ATTACHMENT A

SCHEDULE OF DOCUMENTS – FOI 2429

Document No.	Date	Number of pages	Description	Decision on access[1]	Exemption/s applied
1	11 September 2020	10	Vaccine company Liaison – Meeting between Department and Pfizer	REI	section 47 – part section 47C – part section 47E(d) - part section 47F - part
2	10 July 2020	2	Attendee informal notes from meeting	REI	section 47C – part section 47F – part
3	23 July 2020	5	Email correspondence between Department and Pfizer regarding initial stages of development	REI	section 47F – part
4	30 July 2020	2	Letter from Pfizer to Minister Hunt	RE	section 47F – part
5	July 2020	3	Advice	E	section 42 – full section 45 – full
6	July 2020	5	Advice	E	section 42 – full section 45 – full

[1] E = Exempt in full, RE = Release with exemptions applied, REI = Release with exemptions applied and irrelevant material removed.

Company Liaison Template

Last updated by s 22 **on 11 September 2020**

Company and Contact Details

Company Name	Pfizer Inc /BioNTech SE
Nationality	USA / German
Location/s	Multiple
Contact/s	s 47F
Contact Made	☒ Company reached out ☐ Australia reached out

s 47C. 47E(d)

See also – s 47C, 47E(d)

Product Information

Company Capacity	☒ Vaccine development ☐ Inactivated or attenuated virus ☐ Viral vector ☐ Protein ☐ DNA ☒ RNA – nucleic acid – four candidates being investigated ☐ with Adjuvant (details) ☒ Commercial scale manufacture ☐ Inactivated or attenuated virus ☐ Viral vector ☐ Protein ☐ DNA ☒ RNA – nucleic acid ☐ Adjuvant ☐ Fill and finish ☐ Inactivated or attenuated virus ☐ Viral vector ☐ Protein ☐ DNA ☐ RNA – nucleic acid ☐ Other (details)

Related Entities	BioNTech- clinical development and commercialisation collaboration with Fosun Pharma in China

s47C, 47E(d)

Development and Manufacturing Expectations

Development Timeline (estimates)	BNT162b2 selected from four mRNA vaccine candidates in preclinical work, phase 1/2a clinical trials On 9 September, Pfizer and BioNTech announced preclinical data in mouse and nonhuman primate models from the BNT162b2 candidate (not yet peer reviewed or published). • BNT162b2 immunisation prevented lung and nasal infection in 100% rhesus macaques after challenge with SARS-CoV-2, with no viral RNA detected in the lower respiratory tract of immunised and challenged animals. • Neutralising antibody responses and strong, antigen-specific CD4+ and CD8+ T cell responses were induced in nonhuman primates and mice. ***Phase 1/2a clinical trials* commenced 05/05/20** **12 August** – interim results for BNT162b1 published in Nature. Neutralising antibody titres reached greater than those observed in COVID-19 convalescent human sera. The safety profile was overall favourable and no serious adverse events were reported. **20 August** - Preliminary results comparing BNT162b1 and BNT162b2 available online (preprint) (see https://www.medrxiv.org/content/10.1101/2020.08.17.20176651v1) In both younger and older adults, the 2 vaccine candidates elicited similar dose-dependent SARS−CoV−2−neutralizing geometric mean titers (GMTs), comparable to or higher than the GMT of a panel of SARS−CoV−2 convalescent sera. BNT162b2 was associated with less systemic reactogenicity, particularly in older adults. These results support selection of the BNT162b2 vaccine candidate for Phase 2/3 large−scale safety and efficacy evaluation, currently underway. ***Phase 2/3 clinical trial* commenced 27/07/20**

	modRNA candidate BNT162b2 was chosen following safety and immunogenicity evaluation of four BNT162 RNA vaccine candidates. A two-dose regimen will be tested in up to 30,000 participants across an expected 120 study sites globally (except China), commencing in the USA. 11,000 of 30,000 participants in USA enrolled at 21 August. Pfizer announced on 3 September that preliminary results of the Phase 3 trial were expected as early as October 2020. As at 3 September, 23,000 participants were enrolled in the Phase 3 trial.
Manufacturing facilities	23 fill and finish facilities globally • St Louis, MO (USA), Kalamazoo, MI (USA), Andover, MA (USA), Puurs (Belgium)– Pfizer • Mainz Region (Germany), Idar Oberstein (Germany) – BioNTech
Manufacturing capacity and timelines	13/7/20 The companies currently expect to manufacture up to s 47C doses by the end of 2020 and 1.3 billion doses by the end of 2021.
Any additional requirements for scale up	

s47, s47C, 47E(d)

Relationships and Partnerships

Recipient of Australian funding	☒ No ☐ Yes details - eg MRFF, Industry grants, public university
Contractual arrangements with Australian Government	☐ No ☒ Yes – for other medications/vaccines, details TBC
Other Australian link	☐ No ☒ Yes – non RNA manufacturing facilities in Mulgrave, Victoria, Perth and Adelaide

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<tr>
<td>Other partnerships</td>
<td>☐ No
☒ Yes – USA ‘Warp speed’ project
BioNTech- clinical development and commercialisation collaboration with Fosun Pharma in China

<table>
<tr><th>Date announced</th><th>Country</th><th>Doses/value</th></tr>
<tr><td>5 August 2020</td><td>Canada</td><td>Not announced</td></tr>
<tr><td>31 July 2020</td><td>Japan</td><td>120 million doses</td></tr>
<tr><td>22 July 2020</td><td>USA</td><td>100 million doses USD$1.95 billion</td></tr>
<tr><td>20 July 2020</td><td>UK</td><td>30 million doses</td></tr>
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s47, s47C

Media and public commentary

Date	Article name, source, core points and hyperlink
5/08/20	Canada signs deals with Pfizer, Moderna for experimental COVID-19 vaccines https://www.reuters.com/article/us-health-coronavirus-canada/canada-signs-deals-with-pfizer-moderna-for-experimental-covid-19-vaccines-idUSKCN2511RH
31/07/20	Pfizer and BioNTech to supply Japan with 120 million doses of their BNT162 mRNA-based vaccine candidate https://www.businesswire.com/news/home/20200731005116/en/Pfizer-BioNTech-Supply-Japan-120-Million-Doses
27/07/20	Pfizer and BioNTech commence Phase 2/3 trial for BNT162b2 https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-choose-lead-mrna-vaccine-candidate-0
23/07/20	US agrees to pay Pfizer $2bn for Covid-19 vaccine doses by end of year - 100m doses by Dec 2020, up to another 500m later https://www.theguardian.com/us-news/2020/jul/22/pfizer-coronavirus-covid-vaccine-us-deal
21/07/20	UK secures 90 million doses of potential coronavirus vaccine https://www.abc.net.au/news/2020-07-20/uk-government-secures-90-million-coronavirus-vaccine-doses/12474814
13/07/20	**Pfizer and BioNTech Granted FDA Fast Track Designation for Two Investigational mRNA-based Vaccine Candidates Against SARS-CoV-2** • BNT162b1 and BNT162b2 currently being evaluated in ongoing Phase 1/2 clinical studies in the United States and Germany • 'Fast Track' is a process designed to facilitate the development, and expedite the review, of new drugs and vaccines intended to treat or prevent serious conditions that have the potential to address an unmet medical need. • designation was granted based on preliminary data from Phase 1/2 studies https://www.pfizer.com/science/coronavirus/vaccine
1/07/20	**BioNTech shows positive results** • Pfizer/BioNTech are testing four different versions of the vaccine • BNT162b1 vaccine sparked immune response in adults 18 – 55 • 10, 30 & 100 microgram doses trialled • Caused fever and other side effects, especially at higher doses • Two doses required for immunity • Phase 1/2 Clinical data released on MedRXiv - not peer reviewed https://www.medrxiv.org/content/10.1101/2020.06.30.20142570v1.full.pdf https://www.statnews.com/2020/07/01/covid-19-vaccine-from-pfizer-and-biontech-shows-positive-results/

Meetings

Date	Attendees, notes from discussion
11/9/20	s 47, 47C, 47E(d)
13/8/20	s 47C, 47E(d)
11/8/20	**Pfizer** s47F s47F – Legal Lead, Developed Markets s47F – Head, Regulatory Affairs, ANZ + Korea s47F – Vaccines Lead, ANZ + Korea **DoH** Lisa Schofield, Nick Henderson, s 47F Preliminary discussion of Draft Head of Terms. Under New York law for global consistency. Indemnity discussions, risk sharing to be reviewed by Legals. Pfizer seeking engagement with TGA, hoping for pre-submission meeting mid-September.
4/8/20	**Pfizer/BioNTech** s47 F – Director, Pfizer ANZ s47 F – Global Viral Vaccine s47 F – Director, Technical Projects (Manufacture and Supply) s47 F – Global Vaccine Market Access **Minister Hunt's Office** s 47F **DoH** Lisa Schofield, Professor John Skerritt, Dr Jane Cook, s 47F Pfizer provided an overview of the track record of Pfizer/BioNTech Established scientific discovery, clinical development, reg approval, manufacturing, supply chain, etc. <u>Science –</u> s 47F

Explanation of mRNA vaccines and advantages:

- adjuvant not needed
- less biosafety required
- lower production time

Seeking regulatory approval Q4 2020, as early as October

Phase 1/2 data ready for publication soon:

- 2 doses 3 weeks apart, 30 micrograms
- No SAEs, high level neutralising antibody titres, greater than those in sera from COVID-19-recovered patients aged 65-85 years

Phase 2/3 underway – 1:1 randomisation vaccine:placebo

- Primary endpoints = prevention of COVID-19 in those not previously infected; prevention in those previously infected
- Secondary endpoints = prevention of severe COVID-19
- Adults aged 18-85 years
- Sites – US, Argentina, Brazil, Germany

<u>Manufacturing and supply chain –</u> s 47F
23 fill and finish facilities globally

- St Louis, MO (USA), Kalamazoo, MI (USA), Andover, MA (USA), Puurs (Belgium)– Pfizer
- Mainz Region (Germany), Idar Oberstein (Germany) – BioNTech

US, EU supply chains planned
Shipping from Pfizer to dosing centres
975 vials per shipper (cold container)
-70 degrees C, stable for 10 days. Stability studies underway, development underway for stable lyophilised formulation
No plans at present for manufacturing in Australia

<u>Principles of procurement proposal –</u> s 47F
Value-based pricing
Upfront payment – nominal price of s s 47 (x doses over 2021)

- Upfront payment 50% refundable if reg approval not obtained or not manufactured and delivered

Full payment = s 47 (i.e. s 47 additional to upfront payment)
s 47

s 47, 47C, 47E(d)

10/7/20	Lisa Schofield s 47F s 47F
	Need to progress confidentiality agreements – s 47F working with Legal Provided overview of Pfizer/BioNTec work. Pfizer has strong history in vaccine development and production. 3 mRNA vaccine platforms 4 mRNA vaccine candidates Limited production by end 2020, higher in 2021. Early allocation to priority populations (health care workers etc). Clinical trials – see notes above (media) Pfizer wanted to know - Timeline for doses - ATAGI 'approval' processes Treatments: Two antiviral types/schools under development

Meeting with Pfizer – 10 July

Want to have discussions to move as quickly as possible – commercially sensitive.

What Pfizer has been doing partnership with Biotech
Able to provide further info on pricing principles, vaccine development etc.

s 47F - senior legal director to answer questions about the legal documents.

Supplies to the NIP.

Working to reg authorities to test and manufacture MRNA vaccines.
Could deploy at unprecedented speed.

Up scaling manufacturing and distribution strategies.

Want to consider how we can invest while they progress manufacturing and clinical development.

Want to understand priority population. Front line health workers, elderly and immune compromised.

Products in the vaccine space
Clinical trials . Gov

Studies Pfizer and biotech are conducting
3 MRNA platforms and candidates
Looking at dose level and schedules.

Rest of Pfizer
Ongoing work.
Viral work inhibitors.
Other work too.

Studies conducted in Germany and the US – 4 May first subject vaccinated in the US and Germany in April.

Phase 1/2 being developed – dose finding and candidate selection in healthy adults.

Manufacturing sites across a number of countries that could be used for full scale production. Not in one country or site.
Also looking at distortion approach across the globe.

Supply chains – any risks to getting the materials needed?
Feeling confident.
Possibly s 47C by the end of this year,
1.2 billion doses by the end of 2021.

TGA, FDA, EMA.

Use NIP infrastructure to support efficiency and speed to support distribution processes.

ATAGI role in the assessment process.

Engagement – should they go directly to TGA or should also go to ATAGI.

ATAGI will continue to provide role in terms of regulation but provides policy role.

NIP mechanism to support distortion, workforce capacity building, safety and surveillance and working with states and territories.

ACV – provides advice to TGA.

Engaging with Gavi COVAX.

s 47C

Regulatory processes – is there emergency consideration?

s 47F – non disclosure agreement – to send contact details.

From: s 47F
To: SCHOFIELD, Lisa
Cc: s 47F
Subject: RE: Letter to Minister Hunt re Pfizer vaccine development for COVID-19. [SEC=OFFICIAL]
Date: Thursday, 23 July 2020 10:30:50 AM
Attachments: image001.png
image002.png

Hi Lisa

I just wanted to give you a heads up that Pfizer has been approached by trade media with an enquiry regarding engagement with Government on COVID vaccine procurement and manufacturing.

In response we have provided the following statement attributable to a spokesperson for Pfizer:

"Pfizer is committed to bringing this vaccine to all who need it to help meet the global public health need. Should our vaccine be successful in clinical trials and receive regulatory approval, we will work closely with governments, and other vaccine manufacturers to supply the world as quickly as we can, together. Discussions with government remain confidential."

Please let me know if you have any queries on this.

Also, I assume you have seen the recent news of Pfizer's agreements with the UK and US on vaccine supply. It seems that both our legal representatives are close to resolving the few outstanding issues with the CDA. I look forward to scheduling another meeting with you to progress our discussions once this is signed.

Kind regards

s 47F

From: Schofield, Lisa <Lisa.Schofield@health.gov.au>
Sent: Wednesday, 8 July 2020 9:44 AM
To: s 47F
Cc: s 47F

Subject: [EXTERNAL] RE: Letter to Minister Hunt re Pfizer vaccine development for COVID-19. [SEC=OFFICIAL]

Hi s 47F

We are considering the CDA. It is not usual practice for the Commonwealth to sign such documents as we are covered by various legislative requirements to keep information gained through our employment confidential.

I would like to propose that we keep the slot on Friday morning and have the introductory/exploratory discussion you suggest. We can always line up subsequent ones as needed.

Cheers
Lisa

From: s 47F
Sent: Tuesday, 7 July 2020 6:05 PM
To: Schofield, Lisa <Lisa.Schofield@health.gov.au>
Cc: s 47F

Subject: RE: Letter to Minister Hunt re Pfizer vaccine development for COVID-19. [SEC=OFFICIAL]

Hi Lisa

Following up on the below, plus I have some extra information to add.

Once the CDA is signed, we have a lengthy and highly detailed slide deck to run through with you. This goes through the scientific development and clinical trial process underway, medical information on the novel RNA vaccine technology, manufacturing, supply chain and procurement processes.

As a result the strong recommendation is for a 90 minute meeting to have sufficient time to get through all of this detail and Q&A.

Also, we are unable to provide copies of the slide deck so it must be shared through screen-sharing via a video-conferencing link. As mentioned below, I am happy to set that up through WebEx which is our preferred platform.

Please let me know how you would like to proceed. I am on leave tomorrow but will be back on deck on Thursday morning. I am assuming a postponement to next week to enable time to review and sign the CDA, and find an appropriate time slot, is most likely but my local colleagues are keeping 10.30am on Friday free nonetheless

I have cc'd s 47F , with whom I spoke yesterday as she expressed interest to join the call, which is of course fine with us.

Thanks and I look forward to hearing from you.

Kind regards

s 47F

From: s 47F
Sent: Monday, 6 July 2020 5:45 PM
To: Schofield, Lisa <Lisa.Schofield@health.gov.au>
Cc: s 47F
Subject: RE: Letter to Minister Hunt re Pfizer vaccine development for COVID-19. [SEC=OFFICIAL]

Hi Lisa

Thanks for your assistance in organising a (virtual) meeting with you on Friday to discuss Pfizer's approach to COVID-19 vaccine development and distribution (in partnership with BioNTech).

I have just received guidance from my colleagues in Europe managing this project that in order to provide any level of detail on Pfizer's approach we will need to have a Confidential Disclosure Agreement signed by both parties prior to the meeting. Attached is the CDA which our Global

Head of Vaccines is ready to sign should it meet your approval.

If we can get this signed ahead of Friday's meeting then we will include several senior Global Pfizer colleagues on the call to be able to provide the detail you may be seeking on a range issues. However as these colleagues are all based in Europe I will need to request a time change, to be a bit more suitable to all participants (10.30am here is 1.30am in London). Our 4.00pm, or any time after that, usually works best.

Alternatively we are happy to treat this Friday as just an exploratory / introductory meeting without the CDA, in which case it will be limited to my Australian colleagues (including the Managing Director of Pfizer Australia & NZ).

Your guidance on this will be appreciated.

On a separate issue, I note s 47F has included tele-conference dial-in details. We are happy to do this by video-conference to improve the engagement. I can circulate a WebEx link if you are agreeable.

Thanks for your consideration of these matters.

Kind regards
s 47F

From: Schofield, Lisa <Lisa.Schofield@health.gov.au>
Sent: Friday, 3 July 2020 8:34 AM
To: s 47F
Cc: s 47F
Subject: [EXTERNAL] RE: Letter to Minister Hunt re Pfizer vaccine development for COVID-19. [SEC=OFFICIAL]

Hi s 47F

s 47F passed on your email and letter to Minister Hunt.

I am managing the whole of government work on COVID-19 vaccine from the Department of Health.

I would very much appreciate an opportunity to talk to Pfizer about your vaccine work – both the development and manufacturing activities and plans.

I'll ask my EA, s 47F , to get in touch with you and arrange a suitable time.

Cheers
Lisa

Lisa Schofield
First Assistant Secretary, Health Economics and Research Division
Australian Government Department of Health
P: 02 6289 7480 | s 22 **E:** lisa.schofield@health.gov.au

I acknowledge the traditional custodians of the lands and waters where we live and work, and pay my respects to elders past, present and future.

s 47F

From: s 47F
Sent: Tuesday, 30 June 2020 4:38 PM
To: s 47F
Cc: s 47F
Subject: Letter to Minister Hunt re Pfizer vaccine development for COVID-19. [SEC=No Protective Marking]

Hi s 47F

It was really good to catch up last Friday. Thanks for all your time.

As discussed, please find attached a letter from Pfizer Australia MD, s 47F with some information about Pfizer's vaccine development in response to COVID-19

This includes a request for a formal (virtual) engagement opportunity with members of the Vaccines Taskforce to be selected at your discretion. I am able to make senior members of Pfizer's global leadership team available for this discussion, particularly if the Minister and/or Departmental leadership can be involved. As the vaccine development landscape is moving swiftly, including through engagements with other nations, I am requesting this meeting occur at the earliest opportunity.

I am happy to discuss this matter further at any time.

Kind regards

s 47F

Pfizer Australia
s 47F

www.pfizer.com.au
Level 3, 500 Collins Street
Melbourne, VIC, 3000
s 47F

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Pfizer Australia
Level 15-18
151 Clarence Street
Sydney NSW 2000

30 June 2020

The Hon. Greg Hunt MP
Minister for Health
PO Box 6022
Parliament House
Canberra ACT 2600

Dear Minister Hunt,

Thank you for your steadfast leadership during this global health crisis. Pfizer stands in solidarity with all patients around the world and in Australia currently affected by COVID-19, and with the governments, organisations, and health professionals working to respond to the pandemic. Pfizer is committed to playing its part and has created a crisis team of our leading virologists, biologists, chemists, clinicians, epidemiologists, vaccine experts, pharmaceutical scientists, and other key experts to focus solely on addressing this pandemic. I would like to take this opportunity to provide an overview of our candidate vaccine development and manufacturing program and request a meeting with you to open discussions regarding your planning for potential COVID-19 vaccination programs.

Vaccine Development. In collaboration with BioNTech, Pfizer is working closely with regulatory authorities to develop, test and manufacture a potential mRNA-based vaccine that, if approved, could be deployed at unprecedented speed for the prevention of COVID-19 infection. We are leveraging our decades of scientific expertise in pioneering vaccine discovery and development to respond to this global health crisis.

Pfizer and BioNTech are working with regulatory authorities to advance multiple COVID-19 vaccine candidates into human clinical testing with our R&D program now underway globally. The Phase 1/2 study is unique in that it is testing four vaccine candidates simultaneously, each representing a unique combination of mRNA format and target antigen. Each of those four vaccine candidates is potentially being tested in three different doses and two different age populations in a single Phase 1/2 study. The design of the trial allows us to move urgently, while preserving the highest quality and safety standards.

Vaccine Delivery. We are actively scaling up our manufacturing capacity and distribution infrastructure to be ready to bring a candidate vaccine to the world faster than we have ever done before. By doing many steps in the manufacturing process in parallel, rather than sequentially, we have the potential to supply millions of vaccine doses by the end of 2020, subject to technical success and regulatory approvals, then rapidly scale up to produce hundreds of millions of doses in 2021.

Vaccines are an important part of the long-term solution for ending this pandemic and we are committed to bring our deep heritage in vaccine development, remarkable reach and scale, and capital resources to serve the millions of people around the world impacted by this devasting illness.

Should our candidate vaccine be successful in clinical trials and receive regulatory approval or emergency use authorisation, we want to work with governments, as well as other vaccine manufacturers and global bodies, to supply the world as quickly as we can.

I would welcome an opportunity to discuss our candidate vaccine development in more detail, and open discussions on how we might work together to support planning for potential COVID-19 vaccinations in Australia and continue to build a strong partnership for the future.

Pfizer's s 47F will be in touch to schedule a meeting. I look forward to meeting you and working with you into the future.

Yours sincerely

s 47F

Pfizer Australia & New Zealand