

Mechanisms for administering the COVID Vaccine(s) – Summary

This document should be read in conjunction with the more detailed document on the same topic available here: <https://www.england.nhs.uk/coronavirus/publication/legal-mechanisms-for-administration-of-the-covid-19-vaccines/>

This document summarises each of the mechanisms to aid local areas with identifying which mechanism is most suitable to be used based on the local staffing mix and models for delivery based on the legal framework they must be used within. The table and summary on the following pages outline which mechanism can be used by which staff member and whether tasks can be delegated. **The primary mechanism in all deployment models is the National Protocol.**

To note that doctors and nurse or pharmacist independent non-medical prescribers (NMPs) as 'appropriate practitioners' can supply prescription only medicines without prescriptions and administer injectables without directions ([Human Medicines Regulations reg.214\(1\) and \(2\) \(3\).](#))

This means that a Patient Specific Direction (PSD) or another type of written direction is not required as long as the doctor or NMP is carrying out the whole process of clinical assessment, consent and administration. A clinical record of this must be made (using the relevant IT system) as is normal practice.

However, if tasks are being split with a different Health Care Professional (HCP) or trained staff member carrying out the vaccine administration process this would require a written PSD to be in place to cover legal supply and administration by the other healthcare professional or trained staff member. A PSD requires a prescriber to carry out the clinical assessment process.

With a Patient Group Direction (PGD) the clinical assessment cannot be split from the administration and both of these need to be undertaken by the same health care professional authorised to work under the PGD, as does completion of the clinical record.

If any element of the vaccination process needs to be split between healthcare professionals, then it is recommended that the national protocol is used.

Dentists

Specific regulations also apply to dentists. Dentists as prescribers and appropriate practitioners are usually able to administer a prescription only medicine without the need for any direction in place (as above) however for dentists this only applies if the person being vaccinated can be defined as being a patient of the dentist. This therefore cannot be applied in the context of administering vaccinations. Dentists are also not able to prescribe or write a PSD for the covid vaccine.

As a prescriber, dentists cannot work under a PGD, therefore the only real options, are a *patient specific direction* or the *national protocol*.

If a PSD is used, dentists are able to work under an authorisation from another prescriber (i.e. a patient specific direction) and they are able to carry out the whole process (or part of the process) under this direction but only if they are working in a hospital setting.

Therefore, the key route for input from a dentist into vaccinations will be working (as a team or alone) under the **national protocol**. Dentists are in practice allowed to do all operational stages of activity under the approved national protocol but are not able to act as the clinical supervisor (as defined in the protocol) even if they can undertake all operational stages themselves without any supervision required.

Summary of key changes made to the regulations in October 2020

In order to aid with some flexibility around workforce for the COVID-19 and influenza vaccination programme key changes were made to the medicines regulations that affect the mechanisms used for the supply or administration of the vaccine. Key relevant changes are summarised below:

- Splitting of tasks is not permitted within the PGD framework therefore a separate framework has been developed. The introduction of the National Protocol which allows tasks to be split between registered and non-registered healthcare professionals throughout the vaccination process from clinical assessment and consent to administration and post vaccination observation.
- Amendment to the PGD regulations which previously haven't allowed a PGD to be used for the supply or administration of an unlicensed medicine. Legislation has been introduced to allow a PGD for the administration or supply of a medicinal product that has been authorised under Regulation 174.

All other aspects of the medicines regulations are unchanged and will apply as usual. Therefore, local areas will need to work within the framework of these legal parameters.

Further details on the consultation that took place on the above amendments can be found on the [government website](#).

Further information can also be found on the [Specialist Pharmacy Services Website](#).

What is the appropriate mechanism for COVID-19 vaccination?

There are three mechanisms that can be used for COVID-19 vaccination delivery. **The primary mechanism in all deployment models is the National Protocol.**

The National Protocol (NP)

This can be used by a single registered healthcare professional undertaking all stages or multiple (registered or non-registered) persons undertaking different stages. However, 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 and working under appropriate supervision.

The National Patient Group Direction (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.

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.



Mechanism of delivery	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**?
Patient Specific Directions	It is a written instruction from a prescriber i.e. a doctor, or independent non-medical 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>Patients must be reviewed by a prescriber as being suitable for receiving the treatment.</p> <p>Prescribers would be doctors, independent nurse or pharmacist prescribers*</p>	Non-registered and registered staff can work under a patient specific direction if the prescriber is happy that staff are trained and they take's full accountability for all tasks.	A registered healthcare professional must carry out the clinical assessment. In 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.	Administration can be carried out by trained unregistered or registered healthcare workers under the accountability of the prescriber.
Patient Group Directions	<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 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.</p> <p>These are: chiropodists and podiatrists, dental hygienists, dental therapists, dieticians, midwives, nurses, occupational therapists, optometrists, orthoptists, orthotists and prosthetists, paramedics, pharmacists, physiotherapists, radiographers and speech and language therapists.</p> <p>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>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 medicine 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 National Protocol should be used if any task needs to be split between different healthcare professionals.</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 medicine is to be administered under a PGD, this should be by the same health professional that assessed the patient under the PGD.</p>	<p>The PGD requires that all tasks outlined in the table are carried out by one registered healthcare professional.</p> <p>Further recommendations on the use of PGDs are available from NICE.</p>



<p>National Protocol</p>	<p>This is a new type of instruction that was introduced to support the expanded influenza and COVID-19 Vaccination Campaign. This is a new legal mechanism which has been put in place following amendment of the Medicines Regulations. It will allow 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 the protocol.</p>	<p>Non-registered healthcare workers (e.g. new recruits to NHS and HCW)</p> <p>Registered health care professionals.</p>	<p>Tasks can be split into:</p> <ul style="list-style-type: none"> • Clinical assessment and consent • Preparation and drawing up of vaccine • Administration • Record keeping <p>These tasks can be split and carried out by one or multiple people as required.</p>	<p>The clinical assessment must be carried out by a registered healthcare professional. These are the same healthcare professionals who can clinically assess patients under a PGD and doctors or dentists.</p>	<p>Can be carried out by trained unregistered or registered workers under clinical supervision.</p>
---------------------------------	--	--	---	--	---

*other non-medical prescribers cannot prescribe unlicensed or authorised medicines. Dentists are not able to write a PSD for the COVID vaccines as they need to work within their professional competency.

****Legislation covering preparation of the Vaccine**

Preparation of the vaccine (i.e. dilution and drawing up) is covered by separate specific regulations. This has recently been amended for clarity in relation to the Covid-19 vaccine in [new reg.3A \(1\)](#) of the Human Medicines Regulations. 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.**

Further details on this aspect of the process can be found in the following letters from the NHS England and Improvement, Chief Pharmaceutical Officer, Dr Keith Ridge.

[Governance, handling, and preparation of vaccines by GP led Local Vaccination Centres \(PCN designated sites\)](#)

[Governance, handling and preparation of vaccines in hospital hubs and vaccination centres](#)

[Governance handling and preparation of vaccines in community pharmacy](#)