EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AMENDMENT) REGULATIONS 2026

2026 No. [XXXX]

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of His Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments and the Secondary Legislation Scrutiny Committee.

2. Declaration

2.1 Baroness Merron, Parliamentary Under-Secretary of State (for Women's Health and Mental Health) at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 The Department of Health and Social Care can be contacted by email at the following address with any queries regarding the instrument: hmr.consultation@dhsc.gov.uk. Alternatively, the department can be contacted by telephone: 0300 790 4007.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 This instrument makes amendments to the Human Medicines Regulations 2012 ("HMRs") to (a) introduce permanent legislation where time-limited provisions made during the COVID-19 pandemic are due to lapse on 1 April 2026 and (b) expand the regulations relating to vaccine supply, distribution and administration to any vaccine against an infectious disease, instead of being limited to COVID-19 and influenza.

4.2 The legislation will support development of a vaccination system fit for the future, through supporting the safe supply, distribution and administration of a wider range of vaccines both now and in the future. The amendments will (a) increase flexibility in the movement, preparation and labelling of vaccinations in defined circumstances with appropriate safeguards; (b) increase flexibility in the vaccinator workforce; and (c) enable community pharmacies to deliver vaccinations off site.

Where does the legislation extend to, and apply?

4.3 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales, Scotland and Northern Ireland.

4.4 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England and Wales, Scotland and Northern Ireland.

4.5 Medicines regulation is a reserved matter (to the UK Parliament) in relation to Scotland and Wales. It is a transferred matter in Northern Ireland, which is why changes to the UK-wide HMRs, in so far as they affect Northern Ireland are made under the Medicines and Medical Devices Act 2021 jointly by the Secretary of State and the Department of Health in Northern Ireland.

5. Policy Context

What is being done and why?

5.1 In response to the COVID-19 pandemic, multiple temporary amendments were made in 2020 to the HMRs by two Statutory Instruments: the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125) and the Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594) to (a) provide greater flexibilities for the movement and supply of COVID-19 and influenza vaccines and (b) enable safe deployment of the COVID-19 and influenza vaccination programmes at scale and at pace.

5.2 To support the continuation of these vaccination programmes, regulations 3A, 19 and 247A of the HMRs were extended in 2022 and then again in 2024, following public consultation where the government agreed to develop a permanent solution for 2026. Temporary amendments to regulation 233 and schedule 17 were made permanent in 2022, following public consultation.

5.3 The overarching policy objective is to safeguard public health, in line with the power to make regulations under section 2(1) of the Medicines and Medical Devices Act 2021 (MMDA). This instrument will fulfil this objective through increasing access to vaccines to support uptake and increasing effectiveness in the vaccination system (workforce, supply chain and administrative) while maintaining important safety measures.

5.4 This instrument aims to create a vaccination system fit for the future, supporting delivery of ongoing national vaccination programmes and enabling the health system to rapidly respond to need, including in response to any potential future pandemic. Regulations 3A, 19 and 233 will be expanded in scope, and the new permanent legal mechanism replacing regulation 247A has been drafted, to include vaccinations against any infectious disease, where these are currently limited to COVID-19 and influenza. This will build on the lessons learned during the COVID-19 pandemic and the successful rollout of the COVID-19 and influenza vaccination programmes. The occupational health vaccinator provisions in Schedule 17 will be expanded in scope to cover any vaccinations supplied in the course of an occupational health scheme.

5.5 We assessed the proposed amendments in line with the relevant duties when making regulations under section 2 of the MMDA. We assess that the proposed amendments support the overarching policy objective of the HMRs (safeguarding public health) and that the benefits outweigh the risks, including in relation to the safety and availability of human medicines.

5.6 After clean water, vaccination is the most effective public health intervention in the world for saving lives and promoting good health. Creating a vaccination system fit for the future will contribute to delivery of the 10 Year Health Plan for England's shift from sickness to prevention. In line with the 10 Year Health Plan for England, this legislation will expand the role of community pharmacies in vaccine delivery and facilitate targeted outreach for vaccinations, helping to improve vaccine uptake.

What was the previous policy, how is this different?

Relating to preparation and labelling of vaccines

5.7 R3A of the HMRs contained two broad provisions, under paragraphs (1) and (2), that generally supported final acts of preparation and assembly of COVID-19 vaccines to be undertaken by and under supervision of doctors, nurses and pharmacists without

additional marketing authorisations or manufacturer's licences being required, and included a specific provision about product reformulation.

5.8 R3A (1) and (2), together with regulation 247A, ensured that there would be enough legal flexibility for NHS teams to work more flexibly, collaboratively and effectively through the mass vaccination centre model or, in England, the primary care network (PCN) grouping model while maintaining safety through robust governance structures. This has contributed to delivering significant operational benefits, improving access to COVID-19 vaccines and maximising vaccine uptake. The flexibility provided by R3A (1) and (2) has been similarly useful for vaccination programmes in devolved nations.

5.9 R3A (3) and (4) have permitted holders of wholesale dealer's licences, who do not hold manufacturer's licences, to label COVID-19 vaccines to reflect changes in shelf life resulting from product thawing (R3A (3)) and make provision in relation to the application of the packaging and package leaflet requirements to take account of these allowances (R3A (4)).

5.10 R3A (1) and (2) will be allowed to lapse on 1 April 2026, with R3A (3) and (4) being retained as permanent legislation with an expanded scope for any vaccine against an infectious disease.

5.11 The provisions under R3A (1) and (2) have provided the necessary flexibility to support the final stage preparation and assembly of vaccines in order to meet the demands and scale of the COVID-19 vaccination programme during the pandemic. Allowing R3A (1) and (2) to lapse reflects the fact that we are no longer operating in a pandemic scenario and have moved to a more targeted approach offering COVID-19 vaccination to those at greatest risk. Where necessary, any exceptional preparation or assembly will be satisfactorily covered by the amended regulation 3 and the existing regulation 4 of the HMRs. In the light of this expectation, we consider that the broad flexibilities in R3A (1) and (2) can be removed.

5.12 Retaining R3A (3) and (4) with an expanded scope will help future proof the regulations and support the UK to implement vaccine technologies which require ultra-low storage conditions in the supply chain.

Relating to movement of vaccines between sites

5.13 Regulation 19 ((4A) to (4D) (R19) currently allows COVID-19 and influenza vaccines to be moved between different NHS service provider organisations at the end of the supply chain by providers operating under NHS arrangements or the medical services of His Majesty's Armed Forces, without the need for a wholesale dealer's licence. This provision is set to lapse on 1 April 2026.

5.14 R19 has increased flexibility for vaccines to be moved swiftly and safely between sites in response to need without a wholesale dealer's licence, enabling more timely access to vaccinations. This has helped reduce health inequalities by enabling vaccinations to be delivered in areas of need. It has also helped to reduce vaccine wastage.

5.15 The HMRs provide the legal mechanisms for vaccine supply, deployment and administration. In amending R19, this instrument will introduce conditions requiring local and national decision makers to be content that exceptional circumstances have been met before the provision can be utilised. This will minimise misuse of the provisions and strengthen the governance and assurance processes associated with the movement of stock outside the regulated supply chain.

5.16 R19 will be retained as permanent legislation with appropriate preconditions and safeguards set out in legislation and an expanded scope to cover any vaccine against an infectious disease. This will enable the health system to ensure vaccines can be rapidly deployed in response to urgent public health needs, supporting development of a vaccination system fit for future requirements.

Relating to expanding the workforce for administering vaccines

5.17 Regulation 247A (R247A) currently enables the use of an extended workforce who are legally and safely able to administer COVID-19 or influenza vaccines without the input of a prescriber, using an approved protocol. This provision is set to lapse on 1 April 2026.

5.18 R247A has helped to ensure there is a sufficient workforce to deliver COVID-19 and influenza vaccines to a large number of people through the introduction of the national protocol model. This protocol enabled a wholly new vaccinator workforce of appropriately trained and competent individuals to undertake parts of the vaccination process, provided they met the specified conditions.

5.19 R247A will be allowed to lapse on 1 April 2026, with a new permanent legal mechanism (Regulation 235A, or R235A) being introduced by this instrument, which will support the use of an extended workforce to administer any vaccine against any infectious disease as directed by a national body as required by the legislation and approving a Vaccine Group Direction (VGD). R235A will ensure the UK has the necessary agile and flexible workforce to deliver a wider range of nationally commissioned vaccination programmes, including in the event of a future potential public health emergency requiring rapid vaccine deployment.

5.20 Appropriate safeguards will be in place in terms of the responsible parties for drafting and approving VGDs, and in the requirement for robust competency assessments, safeguarding training, and supervision requirements to further protect the clinical safety of everyone being vaccinated by the extended workforce.

Relating to community pharmacies delivering vaccines away from their registered premises

5.21 Regulation 233 (8) currently enables persons lawfully conducting a retail pharmacy business to deliver COVID-19 and influenza vaccination services off the registered premises under a patient group direction (PGD).

5.22 R233 (8) has enabled community pharmacies to deliver outreach services tailored to the needs of the populations they serve, increasing access to COVID-19 and influenza vaccines. The provisions enabled pop-up vaccination clinics to be set up closer to the community, particularly supporting groups where there were infection clusters or clusters of unvaccinated patients and helping to reduce health inequalities.

5.23 The provision of R233 (8) will be expanded to cover any vaccine against an infectious disease to enable community pharmacies to provide vaccinations off-site and support a wider range of national vaccination programmes.

5.24 Amending R233 (8) is supported by amendments to regulation 3 (R3) to include pharmacists so that they can continue to assemble and prepare vaccines when delivering off-site services, subject to the same conditions placed on doctors, dentists, nurses and midwives. As well as ensuring parity between pharmacies and other healthcare providers that can already provide any vaccination off-site, this change reflects the evolving clinical role of community pharmacists, with many now qualified as independent prescribers. It allows a pharmacist who is taking a treatment decision

to follow through on that decision if it requires acts of preparation and assembly that trigger the need for a statutory exemption, building specifically on the arrangements already in place for doctors, dentists, nurses and midwives.

Relating to vaccine administration by occupation health vaccinators

5.25 Schedule 17 (S17) currently enables occupational health vaccinators who are permitted under the written directions of a doctor to administer COVID-19 and influenza vaccines as part of an NHS or local authority occupational health scheme (OHS).

5.26 S17 has increased flexibility in delivering COVID-19 and influenza vaccines as part of an OHS through expanding the 'occupational health vaccinator' workforce. The provisions have helped improve reach and uptake of vaccines in the health and social care system, protecting healthcare staff in the vital roles they do.

5.27 Under the new policy reflected in the legislation, the definition of an ‘occupational health vaccinator’ in S17 will align with the list of professions set out in part 4 of schedule 16 (those who can supply medicines under a PGD, where this is limited to health care professionals) to provide a clear and consistent approach across the vaccination system. The scope of the relevant provisions in S17 is expanded to include private OHS providers, enabling them to use the ‘occupational health vaccinator’ role, expanding the workforce able to deliver vaccinations under a private OHS and providing parity with the NHS and local authority OHS. These provisions are also expanded to all vaccinations or immunisations covered under an OHS, as the ‘occupational health vaccinator’ role is currently limited to administering COVID-19 and influenza vaccines. These changes aim to improve occupational health vaccine access and uptake for staff within and beyond the health and social care sector.

6. Legislative and Legal Context

How has the law changed?

Context

6.1 The HMRs establish a comprehensive regime for the authorisation of medicinal products for human use, and for their manufacture, distribution, sale, supply, labelling, advertising, and for pharmacovigilance.

6.2 There are certain presumptions in the HMRs restricting dealings in medical products and in relation to the administration of medicines. These presumptions relate to the activities that can be undertaken in relation to medicinal products that require a licence. These activities include the assembly of the medicinal product and how it is distributed to healthcare providers; and a presumption that prescription only medicines, which are for parenteral administration (drugs given by routes other than the digestive tract), must be administered by specific registered health care professionals.

6.3 This instrument amends provisions that had been inserted into the HMRs during the course of the COVID-19 pandemic by two Statutory Instruments: the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125) and the Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), and introduces a new provision, for vaccine group directions, that reflects the landscape as it was introduced by the provisions introduced for the pandemic.

Regulations

6.4 Regulation 1 of this instrument sets out the commencement and extent of the Regulations.

6.5 Regulation 2 of this instrument sets out that the Instrument amends the HMRs.

6.6 Regulation 3 of this instrument amends regulation 3 of the HMRs. This will enable pharmacists, at any location, to prepare or assemble medicines for a patient without a manufacturer's licence, where it is the pharmacist who takes the treatment decision to supply the medicine. The existing arrangements for preparation or assembly by pharmacists in regulation 4 of the HMRs, generally at community pharmacies and hospitals, will continue to apply where someone other than the pharmacist takes the treatment decision to supply or administer the medicine. Regulation 15 of this instrument amends schedule 26 to the HMRs consequentially to specify the labelling requirements that would apply in this circumstance.

6.7 Regulation 4 of this instrument amends regulation 3A of the HMRs, which had been introduced by the Human Medicines (Coronavirus) (Further Amendments Regulations 2020 (S.I. 2020/1594), originally with a sunset of 1 April 2022, but subsequently extended to 1 April 2026. The effect of the amendment is to make regulation 3A a permanent provision that extends to all vaccines against infectious diseases. However, regulation 3A of the 2012 Regulations is now limited only to assembly by holders of a wholesale dealer's licences to take account of changes to shelf life and no longer applies to acts of preparation and assembly undertaken by or under the supervision of a doctor, nurse or pharmacist. Where such acts of preparation and assembly need to take place, existing exemptions under regulations 3 and 4 of the HMRs, as well as the new bespoke exemption for pharmacists included by regulation 3 of this instrument may be relied upon.

6.8 Regulation 5 and regulation 7 of this instrument insert new definitions consequential upon the changes made by this instrument.

6.9 Regulation 6 of this instrument amends regulation 19 of the HMRs so that it is a permanent provision that extends to all vaccines against infectious diseases. Regulation 19 of the HMRs provides for certain exemptions from the requirement to hold a wholesale dealer's licence, and paragraphs (4A) to (4F) of that regulation (which includes new paragraphs added by regulation 6) permit distribution of stocks of vaccinations between vaccination centres without the need for such a licence. Conditions are imposed to ensure the exceptional use of this exemption, which include that the situation must be such that there is an urgent public health need, there is no alternative medicine capable of meeting that need without undue delay, and there is no alternative route for the patient to receive the product without undue delay.

6.10 Subject to various exceptions in Part 12 of the HMRs, prescription only medicines and pharmacy medicines must be sold or supplied, by or under the supervision of a pharmacist, on premises that are a registered pharmacy. Regulation 233 of the 2012 Regulations provides that persons lawfully conducting a retail pharmacy business are exempted from this restriction if the supply or administration to the patient is in accordance with a PGD (amongst other conditions). However, prior to this instrument, supply or administration of medicines under a PGD medicines had to take place on site, with the exception of COVD 19 and influenza vaccinations. Regulation 8 of this instrument amends regulation 233 of the HMRs to extend the exemption to cover any vaccine against an infectious disease.

6.11 Regulation 9 of this instrument introduces a new regulation 235A in the HMRs, which exempt the supply or administration of certain vaccines from the requirements relating to the supply of medicines under regulations 214, 220 and 221, where the administration to the patient is in accordance with a vaccine group direction produced by a public health agency (as defined in the regulation) and subject to other pre-conditions as outlined in the regulation. Regulation 13 of this instrument makes consequential amendments to Schedule 16 to the HMRs.

6.12 Regulation 10 removes regulation 247A of the HMRs (as this is replaced by the above inserted regulation 235A of the HMRs). Regulations 11 and 12 of this instrument make consequential amendments as a result of the removal of regulation 247A and the insertion of the new regulation 235A in the HMRs.

6.13 Regulation 14 amends schedule 17 to the HMRs to enable occupational health vaccinators to administer any vaccine as part of an occupational health scheme (which is not restricted to a scheme operated by the NHS). The definition of an 'occupational health vaccinator' is amended by regulation 5 of this instrument (as mentioned above) to align with the classes of individuals set out in Part 4 of schedule 16 to the HMRs.

Why was this approach taken to change the law?

6.14 The previous amendments to the HMRs relating to COVID-19 and influenza which were time limited (regulations 3A, 19 and 247A) have already been extended twice and were due to lapse on 1 April 2026. The consultation response published in 2023 committed to agreeing a permanent solution ahead of the provisions lapsing to bring clarity and consistency to the vaccination system and vaccinator workforce. These provisions and the remainder (regulation 233 and schedule 17) were applicable only to vaccines for coronavirus and influenza. The scope will now be expanded to include a wider range of vaccinations.

7. Consultation

Summary of consultation outcome and methodology

7.1 The Department of Health and Social Care, in relation to England, Scotland and Wales, and the Department of Health in Northern Ireland issued a joint public consultation, "Proposal to amend the Human Medicines Regulations 2012 to support the ongoing supply and deployment of vaccinations across the UK", which was published on GOV.UK and ran for 12 weeks from 5 September to 28 November 2025. This consultation was necessary under the MMDA, and it sought views on amending regulations 3A, 19, 247A, 233 (8), 3 and schedule 17 of the HMRs.

7.2 A total of 218 responses were received, one of which raised points outside the scope of the proposals. Awareness was raised and participation in the consultation encouraged by the Department of Health and Social Care (DHSC) and Department of Health in NI (DoH NI). Each Department directly communicated with key stakeholder organisations. The consultation was also promoted in Wales by NHS Wales and the Welsh Government and in Scotland by Public Health Scotland and the Scottish Government to encourage responses from partners.

7.3 Overall, of the 217 responses received which addressed the specific proposals, most responses were supportive of the proposals outlined in the consultation. 61% of responses were received from individuals sharing their professional views. 34% of responses were received on behalf of organisations. 4% of responses were received from individuals sharing their personal views.

7.4 A breakdown of the responses on amendments to each regulation are included below.

7.5 Do you agree or disagree with the proposal to let the provisions under R3A (1) and (2) lapse from 1 April 2026? 47% of respondents agreed with this point, with 35% disagreeing, 11% neither agreeing nor disagreeing, and 7% stating that they did not know.

7.6 Do you agree or disagree with the proposal to retain the provisions under R3A (3) and (4) as permanent legislation? 72% of respondents agreed with this point, with 8% disagreeing, 12% neither agreeing nor disagreeing, and 7% stating that they did not know.

7.7 Do you agree or disagree with the proposal to expand the provisions under R3A (3) and (4) to all vaccine preventable diseases? 72% of respondents agreed with this point, with 13% disagreeing, 10% neither agreeing nor disagreeing, and 5% stating that they did not know.

7.8 Do you agree or disagree with the proposal to retain the provisions under R19 (4A) to (4C) as permanent legislation to support distribution when necessary? 76% of respondents agreed with this point, with 10% disagreeing, 10% neither agreeing nor disagreeing, and 5% stating that they did not know.

7.9 Do you agree or disagree with the proposal to expand the provisions under R19 (4A) to (4C) to all vaccine preventable diseases? 76% of respondents agreed with this point, with 12% disagreeing, 9% neither agreeing nor disagreeing, and 3% stating that they did not know.

7.10 Do you agree or disagree that the legislation should set out preconditions and safeguards to regulate the use of R19 (4A) to (4C)? 78% of respondents agreed with this point, with 4% disagreeing, 13% neither agreeing nor disagreeing, and 5% stating that they did not know.

7.11 Do you agree or disagree with the proposal to let R247A lapse from 1 April 2026? 59% of respondents agreed with this point, with 32% disagreeing, 6% neither agreeing nor disagreeing, and 3% stating that they did not know.

7.12 Do you agree or disagree with the proposal to introduce a new permanent provision from 1 April 2026 to support the use of an extended workforce to supply and administer COVID-19 and influenza vaccines, with the option for this provision to be used on other vaccination programmes commissioned by the NHS? 79% of respondents agreed with this point, with 16% disagreeing, 4% neither agreeing nor disagreeing, and 2% stating that they did not know.

7.13 Do you agree or disagree that an age condition should be included in the proposed provision which specifies that a VGD cannot be used to vaccinate those below a certain age (principally infants eligible to receive a vaccination as part of the routine childhood immunisation schedule)? 49% of respondents agreed with this point, with 32% disagreeing, 15% neither agreeing nor disagreeing, and 4% stating that they did not know.

7.14 Do you agree or disagree with the proposal to extend the provisions under R233 (8) to all other vaccine preventable diseases? 68% of respondents agreed with this point, with 17% disagreeing, 10% neither agreeing nor disagreeing, and 5% stating that they did not know.

7.15 Do you agree or disagree with the proposed amendment to regulation 3 to make provision for pharmacists and pharmacy technicians to prepare or assemble medicines for patients without a manufacturer's licence? 61% of respondents agreed with this

point, with 17% disagreeing, 14% neither agreeing nor disagreeing, and 9% stating that they did not know.

7.16 Do you agree or disagree with the proposal to expand the category of occupational health vaccinators in S17 to include a wider cohort of healthcare professionals in alignment with part 4 of schedule 16? 69% of respondents agreed with this point, with 11% disagreeing, 12% neither agreeing nor disagreeing, and 8% stating that they did not know.

7.17 Do you agree or disagree with the proposal to extend the relevant provisions under S17 to include private healthcare providers? 46% of respondents agreed with this point, with 23% disagreeing, 22% neither agreeing nor disagreeing, and 10% stating that they did not know.

7.18 Do you agree or disagree with the proposal to extend the provisions related to the category of occupational health vaccinators in S17 to cover all vaccinations or immunisations offered as part of an OHS? 60% of respondents agreed with this point, with 16% disagreeing, 15% neither agreeing nor disagreeing, and 9% stating that they did not know.

7.19 The consultation response document can be found on the following webpage: https://www.gov.uk/government/consultations/amend-regulations-to-support-the-supply-and-deployment-of-vaccines

7.20 Under Article 36(4) of the UK GDPR, the government is required to consult the Information Commissioner's Office (ICO) on any proposals for legislative or statutory measures they are developing which involve the processing of personal data. The government duly consulted the ICO on the development of this instrument.

8. Applicable Guidance

8.1 Resources, including guidance, is made available by NHS England, NHS Scotland, NHS Wales and by UKHSA. These materials will be updated as required to support the roll-out and distribution of vaccines against an infectious disease by the NHS in each nation, as appropriate. These resources deal with matters such as who can administer vaccines and training requirements. Links to current COVID-19 vaccination resources can be at the following links:

8.2 NHS England: https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/

8.3 NHS Scotland: https://www.nes.scot.nhs.uk/nes-current/covid-19-vaccination-programme/

8.4 Public Health Wales: https://phw.nhs.wales/topics/immunisation-and-vaccines/vaccines-professionals/

8.5 UKHSA National Minimum Standards and Core Curriculum for Vaccination Training: https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared for this instrument because the regulatory changes are expected to have low levels of impact on business and therefore a De Minimis Assessment (DMA) was carried out by the DHSC. This will

be published alongside the Explanatory Memorandum on the legislation.gov.uk website.

Impact on businesses, charities and voluntary bodies

9.2 There is minimal impact on business, charities or voluntary bodies.

9.3 The legislation does impact small or micro businesses through regulating vaccination services delivered by community pharmacies and private occupational health service (OHS) providers.

9.4 No specific action is proposed to minimise regulatory burdens on small businesses. The instrument does not mandate (a) community pharmacies to deliver off-site vaccination services or (b) the use of an extended vaccinator workforce by public or private OHS providers, therefore they do not have to adopt the practice of using them should they choose not to do so.

9.5 The impact on the public sector and to businesses is considered to be minimal. There may be direct costs to providers such as additional training costs, should they choose to exercise provisions enabled by the proposed changes to schedule 17. However, these costs are likely to be small and could be partially offset by the potential benefits of the proposed changes, hence net costs are expected to be below the £10m Equivalent Annual Net Direct Cost to Business threshold. The previous published 2023 IA, where the policy proposals were to temporarily extend the relevant regulations, stated that there are no direct impacts to business associated with the amendments to regulation 3A, 19 and 247. Making the regulations permanent and expanding is therefore unlikely to create any significant additional impacts to business over a £10m threshold.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 Section 46 of the MMDA requires the Secretary of State to lay a report before Parliament every two years on the operation of regulations of regulations made under section 2(1) (and other powers under the Act) with the next reporting period concluding in July 2027. Consequently, the instrument does not include a statutory review clause, and in line with the requirements of the Small Business, Enterprise and Employment Act 2015, the Parliamentary Under-Secretary of State for Women's Health and Mental Health has made the following statement:

"It is not appropriate in the circumstances to make provision for review in this instrument. This is because there is already a requirement in section 46 of the Medicines and Medical Devices Act 2021 to review the operation of these Regulations every 24 months".

10.2 Regulation 346 of the HMRs will also contain a review provision as a consequence of regulation 12 of this instrument

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 This instrument is made under powers in the MMDA. It amends the HMRs, which were made under section 2(2) of the European Communities Act 1972. This instrument is subject to the draft affirmative procedure.

11.2 Amendments to regulations 233 (8) and 3 will contribute to delivery on a commitment made to Parliament by the Rt Hon Wes Streeting, Secretary of State for Health and Social Care, on 3 July 2025: "Pharmacies will play an expanded role in the neighbourhood health service. They will […] screen for disease and vaccinate against it".[1]

12. European Convention on Human Rights

12.1 The Parliamentary Under-Secretary of State for Women's Health and Mental Health in the Department of Health and Social Care, has made the following statement regarding Human Rights:

"In my view the provisions of the Human Medicines (Amendment) Regulations 2026 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").

[1] HC Deb 3 July 2025, vol 770, col 444, NHS 10-Year Plan https://hansard.parliament.uk/Commons/2025-07-03/debates/DC09ACAA-D05F-4BE8-9517-16A2D53DA49E/NHS10-YearPlan#contribution-16E27489-FC11-4D80-9193-41F0338B950C