# **FPM Open Consultation Supporting the delivery of COVID-19 and influenza vaccination**

**Guidance:** Please respond to each question to the best of your knowledge within this document. **Please provide your name alongside your comments.** The completed document will then be circulated to the FPM PCG and any pertinent internal stakeholders (other contributors) for review.

**From:** UK Government

**Deadline:** **11:59 PM (GMT) 18th September 2023**

**FPM Deadline: EOD 8th September 2023**

[**Consultation Description:**](https://www.gov.uk/government/consultations/supporting-the-delivery-of-covid-19-and-influenza-vaccination?utm_medium=email&utm_campaign=govuk-notifications-topic&utm_source=4b0503f9-8171-4526-bcc1-ac006951c5f1&utm_content=daily)

The Human Medicines Regulations were amended by [The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020](https://www.legislation.gov.uk/uksi/2020/1125/contents/made) to provide greater flexibilities for the movement and supply of certain type of vaccines, in light of the COVID-19 pandemic.

The Department of Health and Social Care is looking to ensure that the flexibilities established by those regulations are maintained for a further time-limited period to support the continuing supply, distribution and administration of COVID-19 and influenza vaccines as we transition out of the pandemic. Specifically, we are interested in the following provisions:

* regulation 3A
* regulation 19
* regulation 247A

**Related documents:** Can be found [here.](https://www.gov.uk/government/consultations/supporting-the-delivery-of-covid-19-and-influenza-vaccination/amendments-to-regulations-3a-19-and-247a-of-the-human-medicines-regulations-2012-to-support-the-ongoing-delivery-of-covid-19-and-influenza-vaccinatio)

**Questions:**

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

# **Amending regulation 3A**

[Regulation 3A](https://www.legislation.gov.uk/uksi/2012/1916/regulation/3A) enables the final stage preparation of COVID-19 vaccines to be carried out by suitably qualified healthcare professionals without the need for manufacturing licences or marketing authorisations, until 1 April 2024. We would like to extend the provisions supported within this regulation to 1 April 2026.

Do you agree or disagree that the provisions provided in regulation 3A should be extended? (optional)

Agree / ~~Disagree /Don’t Know~~

Please explain your answer (optional, max. 500 words):

*The final preparation of the current vaccines for COVID-19 includes thawing of the frozen concentrate, followed by dilution, which are well within the competence of trained vaccine administrators.*

We have suggested that the regulation 3A is extended to 1 April 2026, whilst in parallel we continue to work with system partners to develop longer term and permanent proposals for the future of these regulatory provisions.

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

~~Agree~~ / Disagree /~~Don’t Know~~

Please explain your answer (optional, max. 500 words):

*Given that this provision is well within competence for any vaccination program, it seems reasonable to make this provision unlimited.*

# **Amending regulation 19**

[Regulation 19](https://www.legislation.gov.uk/uksi/2012/1916/regulation/19) 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, until 1 April 2024. We would like to extend the provisions supported within this regulation to 1 April 2026.

Do you agree or disagree that the provisions provided as part of regulation 19 should be extended?  (optional)

Agree / ~~Disagree /Don’t Know~~

Please explain your answer (optional, max. 500 words):

*Again, this is well within the competence of the practitioners’ concerns, e.g., pharmacy chains to enable efficient management of their supplies.*

Like regulation 3A, we have suggested that regulation 19 is extended to 1 April 2026, while in parallel we continue to work with system partners to develop longer term and permanent proposals for the future of these regulatory provisions.

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

~~Agree~~ / Disagree /~~Don’t Know~~

Please explain your answer (optional, max. 500 words):

*There appears to be no reason to time limit these provisions as any may be replaced by permanent proposals covering all vaccine programs regardless of the rationale for use.*

*It would seem reasonable for this provision to be unlimited pending the development of any further regulation*

# **Amending regulation 247A**

[Regulation 247A](https://www.legislation.gov.uk/uksi/2012/1916/regulation/247A) enables the use of an extended 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.

We are proposing to make a time limited change (to 1 April 2026) to this regulation to remove condition A from the regulation which specifies that the use of an extended workforce via protocol is only possible where there is a) a pandemic, and b) a serious risk or potentially serious risk to human health.

Do you agree or disagree with the proposal to remove Condition A from regulation 247A?  (optional)

~~Agree~~ / Disagree /~~Don’t Know~~

Please explain your answer (optional, max. 500 words):

*While there is merit to having an extended workforce able to administer vaccinations, it is inappropriate to create a situation where there may be no named individual carrying personal responsibility for providing advice to individual patients and taking consent for administration where appropriate, even though the administration of the vaccination itself is delegated. In addition to ensuring adequate tracking of adverse effects, the patient’s GP should be informed concerning vaccine receipt and administration timing linked to the patient’s health record to support subsequent management of any safety-related vaccine issues.*

In recognition that the use of regulation 247A may not be the most appropriate model for the ongoing use of an expanded workforce outside of the pandemic response, we are proposing to time limit the provision until 1 April 2026. During this period, there will be fuller consideration, and potential introduction (where agreed to be beneficial and subject to consultation) of an alternative longer-term mechanism which can be deployed to better support the use of an extended vaccination workforce.

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

~~Agree /~~ Disagree /D~~on’t Know~~

Please explain your answer (optional, max. 500 words):

*As noted previously there does not appear to be a good reason to time limit these proposals pending a permanent regulation for all vaccinations being developed.*

# **NHS response if these amendments are not made**

The following question is aimed at those who have been involved in the delivery of the COVID-19 and influenza national vaccination programmes and asks you to consider a situation where these regulations lapse or cannot be used. Please skip the next question if you feel unable to answer this question.

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?  (optional)

* 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 (optional, max. 500 words):

# **Public sector equality duty**

In line with the government's requirement to consider the impact of policy on the protected characteristics, the following question is designed to understand whether you feel the proposal risks impacting people differently or could impact adversely on any of the protected characteristics covered by the public sector equality duty set out in section 149 of the Equality Act 2010 or by section 75 of the Northern Ireland Act 1998.

The following characteristics are protected characteristics:

* age
* disability
* gender reassignment
* marriage and civil partnership
* pregnancy and maternity
* race
* religion or belief
* sex
* sexual orientation

Do you think the proposals risks impacting people differently with reference to their protected characteristics?  (optional)

Yes / No / Don’t Know

Please explain your answer and reflect if your view varies by regulation (optional, max. 500 words):

*An elderly age group with multiple concomitant medical issues & non-English speaking patients may potentially be at greater risk of the proposals, where an extended workforce who are administering a COVID-19 or influenza vaccine without the input of a prescriber or known to a GP practice. Is there any data available to assess whether certain patient groups are at greater risk of these proposals?*