

Summary of legal mechanisms for administering Covid-19 and influenza vaccines

Background

This document summarises the legal mechanisms which enable administration of Covid-19 and influenza vaccines. Local services will need to work within the framework of these legal parameters, and this document can be used as an aid to identify which mechanism is most suitable for use based on local staffing mix and preferred models for delivery.

The table and summary on the following pages outline which mechanism can be used by which staff member and whether tasks can be delegated. Further practical information can also be found on the [Specialist Pharmacy Service Website](#).

Summary of key changes made to the regulations.

To aid flexibility around workforce for the Covid-19 and influenza vaccination programme, **temporary changes** were made to the Human Medicine Regulations 2012 (HMR) that affected the legal mechanisms used for the supply and/or administration of the vaccines.

Key amendments made to the regulations are summarised below.

- Addition of [Regulation 3A](#), which allows for the preparation of the Covid-19 vaccine outside of a licensed manufacturing unit by an individual under direct supervision of a doctor, nurse or pharmacist.
- Addition of [Regulation 247](#), which allows for the supply and administration of certain vaccines (Covid-19 and influenza) under a National Protocol.



- Amendment to Patient Group Direction (PGD) regulations to allow the supply and administration of an unlicensed medicine, including a medicine authorised under [Regulation 174](#); emergency authorisation. However, all vaccines used in the Covid-19 vaccine programme are now licensed medicines.

What is the appropriate mechanism for Covid-19 and influenza vaccination?

There are several mechanisms that can be used to support vaccination.

Patient Specific Direction (PSD)

Where an individual does not fall into the inclusion criteria stated in the National Protocol or national PGD, they will need to be assessed by a prescriber who will use their clinical judgement to decide if it is appropriate for the individual to receive a vaccine. Following a patient specific assessment of the risk versus benefit of vaccination, if the clinician decides it is in the best interest to vaccinate the individual, they must write a PSD for the individual to be vaccinated.

Sites choosing to operate a prescriber-led model may utilise this mechanism routinely.

National Patient Group Direction (PGD)

This mechanism fits the deployment method where a single specified registered healthcare professional undertakes the entire process. The registered HCP must be listed in the PGD legislation (summarised here) and the PGD. Under a PGD all stages must be undertaken by the same registered healthcare professional, delegation is not permitted. If it is required that any part of the process be undertaken by another person, an alternative legal mechanism should be used.

National Protocol

A Clinical Supervisor must be present and provide clinical supervision for the overall provision of clinical care provided under the legal authority of the protocol. They are accountable for the whole vaccination process across a vaccination site. This role must be a Doctor, Nurse or Pharmacist who is trained and competent in all aspects of the National Protocol. Further detail can be found in the relevant National Protocol.

Each distinct stage of activity under the protocol may be carried out by a different person or the same person, so long as the professional registration and minimum training requirements are met for fulfilling each stage of activity. The clinical assessment and consent under the National Protocol (Stage 1) must only be undertaken by a **prescriber or specified registered healthcare professional**. No element of Stage 1 activity can be delegated to a non-registered person. 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, competent, and working under appropriate supervision. Further detail can be found in the relevant National Protocol. Legislation requires protocols to be authorised by ministers.

Written instruction (WI)

An exemption in Schedule 17 of the Human Medicines Regulations (HMR) 2012, applicable to Occupational Health Services (OHS), allows medicines to be provided under a written instruction. The written instruction can be used by OHS to vaccinate staff employed by an NHS Body or local authority organisations against influenza following the signed authorisation of the written instruction by an appropriate doctor.

A written instruction is different to a PGD and is an arrangement between the named registered professional administering the vaccine and the authorising doctor and is subject to different legislative framework.

Covid-19 vaccines cannot currently be administered via written instruction.

Useful Links

- [Specialist Pharmacy Service \(SPS\): Legal mechanisms and their application to give Covid-19 vaccines.](#)
- [UKHSA: Covid-19 vaccination - information for healthcare practitioners.](#)
- [UKHSA: The Green Book](#)



Mechanism of delivery for which vaccines	What is it?	Who can use it?	Can tasks be split?	Who can carry out the clinical assessment and consent?	Who can carry out administration of the vaccine?
<p>Patient Specific Directions (PSD)</p> <p>Covid-19 and Influenza</p>	<p>It is a written instruction from a prescriber i.e., a doctor, or independent prescriber for medicines to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis.</p>	<p>Patients must be individually reviewed by a prescriber as being suitable for receiving the treatment.</p> <p>Where the medicine is licensed, any independent prescriber (except optometrists) can write a PSD if it falls within their clinical competence.</p>	<p>Yes</p> <p>Non-registered and registered staff can work under a patient specific direction if the prescriber is assured that staff are trained, competent and they take full accountability for all tasks.</p>	<p>A registered healthcare professional must carry out the clinical assessment. For a PSD this would usually be done by the prescriber. Other staff may be able to pre-screen in advance however the prescriber must be able to review responses and confirm responses as needed.</p>	<p>Administration can be carried out by trained and competent non-registered or registered healthcare workers. The prescriber must be satisfied that the person to whom the administration is delegated has the qualifications, experience, knowledge and skills required to complete the task.</p>

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Patient Group Directions (PGD) Covid-19 and Influenza	<p>Registered Health Care Professionals can operate under a PGD where their registered profession has been defined by the law.</p> <p>The PGD allows only these registered healthcare professionals to administer the vaccine without the need for a direction by the prescriber.</p>	<p>Registered Staff only as defined in the law. Non-registered staff such as healthcare assistants and any registered professions not listed in the legislation are not able to work under a PGD.</p>	<p>No</p> <p>Supply and/or administration of a medicine must not be assigned or delegated to any other person under a PGD, regardless of their professional group or level of training.</p> <p>For example, if the vaccine is to be administered under a PGD, this should be by the same health professional that assessed the patient under the PGD, and they will also need to be the one to record it in the patient records.</p> <p>The addition of temporary regulation 3A does support separation of vaccine preparation¹. The national PGD does allow for a separate</p>	<p>Registered healthcare professionals permitted to operate under a PGD can carry out clinical assessment and consent. It must be the same individual who completes all parts of the process.</p>	<p>The PGD requires that all tasks outlined are carried out by the same registered healthcare professional. More information can be found here.</p> <p>Further recommendations on the use of PGDs are available from NICE and SPS.</p>

¹ Preparation of the vaccine (i.e. dilution/mixing) is covered by a temporary amendment to the HMR 2012, specifically Regulation 3A. The relevant exemptions that exist for healthcare professionals at the final stages of supply are in place for doctors, nurses and pharmacists. It is expected that preparation of the vaccine is carried out by registered healthcare professionals or suitably trained and experienced non-registered healthcare workers with the relevant skills and experience in aseptic technique, under the supervision of a doctor, nurse or pharmacist if not one themselves.

Mechanism of delivery for which vaccines	What is it?	Who can use it?	Can tasks be split?	Who can carry out the clinical assessment and consent?	Who can carry out administration of the vaccine?
			<p>person to prepare the vaccine under the supervision of a doctor, nurse or pharmacist.</p> <p>Alternative legal mechanisms (e.g., National Protocol or PSD) should be used if any other task needs to be completed by other healthcare staff.</p>		



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National Protocol Covid-19 and Influenza	This is a new legal mechanism, following temporary amendment of the Human Medicines Regulations 2012, that was introduced to support the expanded influenza and Covid-19 Vaccination Campaign. It allows those who are registered healthcare professionals who cannot operate under a PGD, and those who are not registered healthcare professionals, to safely administer a licensed or temporarily authorised Covid-19 or influenza vaccine under	Non-registered healthcare workers (e.g., new recruits to NHS and HCW) Registered healthcare professionals.	Yes An appointed Clinical Supervisor ² (doctor, nurse or pharmacist) must be in place when using the National Protocol. In this senior role, the individual is responsible for the safe and effective delivery of the entire vaccination process across the site. Stages can then be split and carried out by one individual or multiple people as required: Stage 1: Operational stages of activity under the protocol can only be carried out by specified registered healthcare professionals and cannot be delegated. Specified registered healthcare professionals Only (see Table 2)	The clinical assessment must be carried out by a registered healthcare professional and cannot be delegated. These are the same healthcare professionals who can clinically assess patients under a PGD.	Can be carried out by trained unregistered or registered workers under clinical supervision.

² This is a senior role and the individual is responsible for the safe and effective delivery of the whole of the vaccination process across the site. They must act in line with their competence, should always be immediately available to respond to queries or problems that arise, and are accountable for the appropriate ratio and skill mix of staff delivering the clinical service.

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	the protocol during a pandemic, in the absence of a prescriber.		<p>a. Assessment of the individual presenting for vaccination</p> <p>b. Provide information and obtain informed consent</p> <p>c. Provide advice to the individual</p> <p>Stage 2: Vaccine preparation by registered or non-registered persons</p> <p>Stage 3: Administration of vaccine by registered or non-registered persons</p> <p>Stage 4: Record keeping by registered or non-registered persons</p>		



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Written Instruction Influenza only	The written instruction can be used by Occupational Health Services to vaccinate staff employed by NHS Body or local authority organisations against influenza following the signed authorisation of the written instruction by an appropriate doctor.	Registered nurse under written instruction of a doctor.	Yes The written instruction can be used by nurses of an Occupational Health Services to vaccinate staff employed by NHS Body or local authority organisations against influenza following the signed authorisation of the written instruction by an appropriate doctor.		Can be carried out by a nurse undertaking a role in an Occupational Health Service.

