

Summary of the legal mechanisms for administering the COVID-19 vaccine(s)

This document summarises each of the mechanisms to aid local areas with identifying which is most suitable to be used based on the local staffing mix and models for delivery, and based on the legal framework they must be used within. The table on the following page summarises which mechanism can be used by which staff member and whether tasks can be delegated.

This summary should be read alongside the more detailed version:

<https://www.england.nhs.uk/coronavirus/publication/legal-mechanisms-for-administration-of-the-covid-19-vaccines/>

To note that **doctors** and nurse and 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 healthcare professional authorised to work under the PGD, as does completion of the clinical record.

Summary of key changes made to the regulations in October 2020

To help with workforce flexibility for the COVID-19 and influenza vaccination programmes, key changes were made to the medicines regulations that affect the mechanisms used for the supply or administration of the vaccine. The key changes are:

- 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 is on [GOV.UK](#). Further information can also be found on the [Specialist Pharmacy Services website](#).

Legal Mechanism	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 an instruction from a prescriber i.e. a doctor, dentist, 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 nurses 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 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>Only Registered Health Care Professionals can operate under a PGD where their registered profession has been defined by 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>All tasks must be carried out by a registered healthcare professional (as defined) and cannot be delegated to others.</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>	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>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>	The PGD requires that all functions are carried out by one registered healthcare professional

Classification: Official

<p>National Protocol #</p>	<p>This is a new type of instruction that was introduced to support the expanded influenza and COVID-19 vaccination programmes. 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>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.</p>	<p>Can be carried out by trained unregistered or registered workers under clinical supervision.</p>
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*other non-medical prescribers cannot prescribe unlicensed or authorised medicines. Dentists are not able to write a PSD for the COVID-19 vaccines.

All stages can be undertaken by one competent person (the registered healthcare professional) but in the case of large vaccination centres these tasks can be split with each person trained and authorised to complete their specific task as defined in the protocol.

** preparation of the vaccine is covered by separate specific regulations. The relevant exemptions that exist for healthcare professionals at the final stages of supply are in Regulation 3 of the Human Medicines Regulations (these are in place for doctors, nurses and pharmacists). Further details on this aspect of the process can be found in the following letters from 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 by designated community pharmacies](#)