GUERNSEY STATUTORY INSTRUMENT

2020 No. 125

The Medicines (Coronavirus and Influenza) (Bailiwick of Guernsey) Regulations, 2020

Made	*8th December, 2020*
Coming into operation	*9th December, 2020*
Laid before the States	*, 2021*

THE COMMITTEE FOR HEALTH & SOCIAL CARE, in exercise of the powers conferred on it by sections 7(3) and (3A), 15, 34, 39, 75 and 132 of the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008[a], section 15(2) and (3) of the Prescription Only Medicines (Human (Bailiwick of Guernsey) Ordinance, 2009[b] (following consultation with the Policy & Resources Committee of the States of Guernsey, the Policy and Finance Committee of the States of Alderney and the Medical & Emergency Services Committee of the Chief Pleas) and all other powers enabling it in that behalf, hereby makes the following Regulations:-

Designation of vaccines.

1. (1) The medicinal product specified in paragraph (2) is designated to be used for vaccination or immunisation against the coronavirus.

(2) Paragraph (1) refers to the COVID-19 mRNA Vaccine BNT162b2 concentrate for solution for injection, also known as the Pfizer-BioNTech

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a Order in Council No. V of 2009; as amended by Ordinance No. XXIV of 2009; No. XLI of 2013; No. IX of 2016.

b Ordinance No. XXV of 2009; as amended by No. XXV of 2010; No. IX of 2016; No. XXXIV of 2020.

COVID-19 Vaccine.

(3) The designation in paragraph (1) is subject to the conditions specified in the document entitled "Vaccine BNT162b2 – Conditions of Authorisation under Regulation 174" dated 2 December 2020 set out in the Schedule.

Exemption from section 7 of the Law.

2. A designated vaccine is exempt from section 7 (General provisions as to dealing with medicinal products) of the Law if it is sold or supplied, procured to be sold or supplied, procured to be manufactured or assembled, or otherwise placed on the market in the Bailiwick –

(a) by or on behalf of the Committee, or otherwise, under arrangements made by the Committee,

(b) under Her Majesty's Forces' arrangements, or

(c) under a Patient Group Direction or a protocol.

Exemption from section 8 of the Law.

3. (1) Section 8 (Provisions as to manufacture and wholesale dealing) of the Law does not apply in connection with the distribution by way of wholesale dealing of a relevant medicinal product where condition A or B is satisfied.

(2) Condition A is satisfied where the person distributing the medicinal product –

(a) was supplied with the medicinal product for the purposes of the administration of it under relevant arrangements,

(b) is supplying the medicinal product for the purposes of

the administration of it by the person to whom it is being supplied (or by a person employed or engaged by them) under relevant arrangements, and

(c) is authorised by the Committee to supply the medicinal product as mentioned in subparagraph (b) under the relevant arrangements.

(3) Condition B is satisfied where the medicinal product is intended to be supplied or administered in accordance with a protocol and the person distributing the medicinal product –

(a) was supplied with the medicinal product for the purposes of the supply or administration of it to a patient under relevant arrangements,

(b) is supplying the medicinal product for the purposes of the supply or administration of it to a patient by the person to whom it is being supplied (or by a person employed or engaged by them) under relevant arrangements, and

(c) is authorised by the Committee to supply the medicinal product as mentioned in subparagraph (b) under the relevant arrangements.

(4) In this regulation, "**relevant medicinal product**" means the designated vaccine or a medicinal product to be used for vaccination or immunisation against influenza virus.

(5) This regulation expires on the 1st April, 2022.

Exemption from section 29 of the Law.

4. (1) Subject to paragraph (2), a designated vaccine is exempt from section 29 (Sale or supply of medicinal products not on general sale list) of the Law where it is sold or supplied, or offered or exposed to be sold or supplied –

(a) under relevant arrangements, or

(b) under a Patient Group Direction or a protocol.

(2) Nothing in this regulation limits the effect of the Medicines (Human) (Pharmacy and General Sale – Exemption) (Bailiwick of Guernsey) Order, 2009[c].

Amendment of Medicines (Human) (Sale and Supply) (Bailiwick of Guernsey) Regulations, 2009.

5. Regulation 2 of the Medicines (Human) (Sale and Supply) (Bailiwick of Guernsey) Regulations, 2009[d] is amended as follows –

(a) in paragraph (1), for "paragraph (2)", substitute "paragraphs (2) and (3)", and

(b) immediately after paragraph (2), insert the following paragraph –

"(3) A person may, in the course of a business consisting (wholly or partly) of manufacturing medicinal products or of selling products by way of wholesale

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c G.S.I. No. 69 of 2009.

d G.S.I. No. 71 of 2009.

dealing, sell by way of wholesale dealing a prescription only medicine to any person who, by virtue of section 15A of the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009, may supply or administer that medicine in accordance with a protocol of the type mentioned in that provision.".

Amendment of Medicines (Human) (Advertising) (Bailiwick of Guernsey) Regulations, 2009.

6. (1) The Medicines (Human) (Advertising) (Bailiwick of Guernsey) Regulations, 2009[e] is amended as follows.

(2) In regulation 1 of those Regulations, immediately after "the product", insert "or the product is a designated vaccine and the advertisement is issued as part of a campaign approved by the Committee for Health & Social Care".

(3) In each of regulations 6, 7 and 8 of those Regulations, for "regulation 11", substitute "regulations 10A and 11".

(4) In regulation 9 of those Regulations, for "regulation 10", substitute "regulations 10 and 10A".

(5) Immediately after regulation 10 of those Regulations, insert the following regulation –

"**Campaigns relating to designated vaccines**.

10A. Regulations 6, 7, 8(d) and 9(e) do not apply to an advertisement as part of a campaign –

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e G.S.I. No. 70 of 2009.

(a) that relates to the use of –

(i) a designated vaccine for vaccination or immunisation against the coronavirus, or

(ii) a medicinal product for vaccination or immunisation against influenza virus, and

(b) that is approved by the Committee for Health & Social Care.".

(6) In regulation 36(1) of those Regulations, insert in the appropriate alphabetical order, the following definitions –

""**the coronavirus**" has the meaning given by section 20(1) of the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009,", and

""**designated vaccine**" has the meaning given by section 20(1) of the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009,".

(7) In Schedule 1 to those Regulations –

(a) in paragraph 1, immediately before "The marketing", insert "Except in the case of a designated vaccine,",

(b) in paragraph 2, immediately after "certificate of registration", insert ", or in the case of a designated vaccine, the temporary authorisation given for the vaccine under regulation 174 of the Human Medicines

Regulations, 2012,",

(c) in paragraph 5, immediately after "herbal registration", insert ", or in the case of a designated vaccine, the conditions subject to which the vaccine is designated", and

(d) in each of paragraphs 6 and 7, immediately after "product characteristics", insert ", or in the case of a designated vaccine, in any equivalent summary published by the holder of the temporary authorisation given for the vaccine under regulation 174 of the Human Medicines Regulations, 2012,".

(8) In Schedule 2 to those Regulations –

(a) in paragraph 1, immediately after "certificate of registration", insert ", or in the case of a designated vaccine, the temporary authorisation given for the vaccine under regulation 174 of the Human Medicines Regulations, 2012,",

(b) in paragraph 5 –

(i) immediately after "certificate of registration", insert ", or in the case of a designated vaccine, the temporary authorisation given for the vaccine under regulation 174 of the Human Medicines Regulations, 2012,", and

(ii) immediately after "product characteristics",

insert ", or in the case of a designated vaccine, in any equivalent summary published by the holder of the temporary authorisation given for the vaccine under regulation 174 of the Human Medicines Regulations, 2012".

Interpretation.

7. In these Regulations –

"**the Committee**" means the Committee for Health & Social Care,

"**the coronavirus**" means the Severe Acute Respiratory Syndrome Coronavirus 2, the virus causing the disease COVID-19,

"**the designated vaccine**" means the medicinal product specified in regulation 1(2),

"**Her Majesty's Forces' arrangements**" means arrangements for the provision of services as part of the medical services of Her Majesty's Forces,

"**the Law**" means the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008, and

"**the Ordinance**" means the Prescription Only Medicines (Human (Bailiwick of Guernsey) Ordinance, 2009,

"**Patient Group Direction**" has the meaning given by section 15(4) of the Ordinance,

"**product**" means the medicinal product sold, supplied or administered in circumstances falling within section 1(1)(c),

"**protocol**" means any protocol for the sale, supply or administration of the designated vaccine approved under or for the purposes of section 15A of the Ordinance, and

"**relevant arrangements**" means –

(a) arrangements made by the Committee, or

(b) Her Majesty's Forces' arrangements.

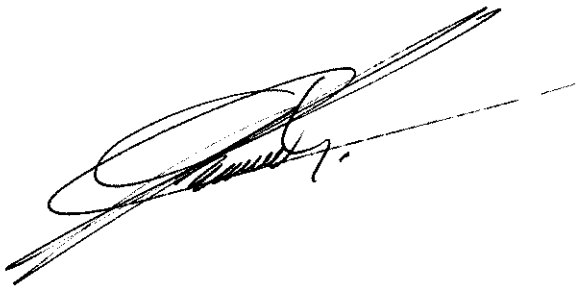
Citation.

8. These Regulations may be cited as the Medicines (Coronavirus and Influenza) (Bailiwick of Guernsey) Regulations, 2020.

Commencement.

9. These Regulations come into force on the 9th December, 2020.

Dated this 8th day of December, 2020



Deputy A.H. Brouard

President of the Committee for Health & Social Care

For and on behalf of the Committee

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations designate the COVID-19 mRNA Vaccine BNT162b2 concentrate for solution for injection, also known as the Pfizer-BioNTech COVID-19 Vaccine ("**the designated vaccine**"), to be used for vaccination or immunisation against the coronavirus.

These Regulations also exempt the designated vaccine from sections 7 (General provisions as to dealing with medicinal products), 8 (Provisions as to manufacture and wholesale dealing) and 29 (Sale or supply of medicinal products not on general sale list) of the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008, where the vaccine is being sold, supplied, placed on the market, distributed by way of wholesale dealing or otherwise dealt with under arrangements made by the Committee for Health and Social Care or made in relation to Her Majesty's Forces, or under a Patient Group Direction or protocol approved under the Prescription Only Medicines (Human (Bailiwick of Guernsey) Ordinance, 2009.

In addition, these Regulations provide an exemption from section 8 (Provisions as to manufacture and wholesale dealing) of the Law, for distribution by way of wholesale dealing of influenza vaccines under arrangements made by the Committee or made in relation to Her Majesty's forces, or a protocol approved under the Prescription Only Medicines (Human (Bailiwick of Guernsey) Ordinance, 2009.

Further, these Regulations consequentially amend the Medicines (Human) (Sale and Supply) (Bailiwick of Guernsey) Regulations, 2009 and the Medicines (Human) (Advertising) (Bailiwick of Guernsey) Regulations, 2009, to provide specially for wholesale dealing (if required) and advertising of the designated vaccine.

These Regulations will come into force on the 9th December 2020.

Medicines & Healthcare products Regulatory Agency

MHRA

Vaccine BNT162b2 – CONDITIONS OF AUTHORISATION UNDER REGULATION 174

2 December 2020

This authorisation under Regulation 174 of the Human Medicine Regulations 2012 (as amended) is subject to a number of conditions attached under regulation 174A(1) to all the entities involved in the manufacture and supply of this product across the medicines supply chain.

General

- This temporary Authorisation under Regulation 174 permits the supply of identified COVID-19 mRNA Vaccine BNT162b2 batches, based on the safety, quality and efficacy data submitted by Pfizer/BioNTech to MHRA in the period from 1st October to 2 December 2020;
- This authorisation is not a marketing authorisation;
- As provided in Regulation 174A(2) of the Human Medicine Regulations the sale or supply of this vaccine will not be deemed authorised if the supply is for the purpose of any use other than the recommended or required use, or if a condition in this authorisation is breached;
- The entity responsible for physically supplying the product in the United Kingdom is Pfizer Limited (incorporated in England and Wales under registered number 526209). Pfizer Limited and BioNTech Manufacturing GmbH (An der Goldgrube 12, 55131 Mainz, Germany) will be jointly and separately responsible for placing the product on the market in the United Kingdom for the purposes of The Human Medicines Regulations including Reg 345(3) (hereinafter "Pfizer/BioNTech");
- Pfizer/BioNTech are jointly and separately responsible, with the manufacturers of the product, for the conditions relating to the manufacture of the product and to product release to the market under the terms of this authorisation;
- Pfizer/BioNTech is not only responsible for compliance with the conditions expressly applied to it in this authorisation but also, where the conditions apply legislation or guidance that confers responsibilities on marketing authorisation holders, for compliance with any responsibility however worded that applies to a marketing authorisation holder in the applied legislation or guidance;
- Pfizer/BioNTech must promptly provide to MHRA any further data that is generated by them, or which otherwise come into their possession, which is relevant to the risk / benefit profile of the product;
- Pfizer/BioNTech must respond in a timely manner to any requests for further supplementary data relating to product;
- Any deviations from any of these conditions can only be made with the prior agreement of the MHRA;

- MHRA may review and adjust these conditions for temporary supply in response to any developments which it considers material, including any subsequent market authorisations that might be issued by other medicines regulators;

- This authorisation will be valid until expressly withdrawn by MHRA or upon issue of a full market authorisation by the MHRA.

Quality

- The supply of batch EJ0553 is authorised providing that:
    - Pfizer/BioNTech ensure that Good Laboratory Practice studies are performed to standards in UK national regulations, relevant guidelines and the OECD Principles of Good Laboratory Practice.
    - Pfizer/BioNTech ensure that clinical trials are performed to national regulations and relevant guidelines including ICH GCP E6R2
    - Pfizer/BioNtech submit to MHRA GCP inspections to assess the compliance any of the clinical trials and applicable data attached to the authorisation by virtue of regulation 174A. The powers of inspection will be the same as those outlined in regulations 325, 326 and 327
    - Pfizer/BioNtech ensure that all drug substance and drug product manufacture outside the UK is in accordance with EU GMP and the Human Medicines Regulations 2012 (as amended) in facilities with current EU GMP certificates or other acceptable and suitable authorisation to MHRA.
    - QP certification is provided for the final dosage form and applying the approach and standards in EU GMP Annex 16.
    - Any importation or manufacturing facilities located within the UK must be authorised by the MHRA to handle Regulation 174 products. All drug substance and drug product manufacture must be in accordance with EU GMP and the Human Medicines Regulations 2012 (as amended) in facilities with current EU GMP certificates or other acceptable and suitable authorisation to MHRA.
    - Compliance with GMP requirements is documented in the QP check sheets and Pfizer/BioNTech provide these to the MHRA for each batch along with the QP certificates of conformance. QP certification must take into NIBSC certification process, as this in itself does not imply release to market.
    - QP certification declares: (i) compliance with all stages of EU GMP (where non-compliant, a gap analysis must be performed, and captured on the QP checksheet), and (ii) that the batch has been manufactured as per the dossier supplied (currently Emergency Use Authorisation).
    - A certificate of conformance with GMP and the conditions of this authorization must be generated by the releasing QP and supplied to the onward supply chain.

- Further batches are authorised for supply, subject to batch specific approval by MHRA and providing that the full product lifecycle is in compliance with the conditions specified above in relation to batch EJ0553;
- Pfizer/BioNTech must provide relevant additional characterization data regarding drug product manufacturing process and product quality reasonably requested by MHRA, and will provide relevant additional characterization data regarding drug product manufacturing process and product quality, whether or not requested by MHRA, as soon as they become available.
- Any changes to or deviation from the manufacture of the product must be notified to MHRA for approval on allocation of the batch to UK use.

Product information and Instructions for Use (PIL and SmPC equivalent)

- Pfizer/BioNTech must liaise with the Agency to provide suitable instructions for usage of the product.
- The instructions for usage that will be agreed with Pfizer/BioNTech are to be considered as conditions of this authorisation.

Clinical and Pharmacovigilance

- Pfizer/BioNTech must operate a comprehensive pharmacovigilance system for this product in accordance with UK legislation for licensed products, as if they were market authorisation holders
- Pfizer/BioNtech must submit to MHRA inspections to assess compliance with any and all pharmacovigilance obligations attached to the authorisation by virtue of regulation 174A. The powers of inspection will be the same as those outlined in regulations 325, 326 and 327.
- Pfizer/BiotNTech must ensure compliance with the BTN162b2 RMP, including the additional pharmacovigilance elements laid out in sections 6b-g of the MHRA core RMP for COVID-19 vaccines.
- Pfizer/BioNTech must:
    - Submit protocols for the studies stated in the BTN162b2 RMP pharmacovigilance plan
    - Provide the interim analysis and final clinical study reports for study BNT162-01 once available, including data on healthy subjects
    - Ensure that any participants in study c4591001 that choose to be unblinded and then have a Covid-19 vaccination if they are on placebo arm, should have an end of study visit including immunogenicity assessment (including anti-N antibodies) and also NAAT. This is to ensure that they have a complete status before they become unevaluable for the control arm.

Deployment

Pfizer/BioNTech has assured the MHRA that, in light of the UK and Crown Dependency deployment model:

- The product as supplied in ultra low temperature conditions (ULT) has a stability of six months at a temperature of -70 +/- 10 degrees Centigrade.
- Distribution as part of the deployment can be controlled at either ULT (-70 +/- 10 degrees Centigrade) within four transitions below -15 degrees Centigrade, or in 2-8 degrees Centigrade within 120 hours of leaving ULT.
- Further packing down of lots to aid deployment can occur at 2-8 degrees Centigrade within the 120 hours shelf life of leaving ULT.
- Transit of the undiluted product at 2-8 degree Centigrade can occur either in two journeys each up to 6 hours or, where there are real deployment needs, for a maximum of 12 hours in one sitting. These times are to be taken within the 120 hour shelf life.
- The undiluted product can be held at room temperature below 25 degrees Centigrade for up to two hours prior to dilution.
- The product can be diluted at room temperature less than 25 degrees Centigrade using sterile unpreserved 0.9 percent sodium chloride and in line with the healthcare professional information supplied by the company
- The diluted product can be used within 6 hours of dilution and then must be discarded. Diluted product cannot be transported.

It is a condition of the authorisation to supply the product that the above assurances are accurate and that the product can be supplied and held safely in accordance with the above assurances throughout the supply chain.

Supply chain and distribution

The deployment model developed for the distribution and administration of the product by the NHS in each of the four countries of the United Kingdom and Crown Dependencies should comply with the above conditions in order to ensure the safety, quality and efficacy of the product is not compromised. Where appropriate, the above assurances must be reflected in the conditions imposed on NHS contractors by NHS commissioners.

In the United Kingdom, the vaccines will be delivered to designated NHS bodies or NHS contractors that have capacity to hold the vaccines at ultra low temperatures. Thereafter, the NHS arrangements for the onward and (if different) final distribution of the products, and their final deployment, are still being developed, but the bodies responsible under NHS arrangements in each of the four countries for any aspect of the distribution or final deployment of the vaccine must comply, as conditions of this authorisation, with the conditions that are applicable to that aspect of the distribution or final deployment in this authorisation.

The bodies responsible for the transit of the product to the designated NHS bodies or NHS contractors in the UK from the manufacturer must also comply, as conditions of this authorisation, with the conditions of the authorisation that are applicable to them.

In addition:

- All wholesalers and manufacturing license holders distributing or holding this product must be authorised to handle Regulation 174 products
- All activities are to be conducted in accordance with GDP.
- A manufacturing licence holder can pack down the authorised product without being named on the Company submission.
- Pack down prior to distribution must occur in accordance with GMP and requires QP certification that it has occurred in accordance with GMP and the specification provided by the contract giver.
- Manufacturers and authorised persons performing the pack down activities must be authorised to handle regulation 174 products and immunological products.
- WDA(H) holders and NHS acute trusts and Boards in Wales, Scotland and Northern Ireland are authorised to apply the change in storage condition label to the product, to indicate the timing of the removal from ultra low temperature without a manufacturing licence.
- All distribution must be controlled at either ULT within four transitions, or in 2-8 degrees Centigrade within 120 hours from leaving ULT
- The WDA(H) receiving the boxes must be authorised for Regulation 174 products and ULT cold chain.
- Pack down under section 10 of the Medicines Act 1968 or regulation 3 of the Human Medicines Regulations 2012 for supply by the same legal entity must take place in a manner and environment that ensure, and must be subject to NHS governance arrangements and standard operating procedures that ensure, that the safety, quality and efficacy of the product is not compromised. Any guidance in respect of the packing down of the product under section 10 or regulation 3 published by the licensing authority on Gov.uk must be appropriately adhered to.
- Final preparation of the product for administration must take place in a manner and environment ensure, and must be subject to NHS governance arrangements and standard operating procedures that ensure, the safety, quality or efficacy of the product is not compromised. Any guidance in respect of the final preparation of the product published by the licensing authority on Gov.uk must be appropriately adhered to
- In light of the batch specific nature of this approval, and the high demand for this product, authorities administrating this vaccine should ensure that they have provision for two doses for each patient treated.