

Document Type:	Guideline	
Reference Number : 2673	Version Number: 1	Next Review Date: 23 December 2023.
Title:	Ordering Pfizer-BioNTech COVID-19 Vaccine from Public Health England (PHE)	
Document Author:	Pharmacy Operations Manager	
Applicability:	All Pharmacy Procurement Staff	

1. Purpose

This SOP describes the process for ordering Pfizer-BioNTech COVID-19 (BNT162b2) Vaccine from Public Health England (PHE).

2. Scope

Ordering of Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) from PHE. This procedure should be used in conjunction with local procedures for the ordering of medicines.

3. Responsibility

Pharmacy procurement staff are responsible for the ordering / purchasing tasks within this procedure.

The Clinical Director - Pharmacy is professionally accountable for the supply chain and oversight of management of stock on all vaccination sites operating within or under the jurisdiction of Torbay & South Devon NHS Foundation Trust.

4. Procedure

4.1. Stock holding

4.1.1. Purchases are made using the pharmacy stock control system. System parameters will not be used to automatically generate orders. Orders will be placed based on stock holding and clinic schedules.

4.2. Product Details

Supplier Product Code	Product Description	Pack Size	Outer Size
BNT162b2	Courageous 30micrograms/0.3ml dose concentrate for suspension for injection multidose vials	1 vial (0.45ml)	195 vials

4.3. Scheduled routine orders

- 4.3.1. Purchase orders are placed with PHE.
- 4.3.2. Once raised and duly authorised on the stock control system, submit the order on the ImmForm portal.
- 4.3.3. Log on to the ImmForm portal at <https://portal.immform.phe.gov.uk/Logon.aspx?returnurl=%2f>. The user name and password is specific to each Pharmacy purchaser.
- 4.3.4. Enter the purchase order details on to the online order form.
- 4.3.5. For each item ordered check the correct product, quantity, pack size and multiple order quantity is entered
- 4.3.6. When each item has been entered, submit the order.
- 4.3.7. Orders placed on ImmForm portal before 11:55am Monday to Friday will receive next day delivery (Tuesday to Saturday respectively).
- 4.3.8. Orders placed on ImmForm portal after 11:55am Friday and before 11:55am Saturday will be delivered Monday.
- 4.3.9. Orders placed on ImmForm portal after 11:55am Saturday and before 11:55am Monday will be delivered Tuesday.
- 4.3.10. A separate delivery schedule is applicable over the Christmas holiday period

4.4. Unscheduled urgent orders

4.4.1. An emergency delivery schedule is not available. Orders after cut off will be processed the next day.

4.5. Associated Supplies

The vaccine will be delivered with 5 other components:

- 0.9% sodium chloride (preservative free) diluent for injection (5ml plastic amps in a pack of 20)
- Syringe/needle for the dilution step
- Patient factsheet (box of 1000)
- Patient record card (box of 1000)
- Combined needles and syringes for administration

5. References

Central storage and UK distribution of Covid vaccines, associated products and combined needles and syringes for administration - Operating Model Vaccines & Countermeasures Response, PHE Version 4.0 22 November 2020

Document Control Information

This is a controlled document and should not be altered in any way without the express permission of the author or their representative.

Please note this document is only valid from the date approved below, and checks should be made that it is the most up to date version available.

If printed, this document is only valid for the day of printing.

This guidance has been registered with the Trust. The interpretation and application of guidance will remain the responsibility of the individual clinician. If in doubt contact a senior colleague or expert. Caution is advised when using clinical guidance after the review date, or outside of the Trust.

Ref No:	2673		
Document title:	Ordering Pfizer-BioNTech COVID-19 Vaccine from Public Health England (PHE)		
Purpose of document:	This SOP describes the process for ordering Pfizer-BioTech COVID-19 (BNT162b2) Vaccine from Public Health England (PHE).		
Date of issue:	23 December 2020	Next review date:	23 December 2023
Version:	1	Last review date:	
Author:	Operations Manager - Pharmacy Dept		
Directorate:	Trustwide		
Equality Impact:	The guidance contained in this document is intended to be inclusive for all patients within the clinical group specified, regardless of age, disability, gender, gender identity, sexual orientation, race and ethnicity & religion or belief		
Committee(s) approving the document:	Clinical Director – Pharmacy and Prescribing		
Date approved:	18 December 2020		
Links or overlaps with other policies:			

Have you identified any issues on the Rapid (E)quality Impact Assessment. If so please detail on Rapid (E)QIA form.	Yes <input type="checkbox"/>	
	Please select Yes No	
Does this document have implications regarding the Care Act? <i>If yes please state:</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this document have training implications? <i>If yes please state:</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Procurement staff need adequate access to relevant ordering portals and training		
Does this document have financial implications? <i>If yes please state:</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Is this document a direct replacement for another?		
<i>If yes please state which documents are being replaced:</i>		
	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Document Amendment History

Date	Version no.	Amendment summary	Ratified by:
23 December 2020	1	New	Clinical Director – Pharmacy and Prescribing

The Mental Capacity Act 2005

The Mental Capacity Act provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they lack capacity in the future. It sets out who can take decisions, in which situations, and how they should go about this. It covers a wide range of decision making from health and welfare decisions to finance and property decisions

Enshrined in the Mental Capacity Act is the principle that people must be assumed to have capacity unless it is established that they do not. This is an important aspect of law that all health and social care practitioners must implement when proposing to undertake any act in connection with care and treatment that requires consent. In circumstances where there is an element of doubt about a person's ability to make a decision due to 'an impairment of or disturbance in the functioning of the mind or brain' the practitioner must implement the Mental Capacity Act.

The legal framework provided by the Mental Capacity Act 2005 is supported by a Code of Practice, which provides guidance and information about how the Act works in practice. The Code of Practice has statutory force which means that health and social care practitioners have a legal duty to have regard to it when working with or caring for adults who may lack capacity to make decisions for themselves.

“The Act is intended to assist and support people who may lack capacity and to discourage anyone who is involved in caring for someone who lacks capacity from being overly restrictive or controlling. It aims to balance an individual's right to make decisions for themselves with their right to be protected from harm if they lack the capacity to make decisions to protect themselves”. (3)

All Trust workers can access the Code of Practice, Mental Capacity Act 2005 Policy, Mental Capacity Act 2005 Practice Guidance, information booklets and all assessment, checklists and Independent Mental Capacity Advocate referral forms on ICON.

<https://icon.torbayandsouthdevon.nhs.uk/areas/mental-capacity-act/Pages/default.aspx>

Infection Control

All staff will have access to Infection Control Policies and comply with the standards within them in the work place. All staff will attend Infection Control Training annually as part of their mandatory training programme.

Rapid (E)quality Impact Assessment (EqIA) *(for use when writing policies)*

Policy Title (and number)		Version and Date	
Policy Author			
An (e)quality impact assessment is a process designed to ensure that policies do not discriminate or disadvantage people whilst advancing equality. Consider the nature and extent of the impact, not the number of people affected.			
Who may be affected by this document?			
Patients/ Service Users	<input type="checkbox"/>	Staff	<input type="checkbox"/>
Other, please state...		<input type="checkbox"/>	
Could the policy treat people from protected groups less favourably than the general population? PLEASE NOTE: Any 'Yes' answers may trigger a full EIA and must be referred to the equality leads below			
Age	Yes <input type="checkbox"/> No <input type="checkbox"/>	Gender Reassignment	Yes <input type="checkbox"/> No <input type="checkbox"/>
Race	Yes <input type="checkbox"/> No <input type="checkbox"/>	Disability	Yes <input type="checkbox"/> No <input type="checkbox"/>
Gender	Yes <input type="checkbox"/> No <input type="checkbox"/>	Pregnancy/Maternity	Yes <input type="checkbox"/> No <input type="checkbox"/>
Sexual Orientation		Yes <input type="checkbox"/> No <input type="checkbox"/>	
Religion/Belief (non)		Yes <input type="checkbox"/> No <input type="checkbox"/>	
Marriage/ Civil Partnership		Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is it likely that the policy could affect particular 'Inclusion Health' groups less favourably than the general population? (substance misuse; teenage mums; carers ¹ ; travellers ² ; homeless ³ ; convictions; social isolation ⁴ ; refugees)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Please provide details for each protected group where you have indicated 'Yes'.			
VISION AND VALUES: Policies must aim to remove unintentional barriers and promote inclusion			
Is inclusive language ⁵ used throughout?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
Are the services outlined in the policy fully accessible ⁶ ?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
Does the policy encourage individualised and person-centred care?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
Could there be an adverse impact on an individual's independence or autonomy ⁷ ?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
EXTERNAL FACTORS			
Is the policy a result of national legislation which cannot be modified in any way?			Yes <input type="checkbox"/> No <input type="checkbox"/>
What is the reason for writing this policy? (Is it a result in a change of legislation/ national research?)			
Who was consulted when drafting this policy?			
Patients/ Service Users	<input type="checkbox"/>	Trade Unions	<input type="checkbox"/>
Protected Groups (including Trust Equality Groups)		<input type="checkbox"/>	
Staff	<input type="checkbox"/>	General Public	<input type="checkbox"/>
Other, please state...		<input type="checkbox"/>	
What were the recommendations/suggestions?			
Does this document require a service redesign or substantial amendments to an existing process? PLEASE NOTE: 'Yes' may trigger a full EIA, please refer to the equality leads below			Yes <input type="checkbox"/> No <input type="checkbox"/>
ACTION PLAN: Please list all actions identified to address any impacts			
Action	Person responsible	Completion date	
AUTHORISATION:			
By signing below, I confirm that the named person responsible above is aware of the actions assigned to them			
Name of person completing the form		Signature	
Validated by (line manager)		Signature	

Please contact the Equalities team for guidance:

For Devon CCG, please email d-ccg.equalityanddiversity@nhs.net & d-ccg.QEIA@nhs.net

For Torbay and South Devon NHS Trusts, please call 01803 656676 or email pdf.sdhct@nhs.net

This form should be published with the policy and a signed copy sent to your relevant organisation

Consider any additional needs of carers/ parents/ advocates etc, in addition to the service user

² Travelers may not be registered with a GP - consider how they may access/ be aware of services available to them

³ Consider any provisions for those with no fixed abode, particularly relating to impact on discharge

⁴ Consider how someone will be aware of (or access) a service if socially or geographically isolated

⁵ Language must be relevant and appropriate, for example referring to partners, not husbands or wives

⁶ Consider both physical access to services and how information/ communication is available in an accessible format

⁷ Example: a telephone-based service may discriminate against people who are d/Deaf. Whilst someone may be able to act on their behalf, this does not promote independence or autonomy

Clinical and Non-Clinical Policies – Data Protection

Torbay and South Devon NHS Foundation Trust (TSDFT) has a commitment to ensure that all policies and procedures developed act in accordance with all relevant data protection regulations and guidance. This policy has been designed with the EU General Data Protection Regulation (GDPR) and Data Protection Act 2018 (DPA 18) in mind, and therefore provides the reader with assurance of effective information governance practice.

The UK data protection regime intends to strengthen and unify data protection for all persons; consequently, the rights of individuals have changed. It is assured that these rights have been considered throughout the development of this policy. Furthermore, data protection legislation requires that the Trust is open and transparent with its personal identifiable processing activities and this has a considerable effect on the way TSDFT holds, uses, and shares personal identifiable data.

Does this policy impact on how personal data is used, stored, shared or processed in your department? Yes No

If yes has been ticked above it is assured that you must complete a data mapping exercise and possibly a Data Protection Impact Assessment (DPIA). You can find more information on our [GDPR](#) page on ICON (intranet)

For more information:

- Contact the Data Access and Disclosure Office on dataprotection.tsdf@nhs.net,
- See TSDFT's [Data Protection & Access Policy](#),
- Visit our [Data Protection](#) site on the public internet.