manx care
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Patient Group Direction for Covid-19 mRNA vaccine BNT162b2 (Pfizer/BioNTech)

(Publications approval reference C1378) ("the PGD")

Reference no:	COVID-19 mRNA vaccine BNT162b2 PGD
Version no:	v05.00
Valid from:	20 September 2021
Review date:	1 October 2021
Expiry date:	31 March 2022

Status

This document is to be read in conjunction with the PGD and shall not be deemed or implied to alter or amend the terms of the PGD in any way. This document seeks to explain and confirm certain parts of the PGD in the context of the Isle of Man and sets out guidance for practitioners intending to sign the PGD and working within it in order to mitigate any risks of non-compliance which would invalidate the cover provided for practitioners working to the PGD.

Background to the PGD

The PGD has been developed by Public Health England ("PHE") for authorisation by NHS England and NHS Improvement (together, "NHS") to facilitate the delivery of the national COVID-19 vaccination programme ("the vaccination programme"). The PHE, and NHS have developed and obtained organisational authorisation under the terms of the PGD to issue it.

The PGD has not been adapted for use in the Isle of Man but instead Manx Care will follow the PGD for the purposes of the vaccination programme from the date of the issue of this letter until any new or revised PGD comes into force. The PGD is therefore endorsed by Manx Care for practitioners to adhere to in the vaccination programme, subject to the matters set out in this letter. Using the PGD authorises practitioners to administer the Covid -19 mRNA vaccine BNT162b2 (Pfizer/BioNTech).

Signing the PGD

All registered practitioners working under the PGD are required individually to sign section 7 of the PGD. An authorising manager must sign as a counter-signatory. Such signature provides the authority for the practitioner to administer the vaccination programme subject to the terms of the PGD. Persons qualified to administer, and additional requirements are set out in section 3 of the PGD which practitioners should ensure that they are aware of, and can comply with, prior to signing the PGD. Only those authorised by name can work according to the PGD.

Note that in accordance with the PGD, versions of it may be updated, and in that case Manx Care will use all reasonable endeavours to notify all practitioners of any updates however, practitioners must assure themselves they are working on the current version. Practitioners

and authorising managers are responsible for compliance with the terms of the PGD. Indemnity will be addressed under separate cover.

PGD conditions

There are conditions for administering the vaccination programme under the PGD. In summary, these are:

1. That current national recommendations should be followed – this means recommendations by PHE or the NHS ;
2. That additional requirements which include all those set out in section 3 are satisfied;
3. That the practitioner ensures clinical conditions set out in section 4 of the PGD are met.

In relation to the additional requirements, particularly relating to training, recommendations or other clinical conditions, contact will be made with any of the signatories detailed below.

Isle of Man Legal Position

Section 5 of the PGD sets out the status of the marketing authorisation of the vaccine, specifically that a temporary authorisation is provided by the Medicines & Healthcare products Regulatory Agency (MHRA) for supply in the United Kingdom. Manx Care confirms that the equivalent legislation is in place in the Isle of Man, and that those regulations provide for immunity from civil liability provided that the practitioner uses the product in accordance with the recommendation or requirement of the MHRA.[1] This requires all practitioners working to the PGD to administer in accordance with the manufacturer's instructions.

The liability and indemnification of individual officers in respect of the administration of the vaccine is set out under separate cover.

Signed on 21st September 2021

[redacted]

[redacted]

[redacted]

[1] The Medicines for Human Use (Amendment) Regulations 2020 were approved by Tynwald on 18 November 2020 and came into operation on 20 November 2020. These Regulations inserted a new regulation 4A (immunity from civil liability) into the Medicines for Human Use Regulations 2005.