

**From the Chief Medical Officer
Professor Sir Michael McBride**



Department of
Health

An Roinn Sláinte

Mánnystrie O Poustie

www.health-ni.gov.uk

HSS(MD) 16/2026

FOR ACTION

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Our Ref: HSS(MD) 16/2026

Date: 1 April 2026

Dear Colleague

**SUPPORTING THE ONGOING SUPPLY AND DEPLOYMENT OF VACCINATIONS
ACROSS THE UK – HUMAN MEDICINES (AMENDMENT) REGULATIONS 2026**

In response to the COVID-19 pandemic, multiple regulations were put in place to enable the rollout of the COVID-19 and influenza vaccination programmes and to ensure there was a sufficient vaccination workforce to administer them. These regulations were made by making amendments to the [Human Medicines Regulations 2012](#) (HMRs) through the:

- [Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020](#)
- [Human Medicines \(Coronavirus\) \(Further Amendments\) Regulations 2020](#)

Following a joint UK-wide consultation, the Department has put in place further amendments to the HMRs to support the ongoing supply and deployment of vaccinations across the UK. These proposals build upon the successes of vaccination programmes during the pandemic, with the intention of developing a vaccination system that is fit for the future. The remit of the regulations that were consulted on is summarised below:

- [Regulation 3A](#) (R3A) enables trained healthcare professionals or staff under the supervision of trained healthcare professionals to conduct the final stage of assembly, preparation and labelling of COVID-19 vaccines without additional marketing authorisations or a manufacturer's licence being required. R3A has enabled NHS teams across the UK to work more flexibly, collaboratively and effectively through the mass vaccination centre model while maintaining safety through robust governance structures. This has contributed to delivering significant operational efficiencies.

- [Regulation 19 \(4A\) to \(4D\)](#) (R19) has allowed COVID-19 and influenza vaccines to be moved between different NHS service providers 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. R19 has increased flexibility for vaccines to be moved swiftly and safely between sites in response to need without a wholesale dealer's licence, helping to reduce vaccine wastage and enabling more timely access to vaccinations. **Please note that from 1st April 2026 new requirements must be met before the provisions in R19 can be utilised. Please see below for further information.**
- [Regulation 247A](#) (R247A) 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. R247A has helped to ensure there is a sufficient workforce to deliver COVID-19 and influenza vaccines to a large number of people.
- [Regulation 233 \(8\)](#) (R233) 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). 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.
- [Regulation 3](#) enables doctors, dentists, nurses and midwives to be able to prepare or assemble medicines for a patient in the course of their treatment without a manufacturer's licence.
- [Schedule 17](#) (S17) enables occupational health vaccinators who are permitted, as part of an occupational health scheme (OHS) under the written directions of a doctor, to administer COVID-19 and influenza vaccines as part of an NHS or local authority OHS. 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 in R3A, R19 and R247A proved vital to the success of the COVID-19 and influenza vaccination programmes during the COVID-19 pandemic and enabled the continued safe and effective deployment of vaccines across the UK to help safeguard public health. R3A, R19 and R247A are time limited provisions which are due to lapse on 1 April 2026 and so there is a need to agree the future of these provisions beyond this date. R233, regulation 3 and S17 are permanent provisions, but making the proposed amendments is intended to improve the vaccination system and ensure the legislation is able to support ongoing programme delivery.

Information on the new legislative amendments

The Human Medicines (Amendment) Regulations 2026 were made on 26th March 2026 and came into operation on 31 March 2026 making further amendments to the 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 flu.

This legislation aims to support the 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 by making amendments to the HMRS:

- allowing R3A (1) and (2) to lapse to reflect our shift from a pandemic scenario to a more targeted approach to recent COVID-19 vaccination campaigns;
- retaining R3A (3) and (4) and R19 as permanent legislation to maintain flexibilities in the labelling and movement of vaccines in defined circumstances with appropriate safeguards in place. **These safeguards set out several conditions which must be met, including requirements that vaccine providers notify the relevant body (in NI, the Public Health Agency) and that the relevant body is satisfied that the movement of vaccines is considered necessary to address an urgent public health need which cannot be met by alternative routes. The PHA will provide further detail to providers as to the relevant conditions which must be met;**
- replacing R247A with R235A, setting out a new permanent provision known as Vaccine Group Directions (VGDs) to help increase the workforce capacity to deliver vaccines at scale and pace;
- expanding the scope of provisions in R3A, R19, R233 and the new provision replacing R247A (VGDs) to include any vaccine against an infectious disease caused by a virus or bacteria, providing flexibility for a wider range of vaccination programmes;
- amending R233 and regulation 3 to increase flexibility for community pharmacies to deliver vaccination services outside registered premises. This will enable community pharmacies to deliver targeted outreach, improving access to vaccines and helping reduce health inequalities;
- expanding the relevant provisions in S17 to cover all vaccinations or immunisations offered as part of an OHS to help improve vaccine access for eligible staff, ensuring better protected workforces in delivering the vital roles they do, within and beyond the health and social care sectors;
- aligning the list of professionals who can administer vaccines under an NHS or local authority OHS in S17 with those who can supply medicines under a PGD (part 4 of schedule 16) to provide clarity and consistency; and
- expanding the scope of the relevant provisions in S17 to include private OHS providers, enabling them to use the 'occupational health vaccinator' role and providing parity with the NHS and local authority OHS

The overarching policy objective is to ensure that lessons learned will be used to increase effectiveness within the system and help protect public health and patient safety in accordance with section 2 (2) of the [Medicines and Medical Devices Act 2021](#).

Further information

Further information can be accessed on the legislation.gov.uk website with the following link: [The Human Medicines \(Amendment\) Regulations 2026](#).

Information for healthcare professionals about the implications of these amendments can be found on the [NHS Specialist Pharmacy Service](#) website.

Yours sincerely



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Chief Medical Officer



Professor Cathy Harrison
Chief Pharmaceutical Officer

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