amendments to 2 parts of dossier	302	329	8.93%
Variations: other licence variations applications fees - Clinical trial authorisations - Amendments to 3 parts of dossier	302	329	8.93%
Variations: other licence variations applications fees - Clinical trial authorisations - Protocol	302	329	8.93%
Variations: other licence variations applications fees - Manufacturer’s licences (including traditional herbal medicines) - Administrative	345	376	8.93%
Variations: other licence variations applications fees - Wholesale dealers’ licences (includes THMPD) - Administrative	345	376	8.93%
Variations: Traditional Herbal Registration Scheme fees - Administrative	186	203	8.93%
Variations: Traditional Herbal Registration Scheme fees - Complex	773	842	8.93%
Variations: Traditional Herbal Registration Scheme fees - New excipient	8,748	9,529	8.93%
Variations: Traditional Herbal Registration Scheme fees - Standard	293	319	8.93%

Fee	Current fee (£)	Proposed fee (£)	% change
Licence applications: Phase 1 Accreditation Scheme fees - Phase I Accreditation Scheme - Certificate of accreditation	75	82	8.93%
Wholesale distribution authorisations: fees - New Applications - Change of ownership	478	521	8.93%
Wholesale distribution authorisations: fees - Variations - Administrative variation	345	376	8.93%
Wholesale distribution authorisations: fees - Variations - Standard variation	652	710	8.93%
Early Access to Medicines Scheme (EAMS) - Promising Innovative Medicine (PIM) designation	4,852	5,285	8.93%
Early Access to Medicines Scheme (EAMS) - Renewal fee for new indications	5,057	5,509	8.93%
Early Access to Medicines Scheme (EAMS) - Renewal fee for new medicinal products	15,607	17,001	8.93%
Early Access to Medicines Scheme (EAMS) - Scientific opinion for new indications	10,115	11,018	8.93%
Early Access to Medicines Scheme (EAMS) - Scientific opinion for new medicinal products	31,214	34,001	8.93%
Distance selling logo application - Annual renewal fee	97	106	8.93%
Distance selling logo application - Registration fee	100	109	8.93%

* We propose to add a minor amend to make more clear that for the MHRA's periodic fees the term "total value of the product sold" refers to gross value and not net value.

**Under regulations 304-307 of the Human Medicines Regulations 2012, the MHRA reviews advertising submitted for pre-publication vetting to check compliance with the legislation. This work has previously been undertaken without charge. We propose to introduce a fee to recover the cost of this activity. Advertising complaint investigations remain outside the new fees.

Proposal 2 - Targeted increases for higher-value services

Fee	Current fee (£)	Proposed fee (£)	% change
Clinical trials: application fees - Applications with an IMP dossier - Higher fee (Phase 1, Full and Simplified IMPD)	4,656	5,900	27%
Clinical trials: application fees - Applications without an IMP dossier - Lower fee (Phase IV, Cross referral, Additional protocol)	343	435	27%
Clinical trials: application fees - Assessment of annual safety reports	343	435	27%
Clinical trials: application fees - CT variations/amendments	343	435	27%
Change of Ownership for Product Licences - Change of ownership (including THMPD registrations)	592	750	27%
Licence applications: marketing authorisation fees - Abridged complex - National fee (any other case including hybrid applications)	34,335	43,506	27%
Licence applications: marketing authorisation fees - Abridged simple - National fee (all other cases)	3,433	4,350	27%
Licence applications: marketing authorisation fees - Abridged standard - Standard International Recognition Type A application for GB or UK*	7,743	9,811	27%
Licence applications: marketing authorisation fees - Abridged standard - Standard: (Previously granted by EU) - unfettered access route to GB	7,743	9,811	27%
Licence applications: marketing authorisation fees - Major - Major International Recognition Type A application for GB or UK*	24,688	31,282	27%

Fee	Current fee (£)	Proposed fee (£)	% change
Licence applications: marketing authorisation fees - Major - Major International Recognition Type B application for GB or UK*	83,580	105,904	27%
Licence applications: marketing authorisation fees - Major - National fee (any other case including hybrid applications)	124,194	157,366	27%
Medicines export certificates: fees - Standard request: ten working days - Electronic copy	82	104	27%
Medicines export certificates: fees - Urgent request: two working days - Electronic copy	182	231	27%
Licence renewals, reclassifications and assessment of labels and leaflets: fees - Assessment of labels and leaflets - Parallel imports	440	558	27%
Licence renewals, reclassifications and assessment of labels and leaflets: fees - Assessment of labels and leaflets - Single or first application	992	1,257	27%
Pharmacovigilance (PV) Safety Review: fees - PV Periodic Safety Update Report (PSUR) single assessment: Full Fee	1,066	1,351	27%
Pharmacovigilance (PV) Safety Review: fees - PV Periodic Safety Update Report (PSUR) single assessment: Half Fee	534	677	27%
Scientific advice meetings: fees - Pharmacovigilance advice meetings - Advice on labels and leaflets	3,757	4,760	27%
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	1,593	2,018	27%

Fee	Current fee (£)	Proposed fee (£)	% change
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	1,528	1,936	27%
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	833	1,055	27%
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	2,212	2,803	27%
Variations: other licence variations applications fees - Parallel import (PI) - Standard	479	607	27%
Variations: other licence variations applications fees - Wholesale dealers' licences (includes THMPD) - Standard	652	826	27%

* These fees were previously not charged under a specific provision but the general "any other case" provision. It is proposed to include them specifically in the regulations.

Proposal 3 - Enhanced service standards, guaranteed timelines and rebates for selected services

Fee	Current fee (£)	Proposed fee (£)	% change
New Active Substances (NAS) - Priority Pathway fee per slot (in addition to standard NAS fee)	0	100,000	New

Proposal 5 - Improvements to the MHRA's scientific advice service

	Current fee (£)	Proposed (£)	Fast track (45 days) fee (£)
High complexity advice (90 days)	17,516	22,555	45,111
Medium complexity advice (90 days)	13,137	16,917	33,833
Low complexity advice (90 days)	8,758	11,278	N/A
Simple complexity advice (90 days)	986	1,270	N/A
Customer Relationship Service: Non-scientific regulatory queries, per block purchase model	N/A	1,000 or alternatives to ensure recovery	N/A

Proposal 6 - A phased approach to the medical devices post-market surveillance registration fee

Fee	Current fee (£)	Proposed fee (£)	% change
Statutory Fee – Post Market Surveillance	300	511	70%

Proposal 7 - Adjustments to some existing fees

Fee	Current fee (£)	Proposed fee (£)	% change
Abridged complex - Complex International Recognition Type B application for GB or UK*	23,205	44,486	92%
Blood banks and other blood establishments: fees - Blood Establishments - Inspections - Standard Inspection Fee: daily rate	5,324	6,142	15%
Blood facilities: contract laboratories fees - Inspections - Inspection fee (per additional site if required)	5,324	6,142	15%
Clinical investigations for devices: fees - Consultation - Device Regulatory Advice meeting	987	2,245	127%
Control Testing - Daily rate	5,093	5,736	13%
Devices Regulatory Advice meeting – fee for meeting	987	2,245	127%
Homeopathic National Rules Scheme: fees for inspections - All GMP, GCP and pharmacovigilance inspections	5,251	6,110	16%
Homeopathic National Rules Scheme: fees for inspections - Full day rate - GDP	4,136	4,813	16%

Fee	Current fee (£)	Proposed fee (£)	% change
Homeopathic National Rules Scheme: fees for inspections - Office based risk assessments - GDP	3,810	4,457	17%
Homeopathic National Rules Scheme: fees for inspections - Office-based risk assessments - GMP/GCP/Pharmacovigilance	4,924	5,754	17%
Homeopathic National Rules Scheme: fees for inspections - Reduced rate	2,068	2,406	16%
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	5,251	6,110	16%
Inspection: fees - GDP (wholesale dealers including homeopathic wholesalers) - Full day rate	4,136	4,813	16%
Inspection: fees - GDP (wholesale dealers including homeopathic wholesalers) - Reduced rate (see notes below)	2,068	2,406	16%
Inspection: fees - Office based evaluation and risk assessments	4,924	5,754	17%
Licence applications: marketing authorisation fees - Abridged complex - Complex International Recognition Type A application for GB or UK*	13,983	27,966	100%
Licence applications: marketing authorisation fees - Abridged standard - National fee (all other cases)	12,589	24,134	92%
Licence applications: marketing authorisation fees - Abridged standard - Standard International Recognition Type B application for GB or UK*	8,503	16,301	92%
Licence applications: parallel imports fees - Simple application	2,400	5,081	112%
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications	86	95	11%

Fee	Current fee (£)	Proposed fee (£)	% change
- 1 – 20			
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 1,001-2,000	8,521	9,452	11%
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 10,001-15,000	51,125	56,713	11%
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 101 to 500	2,131	2,364	11%
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 15,001-20,000	68,166	75,617	11%
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 2,001-5,000	17,042	18,905	11%
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 20,001-25,000	85,208	94,521	11%
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 21 – 100	427	474	11%
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 25,001-30,000	102,249	113,425	11%
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 30,001-35,000	119,291	132,330	11%
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 35,001-40,000	136,333	151,234	11%

Fee	Current fee (£)	Proposed fee (£)	% change
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 40,001-45,000	153,375	170,139	11%
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 45,001-50,000	170,417	189,044	11%
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 5,001-10,000	34,083	37,808	11%
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Notifications - 501 to 1000	4,261	4,727	11%
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	18,905	11%
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - 1 – 5	122	135	11%
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - 101 – 200	4,869	5,401	11%
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - 11– 20	487	540	11%
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - 21 – 50	1,218	1,351	11%
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - 51 – 100	2,435	2,701	11%

Fee	Current fee (£)	Proposed fee (£)	% change
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - 6 – 10	487	540	11%
Safety and quality vetting of unlicenced imported medicines fees - Number of annual Product Codes - Per additional 100 codes above 200	2,435	2,701	11%
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	419	1,676	300%
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	419	1,048	150%
Variations: licence variations application fees - Applications for variations of marketing authorisations falling within the scope of Chapter IIa of Commission Regulation (EC) No 1234/2008 and of marketing authorisations in force in Great Britain. - National Type II Complex Variation	11,126	21,330	92%
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	40,173	77,016	92%
Variations: other licence variations applications fees - Manufacturer’s licences (including traditional herbal medicines) - Standard	688	1,000	45%
Wholesale distribution authorisations: fees - Inspections - Office Based Risk Assessments	3,810	4,457	17%
Wholesale distribution authorisations: fees - Inspections - Reduced rate Inspection fee	2,068	2,406	16%

Fee	Current fee (£)	Proposed fee (£)	% change
Wholesale distribution authorisations: fees - Inspections - Standard Inspection Fee (per site)	4,136	4,813	16%
Wholesale distribution authorisations: fees - New Applications - Reduced application plus reduced Inspection fee - General Sales List (GSL) only	3,060	4,136	35%
Wholesale distribution authorisations: fees - New Applications - Reduced application plus full inspection fee	5,128	7,286	42%
Wholesale distribution authorisations: fees - New Applications - Standard application plus full inspection fee	6,295	7,165	14%
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	5,969	6,809	14%
Active pharmaceutical ingredients manufacturers and importers registration: fees - Manufacturer - New applications - New application for registration as a manufacturer of active substances	8,687	9,853	13%
Broker registration fees - New Applications - New application for registration as a broker	5,793	6,617	14%
Wholesale distribution authorisations: fees - Inspections - Inspection fee reduced rate** THMP/Homeopathic only	1,114	2,406	116%
Wholesale distribution authorisations: fees - Inspections - Inspection fee THMP/Homeopathic only**	2,047	4,813	135%
Wholesale distribution authorisations: fees - New Applications - Inspection Fee (per additional site if required)	4,136	4,813	16%
Blood banks: application fees for a Review Panel hearing - Fee	11,974	36,130	202%

Fee	Current fee (£)	Proposed fee (£)	% change
Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or distributor - New applications - Inspection fee (per site if required)	2,898	4,813	66%
Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or distributor - Variations - Inspection fee (per site if required)	2,898	4,813	49%
Active pharmaceutical ingredients manufacturers and importers registration: fees - Importer or distributor - Variations - Notification of changes (variation)	309	376	22%
Active substance importers or distributors: fees - Assessment of the Annual Compliance Report: Active Substance Importer / Distributor	309	376	22%
Active substance importers or distributors: fees - Notification of changes	309	376	22%
Active substance importers or distributors: fees - Persons appointed appeals procedure fee	11,974	36,130	202%
Active substance importers or distributors: fees - Standard daily rate for Inspection	2,898	4,813	49%
Active substance manufacturers: fees - Assessment of the Annual Compliance Report	309	376	22%
Active substance manufacturers: fees - Inspection days	3,975	6,110	54%
Active substance manufacturers: fees - Notification of Changes	309	376	22%
Broker registration fees - New Applications - Inspection Fee (per site if required)	3,241	4,813	49%
Active substance importers or distributors: fees - Assessment of initial application: active substance importer / distributor	3,810	4,457	17%
Active substance manufacturers: fees - Assessment of Initial Application	4,924	5,754	17%

* These fees were previously not charged under a specific provision but the general “any other case” provision. It is proposed to include them specifically in the regulations.

** We propose to align the wholesale dealer’s licence inspection fee for traditional herbal medicinal products in Schedule 3, paragraphs 6(2)(a) and (b), with the 3 hours and 30 minutes threshold in paragraph 7(1) for GSL wholesale dealers falling within paragraph 7(1)(a), as the nature and level of inspection work undertaken are equivalent.

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.