EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (CORONAVIRUS AND INFLUENZA) (AMENDMENT) REGULATIONS 2022

2022 No. 350

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 Her Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments and for the Northern Ireland Assembly (and its Health Committee), which must debate and agree the Statutory Instrument before it is made.

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 (SI 2020/1125) and the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1594). The amendments in late 2020 were made to address a number of challenges that emerged in the early stages of the mass vaccination campaign against COVID-19. The changes made at that time were time limited so that they cease to have effect on 1 April 2022. See Section 7.1 below.

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 & Medical Devices Act 2021 ("the MMDA") (c. 3). 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 and is being made under powers conferred after 21 June 2017. The procedural and publication requirements of paragraphs 13 and 14 of Schedule 8 to the European Union (Withdrawal) Act 2018 therefore do not apply. The statement required by paragraph 15 of Schedule 8 to that Act is set out in the Annex to this memorandum.

Matters of special interest to the Northern Ireland Assembly

3.2 Section 2(6)(b)(ii) of the MMDA provides that in relation to the Northern Ireland, regulations under section 2 can be made by the Department of Health in Northern Ireland and the Secretary of State acting jointly. Section 47(6)(c) of the MMDA provides that in the case of regulations being made jointly, the Regulations must be laid before and approved by a resolution of each House of Parliament, and the Northern Ireland Assembly.

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 Parliamentary Under Secretary of State at the Department of Health and Social Care, Lord Syed Kamall, has made the following statement regarding Human Rights:

"In my view the provisions of the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022 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 and advertising – and for pharmacovigilance. Directive 2001/83/EEC and the tertiary directives on human medicines have all been transposed into UK law by the Human Medicines Regulations 2012.

6.2 There are also general presumptions in the HMRs restricting the supply of prescription only medicines. The relevant provisions restrict both who can prescribe or administer prescription only medicines and the locations where they can be supplied. However, there is a range of exceptions – in Part 12 of the HMRs and the related Schedules – which include the ability to supply under Patient Group Directions ('PGDs').

6.3 This instrument amends certain provisions inserted into 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) which are due to cease to have effect on 1st April 2022.

6.4 Those amendments in late 2020 were made relying on section 2(2) of the European Communities Act 1972. The MMDA now provides enabling powers to make provisions amending or supplementing the "law relating to human medicines", which includes the HMRs. The MMDA was put in place as part of the UK's exit from the European Union.

7. Policy background

What is being done and why?

7.1 The provisions in the 2012 Regulations which are amended by this instrument are presently due to cease to have effect on 1 April 2022. The primary purpose of the policy reflected in the amendments from late 2020 is to support the successful roll-out of safe and effective COVID-19 and influenza vaccines, in order to protect public health. The provisions enable mass vaccination against both influenza and coronavirus to be carried out at pace whilst safeguarding patients and limiting disruption to other NHS services. This SI makes permanent changes about what medicines a range of registered healthcare professionals can administer to NHS and Local Authority staff through occupational health schemes. They extend to 1 April 2024 the ability for influenza and coronavirus vaccine stocks to be shared between locations without the need for a wholesale dealer's licence to be in place and for the final stages of coronavirus vaccine preparation to be completed without the need for additional marketing authorisations or manufacturers licences to be in place.

7.2 The COVID-19 pandemic to date has had substantial direct and indirect health impacts on the entire UK population, including over 12.3 million confirmed cases and

more than 148,000 deaths within 28 days of a positive COVID-19 test up to 28 December 2021. The economic impacts have been vast globally and domestically, with large increases to the unemployment rate, and government borrowing in the UK continuing to rise to the highest cash deficit on record[1]. While non-pharmaceutical interventions (NPIs) reduce exposure and spread of COVID-19, effective and timely vaccines have been shown to be an integral part of addressing the pandemic.

7.3 Effective vaccines have been proven to be the first and best line of defence against the COVID-19 pandemic and for the prevention of seasonal influenza. In the case of COVID-19, vaccines have helped to minimise the harmful impacts of the disease on the nation's health and economy. At the outset of the COVID-19 pandemic, the government needed to ensure that appropriate processes and measures were in place to ensure vaccines could be brought to the market and deployed as quickly as possible to ensure the direct impacts of COVID-19 on mortality and morbidity, as well as indirect impacts on health, society and the economy were minimised as far as possible. The amendments to the HMRs in 2020 added flexibility to some of the governance around vaccine supply to patients as part of the response to the COVID-19 pandemic. Due to the considerable expansion of the annual influenza vaccination programme as part of the COVID-19 pandemic response, the amendments which had the effect of increasing the vaccinator workforce were applied to the influenza vaccine as well.

7.4 All of the population aged 12+ have now been offered 2 doses of a COVID-19 vaccine, and all 18+ have been offered a third booster dose. Severely immunosuppressed individuals have also been offered a fourth dose. The UK Health Security Agency (UKHSA) has estimated that at least 230,000 hospitalisations and 120,000 deaths have been prevented by having an efficient vaccination programme for COVID-19. It is anticipated that further mass campaigns may be needed.

7.5 Seasonal influenza and COVID-19 viruses have the potential to add substantially to the winter pressures usually faced by the NHS, particularly if infection waves from both viruses coincide. The timing and magnitude of potential influenza and COVID-19 infection waves for winter 2022 to 2023 are currently unknown.

Explanations

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

7.6 Before the changes made by this instrument, the changes were in place by virtue of the Human Medicines (Coronavirus and Influenzas) (Amendment) Regulations 2020 (S.I. 2020/1125) and the Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594) but would cease to have effect on 1st April 2022.

Why is it being changed?

7.7 If left unamended, the provisions will cease to have effect on 1st April 2022 which will mean mass vaccination campaigns for COVID-19 and influenza will not be able to continue on the same basis. We have therefore considered whether each provision should be made permanent or continued on a further temporary basis.

What will it now do?

7.8 These Regulations allow:

[1] https://obr.uk/coronavirus-analysis/

7.8.1 **The final stage of preparation of coronavirus vaccine before administration to patients to be carried out by qualified healthcare professionals without the need for manufacturing licences or marketing authorisations until 1 April 2024.** This is a temporary extension of regulation 3A (preparation and assembly of medicinal products used for vaccination or immunisation against coronavirus or in the reformulation of such products) of the HMRs for a further two years. Licensing and marketing authorisations are important parts of the medicines regulation regime. The exceptional circumstances of the pandemic, and the particular requirements for the vaccines in use at this time, continue to provide sufficient justification for this requirement to be set aside at the present time, but maintaining the safeguard of only qualified healthcare professionals undertaking 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 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.

7.8.2 **Sharing of coronavirus stocks between vaccination centres without the need for wholesaler dealer licences until 1 April 2024.** This is a temporary extension of this provision 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 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.

7.8.3 **All registered healthcare professional groups who can supply or administer medicines under a patient group direction (PGD) can administer a parenteral medicine, including a vaccine, under a PGD in a service commissioned by the NHS or local authority.** Regulation 229 (exemption for supply by national health service bodies and local authorities) of the HMR, permits medicines to be supplied for the purposes of administration without a prescription under a PGD provided administration is in accordance with a written direction. This was amended in 2020, to provide that medicines that require parenteral administration can be supplied under a PGD when written directions by an appropriate practitioner in relation to that product are followed.

7.8.4 This instrument makes that change permanent. Without this flexibility there would be significantly fewer professionals able to administer vaccines leading to vaccine wastage, slower pace of administration of vaccines and potentially

greater pressure on the smaller pool of staff. We are not aware of any safety concerns arising from a year of operation of these provisions.

7.8.5 **Community pharmacists to deliver influenza and coronavirus vaccination services outside their normal registered premises, e.g. in school halls and hotels.** This provision is to be made permanent. The ability of community pharmacists to deliver influenza and coronavirus vaccination services in locations convenient to local communities has been a cornerstone of the vaccination campaign, enabling much easier access to vaccination services for patients, and contributing to a significantly higher influenza vaccination rate than is normally seen. Engagement with NHS stakeholders has been very positive about retaining the ability to deliver vaccination services from different premises on a permanent basis. It remains the case that this is an enabling provision only, and community pharmacists are not required to provide services in this way. NHS England sought expressions of interest to provide the service and by the end of September 2021 the pharmacist representative body, the Pharmaceutical Services Negotiating Committee, were reporting that 600 community pharmacy-run sites were offering vaccinations, 128 in Wales and 280 pharmacies in Northern Ireland are currently offering COVID-19 vaccinations. In Scotland, there are 14 pharmacies that supplied the COVID-19 vaccine and over 400 pharmacies that were set up to support influenza vaccination in 2021/22.

7.8.6 **Registered nurses, registered midwives, registered nursing associates (England only), operating department practitioners, paramedics, physiotherapists registered in Part 13, 8 or 9 of the Health and Care Professions Council register and pharmacists to be classed as "occupational health vaccinators" and may administer influenza and coronavirus vaccines under occupational health schemes operated by the NHS or a local authority.** This provision is to be made permanent. Influenza and coronavirus vaccinations for health and care workers are often administered through occupational health schemes, and, prior to the 2020 temporary changes, the only people authorised to administer injectable prescription-only medicines as part of an occupational health scheme were doctors and nurses acting under written instruction of a doctor. This extension to certain other healthcare professionals provides vital flexibility for healthcare and local authority organisations delivering influenza and coronavirus vaccination campaigns to staff in addition to normal workloads. We are not aware of any safety concerns arising from a year of operation of these provisions.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union/trigger the statement requirements under the European Union (Withdrawal) Act 2018.

9. Consolidation

9.1 This instrument makes amendments to the HMRs. This instrument will not seek to consolidate that instrument.

10. Consultation outcome

10.1 Prior to these changes first being made in late 2020, the government ran a public and targeted consultation from 28 August to 18 September. The consultation received 188,036 consultation responses, from a range of stakeholders including individual members of the public, NHS and health service delivery bodies, organisations representing health care professionals, pharmaceutical companies and patient groups. There has been initial informal consultation with stakeholder groups on the provisions in these regulations which indicated that those provisions had been extremely useful and had been used safely and effectively. Stakeholders indicated support for making the workforce provisions permanent and temporarily extending the provisions affecting the possession of licences in the NHS for stock sharing and final preparation.

10.2 The MMDA requires that, before making regulations under section 2, a public consultation be carried out. As part of the development of the proposals being given effect to by this instrument, a UK wide public consultation was held from 8 December to 29 December 2021. The proposals received wide support from NHS bodies and staff who submitted supporting evidence. A large number of the general public who responded shared views and comments which did not directly relate to the specific questions being asked, nor did they include any supportive evidence to back up any points they made. The Government response to the consultation can be found here:- https://www.gov.uk/government/consultations/review-of-temporary-provisions-in-the-human-medicines-regulations-2012-to-support-influenza-and-covid-19-vaccination-campaigns/outcome/review-of-temporary-provisions-in-the-human-medicines-regulations-2012-to-support-influenza-and-covid-19-vaccination-campaigns-consultation-response

11. Guidance

11.1 Resources, including guidance on the operation of these provisions, have been made available by NHS England (see the following link) https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/ and will continue to 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. For Northern Ireland, the information is at https://www.publichealth.hscni.net/covid-19-coronavirus/northern-ireland-covid-19-vaccination-programme/professional-information for Scotland at https://learn.nes.nhs.scot/12751/immunisation and for Wales at https://phw.nhs.wales/topics/immunisation-and-vaccines/covid-19-vaccination-information/resources-for-health-and-social-care-professionals/. These resources deal with matters such as who is able to administer vaccines and training requirements.

12. Impact

12.1 The impact on business, charities or voluntary bodies can be considered insignificant.

12.2 There will be an impact on the public sector as the instrument will facilitate the expansion of the workforce legally allowed to administer influenza and coronavirus vaccines under NHS and local authority occupational health schemes. Additional healthcare professionals in the occupational health workforce will therefore be able to administer influenza and coronavirus vaccines.

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 This instrument does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

14.1 The Human Medicines Regulations 2012 are subject to a regular review by the Secretary of State.

15. Contact

15.1 Claire Potter at the Department of Health & Social Care Telephone: 0113 254 5975 or email: claire.potter@dhsc.gov.uk can be contacted with any queries regarding the instrument.

15.2 Kathryn Glover and Helen Lovell, Deputy Directors for Medicines Regulation & Policy, at the Department of Health & Social Care can confirm that this explanatory memorandum meets the required standard.

15.3 Lord Kamall at the Department of Health & Social Care can confirm that this explanatory memorandum meets the required standard.

Annex

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 2018 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 s. 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 1972.	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 s. 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 1972.	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA 1972, 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.