Proposal to amend the Human Medicines Regulations 2012 to support the ongoing supply and deployment of vaccinations across the UK - consultation document

About you

In what capacity are you responding to this survey?

- An individual sharing my personal views and experiences (such as a patient, carer or member the public)
- An individual sharing my professional views
- On behalf of an organisation

~~**Questions for individuals**~~

~~Where do you live in the UK? (Optional)~~

- ~~England~~
- ~~Northern Ireland~~
- ~~Scotland~~
- ~~Wales~~
- ~~I live outside the UK~~

~~If you live in England, which area of England do you live in? (Optional)~~

- ~~North East England~~
- ~~North West England~~
- ~~Yorkshire and the Humber~~
- ~~East of England~~
- ~~East Midlands~~
- ~~West Midlands~~
- ~~South East England~~
- ~~South West England~~
- ~~London~~

~~Do you work for the NHS? (Optional)~~

- ~~Yes~~
- ~~No~~

~~Are you responding as a healthcare professional? (Optional)~~

- ~~Yes~~
- ~~No~~

~~Which of the following best describes you or your profession? (Optional)~~

- ~~NHS or health service delivery~~
- ~~Social care~~
- ~~Government or civil service~~
- ~~Other public sector~~
- ~~Private sector~~
- ~~Charity or third sector~~
- ~~Retired~~
- ~~Student~~
- ~~Other~~

Questions for organisations

What is the name of your organisation? (Optional) Pharmaceutical Society NI

What type of organisation are you responding on behalf of? (Optional)

- Business
- Not for profit organisation
- Academic institution
- Public sector body

Where does your organisation operate or provide service? (Optional, select all that apply)

- England
- Northern Ireland
- Scotland
- Wales
- The whole of the UK
- Outside of the UK

Regulation 3A proposed amendments

R3A (1) and (2) enable trained healthcare professionals, or staff under the supervision of healthcare professionals, to conduct the final stage of assembly and preparation of COVID-19 vaccines without additional marketing authorisations or manufacturer's licences being required. These provisions are due to lapse on 1 April 2026.

Do you agree or disagree with the proposal to let the provisions under R3A (1) and (2) lapse from 1 April 2026?

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

Please explain your answer. (Optional, maximum 250 words)

The Society agrees that R3A (1) and (2) should lapse, as these provisions were introduced as time-limited emergency measures during an unprecedented public health event. With vaccination programmes having stabilised, usual manufacturing and assembly standards should be reinstated to maintain the highest level of assurance around quality, safety, and accountability.

Continuing such flexibilities beyond the emergency context risks creating inconsistency in the preparation and assembly of vaccines and blurring boundaries between regulated manufacturing standards and clinical activity. Returning to standard licensing requirements ensures appropriate oversight, maintains public trust, and safeguards against variable practice.

Should exceptional circumstances arise in future, emergency legislative mechanisms can be reactivated as required.

R3A (3) permits 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 (4) makes provision in relation to the application of the packaging and package leaflet requirements to take account of these allowances.

Do you agree or disagree with the proposal to retain the provisions under R3A (3) and (4) as permanent legislation?

- Agree
- Neither agree nor disagree

- Disagree
- Don't know

Please explain your answer. (Optional, maximum 250 words)

The Society supports retaining R3A (3) and (4) as permanent provisions, as they provide a proportionate and pragmatic mechanism for managing thawed COVID-19 vaccines. These arrangements allow timely, safe relabelling by wholesale dealers operating within established regulatory frameworks, reducing the risk of administration errors while ensuring clarity for vaccinators and patients.

Relabelling to reflect thawed shelf life is operationally necessary, does not alter the clinical nature of the product, and poses minimal risk when supported by robust governance and quality systems. Retaining these provisions helps support efficient vaccine distribution and minimise wastage while maintaining regulatory safeguard

Do you agree or disagree with the proposal to expand the provisions under R3A (3) and (4) to all vaccine preventable diseases?

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

Please explain your answer. (Optional, maximum 250 words)

Extending these provisions would align regulatory processes across all vaccines with similar logistical requirements, promoting consistency, reducing wastage, and supporting efficient immunisation pathways. Many modern vaccines require controlled thawing or time-limited storage; allowing authorised wholesale dealers to relabel stock appropriately can streamline distribution while protecting patient safety.

However, expansion should be accompanied by clear standards for relabelling, staff competency, audit trails, and temperature-monitoring to ensure the integrity of all vaccines handled under this mechanism.

Regulation 19 proposed amendments

R19 (4A) to (4C) allows for:

- 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

- a medicinal product to be supplied or administered, in accordance with a protocol, by providers operating under NHS arrangements or the medical services of His Majesty's Armed Forces, to someone who is authorised to give the vaccine to a patient (either themselves or through someone they employ). This operates in accordance with regulation 247, with permission from the relevant health authority to make this supply without the need for a wholesale dealer's licence (R19 (4B) and (4C)).

These provisions are due to lapse on 1 April 2026.

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?

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

Please explain your answer. (Optional, maximum 250 words)

The Society supports making these provisions permanent, as they enable flexible and responsive vaccine distribution within NHS structures without compromising safety. During the pandemic, these arrangements reduced delays, avoided wastage, and supported rapid redeployment of vaccine stock to areas of need.

Where transfers occur solely within NHS-commissioned pathways or the Armed Forces, risk is low and can be mitigated through existing governance systems. Permanency would strengthen resilience for seasonal vaccination surges and future public health challenges.

Do you agree or disagree with the proposal to expand the provisions under R19 (4A) to (4C) to all vaccine preventable diseases?

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

Please explain your answer. (Optional, maximum 250 words)

Applying these flexibilities across all vaccines would streamline operational processes, reduce unnecessary administrative burdens, and support equitable access, especially during periods of supply fluctuation. As long as supply remains within NHS or Armed Forces clinical governance systems, these provisions present minimal risk and are compatible with maintaining high safety standards. Safeguards should include clear chain-of-custody procedures and documentation requirements

Do you agree or disagree that the legislation should set out preconditions and safeguards to regulate the use of R19 (4A) to (4C)?

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

Please explain your answer. (Optional, maximum 250 words)

Clear safeguards are essential to ensure consistent implementation and maintain public confidence. Preconditions should include:

- documented temperature-controlled transport procedures,
- clear ownership and accountability at each stage of transfer,
- training and competency requirements,
- audit trails for all redistributed stock, and
- alignment with MHRA and professional regulatory standards.

Such measures will ensure that expanded flexibilities do not dilute oversight or increase risk.

Regulation 247A proposed amendments

R247A provides a mechanism that expands the workforce who are legally and safely able to administer a COVID-19 or influenza vaccine without the input of a prescriber, using an approved protocol. Taking the learnings from R247A's usage during the COVID-19 pandemic, DHSC, working alongside system partners, proposes to replace R247A with a new legal mechanism that supports the use of an extended vaccination workforce through a VGD.

Do you agree or disagree with the proposal to let R247A lapse from 1 April 2026?

- Agree
- Neither agree nor disagree

- Disagree
- Don’t know

Please explain your answer. (Optional, maximum 250 words)

R247A was designed as a temporary mechanism during a public health emergency. Allowing it to lapse is appropriate if replaced with a more comprehensive and permanent legislative structure that supports a trained extended workforce under strong governance. This ensures clarity, consistency, and safe delivery of vaccination programmes across all settings.

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?

- Agree
- Neither agree nor disagree
- Disagree
- Don’t know

Please explain your answer. If you have any comments on the scope and content of the proposed legal provision, please include them here. (Optional, maximum 500 words)

The Society supports a permanent mechanism enabling an extended, appropriately trained workforce to administer vaccines under a VGD. This approach provides long-term resilience, increases capacity, and supports equitable access to vaccination services.

Any permanent model must include:

- clear minimum training and competency standards,
- defined supervision and governance arrangements,
- robust record-keeping and incident-reporting systems, and
- clear communication pathways with pharmacists and other providers.

The new approach should strengthen, not weaken, clinical oversight and ensure alignment across all UK nations for consistency in public messaging and safety standards.

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)?

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

Please explain your answer. (Optional, maximum 500 words)

Vaccinating infants and very young children requires specialist knowledge, skill, and safeguarding considerations. The Society therefore supports an age limit ensuring that VGDs do not apply to the youngest age groups unless administered by appropriately qualified professionals. This protects vulnerable populations while still enabling expanded workforce use for adults and older children.

Regulation 233 and regulation 3 proposed amendments

R233 (8) enables persons lawfully conducting a retail pharmacy business to deliver COVID-19 and influenza vaccination services off the registered premises under a PGD.

Do you agree or disagree with the proposal to extend the provisions under R233 (8) to all other vaccine preventable diseases?

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

Please explain your answer. (Optional, maximum 250 words)

Allowing pharmacists to deliver all NHS vaccination services off registered premises under a PGD, such as in care homes, community settings, and outreach clinics, will improve access, especially for underserved groups. Pharmacists already demonstrate high competence in vaccine delivery; extending this flexibility supports public health aims while maintaining necessary governance and record-keeping standards.

Regulation 3 provides a limited exemption for doctors, dentists, registered nurses and registered midwifes to prepare or assemble medicines for patients, provided the medicinal product is supplied to either:

- a patient in the course of the treatment of that patient
- a patient of another doctor who is a member of the same medical practice

We propose to expand regulation 3 to include pharmacists and pharmacy technicians.

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?

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

Please explain your answer. (Optional, maximum 250 words)

The Society supports this proposal, which reflects the skills and training of pharmacists and pharmacy technicians and aligns with modern practice. Enabling these professionals to prepare or assemble medicines within defined clinical pathways strengthens service efficiency and supports safe patient care. Safeguards should ensure appropriate oversight, documentation, and quality controls consistent with existing regulatory standards.

Schedule 17 proposed amendments

S17 introduced a category of 'occupational health vaccinators' who are permitted, under the written directions of a doctor, to administer influenza and COVID-19 vaccines as part of an NHS or local authority OHS.

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?

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

Please explain your answer. (Optional, maximum 250 words)

Expanding this category increases workforce flexibility and supports delivery of occupational health vaccination programmes without compromising safety, provided all vaccinators meet defined training, competency, and supervision standards. This ensures safe practice while improving organisational capacity.

Do you agree or disagree with the proposal to extend the relevant provisions under S17 to include private healthcare providers?

- Agree
- Neither agree nor disagree
- Disagree
- Don’t know

Please explain your answer. (Optional, maximum 250 words)

Private occupational health services contribute significantly to workforce vaccination coverage. Extending these provisions, under strict governance and competency requirements, ensures consistency of standards across sectors while supporting wider public health protection.

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?

- Agree
- Neither agree nor disagree
- Disagree
- Don’t know

Please explain your answer. (Optional, maximum 250 words)

This provides clarity and consistency across occupational health immunisation programmes, reduces administrative complexity, and supports complete protection for staff. Clear training and governance expectations must accompany the expansion.

Legal duties

Public sector equality duty

The government is required to consider the impact of new policies on the protected characteristics set out in section 149 of the Equality Act 2010, which are:

- age
- disability
- gender reassignment
- marriage and civil partnership
- pregnancy and maternity
- race

- religion or belief
- sex
- sexual orientation

DHSC does not believe the proposals risk impacting people differently with reference to their protected characteristics. Do you agree or disagree with this statement?

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

Please explain your answer. (Optional, maximum 150 words)

The proposals primarily adjust regulatory mechanisms around workforce flexibility, distribution, and governance. They do not restrict access or create barriers for groups with protected characteristics, and many changes may enhance access, particularly where expanded workforce or outreach models reduce inequalities.

Questions for individuals who live in Northern Ireland and organisations who operate in Northern Ireland: equality and rural screening

In Northern Ireland, new policies must be screened under section 75 of the Northern Ireland Act 1998, which places a statutory duty on public authorities to mainstream equality in all its functions so that equality of opportunity and good relations are central to policy making and service delivery. In addition, new or revised policies must be rural proofed in line with the Rural Needs Act (NI) 2016, which requires public authorities to have due regard to rural needs.

The Department of Health in Northern Ireland does not believe the proposals risk impacting people differently with reference where they live geographically in Northern Ireland.

Do you agree or disagree with this statement?

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

Please explain your answer. (Optional, maximum 150 words).

The changes apply equally across all settings and are intended to strengthen system-wide vaccination capacity. If implemented uniformly, they should not create geographical disparities and may help reduce them by supporting outreach and mobile vaccination services.

Final question

If there are any further points you would like to make in relation to the proposals set out within this consultation, please include your comments here. (Optional, maximum 500 words)

The Society welcomes the opportunity to comment on these proposals. Overall, we support the direction of travel towards a resilient vaccination framework that enables trained staff to operate safely within clear governance structures.

Across all provisions, we emphasise the importance of:

- robust training and competency standards for all vaccinators,
- clear accountability and supervision arrangements,
- strong communication between providers, including pharmacies,
- accurate record-keeping and integration with existing systems,
- safeguards to protect medicine integrity and minimise wastage, and
- public confidence in vaccination processes.

As the regulator of pharmacists and pharmacies in Northern Ireland, we stress the need for consistent professional standards, well-defined roles, and systems that protect patient safety across all settings.