

Amendments to regulations 3A, 19 and 247A of the Human Medicines Regulations 2012 to support the ongoing delivery of COVID-19 and influenza vaccination

Royal Pharmaceutical Society response

Do you agree or disagree that the provisions provided in regulation 3A should be extended? *Amendments to R3A allow for the final stage preparation of the COVID-19 vaccines to be carried out by suitably qualified healthcare professionals without the need for manufacturing licences or marketing authorisations.*

- **agree**
- disagree
- don't know

Please explain your answer (maximum 500 words).

It is vital that individual healthcare professionals supplying and administering the vaccination are protected under the specified circumstances. There needs to be clear communication to healthcare professionals, so they clearly understand that they are covered and under which circumstances this applies.

Do you agree or disagree with the proposal to set a time limit on regulation 3A until 1 April 2026?

- **agree**
- disagree
- don't know

Please explain your answer (maximum 500 words).

Extending this to 2026 ensures continued provision of an efficient vaccination service.

Do you agree or disagree that the provisions provided as part of regulation 19 should be extended? *R19 allows COVID-19 and influenza vaccines to be moved between premises at the end of the supply chain by providers operating under NHS arrangements and the medical services of His Majesty's Forces without the need for a wholesaler dealer's licence*

- **agree**
- disagree
- don't know

Please explain your answer (maximum 500 words).

RPS is supportive of a continued relaxation of the wholesaler dealer's licence requirements in these circumstances. There need to be assurances that the recommended storage conditions are maintained, and that relevant documentation is put in place to enable accurate tracing for audit and recall purposes. Where cold storage is required then these conditions must be audited throughout any transfer process to assure the cold chain has been maintained. This change to legislation removes supply barriers for the maintenance of medicine supplies and allow for timely access to medicines for patient benefit, particularly in the deployment of successful vaccination programs.

Do you agree or disagree with the proposal to set a time limit on regulation 19 until 1 April 2026?

- **agree**
- disagree
- don't know

Please explain your answer (maximum 500 words).

Extending this to 2026 ensures continued provision of an efficient vaccination service.

**Do you agree or disagree with the proposal to remove condition A from regulation 247A?
*R247A provided the mechanism that expanded 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***

- **agree**
- disagree
- don't know

Please explain your answer (maximum 500 words).

For any vaccination service, there should be someone on site who is a registered doctor, nurse or pharmacist who has experience in vaccination and how to deal with any crisis such as anaphylaxis. The current protocol states this and this needs to be continued to assure both patient safety and overall quality of service provision. .

Do you agree or disagree with the proposal to set a time limit on regulation 247A until 1 April 2026?

- **agree**
- disagree
- don't know

Please explain your answer (maximum 500 words).

Extending this to 2026 ensures continued provision of an efficient vaccination service.

How confident do you feel that the NHS would have an effective response before 1 April 2026 to support the ongoing delivery of COVID-19 and influenza national vaccination campaigns, if the proposed amendments to regulations 3A, 19 and 247A were not made?

- very confident
- confident
- **somewhat confident**
- slightly confident
- not confident at all
- don't know

Please explain your answer and reflect if your view varies by regulation (maximum 500 words).

Do you think the proposals risk impacting people differently with reference to their protected characteristics?

- yes
- **no**
- don't know

Please explain your answer and reflect if your view varies by regulation(maximum 500 words).

The suggested proposals support a more flexible and inclusive approach for the public and patients with different needs making it easier to access vaccines across the board.