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 22 s 22 s 22
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 22

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 22

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 22 , 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 22
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 22 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 22
Subject: [EXTERNAL] RE: Letter to Minister Hunt re Pfizer vaccine development for COVID-19. [SEC=OFFICIAL]

Hi s 47F

s 22 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 22, 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: s 22 | 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 22

From: s 47F
Sent: Tuesday, 30 June 2020 4:38 PM
To: s 22
Cc: s 47F
Subject: Letter to Minister Hunt re Pfizer vaccine development for COVID-19. [SEC=No Protective Marking]

Hi s 22

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
P: s 47F

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

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