EXPLANATORY MEMORANDUM TO

THE MEDICAL DEVICES (FEES AMENDMENT) REGULATIONS 2026

2026 No. [XXXX]

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency ("MHRA"), an executive agency of the Department of Health and Social Care ("DHSC") and is laid before Parliament by Command of His Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Declaration

2.1 Dr Zubir Ahmed MP, Parliamentary Under-Secretary of State for Health Innovation and Safety at the DHSC, confirms that this Explanatory Memorandum meets the required standard.

2.2 Rose Braithwaite, Chief Finance Officer at the MHRA, confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Maham Masood at the MHRA can be contacted by email at the following address with any queries regarding the instrument: Maham.Masood@mhra.gov.uk.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 This instrument amends the legislation setting out the fees charged by the MHRA in relation to the regulation of medical devices. It replaces the provision for a one-off medical device registration fee with a provision for an annual medical device registration fee. The new annual registration fee helps ensure that the MHRA can recover the costs of delivering its post-market surveillance of medical devices on the United Kingdom ("UK") market.

Where does the legislation extend to, and apply?

4.2 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is the UK.

4.3 The territorial application of this instrument (that is, where the instrument produces a practical effect) is the UK.

5. Policy Context

What is being done and why?

5.1 The MHRA regulates medicines, medical devices and blood components for transfusion in the UK.

5.2 It has recently strengthened the safety and surveillance framework for medical devices following the coming into force of post-market surveillance regulations (S.I. 2024/1368) on 16 June 2025.

5.3 In addition to the clear benefits to patient safety, the new legislation, and the confidence it gives the MHRA in its ability to respond rapidly to performance and safety signals, is an important enabler of its more risk-proportionate, pro-innovation approach to regulation that is heralded in the NHS 10-year plan for England.

5.4 The new regulation is expected to lead to a ~60-70% increase in the MHRA's medical device post-market surveillance workload, at an annual cost of c. £17m per year.

5.5 The MHRA must be able to recover this cost. It recovers most of its costs via fees and does this in adherence to HM Treasury's Managing Public Money[1] guidance. The basic principle of this is to set statutory fees and charges to recover full costs. This means the regulated bear the cost of regulation and the MHRA does not profit from fees or make a loss which must be subsidised by Government or the taxpayer.

5.6 This instrument enables the recovery of these costs by creating a provision for an annual medical device registration fee for all manufacturers that have registered medical devices with the MHRA.

What was the previous policy, how is this different?

5.7 The previous policy was the post-market surveillance of medical devices, which was mostly subsidised by the DHSC, and part paid for by a one-off medical device registration fee paid for by manufacturers with products registered with the MHRA.

5.8 This arrangement did not raise enough money to cover the cost of delivering the post-market surveillance activities, particularly in light of the increased workload arising from new requirements in the post-market surveillance regulations (S.I. 2024/1368). It was also out of step with the standard approach to fees in HM Treasury's Managing Public Money guidance as the full cost of delivering the service for the MedTech sector was not being passed on via fees - in contrast with how post-market surveillance was paid for the pharmaceutical sector, for example.

5.9 The new policy replaces the one-off medical device registration fee with a new annual medical device registration fee, thus ensuring an ongoing source of income for this work. It also intends to remove the Government subsidisation. However, in response to consultation feedback, subsidisation is being removed in a phased way to make the change easier for the sector. This instrument introduces an annual fee for 2026/27 only and that will still be part subsidised. The intention is then to remove the subsidisation of that fee in 2027/28 to make it fully cost-recovering, pending further ministerial and parliamentary approval.

6. Legislative and Legal Context

How has the law changed?

6.1 This instrument is made under section 8C(1)(a) and (c) of, and paragraph 1(1)(ab) of Schedule 4 to, the European Union (Withdrawal) Act 2018 ("EUWA"), and sections 15(1), 16(1) and (2), 17(1)(a) and 43 of the Medicines and Medical Devices Act 2021 ("MMDA").

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

6.2 The Medical Devices Regulations 2002 ("MDR 2002") govern the UK regulatory framework for medical devices. The MDR 2002 implemented EU Directives 90/385/EEC and 93/42/EEC, which are repealed by Regulation (EU) 2017/745. Part VI of the MDR 2002 makes provision for the Secretary of State to charge fees to cover the cost of the regulatory work carried out under the MDR 2002. The MHRA carries out the functions of the competent authority under the MDR 2002 on behalf of the Secretary of State.

6.3 The MMDA provides an enabling power in section 15(1) of the MMDA to make provisions "amending or supplementing" the MDR 2002. Section 16(1) provides that regulations made under section 15(1) may make provision about the requirements that must be met in relation to medical devices in order for them to be marketed, and section 16(2) allows provisions made in reliance on section 16(1)(a) to identify requirements by reference to international agreements or standards relating to the marketing or supply of medical devices. Section 17(1)(a) allows regulations made under section 15(1) to include provision about the charging of fees. This instrument uses those MMDA powers to amend the MDR 2002.

6.4 Statutory fees charged by the MHRA in relation to the regulation of medical devices are also set out in the Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905) ("the 2021 Regulations"). Paragraph 7 of Schedule 4 to the EUWA provides the powers to make regulations for the purpose of altering the amounts of fees. Section 8C of the EUWA provides the power to make regulations in connection with the Northern Ireland Protocol and make provision for charging fees in those regulations. This instrument uses these EUWA powers to amend the 2021 Regulations.

6.5 In making regulations under the MMDA, the overriding objective of the Secretary of State must be safeguarding public health. Accordingly, in making this instrument, the Secretary of State has given regard to (1) the safety of medical devices; (2) the availability of medical devices; and (3) the likelihood of the UK being seen as a favourable place to carry out research related to medical devices, develop medical devices, or manufacture or supply medical devices.

6.6 The Secretary of State having had regard to these factors, considers that this instrument contributes to the overarching objective of safeguarding public health because the fees amendments will help ensure that the MHRA is sufficiently funded and resourced to deliver an efficient regulatory service which facilitates access to high-quality, safe, effective and innovative medical devices. Information on how these factors have been considered can be found in the Government's response to the public consultation on gov.uk at: https://www.gov.uk/government/consultations/mhra-consultation-on-statutory-fees-proposals-on-ongoing-cost-recovery.

Why was this approach taken to change the law?

6.7 This is the only possible approach to make the necessary changes.

7. Consultation

Summary of consultation outcome and methodology

7.1 The MHRA consulted on several proposals as part of its 2025 fees uplift, including the new annual medical device registration fee. The consultation ran from 29 August to 24 October 2024. It was promoted widely and supported by a webinar aimed at small and medium-sized enterprises (SMEs).

7.2 The new medical device registration fee is intended to distribute the MHRA's post-market surveillance costs fairly across the sector by using the Global Medical Device Nomenclature (GMDN) system. The GMDN system codifies medical devices by categorising them into 5 levels of increasing granularity. Manufacturers must register devices using GMDN codes before placing them on the UK market. The original proposal was to charge manufacturers annually based on the number of Level 5 GMDN Categories under which their devices were registered.

7.3 Consultation feedback showed strong opposition to this proposal. Of 195 responses, 141 (72%) did not support it. Respondents said the cost was too high and would disproportionately affect SMEs. In particular, they argued that using Level 5 GMDN Categories in this way would unfairly disadvantage certain manufacturers (e.g. manufacturers of in vitro diagnostics and surgical instruments). Of the remaining responses, 20 (10%) supported the proposal and 34 (18%) said they did not know or had no opinion.

7.4 Given this, the decision was taken to proceed with the wider fees uplift and update the proposal for this fee. The fee will be introduced in phases to help the sector prepare for the change. The fee will also use Level 2 GMDN Categories instead of Level 5 as this results in a more equitable spread of the cost between manufacturers of different product types. The MHRA developed this revised proposal and its implementation approach with input and feedback from a confidential "trusted advisory group" of industry representatives.

7.5 The MHRA published its original consultation response on 6 March 2025, followed by a further response setting out the revised proposal for this fee on 2 September 2025. Both can be found here: https://www.gov.uk/government/consultations/mhra-consultation-on-statutory-fees-proposals-on-ongoing-cost-recovery.

7.6 This instrument is being made by the Secretary of State on a UK-wide basis but officials in Devolved Governments were consulted and are supportive of the change.

8. Applicable Guidance

8.1 Guidance has been published to help the sector prepare on: https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market. The MHRA has begun contacting manufacturers directly to promote the guidance and provide an advanced estimate of their annual fee payable on 1 April 2026. Further communications are planned in early 2026 to ensure the sector is fully aware of the change.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A regulatory de minimis (DMA) assessment has been done for the change rather than a full Impact Assessment as the change falls under the regulatory de minimis (DMA) assessment threshold. This is because the proposed fee is intended to apply for 2026/27 only and is still part-subsidised. DMAs are not usually published but the assessment estimated the impact on businesses as £4.3m for 2026/27 only. The MHRA proposes to move from a part-subsidised fee in 2026/27 to a fully cost-recovering fee in 2027/28, pending ministerial agreement, and will publish a full Impact Assessment ahead of that change.

Impact on businesses, charities and voluntary bodies

9.2 The new fee has been designed to apportion the MHRA's post-market surveillance costs by using the Global Medical Device Nomenclature (GMDN) system. This codifies devices by categorising them into 5 levels of increasing granularity and manufacturers must register devices using GMDN codes before placing them on the UK market.

9.3 This approach is designed to be equitable as larger companies are more likely to have more devices on the market and therefore register more GMDN categories, translating to relatively higher annual fees. Smaller companies generally register fewer GMDN categories and therefore will generally pay lower annual fees.

9.4 Manufacturers will be charged annually based on how many Level 2 GMDN Categories their devices are registered under. If multiple GMDN and products are registered under the one Level 2 Category, they will only be charged once per year for that Level 2 GMDN Category. The estimated unit cost for the fee from 1 April 2026 will be in the region of £300 per year, per Level 2 GMDN Category.

9.5 These costs should be considered alongside the benefits that a robust post-market surveillance system brings. Post-market surveillance enables the MHRA and manufacturers to identify safety issues earlier, reducing the risk to patient safety. It also provides the foundations for the introduction of pre-market regulatory flexibilities designed to support the growth agenda, including innovation pathways and reliance on certain overseas regulatory approvals.

9.6 The impact on charities and voluntary bodies is estimated to be low as they are unlikely to be medical device manufacturers with registered products and therefore will not have to pay the fee.

9.7 The legislation does impact small and micro businesses. The fee will be applicable for all manufacturers with registered products, regardless of size. The MHRA's modelling suggests that 60% of manufacturers will only pay a single charge estimated at £300 per year, and SMEs are likely to fall into that category as they are likely to have a more limited range of products compared to larger companies.

9.8 The MHRA cannot exempt SMEs from the change as it needs to recover its costs.

9.9 The impact on the public sector is expected to be minor. Any public sector bodies manufacturing medical devices and registering them with the MHRA will have to pay the fee. The MHRA's modelling suggests that most will only pay a single charge estimated at £300 per year. If the MHRA gets ministerial and parliamentary approval to move to a fully cost-recovering fee, there will also be a public sector benefit from less subsidisation.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring this legislation is via the MHRA's biennial fees uplifts, which involves stakeholder feedback and fee setting to avoid over- or under-recovery.

10.2 The instrument does not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015, Minister Zubir Ahmed MP has made the following statement:

"Regulations setting out the fees payable in relation to services provided, and regulatory functions carried out, by the MHRA in relation to medical devices are

periodically reviewed. There is also already a requirement in section 46 of the Medicines and Medical Devices Act 2021 to review the operation of these Regulations every 24 months".

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

11.1 The new fee has been designed to apportion the MHRA's post-market surveillance costs by using the GMDN system. This is maintained by the GMDN Agency, which is a registered UK charity and non-profit organisation responsible for the ongoing maintenance of the GMDN Database. The SI uses the power provided in section 16(2) of the MMDA to identify relevant requirements by reference to international agreements or standards relating to the marketing or supply of medical devices, including agreements or standards as they have effect from time to time.

12. European Convention on Human Rights

12.1 The Parliamentary Under-Secretary of State for Health Innovation and Safety at the DHSC has made the following statement regarding Human Rights:

"In my view the provisions of The Medical Devices (Fees Amendment) Regulations 2026 are compatible with the Convention rights."

13. The Relevant European Union Acts

13.1 This instrument is made under section 8C(1)(a) and (c) of, and paragraphs 1(1)(ab) of Schedule 4 to the European Union (Withdrawal) Act 2018 and therefore relates to the withdrawal of the United Kingdom from the European Union. It relates to the withdrawal of the United Kingdom from the European Union because it amends regulations made under section 2(2) of the European Communities Act 1972. The Parliamentary Under-Secretary of State for Health Innovation and Safety at the DHSC has made, below, the relevant statement.

"In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".

13.2 These amendments ensure that the fees payable to the MHRA achieve full cost-recovery of the services it provides, in accordance with HM Treasury guidelines for managing public money.