EXPLANATORY MEMORANDUM TO

THE MEDICAL DEVICES AND BLOOD SAFETY AND QUALITY (FEES AMENDMENT) REGULATIONS 2023

2023 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. Purpose of the instrument

2.1 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.

2.2 The instrument amends a range of fees in line with the increased costs of providing these regulatory services, ensuring that MHRA recovers the cost of its regulatory activity in accordance with Managing Public Money principles. The instrument also introduces new optional services provided by the MHRA in relation to clinical investigations of medical devices and their associated fees.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 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.

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

3.3 MMDA powers are used to amend the Medical Devices Regulations 2002 (S.I. 2002/618). EUWA powers are used to amend the Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), the Blood Safety and Quality Regulations 2005 (S.I. 2005/50), and to revoke and restate the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 (S.I. 1995/449).

3.4 This instrument imposes some fee increases above the rate of indexation. The policy explanation for this, and the level of such fee increases, is set out in section 7 and Annex 2 of this memorandum.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is the whole of the United Kingdom.

4.2 The territorial application of this instrument is the whole of the United Kingdom.

5. European Convention on Human Rights

5.1 The Minister for Health and Secondary Care, Will Quince MP, 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 2023 are compatible with the Convention rights."

6. Legislative Context

6.1 This instrument is made under section 15(1) of the MMDA and Schedule 4 to the EUWA.

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

6.3 The Medical Devices Regulations 2002 ("MDR 2002") (S.I. 2002/618, as amended) 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) 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 Medical Devices (Northern Ireland Protocol) Regulations 2021 ("the 2021 Regulations") (S.I. 2021/905) and the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 ("the 1995 Regulations") (S.I. 1995/449). Paragraph 7 of Schedule 4 to the EUWA provides the powers to make regulations to amend secondary legislation for the purpose of altering fees. This instrument uses this EUWA power to revoke and restate the 1995 Regulations, updating the statutory fees charged by the MHRA. 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 power to amend the 2021 Regulations, updating the statutory fees charged by the MHRA.

6.6 The Blood Safety and Quality Regulations 2005 ("the 2005 Regulations") (S.I. 2005/50), 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.

7. Policy background

What is being done and why?

7.1 The MHRA regulates medicines, medical devices and blood components for transfusion in the United Kingdom, carrying out regulatory functions on behalf of the Secretary of State. Generally, whenever the MHRA provides a direct service for medicines, medical devices or blood components for transfusion regulatory work, a fee is charged to recover the costs. Although medical devices work is primarily funded through grant-in-aid from DHSC, there are aspects of the MHRA's medical devices work that are also fee dependent. As the fees are set in secondary legislation, legislative change is required to amend them.

7.2 This instrument amends the fees currently set out in legislation to ensure the MHRA recovers the cost of regulatory activities.

7.3 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.

7.4 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.

7.5 The MHRA's statutory fees have been adjusted several times in the past to ensure they remain accurate, as is standard practice for government bodies that charge fees. However, more recently the fees have not been updated since financial year 2017/18 for medical devices and 2010/11 for blood components for transfusion. The MHRA has undertaken a review of its statutory fees and identified that numerous activities were no longer fully recovering costs.

7.6 This instrument introduces fee amendments which fall into three categories; (1) a 10% indexation uplift; (2) a further uplift for activities that are currently significantly under-recovering in fees to achieve cost recovery; and (3) the introduction of new fees for services that require cost-recovery since the last fee changes in 2017/18 for medical devices.

7.7 The 22 fees which are being increased by more than the 10% indexation measure have been calculated on the same as basis as all other MHRA statutory fees, to ensure that the MHRA is cost recovering for the activities involved in delivering these services, in accordance with Managing Public Money guidelines. The calculation of these fees was informed by an internal MHRA review, which accounted for all activities involved in delivering the services, the time these activities take, and the staff seniority required to complete them. The extent of each fee amendment in this category varies as it reflects the specific costs of the activities involved in delivering the services. The level of increase for these fees can be found in Annex 2 of this memorandum.

7.8 The new optional services introduced by this instrument relate to clinical investigations of medical devices. A manufacturer or their UK responsible person may request a meeting with the MHRA (on behalf of the Secretary of State) to obtain advice on regulatory requirements relating to an intended clinical investigation or to obtain a statistical review in relation to an intended clinical investigation. This instrument also introduces the associated fees payable for these optional services.

7.9 The fee amendments introduced by this instrument are designed to achieve full cost recovery in line with HM Treasury 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.

7.10 In making regulations under the MMDA, the Secretary of State's overarching objective must be safeguarding public health. Accordingly, in making this instrument, the Secretary of State has given due 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 develop medical devices, carry out research related to medical devices, or manufacture or supply medical devices.

7.11 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 fee 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 products. Additional information on how these factors have been considered can be found in the Government's response to the public consultation: https://www.gov.uk/government/consultations/consultation-on-proposals-for-changes-to-the-medicines-and-healthcare-products-regulatory-agencys-statutory-fees

Explanations

What did any law do before the changes to be made by this instrument?

7.12 Legislation set out fees payable to the MHRA in relation to services provided, and regulatory functions carried out, by MHRA in relation to medical devices and blood components for transfusion.

Why is it being changed?

7.13 This instrument amends the fees payable to the MHRA in order to achieve full cost recovery of these regulatory services, in accordance with HM Treasury guidelines for Managing Public Money.

What will it now do?

7.14 This instrument specifies the updated fee amounts and introduces new optional services provided by the MHRA in relation to clinical investigations of medical devices and the associated fees payable.

8. European Union Withdrawal and Future Relationship

8.1 This instrument is not being made to address a deficiency in retained EU law but relates to the withdrawal of the United Kingdom from the European Union because it is being made partly under Schedule 4 to EUWA. The Minister has made any relevant statements in Part 2 of the Annex to this Explanatory Memorandum.

8.2 Alongside the EU (Withdrawal) Act 2018 powers, the instrument is also being made under Section 15(1) of the Medicines and Medical Devices Act 2021 (the "MMDA").

9. Consolidation

9.1 This instrument does not consolidate legislation but the content of the 1995 Regulations is being revoked and restated (with updated fees) in other legislation.

10. Consultation outcome

10.1 Section 45(1) of the MMDA requires that, before making regulations under section 15, a public consultation be carried out. The MHRA led a joint public consultation on proposed amendments to the MHRA's statutory fees with the Department of Health in Northern Ireland. The consultation ran from 31 August 2022 to 23 November 2022. A total of 99 formal responses were received. The majority were sent on behalf of an organisation (59%) or from individuals working in the sector sharing their professional views (35%); and the remainder (6%) were from individuals (such as a patient, carer or member of the public). Organisation responses were received across a range of trade associations, research organisations, pharmaceutical companies, medical device manufacturers, blood banks and transfusions services, charities, and conformity assessment bodies.

10.2 There was a general acceptance of the need to ensure cost recovery for regulatory activities, and that this was important for ensuring a consistent level of service. One of the main themes raised by respondents was the need for more consistent and improved services, and that any increase in fees should be met with improvements in MHRA performance. By ensuring the MHRA is sufficiently resourced and operating a sustainable cost recovery fee model, this will help the MHRA deliver the required service standards more consistently.

10.3 The MHRA has analysed all responses and considered the feedback received alongside the necessity of actions that must be taken to operate on a cost recovery basis. A summary of the consultation responses and the Government's response can be found here: https://www.gov.uk/government/consultations/consultation-on-proposals-for-changes-to-the-medicines-and-healthcare-products-regulatory-agencys-statutory-fees

10.4 This instrument is being made on a UK wide basis. The Devolved Administrations were consulted during the development of the fee amendments.

11. Guidance

11.1 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.

12. Impact

12.1 The impact on business, charities or voluntary bodies is £1.9 million per year. This cost is the additional fees payable by organisations which use the MHRA's services.

12.2 Some public sector bodies that use the MHRA's services will pay increased fees. However, there is also a public sector benefit as the fee increases will ensure the MHRA is financially sustainable and will not require DHSC to subsidise costs.

12.3 The annual net costs of this instrument are de-minimis (below the +/- £5 million threshold). A full Impact Assessment is submitted with this memorandum and published alongside the Explanatory Memorandum on the legislation.gov.uk website.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 As noted in 12.3, the impact to business is below the +/- £5 million threshold. No specific action is proposed to minimise regulatory burdens on small businesses.

13.3 To minimise burden on businesses generally, the MHRA will review its fees periodically to ensure they are set appropriately to neither profit at the expense of consumers or industry, nor make a loss for taxpayers to subsidise. The MHRA sets fees in accordance with the principles set by HM Treasury in Managing Public Money.

14. Monitoring & review

14.1 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 by the MHRA.

14.2 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 Quince MP has made the following statement:

"Regulations setting out the fees payable in relation to services provided, and regulatory functions carried out, by MHRA in relation to medical devices and blood components for transfusion are periodically reviewed".

15. Contact

15.1 Hannah Kunicki at the MHRA: hannah.kunicki@mhra.gov.uk can be contacted with any queries regarding the instrument.

15.2 Rose Braithwaite, Deputy Director for Finance, at the MHRA can confirm that this Explanatory Memorandum meets the required standard.

15.3 Will Quince MP, Minister of State for Health and Secondary Care at DHSC can confirm that this Explanatory Memorandum meets the required standard.

Annex 1

Statements under the European Union (Withdrawal) Act 2018 and the European Union (Future Relationship) Act 2020

Part 1A

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	Explain the instrument, identify the relevant law before IP completion day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.
Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising section 8 or part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 5 or 19, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 14, Schedule 8	Anybody making an SI after IP completion day under powers conferred before the start of the 2017-19 session of Parliament which modifies subordinate legislation made under s. 2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 15, Schedule 8	Anybody making an SI after IP completion day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before IP completion day, and explaining the instrument's effect on retained EU law.

Part 1B

Table of Statements under the 2020 Act

This table sets out the statements that may be required under the 2020 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraph 8 Schedule 5	Ministers of the Crown exercising section 31 to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees

Part 2

Statements required under the European Union (Withdrawal) 2018 Act or the European Union (Future Relationship) Act 2020

1. Explanations

1.1 The explanations statement has been made in section 7 of the main body of this explanatory memorandum.

Annex 2

Further information on the MHRA fees which are increasing above the 10% indexation measure

Blood Components for Transfusion Fees:

Cost Recovery		
Fee Name	**Previous Fee (£)**	**Revised Fee (£)**
Inspection - Full day rate (Blood banks and other blood establishments)	2,583	3,552
Inspection - Half day rate (Blood banks and other blood establishments)	1,292	1,776
Devices Blood bank annual fee	492	967

Medical Devices Fees:

Cost Recovery		
Fee Name	**Previous Fee (£)**	**Revised Fee (£)**
Initial application for designation (covers both Approved Body and Notified Body)	8,252	35,672
Re-application to address ground for rejection of a previous application	2,063	8,918
Initial designation audit	15,904	58,341
Surveillance	10,160	45,675
Witnessed Audit	4,404	10,072
Re-designation application fee	8,252	35,672
Re-designation audit	15,904	58,341
Follow up Audit - Major Closure	3,876	22,789
Follow up Audit - Special Clinical	2,586	18,583
Follow up Audit - Process Specific	3,876	22,789
TSE Applications UK Conformity Assessment Bodies	532	1,297
In addition to each of the above, the below two fees are for time spent on audit and travel:		
Half day rate for auditing	361	631
Hourly rate for travel	90	171
Class I, IIa, or IIb other than implantable or long-term invasive devices: Notification	3,820	7,472

Class I, IIa, or IIb other than implantable or long-term invasive devices: Notification - re-notification in the event of an objection	2,920	5,711
Class IIb implantable or long-term invasive, Class III, and active implantable devices: Notification	5,040	15,627
Class IIb implantable or long-term invasive, Class III, and active implantable devices: Notification - re-notification in the event of an objection	3,570	11,069
Devices Registration	100	240
Devices Registration amendment	100	240