Chief Medical Officer Directorate

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Scottish Government
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Dear Colleagues,

Amendments to the Human Medicines Regulations (2012)

Thank you to those of you who contributed to the recent UK Government consultation on proposed amendments to the Human Medicines Regulations (HMRs) 2012. Your input was invaluable in ensuring the devolved context was appropriately considered.

Background

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.

A Statutory Instrument (SI) was laid before the UK Parliament by the UK Government on 29 January and has since been signed by the relevant Ministers. The amendments came into force on 31 March 2026. The Human Medicines (Amendment) Regulations 2026 have now been published on legislation.gov.uk, available at http://www.legislation.gov.uk/id/uksi/2026/381.

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 (VGDs).

Summary

The amendments to the HMRs 2012:

1) introduce permanent legislation where time-limited provisions made during the COVID-19 pandemic which were due to lapse on 1 April 2026;
2) 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;

Chief Pharmaceutical Officer
Professor Alison Strath

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Addresses

For action
Chief Executives, NHS Boards
Medical Directors, NHS Boards
Nurse Directors, NHS Boards
Directors of Midwifery, NHS Boards
Primary Care Leads, NHS Boards
Chief Officers of Integration Authorities
Directors of Pharmacy
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Immunisation Co-ordinators
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3) increase flexibility in the movement, preparation and labelling of vaccines in defined circumstances with appropriate safeguards;
4) increase flexibility in the vaccination workforce; and
5) enable community pharmacies to deliver vaccines outside of their registered premises.

To achieve this Regulations (R) 3A, 19 and 233 have been expanded in scope, and a new permanent legal mechanism has been introduced replacing Regulation 247A (R247A). The occupational health vaccinator provisions in Schedule 17 are also expanded in scope to cover any vaccinations supplied in the course of an occupational health scheme.

Key Changes

Regulation 235A and VGDs – expanding the vaccination workforce

R247A which enabled the use of an extended workforce to administer COVID-19 or influenza vaccines without the input of a prescriber, using an approved protocol, has now lapsed. It has been replaced with a new permanent legal mechanism, Regulation 235A (R235A), which supports 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 via a VGD. This ensures we continue to have 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.

R235A also introduces appropriate safeguards in terms of the responsible parties for drafting and approving VGDs. In Scotland this is Public Health Scotland (PHS). There is also a requirement for robust competency assessments, safeguarding training, and supervision requirements to further protect the clinical safety of everyone being vaccinated by the extended workforce. Both PHS and the Scottish Vaccination and Immunisation Programme (SVIP) are working collaboratively with Health Boards to establish robust governance and operational frameworks to ensure that the use of VGDs and any expansion of the workforce supporting wider vaccination programmes balances the need to maximise vaccine uptake against the ability to demonstrate a proportionate risk-based approach.

R235A makes permanent the ongoing use of non-registered staff to participate in the administration of vaccines with appropriate supervision, including for other routine vaccination programmes, where appropriate to do so. National Protocols have been replaced by VGDs, that enable non-registered and registered health care professionals who are unable to operate under a Patient Group Direction (PGD), to deliver certain parts of the vaccination process provided they are under the supervision of a specified registered healthcare professional. It is worth highlighting that only the person administering a vaccine under a VGD, may carry out reconstitution or dilution.

The Specialist Pharmacy Service (SPS) has developed a suite of resources about VGDs to support their use.

Regulation 3A - assembly, preparation and labelling of vaccinations

Regulations 3A (R3A) (1) and (2), which supported final acts of preparation and assembly of COVID-19 vaccines to be undertaken by and under supervision of doctors, nurses and pharmacists without the requirement for additional marketing authorisations or manufacturer's licences, have now lapsed to reflect the fact that the UK is no longer

operating in a pandemic scenario. R3A (3) and (4) have been retained as permanent legislation, permitting wholesale dealer licence holders to relabel COVID-19 vaccines to reflect shelf-life changes following thawing, with an expanded scope for any vaccine against an infectious disease. This will help future proof the regulations and support the implementation of vaccine technologies which require ultra-low storage conditions in the supply chain. The Regulations 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.

Changes to Regulation 3 also enable pharmacists, at any location, to prepare or assemble medicines for an individual 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 19 – movement of vaccines between different NHS service providers at the end of the supply chain

Regulation 19 (R19) has been 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. 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. This will ensure vaccines can be rapidly deployed in response to urgent public health needs, supporting development of a vaccination system fit for future requirements. This minimises misuse of the provisions and strengthens the governance and assurance processes associated with the movement of stock outside the regulated supply chain.

Regulation 233 - persons lawfully conducting a retail pharmacy business delivering vaccination services out with the registered premises

The provision of Regulation 233 (R233) has been 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. 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.

Schedule 17 - occupational health scheme (OHS)

Amendments to Schedule 17 (S17) enables 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 to align with the classes of individuals set out in Part 4 of schedule 16 to the HMRs. The scope will now be expanded to include a wider range of vaccinations.

Thank you for your continued leadership and commitment to delivering safe and effective vaccination services across Scotland.

Yours faithfully,

Alison Strath
Professor Alison Strath
Chief Pharmaceutical Officer