EXPLANATORY MEMORANDUM TO

THE MEDICINES (PRODUCTS FOR HUMAN USE) (FEES) (AMENDMENT) REGULATIONS 2023

2023 No. 314

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 and for the Northern Ireland Assembly.

2. Purpose of the instrument

2.1 This instrument amends the Medicines (Products for Human Use) (Fees) Regulations 2016 (S.I. 2016/190) ("the 2016 Regulations"), to update the fees payable to the MHRA in relation to the regulation of medicinal products for human use.

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 costs of its regulatory activity in accordance with Managing Public Money principles.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments and the Northern Ireland Assembly

3.1 This instrument is made under section 2(1) of the Medicines and Medical Devices Act 2021 ("MMDA") and is subject to the negative procedure. This instrument amends the 2016 Regulations, which were made under section 2(2) of the European Communities Act 1972 (amongst other powers). The requirements of paragraphs 13 and 14 of Schedule 8 to the European Union (Withdrawal) Act 2018 do not apply because the instrument is being made under powers conferred after 21st June 2017. The statements required by paragraph 15 of Schedule 8 to that Act are set out in sections 6 and 7 and Annex 1 of this memorandum.

3.2 This instrument imposes some fee increases above the rate of indexation. Indexation is a way of calculating the changing value of something (e.g. fees) in relation to another value or to a fixed standard (e.g. salaries). The 10% indexation increase, which is used for the majority of the fee amendments, is based on increased MHRA staff costs which, in line with the Civil Service pay award, have risen by 10% since the last substantial medicines fees review in 2016. Staff costs account for over half of the MHRA's total expenditure and therefore have a significant impact on the fees charged by the MHRA. The policy explanation for the fees which are increasing above the rate of indexation, and the level of such fee increases, is set out in section 7 and Annex 2 of this memorandum.

Matters of special interest to the Northern Ireland Assembly

3.3 Section 2(6)(b)(ii) of the MMDA provides that in relation to Northern Ireland, regulations under section 2 can be made by the Secretary of State and the Department of Health in Northern Ireland acting jointly. This instrument will apply to the whole of the United Kingdom and accordingly is made jointly.

3.4 Section 47(5)(c) of the MMDA provides that in the case of the regulations being made jointly under the negative procedure, the regulations are subject to annulment in pursuance of a resolution of either House of Parliament and a negative resolution within the meaning of s41(6) of the Interpretation Act (Northern Ireland) 1954.

4. Extent and Territorial Application

4.1 The 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 As the instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

6.1 The Human Medicines Regulations 2012 (S.I. 2012/1916, as amended) ("the HMRs") govern the arrangements across the United Kingdom for the licensing, manufacture, wholesale dealing, sale or supply, advertising and post-marketing monitoring of medicines for human use. The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031, as amended) ("the 2004 Regulations") govern the conduct of clinical trials of medicinal products for human use. Together, they set the essential framework, alongside the surviving provisions of the Medicines Act 1968, the Medicines Act 1971 and the 2016 Regulations, for the regulation of medicines for human use in the United Kingdom.

6.2 The MHRA carries out the functions of the licensing authority, relating to medicines for human use, under the HMRs and the 2004 Regulations on behalf of the Secretary of State and the Minister of Health in Northern Ireland.

6.3 The 2016 Regulations make provision for the fees payable to the MHRA in relation to the regulatory functions it carries out under the HMRs and 2004 Regulations.

6.4 Section 2(1) of the MMDA provides the power to amend the 2016 Regulations and section 6(1)(a) MMDA provides that regulations made under s2 MMDA can make provision for charging fees. This instrument uses those MMDA powers to amend the 2016 Regulations, updating the statutory fees charged by the MHRA in relation to the regulation of medicines for human use, 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. 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. 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 the 2016 Regulations 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 2016/17 for medicines.

7.6 Decisions not to adjust fees in recent years were made to provide certainty and stability to industry throughout the EU exit period, and while the MHRA and the wider healthcare system responded to the COVID-19 pandemic. In addition, the MHRA had been operating as a Trading Fund since 2003. In 2019 the Office for National Statistics reclassified the MHRA from a Trading Fund to a Market Regulatory Agency. This reclassification, which came into force in April 2022, means that the MHRA is not able to retain and rely on cash reserves to manage areas of under-recovery as it has done previously. This means that cost-recovery across all services is essential to ensure the financial sustainability of the MHRA moving forwards.

7.7 The MHRA has undertaken a review of its statutory fees and identified that numerous activities were no longer fully recovering costs.

7.8 This instrument introduces fee amendments which fall into three categories:

(1) a 10% indexation uplift. The indexation is linked to staff costs which, in line with the Civil Service pay award, have risen by 10% since the last medicines fees review in 2016. Staff costs account for over half of the MHRA's total expenditure and therefore have a significant impact on the fees charged by the MHRA. The remaining expenditure include items such as IT, laboratories and accommodation, the costs of which have risen in line with inflation. At the point the revised fees were calculated, the Consumer Prices Index (CPI) was up 21% since 2016, however the MHRA's cost reduction programmes mean the MHRA is able to cover most increases with the 10% 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.

7.9 The 36 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.

7.10 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.

7.11 In making regulations under the MMDA, the overriding objective of the Secretary of State and the Department of Health in Northern Ireland must be safeguarding public health. Accordingly, in making this instrument, the Secretary of State and the Department of Health in Northern Ireland have given regard to (1) the safety of medicines; (2) the availability of medicines; and (3) the likelihood of the UK being seen as a favourable place to conduct clinical trials, carry out research related to medicines, or manufacture or supply medicines.

7.12 The Secretary of State and the Department of Health in Northern Ireland, having had regard to these factors, consider 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 medicinal 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

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 amending regulations made under section 2(2) of the European Communities Act 1972. The Minister and the Department of Health in Northern Ireland have made any relevant statements in Part 2 of Annex 1 to this Explanatory Memorandum.

9. Consolidation

9.1 This instrument does not consolidate legislation.

10. Consultation outcome

10.1 Section 45(1) of the MMDA requires that, before making regulations under section 2, a public consultation be carried out. The MHRA carried out 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 jointly by the Secretary of State and the Department of Health in Northern Ireland on a UK wide basis. The Scottish and Welsh 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 £9.8 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 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 The 2016 Regulations have provision for certain payment easements for small companies and payment waivers for small and medium sized businesses. The fee changes will not affect these easements/waivers, which continue to be available. More information on financial support offered to small and medium businesses can be found on the MHRA's website: https://www.gov.uk/government/publications/mhra-fees/payment-easements-and-waivers-for-small-and-medium-companies

13.3 No specific additional action is proposed to minimise regulatory burdens on small businesses.

13.4 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 medicines for human use 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".

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, Chief Finance Officer, at the MHRA can confirm that this Explanatory Memorandum meets the required standard.

15.3 Will Quince MP, Minister 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 where amending or revoking regulations etc. made under section 2(2) of the European Communities Act 1972

1.1 The Minister for Health and Secondary Care, Will Quince MP, and the Department of Health in Northern Ireland have made the following statement regarding regulations made under the European Communities Act 1972:

"In our opinion there are good reasons for The Medicines (Products for Human Use) (Fees) (Amendment) Regulations 2023 to amend the Medicines (Products for Human Use) (Fees) Regulations 2016. 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 2

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

Fee Name	Current Fee (£)	Revised Fee (£)
Inspection - Full day rate (Good Manufacturing Practice, Good Clinical Practice and Pharmacovigilance)	2,655	3,651
Inspection - Full day rate (Good Distribution Practice)	1,936	2,662
Inspection - Half day rate (Good Manufacturing Practice, Good Clinical Practice and Pharmacovigilance)	1,328	1,825
Inspection - Half day rate (Good Distribution Practice)	968	1,331
Inspection - Office based evaluation and risk assessments (Good Manufacturing Practice, Good Clinical Practice and Pharmacovigilance)	1,863	2,562
Inspection - Office based risk assessments (Wholesale distribution authorisations)	1,354	1,862
Inspection – Traditional Herbal Medicinal Product/Homeopathic only (Wholesale distribution authorisations)	1,367	1,880
Inspection - reduced rate Traditional Herbal Medicinal Product/Homeopathic only (Wholesale distribution authorisations)	744	1,023
Variation - Extended application group (National fee)	25,643	33,003

Variation - Single kind variation - Type IB (Falling under scope of Chapter II Commission Regulation 1234/2008)	277	344
Variation - Single kind variation - Type II (Falling under scope of Chapter II Commission Regulation 1234/2008)	277	344
Variation - Type IB National	277	344
Variation - Reclassification Type IB	277	344
Variation - Minor Variation (Type IB) Group Application (Falling under scope of Chapter II Commission Regulation 1234/2008)	277	344
Certified Annual Update of a Plasma Master File (PMF)	277	344
Variation - Major (Type II) Group Application (Falling under scope of Chapter II Commission Regulation 1234/2008)	496	1,255
Variation - Type II Standard National	734	1,308
Variation - Reclassification variation application (MA) (analogous product)	734	1,308
Certified Annual Update of a Plasma Master File (PMF) - significant changes to safety information	734	1,308
Parallel imports fees - standard application	6,663	8,722
Reclassification – Prescription Only Medicine to Pharmacy (Additional for MA or PI application)	11,992	33,003

Reclassification – Prescription Only Medicine to Pharmacy (variation application)	11,992	33,003
Safety and quality vetting of unlicensed imported medicines fees:		
Number of annual notifications: 101 - 1,000	2,077	2,400
Number of annual notifications: 1,001 - 5,000	10,383	12,000
Number of annual notifications: 5,001 - 20,000	25,957	30,000
Number of annual notifications: 20,001 - 50,000	51,914	60,000
Number of annual notifications: 50,001 - 100,000	103,828	120,000
Number of annual notifications: 100,001 +	155,742	200,000
The below six lines relate to Control Testing fees payable where the licensing authority carries out a paper-based assessment		
Band A – single component product, other than Botulinum toxin. requiring five or fewer in vitro tests	305	367

Band B – Factor VIII, Factor VIX or intravenous Immunoglobin	305	367
Band C – Multi-component product, or Botulinum toxin, requiring five or fewer in vitro tests	305	992
Band D – product requiring six to nine in vitro tests	677	992
Band E – product requiring (a) ten or more in vitro tests, or (b) one or more in vivo tests	677	1,849
Band F – one or more tests that must be carried out under containment measures applicable to hazard Group 3 or 4 biological agents under Control of Substances Hazardous to Health Regulations 2002 (123) or requires use of human tissues or cells as part of testing	677	1,849