Medicines & Healthcare products Regulatory Agency

Government response

MHRA consultation on statutory fees: proposals on ongoing cost recovery

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Contents

Ministerial foreword

This government was elected with a clear mandate: to fix our broken NHS, drive economic growth and usher in a decade of national renewal. Central to all three will be harnessing the UK's world-class life sciences and medical technology sectors to deliver transformational improvements in patient care. Unlocking this enormous potential will need a regulatory environment fit for the future – one that protects patient safety, fosters innovation, and accelerates access to cutting-edge MedTech.

A leading regulatory environment will support the three big shifts we must realise in our NHS: bringing our analogue NHS into the digital age; moving care from hospital to care in our communities; and focusing on prevention over treatment.

These reforms will also contribute to this government's patient safety and central growth agenda. Innovators must not be held back by a complex and unpredictable regulatory system. Medtech is a hidden gem of the UK economy, and there is a powerful strategic opportunity to unlock this sector, in which the MHRA has a central role to play.

Having an effective and properly funded medical device post-market surveillance system is an important part of that. It is essential for patient safety and also advantageous to our Medtech industry.

I would like to say a heartfelt thank you to all who have taken time to engage thoughtfully with this consultation and the MHRA's wider regulatory reform programme.

Your responses are a rallying call for the government to deliver change, and the insights you share are helping to shape a system that enhances patient safety, supports innovation, and delivers an NHS fit for the future.

Baroness Merron

Parliamentary Under-Secretary of State
for Patient Safety, Women's Health and Mental Health

Executive summary

Our fees are updated on a periodic basis to align with cost recovery principles in line with HM Treasury guidance in "Managing Public Money". This supports ongoing financial sustainability and the delivery of MHRA services.

We held a public consultation on the uplift of our fees for 2025-2027 from 29 August 2024 to 24 October 2024. This was held jointly with the Department of Health in Northern Ireland, in accordance with Section 45(1) of the Medicines and Medical Devices Act 2021.

On 6 March 2025, we published an initial government consultation response. This said that all proposals, apart from Proposal 2 (the proposal to amend our Medical Device Registration fee to cover the costs for medical device post-market surveillance (PMS) work) were to be implemented as planned.

We have strengthened our safety and surveillance system for medical devices following the post-market surveillance legislation (SI 2024 No.1368) that came into force on 16 June 2025. In addition to the clear benefits to patient safety, the new legislation and resulting increased PMS requirements are a critical enabler of our more risk-proportionate, pro-innovation approach to regulation that is heralded in the NHS 10-year plan as we can be more confident of picking up safety issues in real world data. It is therefore vital that we have adequate funding to resource this work.

We have now considered the feedback for Proposal 2 and this further consultation response summarises our revised proposal for that fee (see page 8). The new fee is due to come into force on 1 April 2026 and will apply to all medical device manufacturers with registered products.

We believe our updated proposal addresses the key concerns raised in the consultation: timeframes for introduction have been extended and the fee has been remodelled to more equitably spread the cost across the sector.

Further guidance and support on this change will be published in good time so that the sector is aware and ready for the change. This will be found on our fees pages.

We would like to thank everyone who responded to the consultation.

Introduction

We regulate medicines, medical devices and blood components for transfusion in the UK. We use science and data to inform our decisions, enable innovation and ensure that the healthcare products available in the UK are safe and effective.

We put patients first in everything we do, right across the lifecycle of the products we regulate, and we ensure that medicines and healthcare products available in the UK are effective and acceptably safe.

Medical devices are products or equipment that are used for medical purposes, such as diagnosis, prevention, monitoring or treatment of diseases or injuries. They include a wide range of products, such as pacemakers, blood glucose meters, pregnancy tests, medical decision support software, syringes, and wheelchairs.

We want to develop a future regime for medical devices that enables:

- strengthened patient and public safety;
- innovation;
- close alignment with international best practice;
- earliest possible access to medical devices; and
- risk proportionate regulation of medical devices.

We receive most of our income from charging fees for providing certain services. Generally, wherever we provide a service for regulatory work, a 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'*.

This full cost-recovery approach ensures financial sustainability, the ongoing delivery of services, and our public health role. It also means those who benefit from market access also bear the cost of the regulatory service that they receive, and government bodies do not profit from statutory fees or make a loss that must be subsidised by government and, ultimately, taxpayers, including patients themselves.

Fees are set by considering numerous factors that reflect the cost of the regulatory activity, for example the activities involved in delivering a service, the time taken, and the number and grade of staff involved.

To ensure ongoing cost-recovery, we update our fees on an ongoing basis. Going forward, we intend to update our 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.

Our fees are statutory and legislative change is needed to add new fees or change existing fees. We intend to take forward secondary legislation using the powers in the Medicines and Medical Devices Act 2021 to deliver the uplift[1].

The consultation was conducted pursuant to the consultation requirement in Section 45(1) of the Act, more detail can be found in the final section of this document.

A new fee on medical device PMS activities

Post-market surveillance (PMS) refers to the regulatory oversight of surveillance activities to monitor the safety of devices on the Great Britain (GB) market.

Currently, all PMS activities for medical devices (i.e. everything we do *after* a device is first placed on the GB market) is mostly paid for by a grant from the Department of Health and Social Care (DHSC).

That arrangement is out of step with HM Treasury's guidance "*Managing Public Money*" principle that regulators should recover the full economic cost of the services they provide, and with the rest of our fee structure.

We have also strengthened our safety and surveillance system for medical devices following the post-market surveillance legislation (SI 2024 No.1368) that came into force on 16 June 2025. It is therefore vital that we have adequate funding to resource this work.

We therefore proposed to replace the DHSC funding with a direct, predictable charge to manufacturers, bringing device regulation in this area into line with the model applied to medicines and other MHRA medical device services, such as clinical investigations and approved body audits.

The importance of adequate funding

Our PMS activities for medical devices need dedicated funding as they are:

- **Essential for patient safety.** Continuous real-world monitoring, incident trending, periodic safety-update report assessment and audits enable emerging patient safety risks to be detected early and managed proportionately. The *Independent Medicines and Medical Devices Safety Review* (2020) singled out under-resourced PMS as a root cause of past device failures.

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

- **An enabler to expanded statutory duties.** Amendments that came into force on 16 June 2025 added mandatory reporting, tighter deadlines for Field Safety Corrective Actions and new obligations for proactive surveillance to be reported to us. These will increase workloads and demand.

- **A foundation for our innovation policy.** Robust PMS enables us to consider patient access to innovative devices and underpins the policy intent for international reliance, both of which contribute to the UK Industrial Strategy and growth agenda. Funding for PMS activities therefore provides increased confidence in streamlined pre-market flexibilities.

How the fee was proposed to work

We proposed to replace the current one-off registration fee with an annual fee so that funding continues while a device remains on the market and we continue to carry out PMS activities.

We aimed for an equitable apportionment of the cost via the Global Medical Device Nomenclature (GMDN) system. Every medical device is registered with a GMDN code, which is a standardised international system for naming, categorising, and identifying devices. It codes devices and groups them into 5 category levels of increasing granularity.

The GMDN system can be used to apportion PMS costs equitably, as companies with more devices, and GMDN codes, are more likely to be larger and will require more PMS work within the Agency and should therefore pay a larger fees to cover the costs of this work.

The benefits of the proposed model were that it:

- provides stable revenue for PMS activities, ensuring we can retain specialist staff, run modern analytics platforms and meet statutory provisions.

- handles manufacturers consistently with other regulated sectors, satisfying HM Treasury cost-recovery guidance and reducing reliance on grant funding.

- maintains a level playing field where all manufacturers pay proportionally for the post-market oversight their products require.

- strengthens the credibility of regulatory provisions by demonstrating that accelerated and innovative routes are underpinned by world-class post-market vigilance.

The annual fee proposed in the consultation was £210 per GMDN category registered, per year, and based on the most granular level of GMDN coding (level 5).

Consultation feedback

The consultation invited views on whether respondents agreed with the proposal or not. Most respondents did not agree: 141 respondents (72%) did not support it, 20 respondents (10%) did, 34 respondents (18%) said they didn't know or had no opinion. The original government consultation response includes more detail on the breakdown of respondents.

Respondents thought the new cost was too high and would be a financial burden on businesses and the impact would be especially felt by small and medium sized enterprises (SMEs), who make up most of the sector in the UK. This could create a barrier to market or resulted in product withdrawals, resulting in fewer medical devices available to UK patients and the public.

Some respondents said that certain types of manufacturers (e.g. manufacturers of IVD devices, surgical instruments, dental apparatus and orthopaedic medical devices) would be disproportionally impacted as they have more codes at that the most granular level of GMDN coding (level 5) than others.

Government response to feedback

Given the proposal was not supported, several changes have been made.

We have remodelled the fee, and propose to charge the fee at a higher GMDN category (GMDN level 2) rather than GMDN code (level 5). This less granular category level results in a more equitable spread of the cost between manufacturers of different product types.

We propose manufacturers will be charged annually based on how many level 2 categories they are registered under. If they have multiple products under the one level 2 category, they will only be charged once per year for that level 2 category. Some products fall under more than one level two category, and these will also only be charged once per a year. This new fee will also replace the current one-off registration fee.

There will be a phased implementation of the new fee to make it easier for companies to incorporate it into their budgets. For the financial year 2025-26, the PMS work will continue to be subsidised, and we will continue using the current registration fee for new products. The new fee is planned to come into effect on 1 April 2026 and will apply for the financial year 2026-27. It will replace the current registration fee regime. The new fee will also be part subsidised by government funding for this financial year. We propose to move to full cost recovery in the financial year 2027-28 and we will share more details about this in due course.

The estimated unit cost for the fee from 1 April 2026 will be in the region of £300 per year, per level 2 category.

This fee will apply to all manufacturers with registered products. We estimate that approximately 60% of manufacturers will only pay a single charge and SMEs are likely to fall into that category as they are likely to have more limited range of products compared with larger companies.

Next steps

Following the careful analysis of the responses to this proposal, we will now take forward legislative changes that reflect the results of this consultation.

Before we implement the new fee, we will be taking several steps to help the sector get ready for the change.

We believe there are some obsolete products on the registration database. We will run an exercise to support customers to cleanse the data to ensure an accurate charge is being

calculated for products that are on the UK market. We will provide guidance on how to deregister products and companies can de-register obsolete products free of charge.

This exercise will alter the proposed fee (as it will reduce the number of products that the overall cost is divided by) and we will confirm the final unit cost after the data cleansing exercise.

We will publish updated guidance to better explain what needs to be registered and by whom, and the associated charges. This will be accompanied by an indicative bill for every manufacturer with one or more products registered with us.

Calculation of each manufacturer's 2026/27 fee will be based will be based on the GMDN level 2 categories that their registrations fall under on 1 April 2026.

The 'charging year' will run from 1 April to 31 March in a given year. If a manufacturer registers another product after 1 April during that charging year the registration system will check if the addition falls into a level 2 category that the manufacturer has not paid for. If this is so, the manufacturer will be charged for the new category. The fee will be calculated on a pro rata basis to cover the number of days remaining in the charging year.

The objectives set out in this document will be achieved by amending The Medical Devices Regulations 2002 and the Medical Devices (Northern Ireland) Protocol Regulations 2021. Details of the statutory instrument will be published in the near future.

We are grateful to respondents for considering and providing views on our proposal.

Consideration of matters set out in Section 15 of the Medicines and Medical Devices Act

We propose to make the legislative changes using powers in Part 4 of the Medicines and Medical Devices Act 2021 (the Act), which provides powers to make regulations about medical devices. The consultation was conducted pursuant to the consultation requirement in section 45(1) of the Act.

Section 15(2) of the Act states that safeguarding public health must be the overarching objective of the Secretary of State when making regulations. Section 15 requires that when assessing whether regulations would contribute to that objective, the Secretary of State must have regard to three factors:

1. The safety of medical devices, and, where making regulations may have an impact on the safety of medical devices, the Secretary of State considers that the benefits of doing so outweigh any risks;

2. The availability of medical devices; and

3. The likelihood of the United Kingdom being seen as a favourable place in which to – i. Carry out research relating to medical devices, ii. Develop medical devices; or iii. Manufacture or supply medical devices.

We consider the requirements of the Act to be fulfilled and have (on behalf of the Secretary of State) assessed the proposal against each of the factors set out above:

Safety

Post-market surveillance (PMS) refers to our regulatory oversight and manufacturers' obligations to ensure continuous, systematic monitoring of medical devices once they are in real-world use, whether in hospitals, community settings or patients' homes. By gathering and analysing data from adverse-incident reports, registries, published studies and user feedback, PMS makes it possible to detect safety signals or performance issues that pre-market evaluation may miss. Acting swiftly on those signals protects patients. The Independent Medicines and Medical Devices Safety Review (2020) highlighted how indispensable an effective PMS system is for patient safety; and the scope of PMS activities has recently expanded under the Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024 that took effect on 16 June 2025. Introducing this fee will help ensure we are properly resourced to deliver our PMS functions, better protecting patient safety and therefore we believe the benefits outweigh any risks.

Availability

A properly resourced and effective PMS system also supports patient access to medical devices. Continuous real-world PMS data can enable us to grant proportionate, quicker initial approvals and to clear design updates or expanded indications on an evidence-light, “monitor-then-confirm” basis. This speeds up getting new products to market. Earlier signal detection from PMS also means we can engage earlier with manufacturers so product issues can be remedied through targeted corrective actions instead of product withdrawals. This keeps more devices in service and reduces supply gaps. The proposed fee adds only a relatively small, predictable cost which should mean firms can incorporate it into long-term budgets with minimal risk of deterring new submissions or continued supply. By contrast, under-resourcing PMS would slow approvals and signal detection, drive larger-scale recalls and risk product access gaps. The fee therefore safeguards, rather than threatens, the availability of medical devices for UK patients.

Favourability

A wider benefit of an effective PMS system is that it supports innovation. PMS is important for international reliance, allowing us to rely on certain overseas approvals without duplicating all of their work, knowing that any emerging issues will be detected promptly and managed. This reduces duplication, cuts time-to-market and lowers cost for manufacturers. PMS data also supports other innovation pathways that could accelerate the adoption of transformative technologies, and the availability of continuous PMS data will support the safe and earlier indication expansions for those products. Overall, this fee will enable us to deliver rigorous, proportionate safety monitoring and also flexible, internationally aligned regulation. These are key factors cited by companies when choosing where to develop, trial and supply their products so it will contribute to UK favourability.