



APTUK Position Statement

Pharmacy Technicians and the COVID 19 Vaccination Programme

The Association of Pharmacy Technicians United Kingdom (APTUK) leads, advocates, and represents the Pharmacy Technician profession for the benefit of patients, the public and their members.

APTUK provides advice, information and support to members; championing and safeguarding the Pharmacy Technician profession. This statement relates to the role of the Pharmacy Technician to support the COVID 19 vaccination programme on NHS sites or other centres.

Background

Pharmacy Technicians have responded rapidly and professionally to the pandemic and all its challenges. Now with the regulatory approval of the first COVID 19 vaccine in the UK, we are witnessing the rapid mobilisation of the profession to support the distribution, preparation and administration of the vaccine on NHS Sites or other centres. The experience, skills and knowledge of Pharmacy Technicians will contribute to the success of this programme from receipt, stock management and distribution of the vaccine, to support for preparation of the vaccine prior to administration and administration. APTUK fully support the roll out of the COVID 19 vaccination programme, however, any rapid redeployment of Pharmacy Technicians must be considerate of the impact on the safety, health and wellbeing of the individual and the wider implications for the delivery of core pharmacy services.

With a number of different legal mechanisms in place, the purpose of this statement is to provide Pharmacy Technicians, Pharmacists and employing organisations with suitable information and guidance to ensure appropriate governance, resources, training and procedures are in place for Pharmacy Technicians supporting the vaccination programme.

Guiding Principles for Pharmacy Technicians participating in the COVID 19 Vaccine Programme

The following principles have been prepared to assist in the re- deployment of pharmacy technicians:

The role of the Pharmacy Technician in the COVID 19 vaccination programme must be made clear in the local COVID 19 vaccination policy and SOPs which are approved by the organisation's Drug and Therapeutics Committee or equivalent.

The COVID 19 vaccination policy and SOPs should identify the legal mechanism under which the Pharmacy Technician will be working. e.g. PSD, National Protocol.

The COVID 19 vaccination policy and SOPs should include a definition of supervision for the Pharmacy Technician and the escalation and referral processes.

Before undertaking this role pharmacy Technicians should discuss and agree the scope of practice and accountability with their Chief Pharmacist or designated deputy.

Pharmacy Technicians should always adhere to regulatory professional standards and appropriate professional guidance, including guidance specifically relating to the exceptional circumstances surrounding their roles during the COVID 19 pandemic.



THE ASSOCIATION OF PHARMACY TECHNICIANS UK

https://resolution.nhs.uk/wp-content/uploads/2020/03/20200402-Tripartite_Indemnity_letter.pdf

Pharmacy Technicians participating in the vaccine programme under local COVID 19 vaccination policy and SOP's will be covered by employer indemnity; however individuals may wish to ensure they have suitable personal professional indemnity cover in place.

Pharmacy Technicians must undertake appropriate training and competency assessment and must have access to up-to-date information about the specifications of the COVID 19 vaccines e.g., SmPC

E-learning for Health training can be accessed here <https://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators>

Ideally, Pharmacy Technicians responsible for the preparation of the COVID 19 vaccine should have previous experience of working in a Good Manufacturing Practice (GMP) based aseptic environment.

Vaccine Hubs must operate as and maintain a COVID safe environment.

Appropriate Personal Protective Equipment as per Public Health England (PHE) guidance must be available to Pharmacy Technicians at all times.

Access to priority vaccination as front line NHS staff must be facilitated for Pharmacy Technicians in the role.

Governance

The COVID 19 vaccine is a prescription only medicine (POM) which cannot be administered or supplied unless one of the following types of instruction are in place:

- a) a signed Patient Specific Direction (PSD) or 'prescription'
- b) a Patient Group Direction (PGD)
- c) a National Protocol* (applies to influenza and COVID-19 vaccines only).

Legal Mechanism in Operation in Vaccine Programme	Pharmacy Technician Role	Notes
Patient Specific Direction (PSD)	Pharmacy Technicians can prepare vaccine – see notes below*	A PSD for the supply of medicines is classified as a prescription form. This is a legal document and must comply with legislation on the validation of prescriptions
	Pharmacy Technicians can administer if the prescriber agrees and takes full accountability	A PSD can be prescribed by doctors and/or independent nurse or pharmacist prescribers



THE ASSOCIATION OF PHARMACY TECHNICIANS UK



<p>Patient Group Direction (PGD)</p>	<p>Pharmacy Technicians are not included in the Registered Health care professionals listed in legislation.</p> <p>Under a PGD, a Registered Healthcare Professional should carry out all tasks e.g. preparation and administration</p>	<p>PGDs are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment</p> <p>PGDs can usually only be used for licensed medicines. The recent amendment to the regulations (October 2020) allows the registered healthcare workforce that already operates under PGDs to administer vaccinations to continue to do so in the case of an unlicensed or temporarily authorised COVID 19 vaccine.</p> <p>The PGD for the administration of COVID 19 mRNA vaccine BNT162b2 30micrograms in 0.3ml to individuals in accordance with the national COVID 19 vaccination programme was published 11 December 2020</p>
<p>National Protocol</p>	<p>Pharmacy Technicians are not included in the National Protocol definition of Registered Healthcare Professionals. Therefore they cannot undertake clinical assessment or clinically supervise the process of others.</p> <p>Pharmacy Technicians can be authorised by name to work under this protocol and do so under the supervision of a registered Doctor, Nurse or Pharmacist.</p> <p>Pharmacy Technicians can prepare vaccine</p> <p>Pharmacy Technicians can administer</p>	<p>A National Protocol 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.</p> <p>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.</p> <p>It also allows the process of administration to be split into its component parts i.e. clinical assessment and consent, preparation of the vaccine and administration of the vaccine.</p> <p>All stages can be done 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. The clinical assessment and consent process must be undertaken by a registered healthcare professional and the preparation of the vaccine must only be undertaken and overseen by those health care professionals trained in aseptic technique and have the skills for dilution and drawing up as required by the vaccine.</p>



THE ASSOCIATION OF PHARMACY TECHNICIANS UK

* The aseptic preparation of medicines within hospital pharmacy departments and commercially licensed specials manufacturing units is tightly regulated by the Medicines and Healthcare products Regulatory Agency (MHRA) and Regional Quality Assurance teams (depending upon licensed status) with legal provisions in the Medicines Act 1968 and the Human Medicines Regulations 2012 to ensure the safety of patients and product quality is maintained at all times.

The Human Medicines Regulations 2012 allow pharmacists to prepare medicines. Under section 10 of the Medicines Act 1968 Pharmacists can supervise the preparation of medicines by others. This regularly occurs in many hospital pharmacy aseptic units, and it enables the preparation of various drugs to be done in a safe, controlled environment ensuring the final product is released to the clinical areas as a fit for purpose, ready-to-use, or ready-to-administer-dose.

Please note Regulation 3 enables Doctors and Nurses to also supervise pharmacy technicians in the absence of the absence of a pharmacist. This may be more applicable in primary care settings.

The nature of storage and handling requirements of the Pfizer COVID 19 vaccine mean that it is not possible to prepare the vaccine within a pharmacy aseptic unit. Where the legal mechanism in place is a PSD, the decision to undertake preparation in a hospital/vaccine hub and for pharmacy technicians to be utilised to do this will be made by the Chief Pharmacist/Supervising Pharmacist and must be defined in locally determined COVID19 vaccination policies.

Resources and Information

APTUK encourages Healthcare Professionals to access professional and regulatory websites for all current advice relating to the vaccine, including training resources. Further resources will become available as other COVID 19 vaccinations are approved for use.

<https://www.sps.nhs.uk/>

<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>

<https://www.england.nhs.uk/coronavirus/publication/patient-group-direction-for-covid-19-mrna-vaccine-bnt162b2-pfizer-biontech/>

<https://www.gov.uk/government/publications/national-protocol-for-covid-19-mrna-vaccine-bnt162b2-pfizerbiontech>

Liz Fidler

Ellen Williams

President

Vice President

On behalf of the Association of Pharmacy Technicians UK