EXPLANATORY MEMORANDUM TO

THE MEDICAL DEVICES AND BLOOD SAFETY AND QUALITY (FEES AMENDMENT) REGULATIONS 2025

2025 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 Baroness Merron, Parliamentary Under-Secretary of State for Patient Safety, Women's Health and Mental Health 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: info@mhra.gov.uk can be contacted with any queries regarding the instrument.

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 and blood components for transfusion.

4.2 The instrument amends a range of fees in line with the increased costs of providing these regulatory services, ensuring that the MHRA recovers the cost of its regulatory activity in accordance with Managing Public Money principles. This is necessary to ensure the MHRA's long-term financial sustainability and enable the MHRA to deliver a responsive, innovative and efficient regulatory service that protects and improves patient and public health. The instrument also introduces a new fee associated with a new optional service of providing regulatory advice meetings for medical devices as well as a new payment easement for small and medium enterprises (SMEs) for clinical investigation fees.

Where does the legislation extend to, and apply?

4.3 The extent of this instrument is the whole of the United Kingdom ("UK").

4.4 The territorial application of this instrument is the whole of 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. Generally, whenever the MHRA provides a direct service for regulatory work, a fee is charged to recover the costs. As the fees are set in secondary legislation, legislative change is required to amend them.

5.2 This instrument amends the medical devices and blood components for transfusion fees currently set out in the Medical Devices Regulations 2002 (S.I. 2002/618) ("MDR 2002"), the Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905) ("the 2021 Regulations"), and the Blood Safety and Quality Regulations 2005 (S.I. 2005/50) ("the 2005 Regulations") to ensure the MHRA recovers the cost of regulatory activities in relation to the regulation of medical devices and blood components for transfusion.

5.3 The principles for how the MHRA charges fees are set by HM Treasury in Managing Public Money. The basic principle is to set statutory fees and charges to recover full costs. This means that the regulated bear the cost of regulation and the MHRA does not profit from fees or make a loss which must then be subsidised by Government departments or the UK taxpayer.

5.4 In setting the cost of fees, the MHRA has taken numerous factors into account to ensure costs are covered, including identifying activities involved in delivering a service, the time these activities take, and the staff grade and seniority required to complete the task. In addition, the MHRA is required to factor in corporate overhead costs and system investments.

5.5 To ensure ongoing cost-recovery, the MHRA updates its fees on an ongoing basis. This is standard practice for government bodies that charge fees. The MHRA's fees were last updated in April 2023 and the implementation date for these proposed changes is early Q1 2025/26. The MHRA aims to update its fees every two years as regularity provides more certainty to customers and enables financial planning.

5.6 This instrument increases the statutory fees shown in the Annex to ensure continued cost-recovery until 2027. The proposed increase for each fee has been calculated to ensure it covers all associated costs for the period between April 2025 to March 2027 (the month before the next fees uplift is planned).

5.7 This instrument creates a new fee for a new optional service providing regulatory advice meetings for medical devices. In addition to publishing guidance and addressing written enquiries, the MHRA proposes to further support manufacturers by creating a new service of regulatory advice meetings to support understanding of the application of UK's regulatory framework to their product/s. The service will mainly be for those developing novel and/or complex products with the potential to significantly improve patient outcomes, where the application of the legislation is not straightforward and easily understood.

5.8 This instrument creates a new payment easement for clinical investigation fees for SMEs which will allow them to pay the fees over two instalments.

What was the previous policy, how is this different?

5.9 This instrument amends the medical devices and blood components for transfusion fees currently set out in regulations as these are out of date. This change is to ensure the MHRA recovers the cost of regulatory activities in relation to the regulation of

medical devices and blood components for transfusion. This is in accordance with HM Treasury guidelines for Managing Public Money.

6. Legislative and Legal Context

How has the law changed?

6.1 This instrument is made under section 15(1), 16(1), 17(1)(a) and 43 of the Medicines and Medical Devices Act 2021 ("MMDA") and section 8C(1)(a) and (c), paragraphs 1(1)(ab) and 7(2) of Schedule 4, and paragraph 21 of Schedule 7, to the European Union (Withdrawal) Act 2018 ("EUWA").

6.2 The MHRA regulates medical devices and blood components for transfusion in the UK.

6.3 The 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.

6.4 The MMDA provides an enabling power in section 15(1) of the MMDA to make provisions "amending or supplementing" the MDR 2002. 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, updating the statutory fees charged by the MHRA in relation to the regulation of medical devices, to ensure the MHRA recovers the costs of its regulatory activities.

6.5 Statutory fees charged by the MHRA in relation to the regulation of medical devices are also set out in 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 this EUWA powers to amend the 2021 Regulations, updating the statutory fees charged by the MHRA.

6.6 The 2005 Regulations, set standards of quality and safety for the collection and testing of human blood and blood components, and their processing, storage and distribution when intended for transfusion. The 2005 Regulations implemented EU Directive 2002/98/EC. The MHRA carries out the functions of the competent authority under the 2005 Regulations on behalf of the Secretary of State.

6.7 The statutory fees charged by the MHRA in relation to the regulation of blood components for transfusion are set out in the 2005 Regulations. Schedule 4 to the EUWA provides the powers to make regulations to amend secondary legislation for the purpose of altering fees. This instrument uses the EUWA power to amend the 2005 Regulations, updating the statutory fees charged by the MHRA in relation to the regulation of blood components for transfusion, to ensure the MHRA recovers the costs of its regulatory activities.

6.8 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.

6.9 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?

6.10 This is the only possible approach to make the necessary changes to the legislation.

7. Consultation

Summary of consultation outcome and methodology

7.1 The MHRA carried out a joint public consultation on proposed amendments to its statutory fees with the Department of Health in Northern Ireland.

7.2 The consultation ran from 29 August 2024 to 24 October 2024 and was promoted and accompanied by a webinar to engage with SMEs.

7.3 The MHRA has analysed all responses and published the Government's response to the public consultation on gov.uk. In response to feedback, the MHRA is proceeding with its overall fees uplift and is introducing a new payment easement for SMEs for some of its medical device clinical investigation fees, but is reconsidering the proposal to introduce a new registration free for medical devices and will be putting further advice to ministers.

7.4 This instrument is being made by the Secretary of State on a UK-wide basis. Colleagues in all Devolved Governments were consulted and are supportive of the changes.

8. Applicable Guidance

8.1 Guidance and information regarding fees payable to the MHRA can be found on the MHRA website at: https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees. Updated guidance and information on the new fees will be published in advance of this instrument coming into force.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment is submitted with this memorandum and published alongside the Explanatory Memorandum on the legislation.gov.uk website.

Impact on businesses, charities and voluntary bodies

9.2 The overall impact on business, charities or voluntary bodies is £0.7 million per year after inflation. This is the additional amount payable by organisations that use the MHRA's medical devices and blood components for transfusion services. The published full impact assessment shows a higher cost than this (£15.2 million per year) as it covers the entire MHRA fees uplift and therefore also the cost of the uplift of medicines fees.

9.3 The legislation does impact small and micro businesses.

9.4 This instrument will introduce new payment easements for small and medium sized businesses (SMEs) for the MHRA's clinical investigation fees.

9.5 The impact on the public sector is minimal. Some public sector bodies use the MHRA's services and will pay the increased fees. In 2023, the MHRA's total trading income was approximately £150m and approximately £2.5m of that came from public bodies. This indicates the impact on the public sector will be minimal. There is also a public sector benefit as the fees increases will ensure the MHRA is financially sustainable and will not require the DHSC to subsidise its costs.

9.6 To minimise burden on businesses generally, the MHRA will continue to review its fees periodically to ensure that they are set appropriately to neither profit at the expense of those paying them, nor make a loss for taxpayers to subsidise.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring of this legislation is for the MHRA to monitor fees on an ongoing basis to ensure all fees are set at a level to recover full costs incurred. The MHRA also monitors and takes action on customer service feedback.

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, Baroness Merron 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 and blood components for transfusion 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

11.1 This instrument amends legislation made under section 2(2) of the European Communities Act 1972, section 56(1) and (2) of the Finance Act 1973 and sections 11 and 27 of the Consumer Protection Act 1987. This instrument is made under Schedule 4 to the European Union (Withdrawal) Act 2018 ("EUWA") and the relevant explanations are set out in section 7 of this memorandum.

11.2 This instrument is also made under Section 15(1) of the Medicines and Medical Devices Act 2021 ("MMDA").

11.3 MMDA powers are used to amend the MDR 2002. EUWA powers are used to amend the 2021 Regulations, and the 2005 Regulations.

11.4 Given the different legal positions in relation to the powers to make regulations about fees relating to human medicines, medical devices and blood components for transfusion, the MHRA are using two instruments: this one for medical devices and blood components for transfusion fees laid before the UK Parliament only and subject to the affirmative procedure; and one for human medicines fees and laid before the UK Parliament and the Northern Ireland Assembly and subject to the negative procedure.

11.5 All MHRA fees are set to recover their costs, as per HM Treasury Managing Public Money principles. All fees have had an 8.85% indexation added to ensure they cover staff costs until 2027, the date of our next planned uplift. This is calculated based on half of the 2023/24 Civil Service pay award of 4.5% plus an assumed 2.2% (which is an average for last 5 years) pay award in years 24/25, 25/26 and 26/27.

11.6 This instrument also imposes some fees increases above the rate of indexation. This is because some fees were under-recovering. This was shown via real-time cost recovery modelling, informed by newly available employee activity recording data. Employee activity recording is the practice of monitoring and recording certain activities performed by employees to establish how long they take and so how much they cost. The MHRA does not yet have the capability to carry out employee activity recording all year round so, for the first time, these data were collected for a range of fee earning areas during a 3-month sampling period in 2024 and then the resulting figures were adjusted using volume assumptions. This produced more accurate cost data to underpin the modelling and meant some fees needed to be adjusted.

11.7 The majority of fees have increased by between 8.85-16%. The fees that are rising by more than this are primarily related to clinical investigations as previous fees were under recovering and did not fully represent the work done. The service generally provides a more thorough process than benchmarks abroad. We are also introducing an SME easement for our clinical investigation fees.

12. European Convention on Human Rights

12.1 Baroness Merron, Parliamentary Under-Secretary of State for Patient Safety, Women's Health and Mental Health at the DHSC, has made the following statement regarding Human Rights:

"In my view the provisions of the Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2025 are compatible with the Convention rights."

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts"). It does however relate 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.

13.2 Baroness Merron, Parliamentary Under-Secretary of State for Patient Safety, Women's Health and Mental Health has made the following statement regarding regulations made under the European Communities Act:

"In my opinion there are good reasons for the Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2005 to amend the MDRs, the 2021 Regulations and the 2005 Regulations. This is because the 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."

Annex

Fee name	Current	Proposed
Blood banks: application fees for a Review Panel hearing - Fee	£11,000	£11,974
Blood banks and other blood establishments: fees - Blood Establishments - Haemovigilance - Annual fee	£967	£1,053
Blood banks and other blood establishments: fees - Blood Establishments - Inspections - Standard Inspection Fee: daily rate	£3,552	£5,324
Blood banks and other blood establishments: fees - Blood Establishments - New Applications - Inspection fee (per additional site if required)	£3,552	£3,867
Blood banks and other blood establishments: fees - Blood Establishments - New Applications - Standard application plus full inspection fee	£6,933	£7,547
Blood banks and other blood establishments: fees - Blood Establishments - Periodic Fee - Annual fee	£509	£555
Blood banks and other blood establishments: fees - Blood Establishments - Variations - Standard variation	£570	£621
Blood banks and other blood establishments: fees - Hospital Blood Banks and facilities - Compliance - Annual fee	£751	£818
Blood banks and other blood establishments: fees - Hospital Blood Banks and facilities - Haemovigilance - Annual fee	£967	£1,053
Blood banks and other blood establishments: fees - Hospital Blood Banks and facilities - Inspections - Inspection fee (per additional site if required)	£3,552	£5,324
Blood facilities: contract laboratories fees - Inspections - Inspection fee* (per additional site if required)	£3,552	£5,324
Clinical investigations for devices: fees - Amendment fees - High risk device amendment	£331	£361
Clinical investigations for devices: fees - Amendment fees - Low risk device amendment	£207	£226
Clinical investigations for devices: fees - Consultation - Clinical Investigations statistical review	£782	£852
Clinical investigations for devices: fees - Consultation - Device Regulatory Advice meeting	£906	£987
Clinical investigations for devices: fees - Notification of a clinical investigation - Class I, IIa, or IIb other than implantable or long-term invasive devices	£5,711	£11,701
Clinical investigations for devices: fees - Notification of a clinical investigation - Class I, IIa, or IIb other than implantable or long-term invasive devices	£7,472	£15,309
Clinical investigations for devices: fees - Notification of a clinical investigation - Class IIb implantable or long-term invasive, Class III, and active implantable devices	£11,069	£22,678
Clinical investigations for devices: fees - Notification of a clinical investigation - Class IIb implantable or long-term invasive, Class III, and active implantable devices	£15,627	£32,016
Devices - Day rate for auditing	£1,262	£1,463
Devices - Extension to scope - Extension to scope, where codes are limited	£12,571	£14,568
Devices - Extension to scope - new UKCA codes or Annex	£18,212	£21,105
Devices - Follow up Audit - Major Closure	£22,789	£26,408
Devices - Follow up Audit - Process Specific	£22,789	£26,408
Devices - Follow up Audit - Special Clinical	£18,583	£21,535
Devices - Initial application for designation	£35,672	£41,337
Devices - Initial designation audit	£58,341	£67,606
Devices - Re-application	£8,918	£10,335
Devices - Re-designation application fee	£35,672	£41,337
Devices - Re-designation audit	£58,341	£67,606
Devices - Subsidiary audit	£22,789	£26,408
Devices - Surveillance	£45,675	£52,929
Devices - TSE Applications UK Conformity Assessment Bodies	£1,297	£1,503
Devices - Witnessed Audit	£10,072	£11,672
Devices Registration	£240	£261
Devices Registration amendment	£240	£261
Regulatory advice meeting for medical devices	N/A - new	£987