Australian Government

Department of Health
Therapeutic Goods Administration

The Managing Director
Pfizer Australia Pty Ltd
Level 17, 151 Clarence Street
Sydney NSW 2000

Submission No: PM-2020-05461-1-2
Clinical File: E20-364588
Co-ord. File: E20-364582
PI/CMI File: E21-208354
Qual / Micro. File: E20-364586
RMP File: E20-364684

**Attention:** [redacted]
Regulatory Affairs Manager
[redacted]@pfizer.com
RegulatorAffairs.ANZ@pfizer.com

**Notice of decisions to provisionally register medicine(s), to approve product information, and to impose conditions under the *Therapeutic Goods Act 1989***

Dear Sir/Madam,

I refer to your application letter dated 23 October 2020 for the provisional registration for COMIRNATY (BNT162b2 [mRNA]) COVID-19 VACCINE in the Australian Register of Therapeutic Goods (**ARTG**) under the *Therapeutic Goods Act 1989* (the **Act**). Specifically, your submission relates to the following application:

AUST R 346290 COMIRNATY (BNT162b2 [mRNA]) COVID-19 VACCINE 30 micrograms/0.3 mL concentrated suspension for injection vial

This notice comprises the following parts:

**Part A**: **Decision to provisionally register the medicine(s)**
1. Decision to provisionally register the new biological medicine
2. Duration and commencement of provisional registration period; and
3. Inclusion of the medicine(s) in the ARTG.

**Part B: Decision to approve product information of the medicine(s)**
1. Decision to approve; and
2. Lodgement of product information with the TGA.

**Part C: Decision to impose conditions**

**Part D: Other matters**

## Part A: Decision to provisionally register the medicine(s)

### 1. Decision to provisionally register

I am a delegate of the Secretary of the Department of Health for the purposes of section 25(3) of the Act. Following the completion of an evaluation of the medicine, I have decided to **provisionally register** the above medicine. My decision is based on the evaluation of the information and data provided with your submission and any subsequent correspondence.

The provisionally approved new indication for the medicine is:

*"COMIRNATY (BNT162b2 [mRNA]) COVID-19 Vaccine has provisional approval for the indication below:*

*Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 16 years of age and older.*

*The use of this vaccine should be in accordance with official recommendations.*

*The decision has been made on the basis of short term efficacy and safety data. Continued approval depends on the evidence of longer term efficacy and safety from ongoing clinical trials and post-market assessment."*

### 2. Duration and commencement of provisional registration period

The provisional registration period for the above medicine is **two years** starting on the day specified in the ARTG certificate of registration, which will be available for downloading from the eBS Web Site (https://www.ebs.tga.gov.au/) the day following the entry being written to the ARTG.

**Note:** The above medicine cannot be included in the ARTG until you have provided the TGA with the requisite patent certificate or a notice that such a certificate is not required.

### 3. Inclusion of medicine(s) in the ARTG

Before the medicine can be included in the ARTG, you are required to either:

- notify the Secretary using the approved form that the patent certification under subsection 26B(1) is not required in relation to the application; OR
- provide a certificate required under subsection 26B(1) of the Act.

The requirement for patent certificates does not apply to applicants for registration of medicines who are not required to submit evidence or information to establish the safety or efficacy of the goods as part of the registration process. In these circumstances, applicants are only required to notify the Secretary in the approved form that the subsection 26B(1) patent certificate is not required in relation to the applications.

The notification form and patent certificate can be downloaded via the TGA website (http://www.tga.gov.au/about/international-usa-fta.htm). You should send the completed and signed notification form or certificate quoting the submission number to the attention of Application Support Team, Medicine Authorisation Branch, TGA, at the address on the footer of this letter. Alternatively, please send a copy by return facsimile message to (02) 6232 8140

or email ast.application.support.team@tga.gov.au. As noted above, a certificate of registration can only be issued after receipt of the completed and signed form or certificate.

**Part B: Decision to approve product information for the medicine(s)**

**1. Decision to approve**

I am a delegate of the Secretary of the Department of Health for the purposes of section 25AA(1) of the Act. The text of the product information, provided with your response email received 22 January 2021, as set out in the version at **Attachment 1** is approved under subsection 25AA(1) of the Act for these products.

**2. Lodgement of product information with the TGA**

The product information for the above medicine must be lodged with the TGA **within 2 weeks** of the date of registration of the product.

Further, related Consumer Medicines Information (CMI) document must be lodged with the TGA:

- for new product(s) – prior to supply of the products; or
- for existing product(s) – **within 2 weeks** of the date of registration.

The following statement must be included in the CMI document immediately following the name of the provisionally registered medicine:

> "This medicine has provisional approval in Australia to prevent COVID-19 disease caused by SARS-CoV-2 virus in adults and adolescents from 16 years of age and older. This approval has been granted on the basis of short term safety and efficacy data. Evidence of longer term efficacy and safety from ongoing clinical trials and vaccination in the community continues to be gathered and assessed."

The documents must be lodged in the TGA eBusiness Services system (eBS). Information on how to lodge these documents is available at www.ebs.tga.gov.au.

Note that documents lodged must be in text PDF format – please be aware that scanned PDF documents will not be accepted by the system.

**Part C: Conditions of registration**

I am a delegate of the Secretary of the Department of Health for the purposes of subsection 28(2B) of the Act. Under that subsection, I have decided to impose the following conditions in relation to the above medicine:

(a) conditions applicable to all registered therapeutic goods as specified in the document Standard Conditions Applying to Registered or Listed Therapeutic Goods under Section 28 of the Therapeutic Goods Act 1989 effective 1 July 1995 (see **Attachment 3**);

(b) conditions applicable to specific classes of registered therapeutic goods as specified in the Standard Conditions Applying to Registered or Listed Therapeutic Goods under Section 28 of the Therapeutic Goods Act 1989 effective 1 July 1995 (see **Attachment 3**); and

(c) conditions listed in **Attachment 4 including specific conditions of provisional registration**.

As part of the standard conditions of registration applying to all registered therapeutic goods, it should be noted that, no changes can be made to the goods without the prior approval of the Secretary.

Under paragraph 30(2)(c) of the Act, refusal or failure to comply with a condition of registration to which inclusion of the medicine(s) in the ARTG is subject may result in the suspension or cancellation of registration.

**Part D: Other matters**

1. The above medicine must conform to the manufacturing and product details provided at **Attachment 2**. These details will be included in the computerised database of the ARTG.

2. **Supply** of the medicine is not permitted until those medicines are formally included in the ARTG.

3. In accordance with regulation 9A of the *Therapeutic Goods Regulations 1990* (the Regulations), a patient information document (Consumer Medicines Information - CMI) must be supplied with the goods and be provided to a person to whom the goods are to be administered or otherwise dispensed in such a manner as defined by the subregulation 9A(2). The format of the CMI is set out in Schedule 12 to the Regulations. The CMI submitted with your response email received 22 January 2021 is considered to meet the format as set out in Schedule 12. There is a continuing obligation to ensure that at all times the CMI complies with the statutory requirements, including consistency with the PI. If the related CMI document needs to be changed as a consequence of the change to the approved PI, it must be lodged with the TGA **within 2 weeks** of the date of the changed PI. In the case of changes relating to the safety or safe use of the product, more rapid change of the CMI may be warranted.

4. With regard to the product labels (international labels 'US emergency use labels' and 'COMIRNATY-branded labels') considered and agreed to for initial supply of the product, please note the following:

   a) The TGA has provided separate decision letters for the following consents/exemptions from Australian-specific labelling requirements for the product:
   - consent for non-compliance with Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines (TGO 91); and
   - exemption for absence of the signal heading and cautionary statement, and other general aspects (requirement under the Poisons Standard) (the TGA has also written to State and Territory scheduling bodies alerting them to these exemptions and requesting that any State or Territory that needs to take any action to adopt or endorse such action please do so).

   b) Use of interim labels that do not include an Australian registration number: Subsections 19D(3) and (4) of the Act currently provide that the label of a registered therapeutic good supplied in Australia must set out the Australian registration

number of the good in the manner prescribed in the Regulations. However, a Bill is currently before Parliament that proposes to give the Secretary of the Department of Health a discretion to consent to the supply of goods with labels that do not set out the Australian registration number in the prescribed manner.

Subject to the passage of that Bill, it is anticipated that consent will be given, for an interim period, to the supply of COMIRNATY (BNT162b2 [mRNA]) COVID-19 VACCINE injection vial with labels that do not include the Australian registration number. Reflecting the spirit of the proposed reform, particularly the public interest in obtaining access to a COVID-19 vaccine as soon as possible, and out of respect for the Parliamentary processes, the TGA will not enforce compliance with subsections 19D(3) and (4) in the event that supply of COMIRNATY (BNT162b2 [mRNA]) COVID-19 VACCINE injection vial in Australia commences prior to the anticipated enactment of the Bill and the necessary consent being given. If the Bill is enacted, supply without that consent will be the subject of TGA enforcement action.

Furthermore, as noted above, I have not imposed condition 11 in 'Standard Conditions Applying to Registered or Listed Therapeutic Goods under Section 28 of the Therapeutic Goods Act 1989 effective 1 July 1995', which requires that the registration number of a medicine be placed on the label of a medicine, as a condition of registration,

5. If this product is of biological origin a permission to import should be requested from:

   Biological Program
   Department of Agriculture
   GPO Box 858
   CANBERRA ACT 2601

   Phone: 02 6272 4578

6. If the medicine contains an active or excipient that is produced by a genetically modified organism, the Office of the Gene Technology Regulator should be informed when supply commences. The address is:

   The Office of the Gene Technology Regulator
   GPO Box 9848
   Canberra ACT 2601

7. The National Director of Pharmaceutical Services, Department of Veterans' Affairs, would like to be provided with a copy of the approved PI for this product. Please consider providing a copy to:

   National Director of Pharmaceutical Services
   Department of Veterans' Affairs
   GPO Box 9998
   In Your Capital City

**Request for reconsideration of an initial decision**

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation. Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

**Guidelines for requesting reconsideration of an initial decision**

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled **"<insert person/company name> - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989***" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: '**minister.hunt.DLO@health.gov.au**' and copied to '**decision.review@health.gov.au**'

Requests for reconsideration that include dossiers (or similar bulk material) that cannot easily be attached to the request given first by email, may then be submitted on a USB drive or CD sent by express post or registered mail to:

Mail: **Minister for Health**
**Suite M1 40**
**c/- Parliament House**
**CANBERRA ACT 2600**

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

**NOTE:** This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

Yours sincerely,

Signed and authorised by
[redacted]
Delegate of the Secretary
Clinical Evaluation Section A
Prescription Medicines Authorisation Branch
Email: [redacted]@health.gov.au

24 January 2021

**Attachments**

1. Approved product information.

2. Manufacturing and Product Details to which the Goods Must Conform.

3. Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989.

4. Specific Conditions Applying to this medicine

5. 'US Emergency use - 5 doses label' carton

6 'US Emergency use - 5 doses label' vial

7. 'US Emergency use - 6 doses label' carton

8 'US Emergency use - 6 doses label' vial

9. 'COMIRNATY–branded – 5 doses label' carton

10. 'COMIRNATY–branded – 5 doses label'' vial

11. 'COMIRNATY–branded – 6 doses label' carton

12. 'COMIRNATY–branded – 6 doses label' vial

▼This vaccine is subject to additional monitoring **in Australia**. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

# AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (BNT162b2 [mRNA]) COVID-19 VACCINE

## 1. NAME OF THE MEDICINE

BNT162b2 [mRNA]

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

This is a multidose vial and must be diluted before use.

One vial (0.45 mL) contains 6 doses of 0.3 mL after dilution, see Sections 4.2 and 6.6.

1 dose (0.3 mL) contains 30 micrograms of BNT162b2 [mRNA] (embedded in lipid nanoparticles).

The active ingredient is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

For the full list of excipients, see Section 6.1 List of excipients.

## 3. PHARMACEUTICAL FORM

Concentrated suspension for injection (sterile concentrate).

COMIRNATY is a white to off-white frozen suspension.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

COMIRNATY (BNT162b2[mRNA]) COVID-19 Vaccine has **provisional approval** for the indication below:

Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 16 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

The decision has been made on the basis of short term efficacy and safety data. Continued approval depends on the evidence of longer term efficacy and safety from ongoing clinical trials and post-market assessment.

## 4.2 Dose and method of administration

### Dosage

***Individuals 16 years of age and older***

COMIRNATY is administered intramuscularly after dilution as a course of 2 doses at least 21 days apart. See dosing instructions below.

There are no data available on the interchangeability of COMIRNATY with other COVID-19 vaccines to complete the vaccination course. Individuals who have received 1 dose of COMIRNATY should receive a second dose of COMIRNATY to complete the vaccination course.

### Paediatric population

The safety and efficacy of COMIRNATY in children and adolescents aged less than 16 years of age have not yet been established. Limited data are available in this age group.

### Elderly population

No dosage adjustment is required in elderly individuals ≥ 65 years of age.

### Method of administration

COMIRNATY should be administered intramuscularly after dilution (see Section 6.6).

After dilution, vials of COMIRNATY contain six doses of 0.3 mL of vaccine. In order to extract six doses from a single vial, low dead-volume syringes and/or needles should be used. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

The preferred site of administration is the deltoid muscle of the upper arm.

Do not inject COMIRNATY intravascularly, subcutaneously or intradermally.

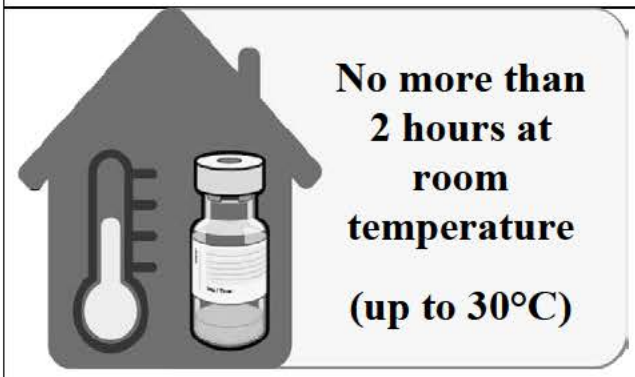
COMIRNATY should not be mixed in the same syringe with any other vaccines or medicinal products.

For precautions to be taken before administering COMIRNATY, see Section 4.4 Special warnings and precautions for use.

***Handling instructions***

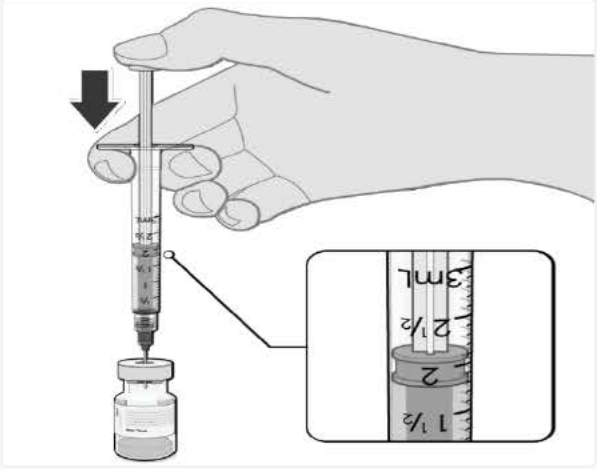
COMIRNATY should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared suspension.

**THAWING PRIOR TO DILUTION**



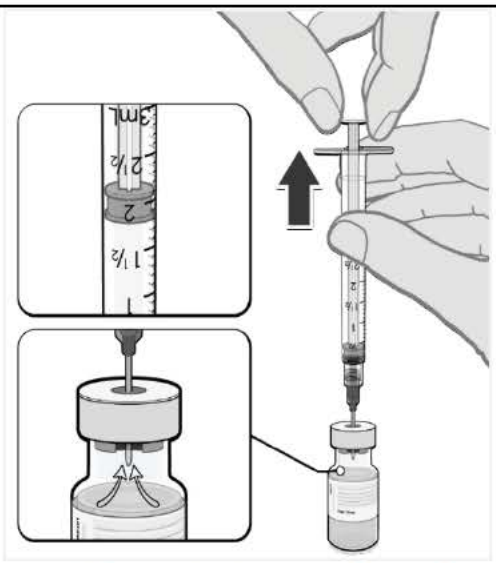
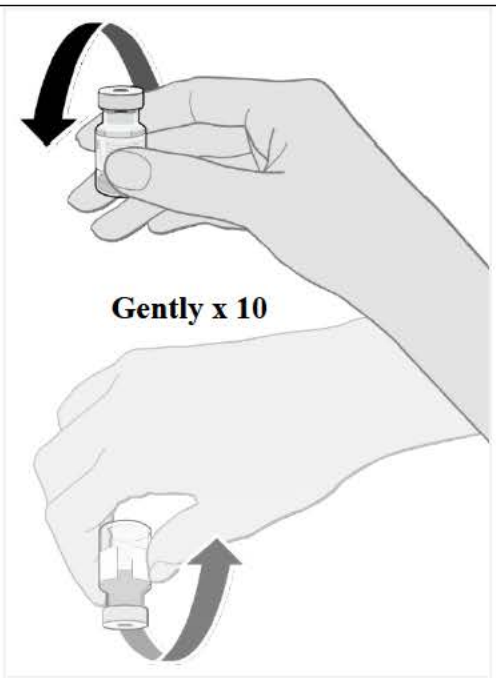

- The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 195 vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30 °C for immediate use.
- Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. **Do not shake**.
- Prior to dilution, the thawed suspension may contain white to off-white opaque amorphous particles.

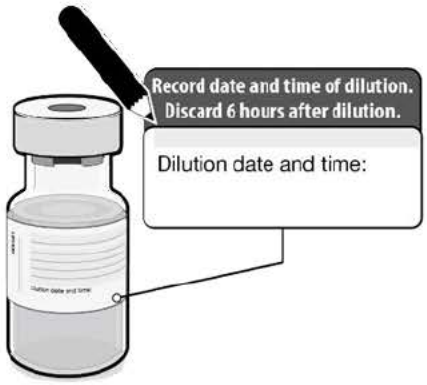
**DILUTION**




**1.8 mL of 0.9% sodium chloride injection**

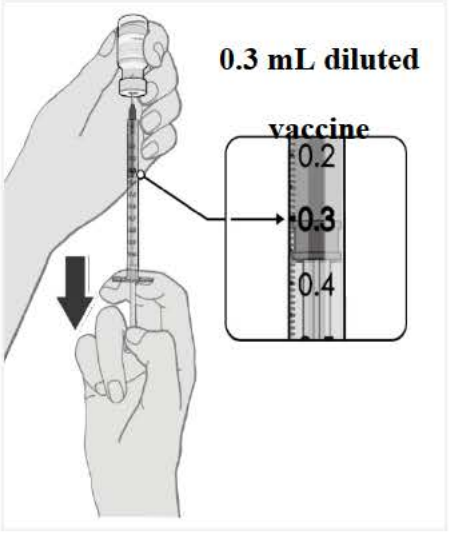
- The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques. Do not use any other diluent.

| | |
|---|---|
|  <br>**Pull back plunger to 1.8 mL to remove air from vial** | • Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.8 mL air into the empty diluent syringe. |
|  <br>**Gently x 10** | • **Gently invert the diluted suspension 10 times. Do not shake**.<br>• The diluted vaccine should present as an off-white suspension with no particulates visible. Discard the diluted vaccine if particulates or discolouration are present. |




- The diluted vials should be marked with the date and time of dilution.
- Do not freeze or shake the diluted suspension. If refrigerated, allow the diluted suspension to come to room temperature prior to use.

**PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY**




- After dilution, the vial contains 2.25 mL from which 6 doses of 0.3 mL can be extracted.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.3 mL of COMIRNATY.
  Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres.
  If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Verify a final injection volume of 0.3 mL prior to administration.
- Discard syringe and needle after administration to a single patient.
- Use a new, sterile needle and syringe to draw up each new dose.
- Discard any unused vaccine 6 hours after dilution.

## 4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in Section 6.1 List of excipients.

## 4.4 Special warnings and precautions for use

### Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be recorded in the Australian Immunisation Register.

### General recommendations

#### *Hypersensitivity and anaphylaxis*

Events of anaphylaxis have been reported. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of COMIRNATY.

The individual should be kept under close observation for at least 15 minutes following vaccination. A second dose of COMIRNATY should not be given to those who have experienced anaphylaxis to the first dose of COMIRNATY.

#### *Anxiety-related reactions*

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.

#### *Concurrent illness*

Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection. The presence of a minor infection and/or low grade fever should not delay vaccination.

#### *Thrombocytopenia and coagulation disorders*

As with other intramuscular injections, COMIRNATY should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.

#### *Immunocompromised individuals*

The efficacy, safety and immunogenicity of COMIRNATY has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of COMIRNATY may be lower in immunosuppressed individuals.

#### *Duration of protection*

The duration of protection afforded by COMIRNATY is unknown as it is still being determined by ongoing clinical trials.

***Limitations of vaccine effectiveness***

As with any vaccine, vaccination with COMIRNATY may not protect all vaccine recipients. Individuals may not be fully protected until 7 days after their second dose of COMIRNATY.

**Use in the elderly**

Clinical studies of COMIRNATY include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy. See Section 5.1 Pharmacodynamic properties, Clinical trials, Efficacy against COVID-19. No dosage adjustment is required in elderly individuals ≥ 65 years of age.

The data for use in the frail elderly (>85 years) is limited. The potential benefits of vaccination versus the potential risk and clinical impact of even relatively mild systemic adverse events in the frail elderly should be carefully assessed on a case-by-case basis.

**Paediatric use**

The safety and efficacy of COMIRNATY in children and adolescents aged less than 16 years of age have not yet been established. Limited data are available.

**Effects on laboratory tests**

No data available.

## 4.5 Interactions with other medicines and other forms of interactions

No interaction studies have been performed.

Concomitant administration of COMIRNATY with other vaccines has not been studied.

## 4.6 Fertility, pregnancy and lactation

**Effects on fertility**

In a combined fertility and developmental toxicity study, female rats were intramuscularly administered COMIRNATY prior to mating and during gestation (4 full human doses of 30 µg each, spanning between pre-mating day 21 and gestation day 20). SARS CoV-2 neutralising antibodies were present in maternal animals from prior to mating to the end of the study on postnatal day 21 as well as in fetuses and offspring. There were no vaccine related effects on female fertility and pregnancy rate.

**Use in pregnancy - Pregnancy Category B1**

There is limited experience with use of COMIRNATY in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition or post-natal development (see Effects on fertility). Administration of COMIRNATY in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus.

**Use in lactation**

It is unknown whether BNT162b2 [mRNA] is excreted in human milk. A combined fertility and developmental toxicity study in rats did not show harmful effects on offspring development before weaning (see Effects on fertility).

## 4.7 Effects on ability to drive and use machines

COMIRNATY has no, or negligible, influence on the ability to drive and use machines. However, some of the effects mentioned under Section 4.8 Adverse effects (undesirable effects) may temporarily affect the ability to drive or use machines.

## 4.8 Adverse effects (undesirable effects)

**Summary of safety profile**

The safety of COMIRNATY was evaluated in participants 16 years of age and older in 2 clinical studies that included 21,744 participants that have received at least one dose of COMIRNATY.

In Study C4591001, a total of 21,720 participants 16 years of age or older received at least 1 dose of COMIRNATY and a total of 21,728 participants 16 years of age or older received placebo (including 138 and 145 adolescents 16 and 17 years of age in the COMIRNATY and placebo groups, respectively). A total of 20,519 participants 16 years of age or older received 2 doses of COMIRNATY.

At the time of the analysis of Study C4591001, a total of 19,067 (9,531 COMIRNATY and 9,536 placebo) participants 16 years of age or older were evaluated for safety for at least 2 months after the second dose. This included a total of 10,727 (5,350 COMIRNATY and 5,377 placebo) participants 16 to 55 years of age and a total of 8,340 (4,181 COMIRNATY and 4,159 placebo) participants 56 years and older.

The most frequent adverse reactions in participants 16 years of age and older were injection site pain (>80%), fatigue (>60%), headache (>50%), myalgia and chills (>30%), arthralgia (>20%), pyrexia and injection site swelling (>10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination. A slightly lower frequency of reactogenicity events was associated with greater age.

**Tabulated list of adverse reactions from clinical studies**

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

Very common (≥ 1/10),

Common (≥ 1/100 to < 1/10),

Uncommon (≥ 1/1,000 to < 1/100),

Rare (≥ 1/10,000 to < 1/1,000),

Very rare (< 1/10,000),

Not known (cannot be estimated from the available data).

**Table 1:Adverse reactions from COMIRNATY clinical trials**

| System Organ Class | Very common (≥ 1/10) | Common (≥ 1/100 to < 1/10) | Uncommon (≥ 1/1,000 to < 1/100) | Rare (≥ 1/10,000 to < 1/1,000) | Not known (cannot be estimated from the available data) |
|---|---|---|---|---|---|
| Blood and lymphatic system disorders | | | Lymphadenopathy | | |
| Immune system disorders | | | | | Anaphylaxis; hypersensitivity |
| Psychiatric disorders | | | Insomnia | | |
| Nervous system disorders | Headache | | | Acute peripheral facial paralysis† | |
| Gastrointestinal disorders | | Nausea | | | |
| Musculoskeletal and connective tissue disorders | Arthralgia; myalgia | | Pain in extremity | | |
| General disorders and administration site conditions | Injection site pain; fatigue; chills; pyrexia*; injection site swelling | Injection site redness | Malaise; injection site pruritus | | |

*A higher frequency of pyrexia was observed after the 2nd dose.

†Throughout the safety follow-up period to date, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

The safety profile in 545 subjects receiving COMIRNATY, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

### Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

## 4.9 Overdose

Overdose data is available from 52 study participants included in the clinical trial that due to an error in dilution received 58 micrograms of COMIRNATY. The COMIRNATY recipients did not report an increase in reactogenicity or adverse reactions.

In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.

For information on the management of overdose, contact the Poisons Information Centre on 131126 (Australia).

# 5. PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: vaccines, other viral vaccines, ATC code: J07BX03

**Mechanism of action**

The nucleoside-modified messenger RNA in COMIRNATY is formulated in lipid nanoparticles, which enable delivery of the non-replicating RNA into host cells to direct transient expression of the SARS-CoV-2 spike (S) antigen. The mRNA codes for membrane-anchored, full-length S with two point mutations within the central helix. Mutation of these two amino acids to proline locks S in an antigenically preferred prefusion conformation. COMIRNATY elicits both neutralising antibody and cellular immune responses to the antigen, which may contribute to protection against COVID-19.

**Clinical trials**

***Efficacy***

Study C459001 is a multicentre, multinational, Phase 1/2/3 randomised, placebo-controlled, observer-blind dose-finding, vaccine candidate selection and efficacy study in participants 12 years of age and older. Randomisation was stratified by age: 12 through 15 years of age, 16 through 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the ≥ 56-year stratum. The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19. Participants with pre-existing stable disease, defined as disease not requiring significant change in therapy or hospitalisation for worsening disease during the 6 weeks before enrolment, were included as were participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV) or hepatitis B virus (HBV). At the time of the analysis of Study C459001, information presented is based on participants 16 years and older.

***Efficacy in participants 16 years of age and older***

In the Phase 2/3 portion, approximately 44,000 participants were randomised equally and were to receive 2 doses of COMIRNATY or placebo separated by 21 days. The efficacy analyses included participants that received their second vaccination within 19 to 42 days after their first vaccination. Participants are planned to be followed for up to 24 months after Dose 2, for assessments of safety and efficacy against COVID-19. In the clinical study, participants were required to observe a minimum interval of 14 days before and after administration of an

influenza vaccine in order to receive either placebo or COMIRNATY. In the clinical study, participants were required to observe a minimum interval of 60 days before or after receipt of blood/plasma products or immunoglobulins through to conclusion of the study in order to receive either placebo or COMIRNATY.

The population for the analysis of the primary efficacy endpoint included, 36,621 participants 12 years of age and older (18,242 in the COMIRNATY group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose. In addition, 134 participants were between the ages of 16 to 17 years of age (66 in the COMIRNATY group and 68 in the placebo group) and 1616 participants 75 years of age and older (804 in the COMIRNATY group and 812 in the placebo group).

### *Efficacy against COVID-19*

At the time of the primary efficacy analysis, participants had been followed for symptomatic COVID19 for in total 2,214 person-years for the COMIRNATY group and in total 2,222 person-years for the placebo group.

There were no meaningful clinical differences in overall vaccine efficacy in participants who were at risk of severe COVID-19 including those with 1 or more comorbidities that increase the risk of severe COVID-19 (e.g. asthma, body mass index (BMI) $\geq 30$ kg/m$^2$, chronic pulmonary disease, diabetes mellitus, hypertension).

COMIRNATY efficacy information is presented in Table 2.

**Table 2:Vaccine efficacy – First COVID-19 occurrence from 7 days after Dose 2, by age subgroup – participants without evidence of infection prior to 7 days after Dose 2 – evaluable efficacy (7 days) population**

| **First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*** | | | |
|---|---|---|---|
| **Subgroup** | **COMIRNATY**<br>**N[a] = 18,198**<br>**Cases**<br>n1[b]<br>Surveillance time[c] (n2[d]) | **Placebo**<br>**N[a] = 18,325**<br>**Cases**<br>n1[b]<br>Surveillance time[c] (n2[d]) | **Vaccine efficacy**<br>% (95% CI)[f] |
| All subjects[e] | 8<br>2.214 (17,411) | 162<br>2.222 (17,511) | 95.0 (90.0, 97.9) |
| 16 to 64 years | 7<br>1.706 (13,549) | 143<br>1.710 (13,618) | 95.1 (89.6, 98.1) |
| 65 years and older | 1<br>0.508 (3848) | 19<br>0.511 (3880) | 94.7 (66.7, 99.9) |
| 65 to 74 years | 1<br>0.406 (3074) | 14<br>0.406 (3095) | 92.9 (53.1, 99.8) |
| 75 years and older | 0<br>0.102 (774) | 5<br>0.106 (785) | 100.0 (-13.1, 100.0) |

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 [*Case definition: (at least 1 of) fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhoea or vomiting.]

* Participants who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not

detected by nucleic acid amplification tests (NAAT) [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of subjects at risk for the endpoint.

e. No confirmed cases were identified in participants 12 to 15 years of age.

f. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time. CI not adjusted for multiplicity.

In the second primary analysis, compared to placebo, efficacy of COMIRNATY in participants from first COVID-19 occurrence from 7 days after Dose 2 compared to participants with or without evidence of prior infection with SARS-CoV-2 was 94.6% (95% credible interval of 89.9% to 97.3%) in participants 16 years of age and older.

Additionally, subgroup analyses of the primary efficacy endpoint showed similar efficacy point estimates across genders, ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19.

## 5.2 Pharmacokinetic properties

Not applicable.

## 5.3 Preclinical safety data

**Genotoxicity/Carcinogenicity**

Neither genotoxicity nor carcinogenicity studies were performed. The components of COMIRNATY (lipids and mRNA) are not expected to have genotoxic potential.

# 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)

2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)

Distearoylphosphatidylcholine (DSPC)

Cholesterol

Potassium chloride

Monobasic potassium phosphate

Sodium chloride

Dibasic sodium phosphate dihydrate

Sucrose

Water for injections

This vaccine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially 'potassium-free'.

This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

## 6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in Section 4.2 Dose and method of administration.

## 6.3 Shelf life

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

**Unopened vial**

Once removed from the freezer, the unopened vaccine can be stored for up to 5 days at 2 °C to 8 °C, and up to 2 hours at temperatures up to 30 °C, prior to use.

Once thawed, COMIRNATY should not be re-frozen.

Closed-lid vial trays containing 195 vials removed from frozen storage (< -60 °C) may be at room temperature (< 25 °C) for up to 5 minutes for transfer between ultra-low-temperature environments. After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for at least 2 hours before they can be removed again.

**Diluted medicinal product**

Chemical and physical in-use stability has been demonstrated for 6 hours at 2 ºC to 30 ºC after dilution in sodium chloride 9 mg/mL (0.9%) solution for injection. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

## 6.4 Special precautions for storage

Store in a freezer at -90 °C to -60 °C.

Store in the original package in order to protect from light.

During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions.

When you are ready to thaw or use COMIRNATY

- Open-lid vial trays, or vial trays containing less than 195 vials removed from frozen storage (< -60 °C) may be at room temperature (< 25 °C) for up to 3 minutes to remove vials or for transfer between ultra-low-temperature environments.
- Once a vial is removed from the vial tray, it should be thawed for use.
- After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for at least 2 hours before they can be removed again.

For storage conditions after thawing and dilution of the medicinal product, see Section 6.3 Shelf life.

For additional advice on storing COMIRNATY, contact Pfizer Australia on 1800 675 229.

## 6.5 Nature and contents of container

2 mL clear multidose vial (Type I glass) with a stopper (synthetic bromobutyl rubber) and a flip-off plastic cap with aluminium seal. Each vial contains 6 doses, see Section 4.2

Pack size: 195 vials

## 6.6 Special precautions for disposal

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

## 6.7 Physicochemical properties

**CAS number**

2417899-77-3

# 7. MEDICINE SCHEDULE (POISONS STANDARD)

S4 – Prescription Only Medicine.

# 8. SPONSOR

Pfizer Australia Pty Ltd
Level 17, 151 Clarence Street
Sydney NSW 2000
www.pfizer.com.au
Medical Information www.pfizermedinfo.com.au or Toll Free Number: 1800 675 229

# 9. DATE OF FIRST APPROVAL

DD Month YYYY

## 10. DATE OF REVISION

Not applicable.

**Attachment 2**

## PROVISIONAL ARTG RECORD

| | | | |
|---|---|---|---|
| **Label Name:** | COMIRNATY (BNT162b2 [mRNA]) COVID-19 VACCINE 30 micrograms/0.3 mL concentrated suspension for injection vial | **Provisional ARTG Number:** | 346290 |
| **Sponsor:** | Pfizer Australia Pty Ltd | **Sponsor ID:** | 405 |

**Approval Area:** Drug Safety Evaluation Branch
**RegistrationType:** Registered
**Black Triangle Scheme Indicator:** Yes
**Black Triangle Scheme Lapse Date:**
**Charge Level:** Registered Biologics Annual Charge

**Standard Conditions of Approval:**

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

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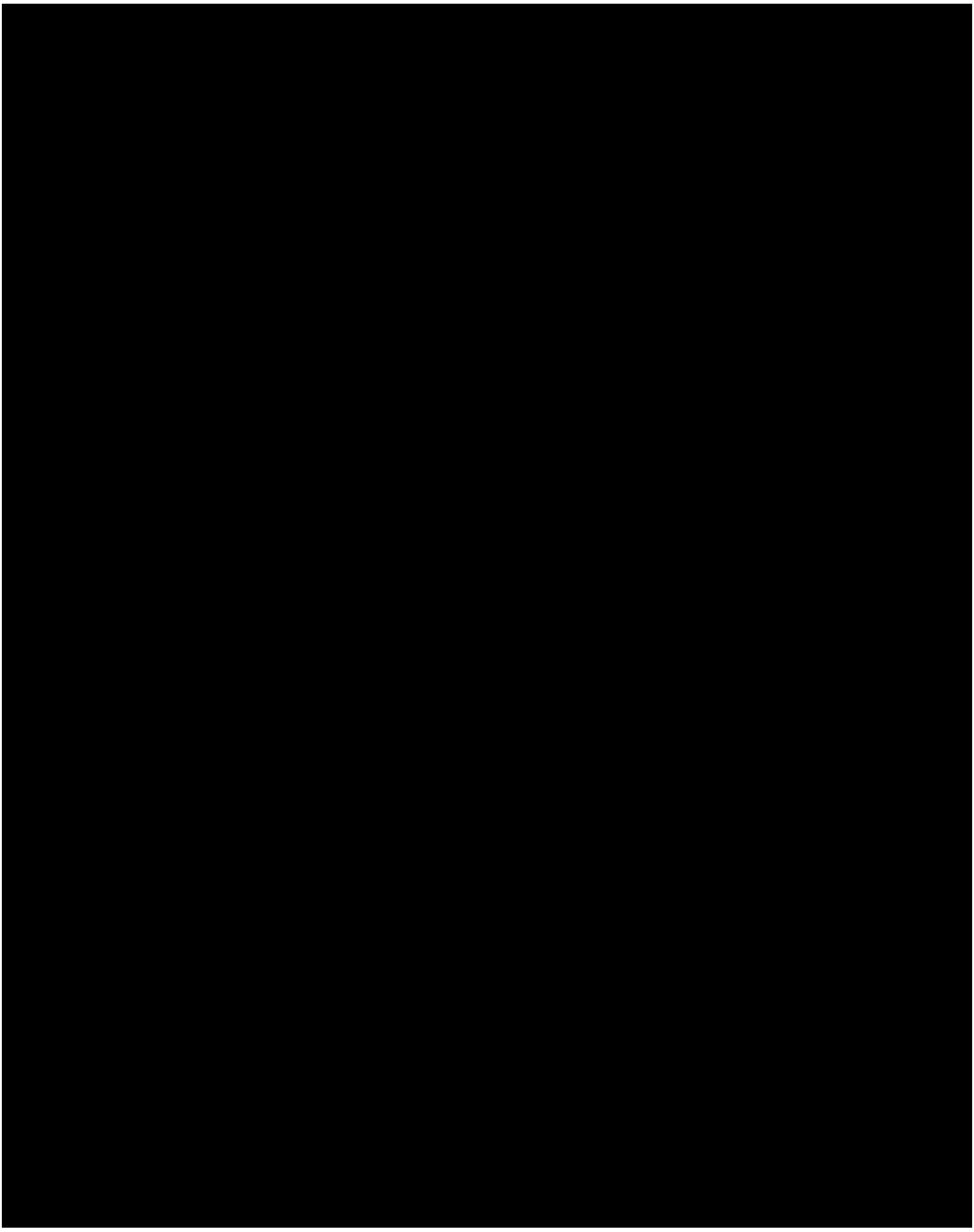
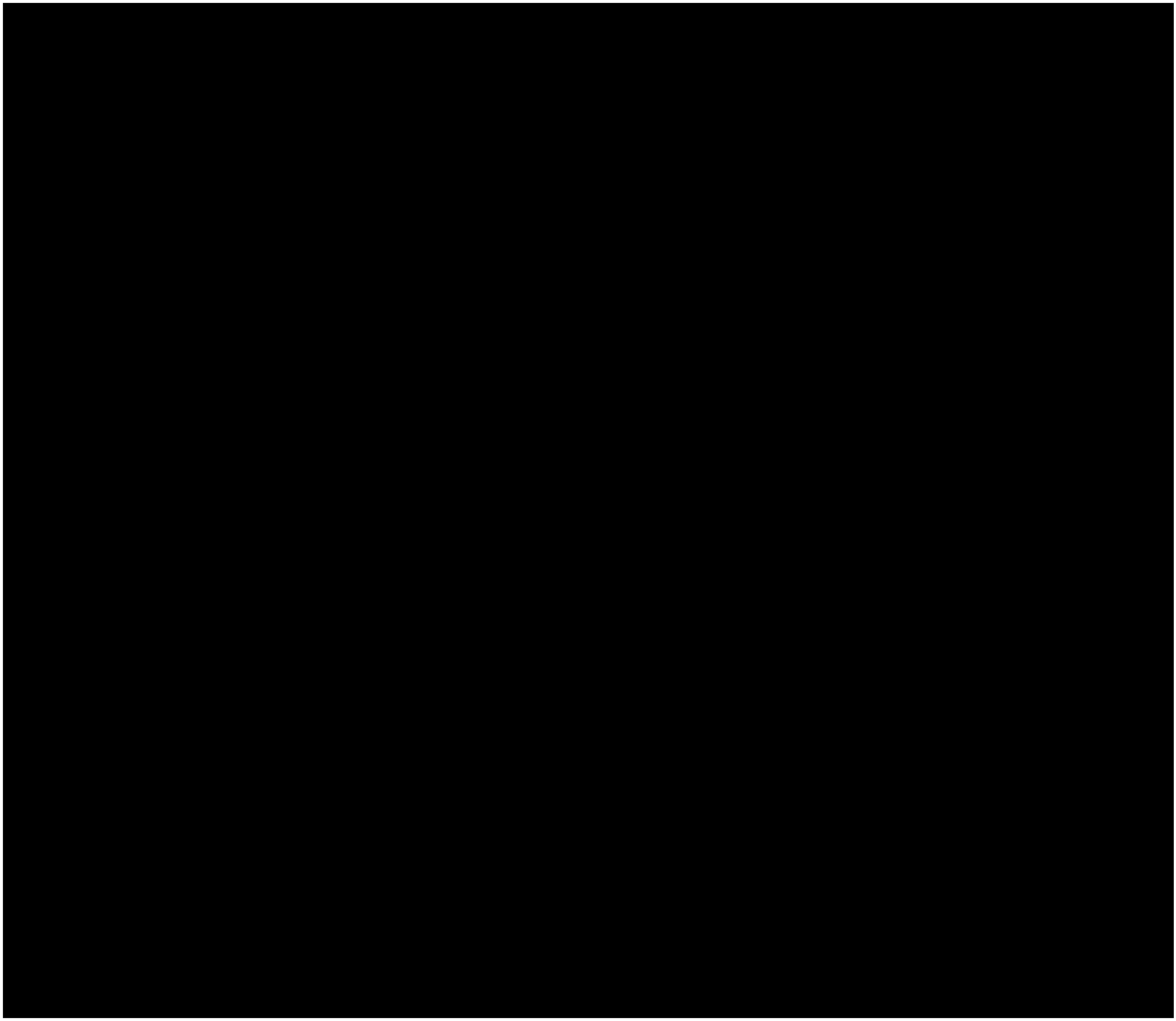
## MANUFACTURERS ASSOCIATED WITH ARTG ENTRY

[redacted]

Provisional ARTG Record: 346290



Provisional ARTG Record: 346290



# PRODUCT DETAILS

**Product Name:** COMIRNATY (BNT162b2 [mRNA]) COVID-19 VACCINE 30 micrograms/0.3 mL concentrated suspension for injection vial

**Product ID:** 745166

**Product Status:**

**Product Type:** Single Medicine Product

**Grouping:** No

**Supplied In Australia:**

**Medicine Product Information:** Container Label
Package Insert
Primary Pack Label

**Non-standard Indications:**

| Indication | Provisionally Registered |
|---|---|
| COMIRNATY (BNT162b2[mRNA]) COVID-19 Vaccine has provisional approval for the indication below:<br>Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 16 years of age and older.<br>The use of this vaccine should be in accordance with official recommendations.<br>The decision has been made on the basis of short term efficacy and safety data. Continued approval depends on the evidence of longer term efficacy and safety from ongoing clinical trials and post-market assessment. | Yes |

**Pack Size**
195 vials

**Poison Schedule**
(S4) Prescription Only Medicine

**PRODUCT CONTAINER**

| Material | Closure | Container Condition | Time | Temperature | Condition |
|---|---|---|---|---|---|
| Glass Type I Clear | Neither child resistant closure nor restricted flow insert | Closed | 6 Months | Store between minus 60 - minus 90 degrees | Protect from Light |

**Shelf Life Additional Information:** Undiluted or thawed vials may be stored at room temperature for no more than 2 hours, or in the refrigerator at 2 degrees to 8 degrees for up to 5 days. Do not refreeze thawed vials. After dilution, store at 2 degrees to 30 degrees and use within 6 hours.

**Container Type:** Vial

**PRODUCT STERILITY**

| Part | Text | Method |
|---|---|---|
| | | Filtration |

# COMPONENT DETAILS

**Product Name:** COMIRNATY (BNT162b2 [mRNA]) COVID-19 VACCINE 30 micrograms/0.3 mL concentrated suspension for injection vial

**Product ID:** 745166

**Component:** COMIRNATY (BNT162b2 [mRNA]) COVID-19 VACCINE 30 micrograms/0.3 mL concentrated suspension for injection vial

**Component ID:** 640508

**Dosage Form:** Injection, concentrated

**Route of Administration:** Intramuscular

**Visual Identification:** White to off-white frozen liquid.

**COMPONENT FORMULATION**

| **Active Ingredients** | **Additional Info** |
|---|---|
| BNT162b2 (mRNA) | |
| | |
| **Excipient Ingredients** | **Additional Info** |
| ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) | |
| dibasic sodium phosphate dihydrate | |
| water for injections | |
| cholesterol | |
| monobasic potassium phosphate | |
| sodium chloride | |
| potassium chloride | |
| 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide | |
| sucrose | |
| distearoylphosphatidylcholine | |
| | |

]

**Attachment 3**

# STANDARD CONDITIONS

**Applying to registered or listed therapeutic goods under Section 28 of the *Therapeutic Goods Act 1989*** (*Effective 1 July 1995*)

For the purposes of these conditions, words used in any of the paragraphs set out below shall have the same meaning as their counterparts in the *Therapeutic Goods Act 1989*. Unless otherwise specified, references to the 'Act' shall be a reference to the *Therapeutic Goods Act 1989*, as amended from time to time, and references to the 'Regulations' shall be to the Therapeutic Goods Regulations as amended from time to time. A reference to 'registered goods' or 'listed goods' shall be a reference to the goods included in the Certificate of Registration or the Certificate of Listing, as the case may be.

## APPLYING TO ALL REGISTERED OR LISTED THERAPEUTIC GOODS

### 1 Standards

The registered/listed goods must comply with standards applicable to those goods under part 2 of the Act;

### 2 Changes to Goods

Changes or variations in respect of any information concerning the registered or listed therapeutic goods, being information that would have been relevant* to a decision to register/list the goods in the Register, including information on the formulation of the registered/listed goods or other aspects of their manufacture, and the labelling of the goods, shall forthwith be notified to the Secretary, or the Secretary's delegate appointed for the purposes of section 28 of the Act, and where necessary*, the change or variation shall not be implemented until approved by the Secretary. (*Reference should also be made to Appendix *Changes to Therapeutic Goods)*

### 3 Australian Manufacturers

The Australian manufacturer or manufacturers of the registered/listed goods, and any subcontractor or testing facilities in Australia contracted to, or otherwise engaged to, manufacture the registered/listed goods, must be appropriately licensed to carry out the manufacture, or a step in the manufacture, of the goods or the class of therapeutic goods within which the registered/listed goods are included, unless otherwise exempted under the Act from the need to comply with such a requirement.

### 4 Records Held

The sponsor of the registered/listed goods shall keep such records relating to the goods as are necessary:

(a) to expedite recall if necessary of any batch of the registered/listed goods;
(b) to identify the manufacturer(s) of each batch of the registered/listed goods.

Where any part of or step in the manufacture in Australia of the registered/listed goods is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relating to such manufacture shall be kept.

### 5

Each sponsor shall retain records of the distribution of all of the sponsor's registered/listed goods for a period of five years and upon the request of the National Manager, Therapeutic Goods Administration, shall provide the records or copies of the records to the National Manager.

### 6 Sampling

The sponsor of the registered/listed goods shall permit officers who have been authorised under the Regulations to do so to take samples of therapeutic goods and carry out related duties in accordance with the Regulations.

## 7 Overseas Regulatory Actions

Where the registered/listed goods are distributed regularly overseas as well as in Australia, product recall or any actions other similar regulatory action taken in relation to the goods outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia must be notified to the National Manager, Therapeutic Goods Administration immediately the action or information is known to the sponsor.

## 8 Date of Supply

The sponsor of the registered/listed goods shall advise the National Manager, Therapeutic Goods Administration (through the Operations Manager, Australian Register of Therapeutic Goods) of the date of initial supply of those goods.

## LISTED THERAPEUTIC GOODS

## 9 Indications

In relation to listed goods, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods and, upon the request of the Director, Chemicals & Non Prescription Drug Branch, or Director, Conformity Assessment Branch, Therapeutic Goods Administration, shall produce such evidence to the Director.

## CONDITIONS APPLYING TO ALL REGISTERED OR LISTED DRUGS

## 10 Labels (see also condition 2)

A copy[1] of the label or, if more than one label, labels to be used in respect of the registered/listed drugs shall be provided to the National Manager, Therapeutic Goods Administration (through the Operations Manager, Australian Register of Therapeutic Goods), upon:

(a) the commencement of the supply of the registered/listed drugs; and
(b) request by the National Manager.

1 Where practicable actual labels should be provided attached to a sheet of paper which identifies the product by its Registration/Listing Name and Number. Photocopies (actual size) are acceptable where the label information is printed or embossed directly onto the container.

## 11 Registration/Listing Number

The registration or listing number shall be placed on the label of the registered/listed drugs in accordance with the requirements of the Therapeutic Goods Act 1989 and in the manner prescribed in the Regulations.

## 12 Expiry dates

The sponsor shall not supply the registered/listed drugs after the expiry date of the goods.

## 13 Colouring

Colouring agents used in registered/listed drugs for ingestion, other agents than those listed for export only, shall be only those included in the list of "Colourings for Use in Pharmaceuticals for

Ingestion" issued by the National Health and Medical Research Council in November 1988 as amended from time to time.

### 14 Adverse reactions

All reports of adverse reactions or similar experiences associated with the use or administration of the registered/listed drugs shall be notified to the National Manager, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of drugs must retain records of such reports for a period of not less than 18 months from the day the National Manager is notified of the report or reports. It is a condition of registration that your company must comply with Appendix 20 of Volume 1 of the Australian Guidelines for the Registration of Drugs. That appendix deals with the reporting of adverse drug reactions.

## CONDITIONS APPLYING TO ALL REGISTERED DRUGS

### 15 Authorised Officer

It is a condition of registration that as the sponsor of this product you will comply with Regulation 24 of the Therapeutic Goods Regulations.

### 16 Overseas Regulatory Action

It is a condition of registration that your company must inform the TGA if an application is rejected in the USA or Canada at any time during or after registration in Australia and must submit detailed reasons for the rejection.

## REGISTERED OR LISTED THERAPEUTIC DEVICES

### 17 Problems with Therapeutic Devices

The sponsor of registered/listed therapeutic devices shall:

(a) keep a log of problems relating to the condition, use or application of the registered/listed therapeutic devices,

(b) as soon as possible after the sponsor becomes aware of it, report to the Director, Conformity Assessment Branch, TGA, all deaths, serious illness and serious injuries arising from or attributable in some way to, the use or application of the registered/listed therapeutic devices.

## REGISTERED THERAPEUTIC DEVICES

### 18 Registration Number

The registration number shall be placed on the label of the registered therapeutic devices in accordance with the requirements of the *Therapeutic Goods Act 1989* and in the manner prescribed in the Regulations.

## 19 Reports of Problems

The sponsor shall provide to the Director, Conformity Assessment Branch, Therapeutic Goods Administration:

(a) a summarised report in respect of problems relating to the condition, use or application of the registered therapeutic devices between 1 July and 1 October following the date of the registration of the registered therapeutic devices,

(b) and then submit annual summarised reports between 1 July and 1 October for the following three years.

## REGISTERED AND LISTED THERAPEUTIC DEVICES SPECIFIED UNDER REGULATION 16 (SCHEDULE 6)

## 20 Labels (see also condition 2)

A copy[1] of the label or, if more than one label, labels to be used in respect of the registered/listed goods shall be provided to the National Manager, Therapeutic Goods Administration (through the Operations Manager, Australian Register of Therapeutic Goods), upon:

(a) the commencement of the supply of the registered/listed goods; and

(b) request by the National Manager.

[1] Where practicable actual labels should be provided attached to a sheet of paper which identifies the product by its Registration/Listing Name and Number. Photocopies (actual size) are acceptable where the label information is printed or embossed directly onto the container.

## CONDITIONS APPLYING TO SPECIFIC CLASSES OF THERAPEUTIC GOODS

## 21 Conditions Applying to Drugs Which Include Bioflavonoids

Bioflavonoids shall comply with the monograph developed by the Nutritional Foods Association and the Therapeutic Goods Administration.

## 22 Conditions Applying to Drugs Which Contain Substances Which Are "Drugs of Dependence"

Where the registered or listed goods contain a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the goods, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.

## 23 Goods Manufactured Overseas

Where the registered/listed goods are imported goods which if manufactured in Australia would be required under the provisions of the Act to be manufactured in licensed premises, the sponsor of the goods shall, upon request at any time by the Secretary or the Secretary's delegate appointed for the purposes of section 31 of the Act, provide to the National Manager, Therapeutic Goods Administration, an acceptable form of evidence which establishes the standard of manufacture of the goods. If this is not available, the sponsor shall pay the costs of an inspection of the principal manufacturer of the goods by Australian inspectors where this is considered necessary by the Secretary or the Secretary's delegate referred to in this paragraph.

# Specific Conditions

**on Registration or Listing applying to specific groups of therapeutic devices under Section 28 of the *Therapeutic Goods Act 1989***

**EFFECTIVE 1 MARCH 1998**

| | Product Type | Applicable Therapeutic Goods Orders | Additional Conditions |
|---|---|---|---|
| 1 | Bandages, dressings and allied products supplied non-sterile | | For non GMP approved manufacturers, total microbial count certificates, must be provided [3] for the subsequent five batches of product supplied following listing of the product. |
| 1.1 | Primary dressings, surgical absorbents or goods specified in Schedule 11 of the Regulations | TGO 11 - 'Standard for Sterile Therapeutic Goods' | Must be sterile and labelled "sterile" |
| 2. | Barium hydroxide lime | TGO 47 - 'Barium Lime' | Test certificate on request[1] |
| 3 | Catheters (Urethral) | TGO 59 - 'Polymer Urethral Catheters for General Medical Use' | Test certificate on request[1] |
| 4 | Condoms | TGO 61 - 'Contraceptive Devices - Rubber Condoms' | Test certificate must be obtained for every batch prior to supply |
| 5 | Contrast media injectors (powered) | | Annual problem reports to be lodged with CAB[2] |
| 6 | Dental restorative materials | TGO 57 - 'Standard for Dental Materials' | Test certificate on request[1] |
| 7 | Diaphragms (Contraceptive) | TGO 28 - 'Standard for Contraceptive Devices - Diaphragms' | Test certificate must be obtained for every batch prior to supply |
| 8. | Disinfectants & Sterilants | TGO 54 - 'Standard for Composition, Packaging, Labelling and Performance of Disinfectants and Sterilants'<br><br>TGO 54A -Amendment to TGO54 | Test certificate on request[1] |
| 9 | Gloves - examination | TGO 52 - 'Gloves for general medical and dental use' | Test certificate on request[1] |
| 9.1 | Gloves - surgical | TGO 53 - 'Single Use , Sterile (Surgical) Rubber Gloves' | Test certificate on request[1] |
| 10 | Implantable patient activated drug delivery systems | | Annual problem reports to be lodged with CAB[2] |

| | Product Type | Applicable Therapeutic Goods Orders | Additional Conditions |
|---|---|---|---|
| 11 | In Vitro Diagnostics [IVDs] containing material of human origin | TGO 34 - 'Standard for Diagnostic Goods of Human Origin' | Test certificate on request[1]<br><br>Current catalogues and detailed records of importation and distribution of the goods must be kept by the sponsor. |
| 11.1 | In Vitro Diagnostics [IVDs] approved for use as screening or as supplemental tests for the diagnosis of infection with Human Immunodeficiency Virus [HIV] (viral load assays excepted). | | May be supplied to authorised laboratories only |
| 11.2 | In Vitro Diagnostics [IVDs] approved as supplemental tests for the diagnosis of infection with Hepatitis C Virus [HCV] | | May be supplied to authorised laboratories only |
| 11.3 | In Vitro Diagnostics [IVDs] for home use or supplied as a Commonwealth Pharmaceutical Benefit under the *National Health Act 1953* or the *Veterans' Entitlement Act 1986* | | Must be accompanied by adequate instructions and information in plain English which outlines clearly the nature, use and limitations of the test and expresses measurements in Standard International units |
| 12 | Insulin syringes | TGO 41 - 'Single-use syringes (sterile) for the injection of 100 units per millilitre of insulin (U-100)' | Test certificate on request[1] |
| 13 | Menstrual tampons | TGO 51 - 'Standard for Tampons - Menstrual' | Test certificate on request[1] |
| 14 | Penile implants - inflatable | | Annual problem reports to be lodged with CAB[2] |
| 15 | Pyrogen free - products presented as being such, and all devices specified in the Order | TGO 50 - 'General Standard for Pyrogen and Endotoxin Content of Therapeutic Goods' | Test certificate on request[1] |
| 16 | Silicone gel - devices containing (breast implants excepted) | | Annual problem reports to be lodged with CAB[2] |
| 17 | Sutures or ligatures | TGO 49 - 'General Standard for Sutures' | Test certificate on request[1] |

[1] **Test certificate on request** - the sponsor of the goods must obtain a test certificate, consisting of a detailed certificate of compliance containing comments against each requirement of the Order, for each batch of goods prior to supply in Australia. These certificates must be held by the sponsor and must be available whenever the Secretary or a delegate of the Secretary appointed for the purposes of Section 28 of the Act, should request it to be produced for inspection.
[2] **Annual problem reports** - a report of problems relating to the condition, use or application of the devices must be submitted to the Director, Conformity Assessment Branch between 1 July and 1 October each year.
[3] **Microbial count certificates** relating to non-sterile bandages, dressings and allied products must be submitted to the Senior Technical Reviewer, Conformity Assessment Branch.

**For further information contact the TGA Publications Office on 1 800 020 653**

**Attachment 4**

**SPECIFIC CONDITIONS APPLYING TO THIS MEDICINE**

1. All of the manufacturing and product details as described in Attachment 2 apply to this therapeutic good.

2. The Product Information applying to this therapeutic good must meet the TGA's approval at all times. Any proposed changes to the approved text of the PI, including safety related changes, must be submitted to, and be approved by, the TGA prior to distribution.

3. Abridged Product Information must accurately reflect the approved Product Information, including safety-related statements, but may be a paraphrase or précis of the approved Product Information.

4. Appropriate quantities of the reference material for the active ingredient, as well as of precursors, degradation products and other impurities for which limits are set in the finished product specifications are to be provided free of charge to the TGA, if required for testing purposes.

5. Promotional material (other than Product Information) relating to the registered good must comply with the requirements of the Code of Conduct of Medicines Australia.

6. You must supply a copy of any or all current labels for these products within two working days of a request from the TGA. Please note that this condition replaces Condition No. 10 of the Standard Conditions Applying to Registered or Listed Therapeutic Goods under Section 28 of the Therapeutic Goods Act 1989 (Effective 1 July 1995).

7. **Clinical studies**

   The following study reports of the two ongoing studies will have to be submitted before a definitive authorization can be considered:

   - Submit safety analysis at 6 months post Dose 2 from Study C4591001 (Phase 2/3) when the analysis is available
   - Submit the final completed study report for Study C4591001 with 24 months follow up duration when it became available.
   - Submit final study reports for study BNT162-01 once completed, including data on healthy subjects

   When available, further data relating to vaccine efficacy against asymptomatic disease, vaccine efficacy in immunocompromised subjects, paediatric subjects, pregnant women, lactating mother, and the information relating to post-market safety and effectiveness studies should be provided to the TGA, as separate submissions, to update the Product information.

8. **Medicine Labels**

   a) Unless otherwise agreed to by the Secretary following an application under section 9D of the Act, the product must only be supplied with the following labels:

i) the international label, referred to here as the 'US emergency use – 5 doses labels' as follows:
   A) carton label (see copy at Attachment 5)
   B) vial label (see copy at Attachment 6)

ii) the international label, referred to here as the 'US emergency use – 6 doses labels' as follows:
   A) carton label (see copy at Attachment 7)
   B) vial label (see copy at Attachment 8)

iii) the international label, referred to here as the 'COMIRNATY-branded – 5 doses labels' as follows:
   A) carton label (see copy at Attachment 9)
   B) vial label (see copy at Attachment 10)

iv) the international label, referred to here as the 'COMIRNATY-branded – 6 doses labels' as follows:
   A) carton label (see copy at Attachment 11)
   B) vial label (see copy at Attachment 12)

b) The sponsor will develop Australian-specific labels for the product, that conform with all relevant Australian labelling requirements, and will take all reasonable steps to implement such labelling before the end of the provisional registration period referred to in subsection 29(3) of the Act (being the period of 2 years starting on the day specified in the ARTG certificate of registration) (noting that, consistent with paragraph 28(5)(aaa) of the Act, changes to such matters as labels that have been agreed to as part of an evaluation under section 25 of the Act may only occur following submission under section 9D of a 'variation' application and approval by the TGA).

c) The sponsor will provide information to the TGA on the proposed strategies and planned timelines for Australian dedicated supplies, as soon as possible, and no later than 24 January 2023.

9. **Batch Release Testing and Compliance**

It is a condition of registration that all independent manufacturing batches of COMIRNATY (BNT162b2 [mRNA]) COVID-19 VACCINE to be supplied in Australia are not released for supply by or on behalf of the Sponsor until samples and the manufacturer's release data have been assessed by, and you have received notification acknowledging authorisation to release from, the Laboratories Branch, TGA.

In complying with the above, the Sponsor must supply the following for each independent batch of the product imported or proposed to be imported into Australia:

- a completed Request for Release Form, available from vaccines@health.gov.au ; and
- complete summary protocols for manufacture and QC, including all steps in production in the agreed format; and
- at least 20 (twenty) vials (Samples) of each manufacturing batch of BNT162b2[mRNA] COVID-19 vaccine with the Australian labels, PI and packaging (unless an exemption to supply these has been granted) representative of all batches of product proposed to be distributed in Australia; and

- if the manufacturing batch has been released in Europe or United Kingdom a copy of the EU Official Control Authority Batch Release (OCABR) certificate (or equivalent from the UK) must also be provided; and
- any reagents, reference material and standards required to undertake testing as requested by Laboratories Branch, TGA.

When samples and data are submitted, they must be forwarded to the Biotherapeutics Section, Laboratories Branch before release for supply and with sufficient lead time to allow for Laboratories Branch testing. The address for courier delivery is:

ATTN: Batch Release Coordinator,
Batch Release Unit,
TGA Laboratories Branch,
136 Narrabundah Lane,
Symonston, ACT 2609.

The shipments (including reagents) to TGA are the responsibility of the Australian Sponsor/Agent who will be required to facilitate the import and customs clearance process.

## 10. Certified Product Details

An electronic copy of the Certified Product Details (CPD) as described in Guidance 7: Certified Product Details of the Australian Regulatory Guidelines for Prescription Medicines (ARGPM) https://www.tga.gov.au/guidance-7-certified-product-details should be provided upon registration of the therapeutic good. In addition, an updated CPD, for the above products incorporating the approved changes is to be provided within one month of the date of approval letter. A template for preparation of CPD for biological prescription medicines and Vaccines can be obtained from the TGA website https://www.tga.gov.au/form/certified-product-details-cpd-biological-prescription-medicines]. The CPD should be sent as a **single bookmarked PDF** document to Vaccines@health.gov.au as soon as possible after registration/approval of the product or any subsequent changes as indicated above.

## 11. Post approval commitments

### Section 3.2.S.2.1 and 3.2.P.3.1 Manufacturers/Section 3.2.A.1

The Sponsor has submitted the list of manufacturing sites along with the responsibilities in the production of the COMIRNATY (BNT162b2 [mRNA]) COVID-19 Vaccine Drug Substance (DS) and Drug Product (DP) and specified functions.

Commitment is required from the Sponsor that they maintain the validity of all manufacturer GMP Clearances for the duration of product supply to Australia. Additionally, that adherence to the conditions of GMP Clearance approval is upheld

### Section 3.2.S.5 Reference standards or materials:

There are no current issues with the methodologies and tools used in testing of the reference material. However, there is a lack of data submitted, with only one batch of the clinical reference material (CRM) tested, while primary reference material

(PRM) and working reference materials (WRM) are still under development. As post-approval commitments the Sponsor should:

- Supply the data for the PRM and WRM once generated and the Certificates of Analysis of reference standards made available upon request.
- Submit additional stability data (for a duration of 1-6 months and 12-60 months) for reference standards and materials as soon as it becomes available.
- Provide a protocol for the establishment of replacement reference standards (WRMs) including acceptance criteria and verification data.
- TGA should be notified of any change to the source of the lipid reference materials.

**Section 3.2.S.7.2 Post-approval stability protocol and stability commitment:**
The Sponsor has provided a post-approval commitment that upon completion of the ICH stability protocols, a minimum of 1 batch of BNT162b2 DS manufactured will been rolled in the commercial stability program at the long term storage conditions of -20±5°C for each year that DS is manufactured. Additionally, a post-approval commitment for the DP that a minimum of 1 batch be placed in the commercial stability program at the long term storage condition of -90 to -60 °C each year of DP manufacture.

As post-approval stability commitments:

- Additional stability data (long term, accelerated and thermal stress study data for a duration of ≥6 months for a minimum of 2-3 clinical or commercial batches) should be submitted as it becomes available. Once additional data have been submitted to the TGA for evaluation, an extended shelf life and/or change in storage conditions for the DS and/or DP may be considered.
- Data and updated protocols for the currently ongoing thermal cycling studies should be submitted once available.
- Any out of specification stability results for DS and/or DP should be submitted to the TGA as soon as they are generated.
- The Sponsor must inform the TGA of any temperature deviation during shipment and not supply product that has been exposed to a temperature excursion outside of the approved storage conditions of -90°C to -60°C.

**Section 3.2.S.4.3 and 3.2.P.5.4 Batch analysis**
Post-approval commitments by the Sponsor include:

- Provide a quality risk assessment or investigation report to explain the reason for the deviation in trend (~10 fold increase increase) observed for the final 3 batches of commercial scale material manufactured at Pfizer, Andover (20Y513C501 20Y513C601 20Y513C701). Additionally, any remediation work that may have been implemented should be outlined.
- Provide clarification of the role of Polymum Scientific in the commercial manufacturing process and confirm if batch analysis for DP batches manufactured at Pfizer, Puurs are representative of the final proposed commercial manufacturing process.

**Commercial scale batches**
Post-approval commitments by the Sponsor include:

- Perform testing of future process-validation batches of the commercial scale finished product according to the comparability testing protocol/plan and results provided for assessment by the TGA when available.
- Provide the process validation data from the commercial scale batches/lots in order to confirm the consistency of the finished product manufacturing process. Results provided for assessment by the TGA when available.

**Microbiology**
Post-approval commitment by the Sponsor include:

- Phase 2 (product specific) and Phase 3 validation data for the proposed rapid sterility test be provided for evaluation as soon as available.

**Container safety**
Post-approval commitment by the Sponsor include:

- To date, no leachables study data has been submitted. The Sponsor has committed to providing 'time zero' data in February 2021 and 6 month data to be submitted in August 2021.

12. The actual date of commencement of supply is to be notified to the Branch Head, Prescription Medicines Authorisation Branch, TGA. Should it be decided not to proceed to supply, notification to this effect should be provided.

13. COMIRNATY vaccine is to be included in the Black Triangle Scheme due to provisional approval. The PI and CMI for COMIRNATY vaccine must include the black triangle symbol and mandatory accompanying text for the products entire period of provisional registration.

14. The COMIRNATY EU-Risk Management Plan (RMP) (version 1.0, dated 21 December 2020; DLP 17 December 2020), with Australian Specific Annex (version 0.2, dated 17 January 2021), included with submission PM-2020-05461-1-2, and any subsequent revisions, as agreed with the TGA will be implemented in Australia.

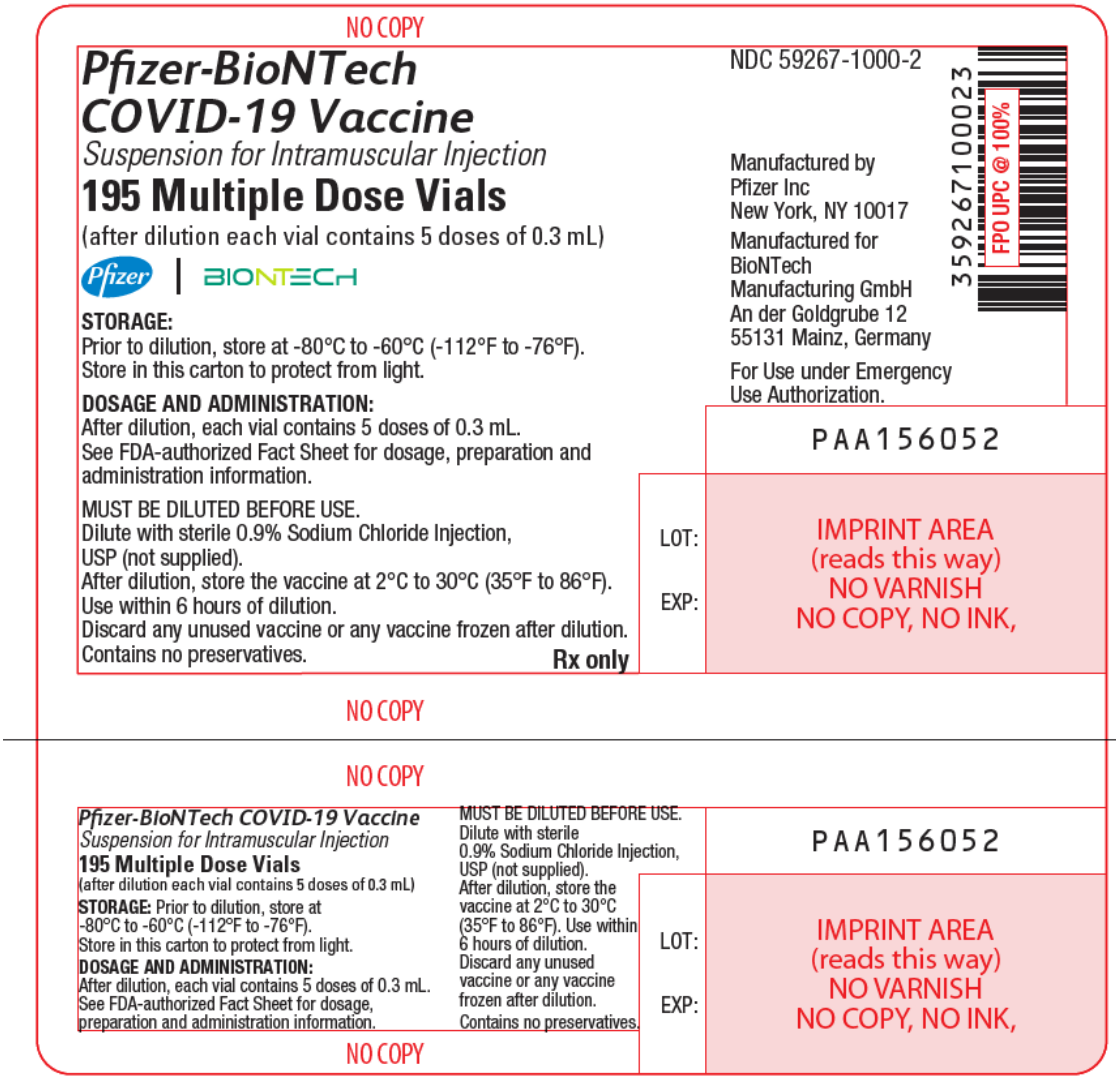
    An obligatory component of risk management plans is routine pharmacovigilance. Routine pharmacovigilance includes the submission of periodic safety update reports (PSURs).

    Unless agreed separately between the supplier who is the recipient of the approval and the TGA, the first report must be submitted to TGA no later than six calendar months after the date of this approval letter. The subsequent reports must be submitted no less frequently than six monthly until the period covered by such reports is not less than three years from the date of the approval letter, or the entire period of provisional registration, whichever is longer.

The reports are to at least meet the requirements for PSURs as described in the European Medicines Agency's Guideline on good pharmacovigilance practices (GVP) Module VII-periodic safety update report (Rev 1), Part VII.B Structures and processes. Note that submission of a PSUR does not constitute an application to vary the registration. Each report must have been prepared within ninety calendar days of the data lock point for that report.

Additional to the routine submission of the routine PSURs, expedited monthly, COMIRNATY safety summary reports (including safety data for patients in Australia) are to be provided for the first 6 months post registration, and thereafter at intervals specified by the TGA..

**Attachment 5**

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rev. 08JUN11

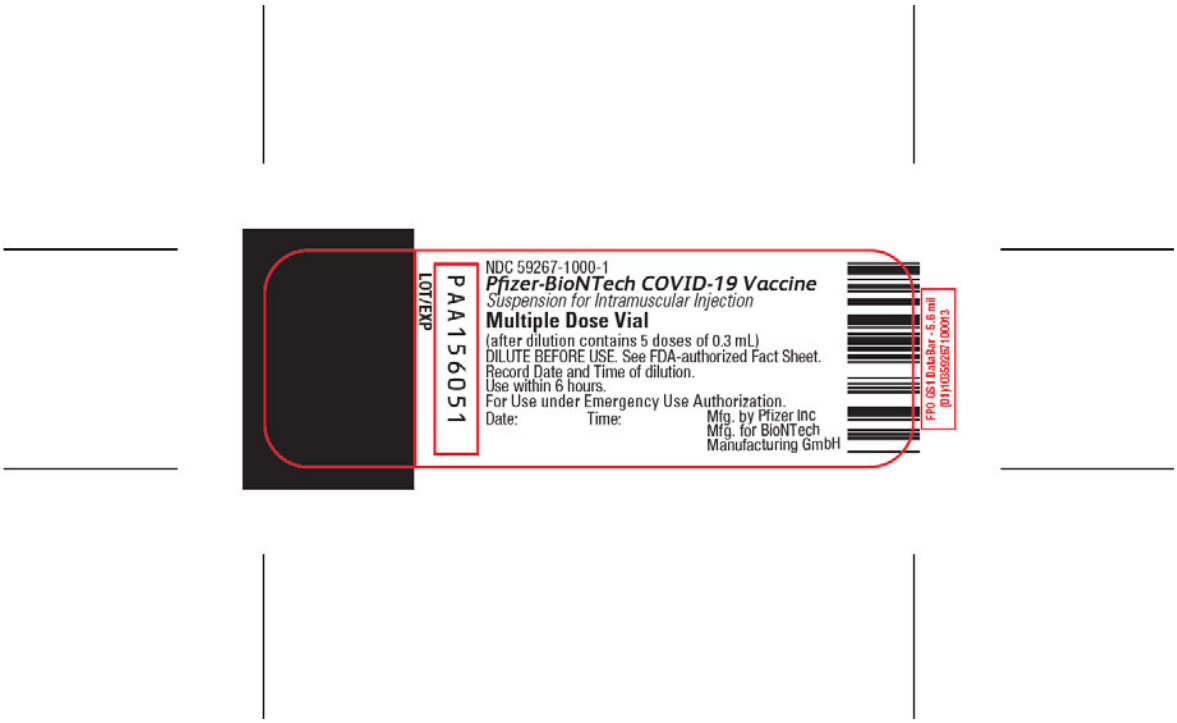
Additional Info:

Colors: Black, Process Blue, PMS 3278, PMS 2297, Dieline, No Varnish

EDITOR'S COPY GS: DATE:

| | | Rev | GA | PR | GS / ART REV (LCA) | GS / ART REV (FA) |
|---|---|---|---|---|---|---|
| Mgr | D. M. Guerin | 4 | | CHANGES OK | CHANGES OK | CHANGES OK |
| GS | J. Wood | | | | | |
| GA | T. Nowak | | | | | |

## Attachment 6

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rev. 08JUN11

Additional Info: Minimum point size - 3.5pt.

Colors: Black, Dieline

EDITOR'S COPY
GS: DATE:

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|---|---|---|---|---|---|---|
| Mgr | D. M. Guerin | 4 | | CHANGES OK | CHANGES OK | CHANGES OK |
| GS | J. Wood | | | | | |
| GA | T. Nowak | | | | | |

NDC 59267-1000-2

# *Pfizer-BioNTech COVID-19 Vaccine*

*Suspension for Intramuscular Injection*

## 195 Multiple Dose Vials

(after dilution each vial contains 6 doses of 0.3 mL)

Pfizer BIONTECH

0359267100023

**STORAGE:**
Prior to dilution, store at -80°C to -60°C (-112°F to -76°F).
Store in this carton to protect from light.

**DOSAGE AND ADMINISTRATION:**
After dilution, each vial contains 6 doses of 0.3 mL.
See FDA-authorized Fact Sheet or scan QR code for information.

MUST BE DILUTED BEFORE USE with sterile 0.9% Sodium Chloride Injection, USP (not supplied).
After dilution, store the vaccine at 2°C to 25°C (35°F to 77°F). Discard after 6 hours.
Contains no preservative.
For use under Emergency Use Authorization.

**Rx only**

Manufactured by
Pfizer Inc
New York, NY 10017

Manufactured for
BioNTech
Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

MADE IN GERMANY

PAA166210

GTIN: 00359267100023
LOT/EXP:

OVERPRINT AREA

INLINE DM AREA

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*Pfizer-BioNTech COVID-19 Vaccine*
*Suspension for Intramuscular Injection*
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(after dilution each vial contains 6 doses of 0.3 mL)
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PAA166210

GTIN: 00359267100023
LOT/EXP:

OVERPRINT AREA

INLINE DM AREA

NDC 59267-1000-2

# Pfizer-BioNTech COVID-19 Vaccine

*Suspension for Intramuscular Injection*

## 195 Multiple Dose Vials

(after dilution each vial contains 6 doses of 0.3 mL)

Pfizer BIONTECH

359267100023

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**DOSAGE AND ADMINISTRATION:**
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See FDA-authorized Fact Sheet or scan QR code for information.

MUST BE DILUTED BEFORE USE with sterile 0.9% Sodium Chloride Injection, USP (not supplied).
After dilution, store the vaccine at 2°C to 25°C (35°F to 77°F). Discard after 6 hours.
Contains no preservative.
For use under Emergency Use Authorization.

**Rx only**

Manufactured by
Pfizer Inc
New York, NY 10017

Manufactured for
BioNTech
Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

PAA166209

GTIN: 00359267100023
LOT/EXP:

OVERPRINT AREA

INLINE DM AREA

*Pfizer-BioNTech COVID-19 Vaccine*
*Suspension for Intramuscular Injection*
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(after dilution each vial contains 6 doses of 0.3 mL)
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MUST BE DILUTED BEFORE USE with sterile 0.9% Sodium Chloride Injection, USP (not supplied). After dilution, store the vaccine at 2°C to 25°C (35°F to 77°F). Discard after 6 hours. Contains no preservative.
PAA166209
GTIN: 00359267100023
LOT/EXP:
OVERPRINT AREA
INLINE DM AREA

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# Attachment 8

inks on file

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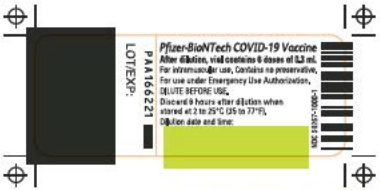


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**Attachment 9**

*(shown without varnish)*


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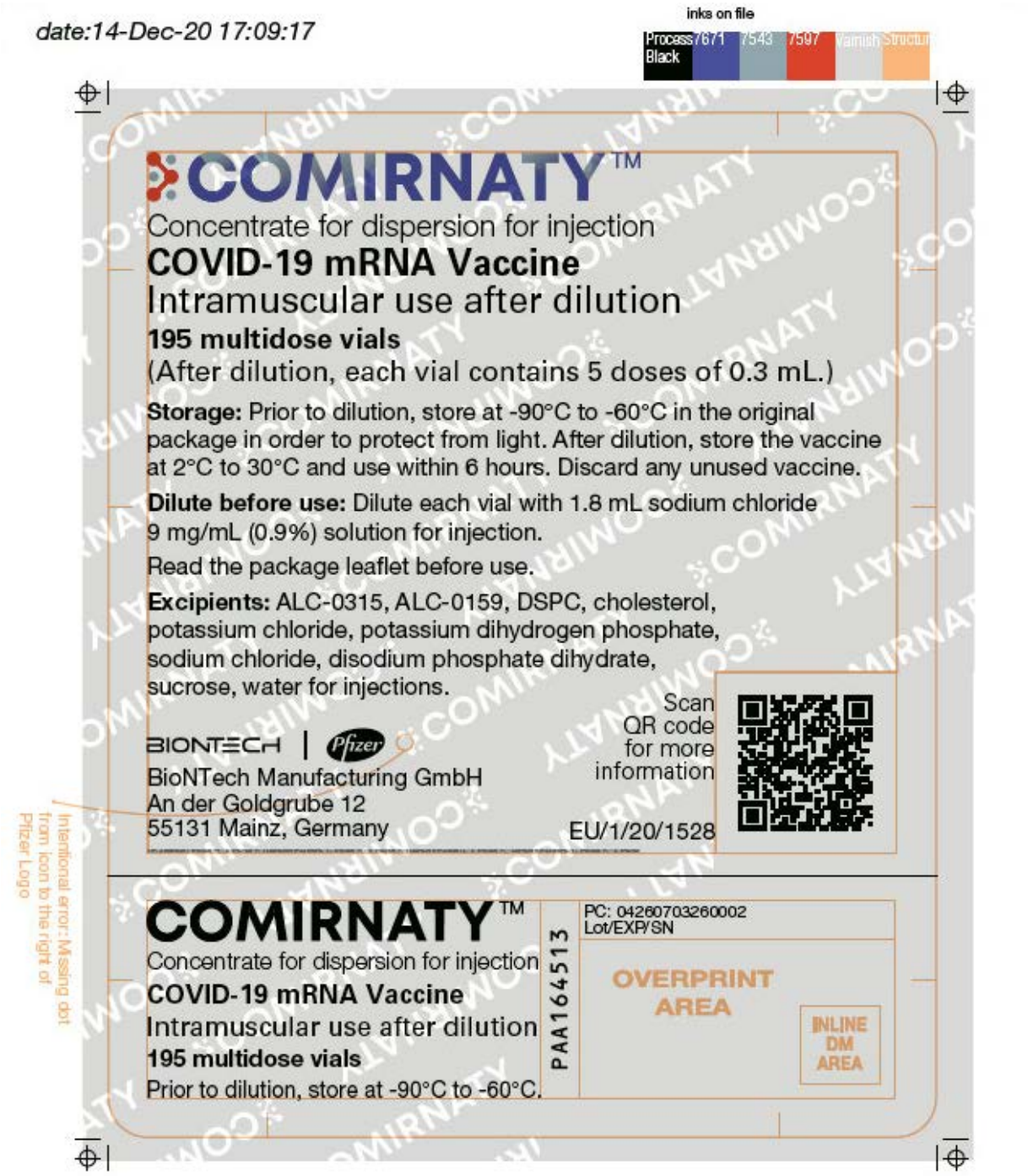


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**Attachment 10**

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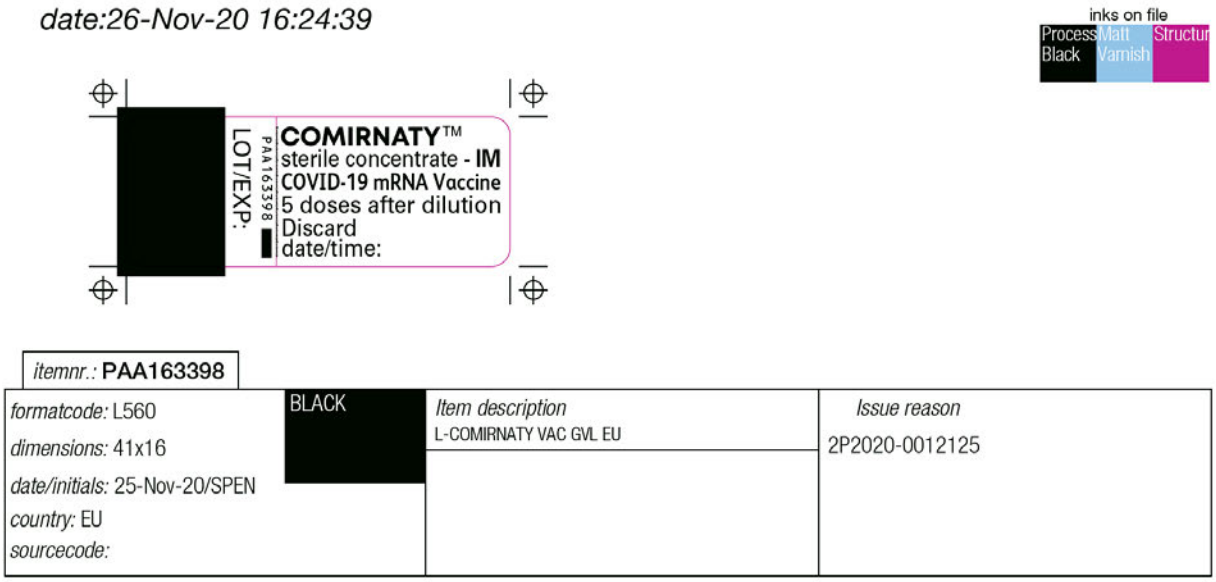


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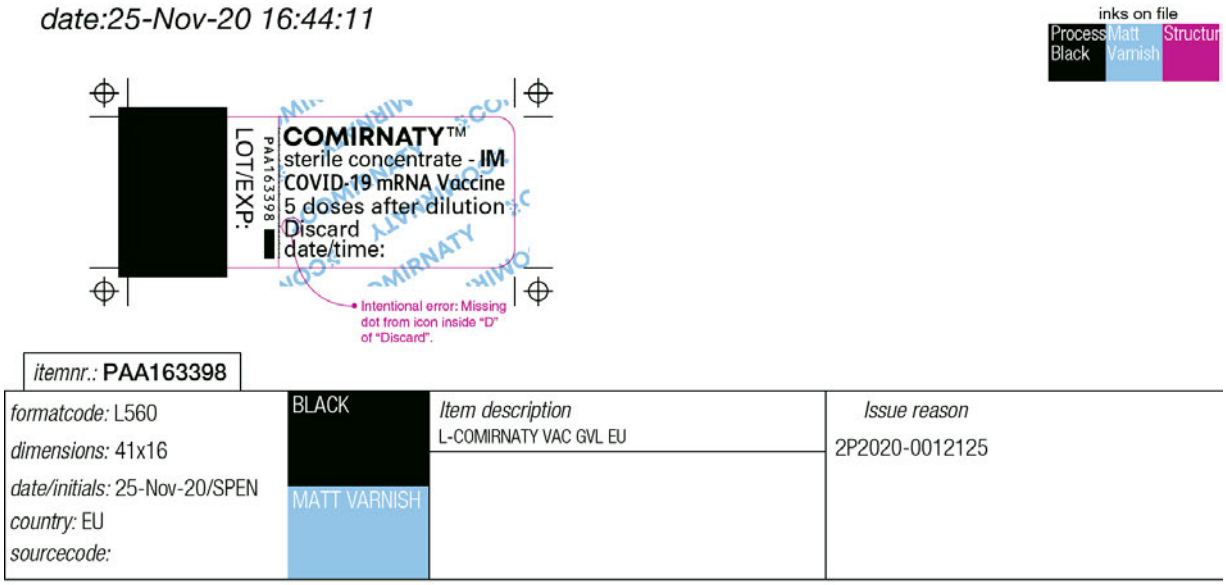

**Attachment 11**

# COMIRNATY™

Concentrate for dispersion for injection

**COVID-19 mRNA Vaccine**

Intramuscular use after dilution

**195 multidose vials**

(After dilution, each vial contains 6 doses of 0.3 mL.)

**Storage:** Prior to dilution, store at -90°C to -60°C in the original package in order to protect from light. After dilution, store the vaccine at 2°C to 30°C and use within 6 hours. Discard any unused vaccine.

**Dilute before use:** Dilute each vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection.

Read the package leaflet before use.

**Excipients:** ALC-0315, ALC-0159, DSPC, cholesterol, potassium chloride, potassium dihydrogen phosphate, sodium chloride, disodium phosphate dihydrate, sucrose, water for injections.

BIONTECH | Pfizer

BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

Scan QR code for more information

EU/1/20/1528

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COMIRNATY™

Concentrate for dispersion for injection

**COVID-19 mRNA Vaccine**

Intramuscular use after dilution

**195 multidose vials**

Prior to dilution, store at -90°C to -60°C.

PAA165993

PC: 04260703260002
Lot/EXP/SN

OVERPRINT AREA

INLINE DM AREA

## Attachment 12

inks on file
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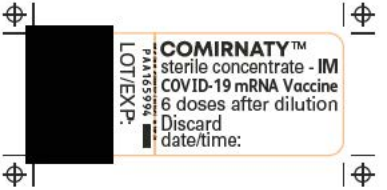


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