



**Specialist  
Pharmacy  
Service**

**NHS**

# Getting to grips with changes to legislation around COVID-19 and flu vaccination

27 January 2020

**The first stop  
for professional  
medicines advice**

---

[www.sps.nhs.uk](http://www.sps.nhs.uk)



## Scope of the webinar

- This webinar will only explain the changes to the legislation
- The aim is to provide information as to how this will affect delivery of services from:
  - Mass vaccination centres
  - Hospital hubs
  - Local vaccination services (PCN designated sites)

## Questions

- We will try to answer any question that came in prior to the webinar
- If you have questions then please put them in the chat box, and we will endeavour to answer them
- Whilst we encourage you to network in the chat box, we cannot endorse any answers given by participants



# What has changed in the legislation?

- Oct 2020 [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020](#)
- Dec 2020 [The Human Medicines \(Coronavirus\) \(Further Amendments\) Regulations 2020](#)
- Both amend the [Human Medicines Regulations 2012](#)
- Some cease to have effect on 1 April 2022

# What has changed in the legislation?

- Changes to WDL
- Changes to Manufacturing & Product Licensing Requirements (**coronavirus only**)
- Supply temporarily authorised under regulation 174 of the HMR 2012 can now be included in a PGD
- Introduction of a new type of protocol (**coronavirus** and **flu**)
- Changes to who can work under a Written Instruction for occupational health provision (**coronavirus** and **flu**) in NHS and Local Authority (LA) only

# Changes to WDL Requirements

Regulation 19 of the HMR 2012 has been amended to provide additional exemptions from the requirement to hold a wholesale dealer's licence, where a medicine is to be used for vaccination against **coronavirus** or **flu**. This allows a person to supply without a WDL if:

- They had been supplied the vaccine under the relevant arrangements, and
- They supply it directly to the vaccinator to administer or to the organisation the vaccinator works for.

This allows transfer without a WDL only really at the end of the supply chain. Vaccine Hubs will be expected to hold a WDL

# Changes to Manufacturing & Product Licensing Requirements (1)

A new regulation – 3A has been added to the 2020 further amendment. This allows further exemptions from the need hold a Manufacturing Licence and a Product Licence:

- Provided that the medicinal product is being used for vaccination or immunisation against **coronavirus** and is manufactured, prepared or assembled by or under the supervision of a doctor, a registered nurse or a pharmacist -
- who is acting in the course of his or her profession; and
- is for the purposes of the supply or administration of the medicinal product to a patient under relevant (pandemic) arrangements.

# Changes to Manufacturing & Product Licensing Requirements (2)

Regulation 3A also provides an exemption from the need hold a Product Licence if the medicinal product is the result of the assembly of an authorised medicinal product (e.g. packing down the vaccine or diluent into smaller lots).

A further provision in Regulation 3A provides an exemption from holding a Manufacturing Licence where a medicinal product used for vaccination or immunisation against **coronavirus** is labelled by a holder of a wholesale dealer's licence to take account of a change to the shelf life of the product because of the thawing of the product.



# Supply temporarily authorised under Regulation 174 of the HMR 2012

Regulation 174 waives the requirement for a medicine to hold a PL when the sale or supply of the medicine is authorised by Ministers, on a temporary basis, in response to the suspected or confirmed spread of:

- Pathogenic agents
- Toxins
- Chemical agents or,
- Nuclear radiation

# Supply temporarily authorised under Regulation 174A

A new regulation – 174A has been added to the 2020 amendment. This allows conditions to the temporary authorisation under Regulation 174 such as:

- It must only be used for the purpose for which it was given temporary licensing. It can't be used or marketed for anything else (e.g. a cure for the common cold).
- The MHRA will set out and agree the conditions under which it is made and these must be adhered to by the manufacturer.

# What has changed for PGDs?

- Amendments to legislation allow a medicine authorised under regulation 174 to be supplied under a PGD
- Nothing else has changed

# Protocols relating to coronavirus and influenza vaccinations (Reg 247A)

- This is a new mechanism
- It is a national protocol as it needs to be authorised by the secretary of state, no local authorisation required
- Allows trained, competent and authorised persons (registered and non registered) to participate in delivering the programme
- Only for **coronavirus** and **flu**

# Protocols relating to coronavirus and influenza vaccinations (Reg 247A)

- The protocol can be used by a single registered HCP undertaking the whole vaccination process, or by multiple persons undertaking the appropriate stages
- These are clearly outlined in the protocol
- All activity under protocol must be under a Clinical Supervisor (doctor, nurse or pharmacist)

# Using the most appropriate mechanism for COVID-19

## Option 1: The National Protocol (NP)

- The primary mechanism for the majority of deployment models.
- This can be used by a single registered healthcare professional undertaking all stages or multiple (registered or non-registered) persons undertaking different stages.
- The clinical assessment under the NP must be undertaken by a prescriber or specified registered healthcare professional
- The other three stages: preparation, administration of the vaccine and record keeping can be undertaken by registered or non-registered persons who are appropriately trained and competent
- Must be under appropriate supervision.

# Using the most appropriate mechanism for COVID-19

## Option 2: The national PGD

- This mechanism fits the deployment method where a single registered healthcare professional undertakes the entire process.
- The registered HCP must be listed in the PGD legislation.
- Under a PGD all stages must be undertaken by the same registered healthcare professional: if it is required that any part of the process is undertaken by another person then the National Protocol should be used and not the PGD.
- The PGD is an option where a specified registered healthcare professional is working without the clinical supervision of a doctor, nurse or pharmacist.

# Using the most appropriate mechanism for COVID-19

## Option 3: A Patient Specific Direction (PSD)

- Where an individual falls out of the inclusion criteria stated in the National Protocol or PGD they may need to be clinically assessed by a prescriber, to see if they should receive COVID-19 vaccine following patient specific assessment of the risk versus benefit of COVID-19 vaccination for them.
- If this results in a decision to vaccinate, the vaccine will need to be administered by a prescriber or under a PSD.



## Working in partnership with other organisations

Vaccination services may be offered by several organisations working in partnership or may be offered across organisational boundaries.

The principles outlined in the following documents can be applied:

- [Patient Group Direction use in Primary Care Networks](#)
- [Patient Group Direction \(PGD\) use in a service provided by multiple organisations](#)



# Inappropriate mechanism for COVID-19

## **Written Instruction (WI)**

This year, the COVID-19 vaccine is being delivered to all adults as a national programme. This year it is not an Occupational Health provision. A Written Instruction is, therefore, not appropriate.

# Written Instructions - what was the position before ?

- Written Instructions are the preferred mechanism for occupational health provision
- They are an exemption in Schedule 17 for occupational health
- Only registered nurses can work under them

# What has changed with Written Instructions?

For **flu** and **coronavirus** vaccines only  
and for an NHS body or Local Authority only:

- Additional registered staff can act as an **occupational health vaccinator**
- NB this is a new term (occupational health vaccinator) introduced in this new legislation

# Who can work as an occupational health vaccinator?

- Registered nurse
- Registered midwife
- Registered nursing associate (in England)
- Registered operating department practitioner
- Registered paramedic
- Registered physiotherapist
- Registered pharmacist

# What is an NHS Body?

- Common Services Agency
- Health Authority
- Special Health Authority
- Clinical Commissioning Group
- National Health Service Commissioning Board (NHS England)
- NHS trust
- NHS foundation trust

Staff must be employed or engaged

# Anything else on Written Instructions?

- There are national Written Instruction influenza templates to assist organisations in implementing this for 20/21. Flublok is included [link](#)
- These will be updated for 21/22
- These changes cease to have effect on 1 April 2022



# Questions

- As per our advert, we agreed to answer all questions received by 20 January.
- We have themed them, so you might not see your exact wording



## Who can do what?

- What can an osteopath do to support COVID-19 vaccination ?
- Can a dentist work under a PGD?

[Giving vaccines legally: mechanisms and application](#)

TR

- Why can't a pharmacy technician work under a PGD? Why can't the legislation be changed?

TR

## Liability and consent

- Now the dosing interval has changed, what effect does that have on the practitioner's liability? Does it affect the consent given by the patient at the first dose?

TR

- Under the National Protocol, can patients be consented by a registered HCP over the phone the day before they are due to be vaccinated?

BG

# Supervision

- We have paramedics giving the vaccine in a care home and under the National Protocol there needs to be a clinical supervisor. Can clinical supervision be undertaken remotely under the National Protocol?

JJ



# Supervision

- I am a pharmacy technician, do I need to be supervised if I am working under a PSD?
- The National Protocol says I can't obtain consent, how can I work under a PSD?

JJ

JJ



## Working under a PGD

- I am a nurse working under the PGD, if I give 3 doses of the AZ vaccine from a vial can another nurse in my team give the remaining doses?

JJ

## Staff vaccination

- Can we vaccinate staff from other organisations?
- What about staff from the independent sector (including social enterprise / CIC organisations), who will vaccinate them? Can independent sectors vaccinate their own staff? If they can, what mechanism should they use?

JJ



# Multiple organisations working together

- We are working with multiple organisations to deliver this programme. We are the lead organisation, what do we need to do about staff not employed by us?

[Patient Group Direction \(PGD\) use in a service provided by multiple organisations](#)

[Patient Group Direction use in Primary Care Networks](#)

JJ



## Extra doses

- What is the legal mechanism for giving a sixth dose of the Pfizer BioNTech vaccine?
- What about the AZ vaccine?

BG





## POLL: A SHORT INTERLUDE.....

While we collate your questions, we would be really pleased if you could complete a 1 minute poll which will appear on your screen. This will help us know how we are doing! The questions are:

**To what extent was this event useful to you?**

**If this webinar was repeated, would you recommend it to your colleagues?**

**THANK YOU – NOW, ON TO YOUR QUESTIONS AND ANSWERS!**



# Questions from Chat Box

Still got a query?

[Inwh-tr.mus-specialistpharmacy@nhs.net](mailto:Inwh-tr.mus-specialistpharmacy@nhs.net)