EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AMENDMENTS RELATING TO CORONAVIRUS AND INFLUENZA) (ENGLAND AND WALES AND SCOTLAND) REGULATIONS 2024

2024 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by 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 temporary provisions inserted into the Human Medicines Regulations 2012 (S.I. 2012/1916) ("the HMRs) by 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).

2.2 It does so in order to maintain certain provisions which were introduced in response to the COVID-19 pandemic. These provisions provide the flexibility for vaccine administration and support collaboration across the system. They also enable the use of an extended workforce who are legally and safely able to administer a COVID-19 or influenza vaccination.

2.3 Two of these provisions were time limited to 1 April 2024 and the other was conditional on a disease being a 'pandemic and serious risk to human health'. The purpose of this instrument is to maintain these regulations by extending these provisions to 1 April 2026 to support the continuing supply, distribution and administration of COVID-19 and influenza vaccines as we transition through the stages of the pandemic.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument is made under the Medicines and Medical Devices Act 2021 ("MMDA") (c.3). This instrument 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 and is being made under powers conferred by the MMDA.

4. Extent and Territorial Application

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

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

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State for Mental Health and Women's Health Strategy, Minister Maria Caulfield has made the following statement regarding Human Rights:

"In my view the provisions of the Human Medicines (Amendments Relating to Coronavirus and Influenza) (England and Wales and Scotland) Regulations 2024 are compatible with the Convention rights."

6. Legislative 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. Directive 2001/83/EEC and the tertiary directives on human medicines have all been transposed into UK law by the HMRs.

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 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 (SI 2020/1125) and the Human Medicines (Coronavirus) (Further Amendments Regulations 2020 (SI 2020/1594

6.4 These three provisions were put in place to enable COVID-19 and influenza vaccines to be safely deployed at speed and scale, and to ensure that there would be sufficient workforce to deliver the mass vaccination programme.

6.5 Two of these provisions are due to cease to have effect on 1 April 2024. These are i) the new Regulation 3A in the HMRS, which had been introduced by the Human Medicines (Coronavirus) (Further Amendments Regulations 2020 (SI 2020/1594); and ii) the amendment to Regulation 19 of the HMRs, which had been introduced by the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125).

6.6 The new Regulation 3A of the HMRs ensured that all professionally justified acts of preparation and assembly of a coronavirus vaccine may be undertaken by or under the supervision of a doctor, nurse, or pharmacist, at any location, without precipitating the need for a manufacturer's licence or marketing authorisation — provided those acts are done under NHS arrangements or arrangements as part of the medical services of His Majesty's Forces. It also allows for authorised medicinal products used for the reformulation of coronavirus vaccines (for example, diluents) to be re- assembled at the end of the medicines supply chain without the resultant products needing marketing authorisations in order to be supplied. Amongst other things, the amended Regulation 19 of the HMRs provided that wholesale dealer's licences are not required when sharing stocks of coronavirus vaccinations between vaccination centres.

6.7 The third provision is limited to circumstances in which a pandemic is occurring. It was inserted as new Regulation 247A of the HMRS, by the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125).

6.8 That new Regulation 247A exempted from the requirements relating to the supply of medicines under regulations 214, 220 and 221, the supply or administration of a medicinal product used for vaccination or immunisation against coronavirus or influenza virus which is made under a national protocol relating to such supply. This regulation removes the requirement, in respect of Great Britain, that the supply or administration shall be made whilst a disease is, or is in anticipation of being imminently, a pandemic and a serious risk or potentially serious risk to human health.

6.9 Regulation 1 of this Instrument sets out the commencement and extent of the Regulations.

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

6.11 Regulation 3 of this Instrument provides for the continuation for a further two years of Regulation 3A of the HMRs.

6.12 Regulation 4 of this Instrument provides for the continuation for a further two years of Regulation 19(4A) to (4C) of the HMRs.

6.13 Regulation 5 of this Instrument provides for the continuation for two years of Regulation 247A of the HMRs and removes the requirement for a pandemic to be imminent or to have materialised.

6.14 Those amendments to the HMRs in late 2020 were made using section 2(2) of the European Communities Act 1972. Subsequent amendments were made in 2022, extending those time limited provisions (and making a number of other provisions permanent) under the MMDA.

6.15 The MMDA provides enabling powers to make provisions amending or supplementing the "law relating to human medicines", which includes the HMRs.

7. Policy background

What is being done and why?

7.1 The purpose of this instrument is to maintain certain provisions introduced in response to the COVID-19 pandemic by amending the limited period in which they can be used. This will support the continuing supply, distribution and administration of COVID-19 and influenza vaccines as we transition through the stages of the pandemic, by ensuring that flexibilities that are due to lapse in April 2024, or that are conditional upon being in a pandemic can be used until April 2026. These provisions in the HMRs were initially introduced in 2020 to support the successful rollout of safe and effective COVID-19 and influenza vaccinations, to protect public health, by allowing mass vaccination to take place at pace, whilst also safeguarding the NHS.

7.2 This was achieved by introducing: a new Regulation 3A of the HMRs, to allow the labelling of COVID-19 vaccines with a new shelf life after thawing, and allowed delegated preparation or reconstitution by the addition of the recommended diluent, without the need for a manufacturer's licence or marketing authorisations; an amended Regulation 19 to enable safe and appropriate vaccine movement between vaccination providers without the need for a wholesale dealer's licence; and R247A to provide the mechanism that expanded the workforce who are legally and safely

able to administer a COVID-19 or influenza vaccine, using an approved protocol. Through the introduction of a new type of national protocol, new Regulation 247A of the HMRs allowed non-registered healthcare workers and those who are registered healthcare professionals who cannot ordinarily administer medicines or vaccines to safely administer a COVID-19 or influenza vaccine under the supervision of a registered healthcare worker.

7.3 Regulation 5 of this Instrument amends Regulation 247A of the HMRs by removing the requirement, in respect of Great Britain, that the supply or administration shall be made whilst a disease is, or is in anticipation of being imminently, a pandemic and a serious risk or potentially serious risk to human health; and, to insert a sunset clause in respect of regulation 247A, which will mean that the regulation ceases to have effect on 1st April 2026. It is not clear when COVID-19 might cease to be considered a pandemic, and this uncertainty causes a significant risk for the NHS across the nations regarding appropriate workforce planning for future COVID-19 and influenza vaccine programmes. Without the continuation of the policy that Regulation 5 delivers, there would be a significant impact on the availability of an appropriate workforce to deliver vaccines because the extended workforce would no longer be legally allowed to administer COVID-19 and influenza vaccinations. This would increase the pressures on other service delivery areas because the registered workforce would be required to focus more of their time administering vaccines, resulting in a lower capacity to provide other health care for patients.

7.4 The Regulations 3A and 19 amendments of the HMRs were temporary provisions. Those provisions originally ceased to have effect on 1 April 2022. However, this was extended to 1 April 2024 following a public consultation in 2021. Regulation 3 of this Instrument amends Regulation 3A of the HMRs, and regulation 4 amends Regulation 19, by extending the provisions to 1 April 2026 so they can continue to support the delivery of COVID-19 and influenza vaccinations, in a safe and effective way.

7.5 Vaccines remain the first line of defence for those at greatest risk from the COVID-19 virus and for the prevention of seasonal influenza. The overarching policy objective is to enable the continued deployment of safe and effective COVID-19 and influenza vaccines to the pace and scale required both now and, in the future, while maintaining public safety. If we were unable to utilise these regulations, this would affect the pace and scale of COVID-19 and influenza vaccine programmes, and this is likely to negatively impact on provision and uptake of these vaccinations.

Explanations

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

7.6 The HMRs were amended by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 to provide greater flexibilities for the movement and supply of certain type of vaccines, in light of the COVID-19 pandemic. Regulation 247A was introduced to expand the workforce capable of administering the COVID-19 and influenza vaccinations. The amendments specified that the use of Regulation 247A is conditional on a disease being considered a 'pandemic and a serious risk to human health'.

7.7 The HMRs amendments also included Regulation 3A and 19. Regulations 3A and 19 (4A) to (4C) provided greater flexibilities in the operational delivery and preparation of COVID-19 and influenza vaccines (as outlined in 7.3 and 7.4 above). These

amendments were brought in as temporary measures and will cease to have effect on 1 April 2024.

Why is it being changed?

7.8 The provisions brought in under the 2020 Regulations are being amended by this instrument because, currently, Regulation 3A and 19 have sunset provisions that mean they would cease to be effective on 1 April 2024, and Regulation 247A can only be used when a disease is considered a pandemic. To allow the continued use of these amendments after 1 April 2024, and when COVID-19 is no longer considered a pandemic and serious risk to human health, this instrument is being introduced, as otherwise it could lapse, and the provisions provided for under these amendments could no longer be utilised to support in the delivery of COVID-19 and influenza vaccination programmes.

7.9 Without these provisions there would be a significant impact on the availability of the appropriate workforce to deliver the vaccine programmes, as it would reduce the amount of healthcare staff who are legally allowed to administer a COVID-19 or influenza vaccine. This would potentially mean that not all people entitled to a vaccination would be able to receive them, resulting in increased hospitalisations, morbidity, and mortality. This instrument will help to vaccinate more people, keeping a greater number of people from falling seriously ill from COVID-19 and/or influenza, helping to prevent NHS services from being overwhelmed and keeping the population safe. The amendments also allow staff to work more flexibly; if a wider cohort of the workforce can vaccinate patients, the registered healthcare workers are freed up to support in other areas, meaning vaccination programmes are less of a burden on other health service areas.

What will it now do?

7.10 These Regulations will do the following:

7.10.1 **Regulation 3 of this instrument will allow the final stage of preparation of COVID-19 vaccine before administration to patients to be carried out by qualified healthcare professionals without the need for additional manufacturing licences or marketing authorisations until 1 April 2026.** This is a temporary extension of Regulation 3A (preparation and assembly of medicinal products used for vaccination or immunisation against COVID-19 or in the reformulation of such products) for a further two years. Licensing and marketing authorisations are important parts of the medicine's regulation regime. However, to deliver mass influenza and COVID-19 vaccination programmes, an increased workforce is required. The continued requirement for the vaccines to protect the population as we transition through the stages of the pandemic continues to provide sufficient justification for this requirement to be set aside at the present time, but maintaining the safeguard that only qualified healthcare professionals undertake the final preparatory work. The professionals who are preparing the vaccines under these arrangements are working within their core competencies. In terms of benefit, this easement has meant that NHS professional staff are not having to spend their time applying for licences for each and every centre but can use their full capacity for vaccine delivery to patients. At this point in time, we therefore are of the view that the benefits substantially outweigh the risks, but this should be further reviewed in two years given the likelihood of different vaccines with different requirements becoming available in that time.

7.10.2 **Regulation 4 of this instrument will allow the sharing of COVID-19 stocks between vaccination centres without the need for additional wholesaler dealer's licences until 1 April 2026.** This is a temporary extension of Regulation 19(4A) to (4C) of the HMRs for a further two years. As with the previous provision, licensing arrangements are important parts of the medicines regulation regime to assure patient safety. The exceptional circumstances of the pandemic, including the need to make best possible use of available vaccine and minimise the risk of wastage, continue to provide sufficient justification for this requirement to be set aside at the present time. In terms of benefit, this easement has enabled, for example, local providers to access additional stock so they can use their full capacity to deliver vaccinations. At this point in time, we therefore are of the view that the benefits continue to substantially outweigh the risks, but this should be further reviewed in two years given the likelihood of different vaccines with different requirements becoming available in that time.

7.10.3 **Regulation 5 of this instrument amends Regulation 247A which will allow the current workforce administering COVID-19 and influenza vaccines under an approved national protocol to continue to do so to provide sufficient workforce as we transition through the stages of the pandemic.** This will be time-limited, to 1 April 2026, in recognition that this mechanism may not be the most appropriate model for the ongoing use of an expanded workforce outside of pandemic response.

7.11 The instrument will prevent Regulations 3A and 19(4A) to (4C) of the HMRs from lapsing on 1 April 2024 and allow Regulation 247A to be used beyond COVID-19 being considered a pandemic. Aside from the time extension and the removal of Condition A in regulation 247A, the HMRs will change in no way. The instrument is instead introduced to prevent the consequences of not having these amendments to the HMRs in place and preventing significant disruption to the delivery of the vaccine programme and increasing the pressure on the NHS workforce.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to the withdrawal from the European Union, nor does it relate to implementation of the Future Relationship Agreement.

9. Consolidation

9.1 This instrument makes amendments to the HMRs. There are no plans to consolidate the legislation this instrument amends.

10. Consultation outcome

10.1 The Department of Health and Social Care (on behalf of England, Scotland and Wales) and the Department of Health in Northern Ireland hosted a joint public consultation on GOV.UK, which ran for six weeks between 7 August and 18 September 2023. The consultation sought views on whether the flexibilities set out in this Instrument should be extended and time-limited until April 2026 and whether Condition A should be removed from Regulation 247A of the HMRs, and time-limited until April 2026.

10.2 Prior to public consultation, there was regular engagement with the Devolved Administrations to ensure that the consultation reflected the context and requirements of all four nations.

10.3 The consultation received a total of 220 responses, including from individuals, NHS and health service delivery bodies, and private and not-for-profit organisations. The majority of responses received were supportive of the proposals, with each amendment supported by at least 80% of respondents. Respondents largely considered all three regulations to provide safe and effective frameworks for improving the delivery of COVID-19 and influenza vaccines. Many respondents told us that the regulations had led to significant improvements in the operational delivery of COVID-19 and influenza vaccines, allowing increased flexibility and collaboration across the system, to enable a more efficient use of resources and to allow vaccines to be deployed at speed and scale.

10.4 On R247A of the HMRs, respondents noted how the amendments had helped to reduce workforce pressures, increasing flexibility within the workforce, and allowing for greater opportunities for career development. A small number of respondents highlighted the need to ensure that adequate training, supervision, and governance structures are in place in all instances where the regulations are being used, particularly for R247A. See section 11 below for information on training, supervision and governance requirements relating to the use of R247A.

10.5 Several respondents were in favour of the regulations being extended indefinitely, while a larger number expressed support for the development of a separate long-term solution to ensure current flexibilities are extended beyond the proposed revised end-date of 1 April 2026. A small number of respondents believed the regulations were no longer necessary and that previous processes provided additional safeguards.

10.6 The consultation and consultation response were carried out on behalf of England, Scotland Wales and jointly with the Department of Health in Northern Ireland. The Devolved Administrations in Scotland and Wales have also been engaged throughout the development of the proposals, consultation response and resulting regulations. The government response to the consultation can be found here: Supporting the delivery of COVID-19 and influenza vaccination - GOV.UK (www.gov.uk)[1]

11. Guidance

11.1 Resources, including guidance, have been made available by NHS England (see the following link) » COVID-19 vaccination programme (england.nhs.uk)[2] , NHS Scotland » Immunisation – COVID-19 vaccination programme[3] , NHS Wales » Vaccine resources for health and social care professionals[4], and by UKHSA »Training Recommendations for COVID-19 vaccinators.[5] These materials will be updated as required to support the roll-out and distribution of COVID-19 vaccines and treatments, and influenza vaccine, by the NHS in each country, as appropriate. These resources deal with matters such as who can administer vaccines and training requirements.

[1] https://www.gov.uk/government/consultations/supporting-the-delivery-of-covid-19-and-influenza-vaccination
[2] https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/
[3] https://learn.nes.nhs.scot/37676/immunisation/covid-19-vaccines
[4] https://phw.nhs.wales/topics/immunisation-and-vaccines/vaccine-resources-for-health-and-social-care-professionals/
[5] https://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators

12. Impact

12.1 There is no, or no significant, impact on business, charities, or voluntary bodies.

12.2 There will be an impact on the public sector as the instrument will continue to facilitate the workforce legally allowed to administer influenza and COVID-19 vaccines under NHS and local authority occupational health schemes for a further two years.

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

12.4 The impact on public health will occur if the instrument is not implemented. Without the regulations being extended until 1 April 2026, and the removal of Condition A for R247A, the Impact Assessment modelled that there would be a 50% reduction in staff capacity, leading to a reduction in administered COVID-19 and Influenza doses. The extension of the regulations prevents this from happening and ensures £1,230m of health benefits are realised between 2024 and 2026. The impacts of this instrument are the standard health benefits of vaccination, from averted mortality and morbidity, which accrue to the vaccinated individual and savings to the NHS from preventing hospitalisations.

13. Regulating small business

13.1 The legislation does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

14.1 Certain provisions of the HMRs are subject to regular review by the Secretary of State. This includes regulation 247A. In addition, section 46 of the MMDA requires the Secretary of State to lay a report before Parliament every two years on the operation of regulations made under section 15 (and other powers under the Act) with the next reporting period concluding in July 2025.

14.2 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 Minister Maria Caulfield 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".

15. Contact

15.1 Rebecca Smith at the DHSC email: Rebecca.Smith@dhsc.gov.uk can be contacted with any queries regarding the instrument.

15.2 Helen Beazer Deputy Director for Health Protection Strategy and Vaccines Directorate at the DHSC can confirm that this Explanatory Memorandum meets the required standard.

15.3 Minister Caulfield, Parliamentary Under Secretary of State for Mental Health and Women's Health Strategy at the DHSC can confirm that this Explanatory Memorandum meets the required standard.