From: \$22
To: Cc:

Subject: RE: Late letter and PM&C contact details [SEC=OFFICIAL]

Date: Friday, 3 December 2021 2:22:38 PM

Attachments: image001.png

Hello **s22**

This is wonderful news and we are very happy!

It does change by the hour...and the changes are all good!

Thank you again

Kind regards

s22

Principal Lawyer

Constitutional Risk Team

Legal Advice and Legislation Branch | Legal & Assurance Division

Corporate Operations Group

Australian Government Department of Health

T: s22

Location: \$22

PO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

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From: s22 @finance.gov.au>

Sent: Friday, 3 December 2021 2:21 PM

To: \$22 @health.gov.au>

Cc: \$22 @health.gov.au>; \$22

@finance.gov.au>

Subject: RE: Late letter and PM&C contact details [SEC=OFFICIAL]

SEC=OFFICIAL

- some good news! s34(3)

. So one less thing for your program area to worry about.

Still need the late letter though 🕾

Cheers

s22

SEC=OFFICIAL

From: \$22 @health.gov.au>

Sent: Friday, 3 December 2021 12:18 PM

To: \$22

Cc: s22 @health.gov.au>; s22

@finance.gov.au>

Subject: RE: Late letter and PM&C contact details [SEC=OFFICIAL]

Thanks again \$22 — you have been so helpful.

We have just finished our meeting with the program area and they will be contacting \$22 today.

Once again, thank you.

Kind regards

s22

Principal Lawyer

Constitutional Risk Team

Legal Advice and Legislation Branch | Legal & Assurance Division

Corporate Operations Group

Australian Government Department of Health

T: s22

Location: s22

PO Box 9848, Canberra ACT 2601, Australia

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From: \$22 @finance.gov.au>

Sent: Friday, 3 December 2021 11:34 AM

@finance.gov.au>

Subject: RE: Late letter and PM&C contact details [SEC=OFFICIAL]

SEC=OFFICIAL

No problem \$22 — anything to get our job done ☺

The relevant adviser in PM&C for the mRNA onshore production issue is \$22

I think that \$22 is expecting to be contacted.

Kind regards

s22

SEC=OFFICIAL

From: \$22 @health.gov.au>

Sent: Friday, 3 December 2021 11:25 AM

To: \$22 @finance.gov.au>

Cc: \$22 @health.gov.au>; \$22

@finance.gov.au>

Subject: RE: Late letter and PM&C contact details [SEC=OFFICIAL]

Dear s22

Thank you very much for this.

You are very helpful – really appreciated.

Kind regards

s22

Principal Lawyer

Constitutional Risk Team

Legal Advice and Legislation Branch | Legal & Assurance Division

Corporate Operations Group

Australian Government Department of Health

T: s22

Location: s22

PO Box 9848. Canberra ACT 2601. Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

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From: \$22 @finance.gov.au>

Sent: Friday, 3 December 2021 11:19 AM

[@health.gov.au]

Cc: \$22 @health.gov.au>; \$22

@finance.gov.au>

Subject: Late letter and PM&C contact details [SEC=OFFICIAL]

SEC=OFFICIAL

His22

As discussed, attached is an example of a late letter from PM to GG. This is what your policy area would need to request PM&C to prepare and progress as soon as possible. I am awaiting contact details of the relevant policy adviser in PM&C and will provide them as soon as they are available.

The second thing that your policy area would need to engage with PM&C on is \$34(3)

. This is also something to raise with the PM&C policy adviser who will likely be liaising with Cabinet Division in PM&C on this matter. Just in case, here's a very helpful contact in Cabinet Division who deals with \$22

Kind regards

s22

SEC=OFFICIAL

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From: Financial Framework (Supplementary Powers) Regulations

To: \$22

Subject: FW: mRNA [SEC=PROTECTED]

Date: Tuesday, 7 December 2021 12:39:47 PM

From: Financial Framework (Supplementary Powers) Regulations

Sent: Tuesday, 7 December 2021 12:39:44 PM (UTC+10:00) Canberra, Melbourne, Sydney

To: \$22

Cc: Financial Framework (Supplementary Powers) Regulations; s22

Subject: RE: mRNA [SEC=PROTECTED]

SEC=PROTECTED

I just spoke to \$22 in PM&C and asked him to help progress the late letter without Minister Hunt having to write to Prime Minister \$34(3).

He spoke to your program area before he spoke to me. You may wish to let them know so that they can confirm with \$22 that they don't need to prepare a letter from Minister Hunt.

Cheers

s22

From: s22

Sent: Tuesday, / December 2021 11:15:28 AM (UTC+10:00) Canberra, Melbourne, Sydney

To: Financial Framework (Supplementary Powers) Regulations

Subject: RE: mRNA [SEC=PROTECTED]

Ah very good then – just checking to make sure everything aligns...

From: Financial Framework (Supplementary Powers) Regulations < FFSPRegs@finance.gov.au>

Sent: Tuesday, 7 December 2021 11:06 AM

To: \$22

(Supplementary Powers) Regulations < FFSPRegs@finance.gov.au>

Subject: RE: mRNA [SEC=PROTECTED]

SEC=PROTECTED

No, PM&C wasn't in touch with me directly. Last I heard from Commercial and Government Services Div here in Finance is that your program area is pushing for it with PM&C. I also alerted Exco Secretariat about this late item, so they would also be able to provide guidance to policy adviser in PM&C if needed on the late letter.

s22

SEC=PROTECTED

From: \$22

Sent: Tuesday, 7 December 2021 11:01 AM

To: Financial Framework (Supplementary Powers) Regulations < FFSPRegs@finance.gov.au>

Subject: RE: mRNA [SEC=PROTECTED]

His22

Have you heard anything about the late letter? Apparently (now this is about 4th hand) PM&C was going to contact you.

Kind regards

s22

From: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>

Sent: Tuesday, 7 December 2021 9:44 AM

To: Constitutional Risk < Constitutional.Risk@protected.health.gov.au >

Cc: \$22 @Protected.Health.gov.au>; \$22

<u>@Protected.Health.gov.au</u>>; Financial Framework (Supplementary Powers)

Regulations < FFSPRegs@finance.gov.au >

Subject: mRNA [SEC=PROTECTED]

SEC=PROTECTED

His22

I understand Moderna option is going ahead. I will kick start the process on our end and instruct OPC to prepare the instrument. Can I please have your input for the ES asap today? Many thanks

s22

SEC=PROTECTED

Be careful with this message

External email. Do not click links or open attachments unless you recognise the sender and know the content is safe.

SEC=PROTECTED

From: Financial Framework (Supplementary Powers) Regulations

To:

Subject: FW: Schedule 1AB: draft instrument for mRNA item [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

Date: Tuesday, 7 December 2021 3:46:12 PM

From: S22

Sent: Tuesday, / December 2021 3:46:32 PM (UTC+10:00) Canberra, Melbourne, Sydney

To: Financial Framework (Supplementary Powers) Regulations

; Constitutional Risk

Subject: RE: Schedule 1AB: draft instrument for mRNA item [SEC=OFFICIAL:Sensitive,

ACCESS=Legal-Privilege]

Thank you, **s22**

I will pass this onto our policy and legal colleagues.

I am still waiting to receive the 1AB templates from them but I hope to receive them shortly.

Kind regards, \$22

Constitutional Risk Assessment Section

s22

<u> ଭhealth.gov.au</u>

constitutional.risk@protected.health.gov.au

From: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>

Sent: Tuesday, 7 December 2021 3:42 PM

To: \$22 @health.gov.au>

Cc: <u>s22</u> @health.gov.au>; Financial Framework

(Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>

Subject: Schedule 1AB: draft instrument for mRNA item [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

His22

Please find attached draft instrument for the mRNA item. OPC did not ask any questions. We do have one question regarding the commencement of the instrument – are you ok with standard commencement the day after registration? If this is very urgent, then we could ask OPC to make the instrument commence immediately after registration but this is only if you needed it to commence on 16 December.

In the interest of time, could you please seek SES clearance of the instrument by **tomorrow** (Wednesday 8 December)? Unless of course you have any comments or would like amendments made.

Kind regards

P.S. I will need to log off around 4.30pm, be back after 9pm. Please send through information for the ES as soon as you have it available.

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

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Attachment A

Letter to the Minister for Finance

Request for a new Schedule 1AB item

I am writing to seek your agreement to insert a new item in Schedule 1AB to the *Financial Framework (Supplementary Powers) Regulations 1997* (the FF(SP) Regulations) to establish legislative authority for government spending on Australia's sovereign capability to manufacture mRNA vaccines and treatments onshore and guarantee supply of those products in Australia. This Schedule 1AB amendment is proposed for consideration by the Governor-General at the Federal Executive Council meeting scheduled for 16 12 2021.

Summary of the proposed Commonwealth expenditure

The Department of Health (the Department) is seeking to establish an onshore mRNA manufacturing capability in Australia to develop COVID-19 vaccines and other potential mRNA products as a response to the ongoing COVID-19 pandemic, through procuring a population-scale mRNA manufacturing capability initially through the Moderna mRNA Partnership.

The Moderna mRNA Partnership would be supported through a 10 year agreement commencing 2021-22 and terminating in 2031-32 that would establish an onshore mRNA manufacturing capability and guarantee the supply of locally-manufactured mRNA vaccines (including COVID-19 vaccines).



Onshore production of mRNA vaccines would strengthen the Commonwealth's capacity against COVID-19 and its variants, as well as future pandemics and other diseases. Through this, the Commonwealth seeks to ensure: ongoing priority access to mRNA vaccines and therapeutics; security of vaccine supply to address future pandemics and other health emergencies; strengthening Australia's biopharmaceuticals sector, including R&D translation and commercialisation.

The objectives of the Commonwealth includes insuring against a proportion of economic costs arising from lockdowns and travel restrictions resulting from future COVID-19 variants and other pandemics and securing onshore population scale vaccine manufacturing capability, supply and resilience to respond to future pandemics, and manage COVID-19 over the long term.

Policy authority

s34(3)

). I request that the proposed amendment to Schedule 1AB to the FF(SP) Regulations be put forward for the Governor-General's consideration at the Federal Executive Council meeting as nominated above.

s47, s47D			
s42			

Attachment A1

Attachment to the letter to the Minister for Finance (additional information)

Description of the proposed new or materially changed Commonwealth expenditure

Moderna mRNA Partnership

The Moderna mRNA Partnership is proposed to be supported through an agreement with Moderna that would commence in 2021-22 and terminate in 2031-32.

Following construction of a facility (estimated completion December 2024) with the capacity to manufacture and supply up to 100 million doses per annum in a pandemic and the relevant approvals from the Therapeutic Goods Administration, the Commonwealth would be required to:

s47, s47D	

Building on the success of breakthrough COVID-19 mRNA vaccines, the Commonwealth recognises that mRNA technology is part of the next generation in advanced health care. Onshore production of mRNA vaccines will strengthen the Commonwealth's capacity against COVID-19 and its variants, as well as future pandemics and other diseases.

The process to establish an mRNA manufacturing capability started at the beginning of the COVID-19 pandemic in 2020, when the Commonwealth was squarely focused on pandemic preparedness. Local mRNA vaccine production capacity has been identified as a priority growth opportunity in the *Medical Products National Manufacturing Priority road map*, published by the Department of Industry, Science, Energy and Resources (DISER) in February 2021, refer to Medical Products National Manufacturing Priority road map (industry.gov.au).

The ongoing COVID-19 pandemic has resulted in challenges to the procurement and delivery of offshore manufactured COVID-19 vaccines, presenting risks to the security of Australia's vaccine supply. Enduring and streamlined manufacturing and supply arrangements for mRNA vaccines would enable a secure and diverse supply of vaccines and will equip Australia to deal with any new challenges for the current COVID-19 pandemic and any future pandemics. Once established, an onshore manufacturing facility for mRNA vaccines would provide Australia with priority access to existing and pipeline mRNA products, rather than relying on delivery from other countries.

The Science and Industry Technical Advisory Group (SITAG) has also maintained support for onshore manufacturing, emphasised the importance of investing in onshore mRNA manufacturing capabilities to ensure Australia has ongoing access to a diverse vaccine portfolio and at a magnitude that provides above population coverage.

A 2020 audit of Australia's vaccine manufacturing capability, followed by a March 2021 business case, identified a need for Australia to undertake onshore mRNA manufacturing. Then in the 2021-22 Budget, the Australian Government announced a measure that included funding to DISER to work with Department of Health (the Department) to develop an onshore mRNA vaccine manufacturing capability in Australia, refer to <u>Budget Paper No. 2</u>.

Further, on 21 May 2021, a joint media release was made between the then Minister for Industry, the Hon Christian Porter MP, and Minister for Health and Aged Care, the Hon Greg Hunt MP, announcing the strengthening of Australia's capacity against future pandemics and other diseases by developing a pathway to Australia's own sovereign manufacturing capability for mRNA vaccines, refer to Australia to develop onshore mRNA manufacturing | Ministers for the Department of Industry, Science, Energy and Resources.

In establishing an onshore mRNA manufacturing capability in Australia, the Commonwealth's objectives are to:

- insure against a proportion of economic costs arising from lockdowns and travel restrictions resulting from future COVID-19 variants and other pandemics;
- secure onshore population scale mRNA vaccine manufacturing capability, supply and resilience to respond to future pandemics and other health emergencies, and manage COVID-19 over the long term;
- provide priority access to mRNA COVID-19 vaccines and other respiratory vaccines should those vaccines obtain regulatory approval from the TGA;

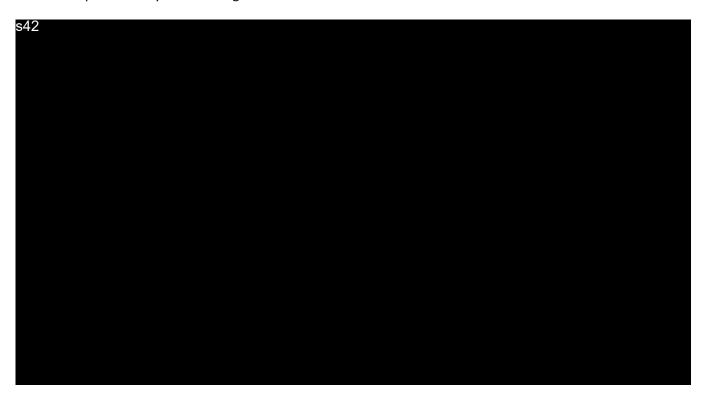
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- place Australia at the forefront of the development of transformative mRNA technology, which
 could have potential widespread applications for cancer, respiratory illnesses and other medical
 conditions; and
- bolster industry growth and job creation, by strengthening Australia's biopharmaceuticals sector, including through enabling potential translation and commercialisation paths for Australian-based research and development.

The overarching requirements in the establishment of a sovereign mRNA manufacturing capability include:

- an end-to-end onshore manufacturing solution for the production and supply of mRNA pandemic and non-pandemic vaccines, for the Australian population;
- participation in the broader mRNA ecosystem including contribution to research and development;
- Annual Advanced Purchasing Agreements to procure Australia's requirement for COVID-19
 vaccines, followed by influenza and other mRNA vaccines such as Respiratory Syncytial Virus
 (RSV) should those vaccines be developed and approved; and
- ongoing pandemic preparedness fees to secure priority access to mRNA pandemic vaccines.

The Department would be the head agency for executing the agreement with Moderna and would provide the ongoing contract management and supplier engagement. The Department would also work closely with DISER who would provide policy support in relation to the research and development ecosystem and regional hub elements.



Statement specifying constitutional head(s) of power

Noting that it is not a comprehensive statement of relevant constitutional considerations, the objective of the item references the following powers in the Constitution:

- the external affairs power (s 51(xxix) of the Constitution);
- the social welfare power (s 51(xxiiiA) of the Constitution); and
- the express incidental power and the executive power (ss 51(xxxix) and 61 of the Constitution),
 including the nationhood aspect.

Statement of the relevance and operation of constitutional head(s) of power

External affairs power (s51(xxix))

Section 51(xxix) of the Constitution empowers the Parliament to make laws with respect to 'external affairs'.

The external affairs power supports legislation implementing Australia's international obligations under treaties to which it is a party.

Article 2 of the International Covenant on Economic, Social and Cultural Rights [1976] ATS 5 (ICESCR), which Australia is a party to, provides that each State Party undertakes to take steps to the maximum of its available resources with a view to achieving progressively the full realisation of the rights recognised in the Covenant, by all appropriate means.

Article 12(1) of the ICESCR recognises the 'right of everyone to the enjoyment of the highest attainable standard of physical and mental health'.

Article 12(2)(c) relevantly requires Australia to take steps necessary for 'the prevention, treatment and control of epidemic, endemic, occupational and other diseases', and Article 12(2)(d) requires Australia to take steps necessary for 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness'.

The proposed measure would fund Australia's onshore mRNA manufacturing capability and the supply of mNRA vaccines and treatments for both non-pandemic and future pandemic purposes. The proposed measure would protect human health by ensuring the Commonwealth is able to act efficiently and effectively in the interests of public health to prioritise access in Australia to mNRA vaccines and treatments. This would strengthen Australia's capacity to address future pandemics and other communicable diseases.

The proposal would significantly enhance timely access to cutting-edge and promising vaccines and treatments in the event of a future pandemic with continued pandemic readiness being necessary for the protection of human health in Australia.

Social welfare power (s51(xxiiiA))

The social welfare power in section 51(xxiiiA) of the Constitution empowers the Parliament to make laws with respect to the provision of pharmaceutical benefits, sickness benefits and medical services.

The proposal relates to the provision of pharmaceutical benefits in order to prevent and treat diseases and medical conditions using mRNA technology.

Executive power and express incidental power (s61 and s51(xxxix))

The express incidental power in section 51(xxxix) of the Constitution empowers the Parliament to make laws with respect to matters incidental to the execution of any power vested in the Parliament, the executive or the courts by the Constitution. Section 61 of the Constitution supports activities that are peculiarly adapted to the government of a nation and cannot be carried out for the benefit of the nation otherwise than by the Commonwealth.

The proposal relates to the onshore production of mRNA vaccines and treatments, in order to enhance Australia's immunisation programs. The proposal would establish a domestic capacity to produce mRNA vaccines and treatments to support Australia's pandemic readiness and responses, including for the current COVID-19 pandemic, and enabling the national supply and availability of such vaccines and treatments are important matters of national significance.

Decisions about Commonwealth expenditure

It is proposed that the Department would provide ongoing funding to deliver the mRNA manufacturing capability, in accordance with applicable legislative requirements and the Commonwealth resource management framework under the *Public Governance, Performance and Accountability Act 2013* (PGPA Act), the *Commonwealth Procurement Rules* (CPRs) and the Department's Accountable Authority Instructions. However, it is expected that the Secretary of the Department (as the relevant Accountable Authority) would make a determination under paragraph 2.6 of the CPRs that Divisions 1 and 2 of the CPRs do not apply to the proposed procurement of onshore mRNA manufacturing capability and supply of mRNA vaccines and treatments for both non-pandemic and pandemic purposes, and all incidental or related matters (the Procurement) on the basis that it is necessary to protect human health. The expenditure would be provided through a procurement decision making process.

If the Secretary of the Department determines that the paragraph 2.6 CPR exemption applies in respect of the Procurement, the requirement to publish the Procurement on AusTender as set out in the CPRs would not apply (however, the Department would need to table details relating to the Procurement in accordance with Senate Order 12).

Any procurement decisions, in particular for vaccine dose ordering, would be based on value for money, including capability and capacity to deliver, and price and risk considerations.



The Department would propose to:

- execute and manage all contracts for the above services for the term of the agreements;
- work collaboratively with DISER and the supplier to meaningfully engage in ecosystem requirements to strengthen mRNA capability in Australia; and

 report on the performance and progress of the mRNA capability, and monitor expenditure on the mRNA capability.

Availability of independent merits review

Procurement decisions made in connection with this measure are not considered suitable for independent merits review, as those decisions would relate to the allocation of a finite resource, from which all potential claims for a share of the resource could not be met. In addition, any funding that had already been allocated would be affected if the original decision was overturned. The Administrative Review Council has recognised that it is justifiable to exclude merits review in relation to decisions of this nature (see paragraphs 4.11 to 4.19 of the guide, *What decisions should be subject to merit review?*).

The re-making of a procurement decision after entry into a contractual arrangement with a successful provider is legally complex, impractical, and could result in delays in ensuring onshore mRNA manufacturing capability in Australia.

Furthermore, procurement for onshore mRNA manufacturing is a financial decision with a significant public interest element. The proposed measure is a response to the ongoing COVID-19 pandemic and would enhance sovereign capability and readiness for future pandemics. Arrangements are required to be entered into rapidly to uphold public confidence in the health systems and the national vaccination programs. The Administrative Review Council has acknowledged that it is justifiable to exclude merits review in relation to decisions of this nature (see paragraph 4.34 of the guide, *What decisions should be subject to merit review?*). While it is acknowledged that reliance on this justification for the exclusion of merits review is rare (see paragraph 4.36 of the guide), the context of a global pandemic is an extremely rare situation.

Consultation

The project was a joint Taskforce activity between the Department, DISER and Department of Finance. Across 2020 and 2021, the following governing bodies and agencies were consulted during the project phase, up to execution of agreements:

- State Governments;
- Australian Technical Advisory Group on Immunisation (ATAGI);
- Therapeutic Goods Administration (TGA);
- Pharmaceutical Benefits Advisory Committee (PBAC);
- COVID-19 Vaccines and Treatments for Australia Science and Industry Technical Advisory Group (SITAG);
- Department of Foreign Affairs and Trade;
- Prime Minister and Cabinet;
- an Expert Advisory Group (EAG) advising on the Approach to Market (ATM) process and the Moderna proposal; and
- Australian Government Solicitor.

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Beyond the implementation phase to the end of the agreements, consultation will continue with:

- State Governments;
- DISER;
- TGA;
- ATAGI;
- relevant industries; and
- the biotechnology research sector, particularly with regard to the development of the R&D ecosystem.

Input to the statement of compatibility with human rights Human rights implications

The amended table item engages the following human rights:

 the right of everyone to the enjoyment of the highest attainable standard of physical and mental health – Article 12 of the *International Covenant on Economic, Social and Cultural Rights* (ICESCR), read with Article 2.

Article 2(1) of the ICESCR requires each State Party to 'take steps... to the maximum of its available resources, with a view to achieving progressively the full realization' of the rights recognised in the ICESCR 'by all appropriate means, including particularly the adoption of legislative measures'.

Article 12(1) of the ICESCR recognises the 'right of everyone to the enjoyment of the highest attainable standard of physical and mental health'.

Article 12(2)(c) requires Australia to take steps necessary for 'the prevention, treatment and control of epidemic, endemic, occupational and other diseases', and Article 12(2)(d) requires Australia to take steps necessary for 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness'.

The proposed measure would fund Australia's onshore mRNA manufacturing capability, which would enable Australia to implement and enhance its immunisation/vaccination programs. mRNA technology is currently used to prevent COVID-19 and also has the potential to treat a range of other medical conditions such as influenza, cancer and human immunodeficiency virus.

The proposed measure would promote the right to health by ensuring that Australia is well prepared to prevent, treat and control diseases and other medical conditions using mRNA technology. Having mRNA manufacturing capability onshore would also ensure that Australia is not subject to potential supply and delivery issues of facilities located offshore. Overall, this measure would support the right of individuals to the enjoyment of the highest standard of health and further contribute to overall community health through the prevention, treatment and control of epidemic, endemic, occupational and other diseases.

Conclusion

The amended table item is compatible with human rights because it promotes the protection of human rights.

From: Financial Framework (Supplementary Powers) Regulations

To: \$22

Subject: FW: FINAL TEMPLATES - TRIM: REVIEW REQUESTED BY MONDAY 6 DEC - REVIEW LIKELY TO BE

REQUESTED EARLY NEXT WEEK - exco sch 1AB templates - mRNA vaccine manufacture [SEC=PROTECTED,

CAVEAT=SH:CABINET, ACCESS=Legal-Privilege]

Date: Wednesday, 8 December 2021 3:49:47 PM

Attachments: Duplicate of 6 December emails below, Documents 11 and 12 have been

extracted from this document

From: s22

Sent: Wednesday, 8 December 2021 3:47:59 PM (UTC+10:00) Canberra, Melbourne, Sydney

To: Financial Framework (Supplementary Powers) Regulations; s22

Cc: Constitutional Risk; s22

Subject: FW: FINAL TEMPLATES - TRIM: REVIEW REQUESTED BY MONDAY 6 DEC - REVIEW LIKELY TO BE REQUESTED EARLY NEXT WEEK - exco sch 1AB templates - mRNA vaccine manufacture [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege]

His22

Below is the final clearance from OCL.

Thanks again!

Kind regards, \$22 [PROTECTED]

s22

From: \$22 @ag.gov.au>

Sent: Wednesday, 8 December 2021 2:49 PM

To: \$22 @Protected.Health.gov.au>

Cc: \$22 @ag.gov.au>; Constitutional Risk

<Constitutional.Risk@protected.health.gov.au>; s22

OCL <OCL@ag.gov.au>

Subject: RE: FINAL TEMPLATES - TRIM: REVIEW REQUESTED BY MONDAY 6 DEC - REVIEW LIKELY TO BE REQUESTED EARLY NEXT WEEK - exco sch 1AB templates - mRNA vaccine manufacture [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege]

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His22

Thanks for providing the updated documents and additional advice.

We have no further comments on the drafts.

Kind regards,

s22

Attorney-General's Department

T: s22 @ag.gov.au

PROTECTED//CABINET

Legal Privilege

From: \$22 @Protected.Health.gov.au>

Sent: Wednesday, 8 December 2021 9:21 AM

To: \$22

Cc: \$22 @ag.gov.au>; Constitutional Risk

<<u>Constitutional.Risk@protected.health.gov.au</u>>; S22

@Protected.Health.gov.au>; \$22

Subject: FINAL TEMPLATES - RE: TRIM: RE: REVIEW REQUESTED BY MONDAY 6 DEC - REVIEW

<u>@ag.gov.au</u>>

LIKELY TO BE REQUESTED EARLY NEXT WEEK - exco sch 1AB templates - mRNA vaccine manufacture [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege]

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Hi s22

Thanks again for your previous advice. I now attach the final templates and AGS advice, both of which address the queries you raised.

s42

We would be grateful for your final advice <u>as soon as possible this afternoon</u> if this is feasible but please let us know if there are any issues at all, as I appreciate that we have imposed some very tight deadlines.

Kind regards, \$22 [PROTECTED]

s22

From: \$22

Sent: Monday, 6 December 2021 1:51 PM

<u>@Protected.Health.gov.au</u>>; OCL <<u>OCL@ag.gov.au</u>>

Cc: \$22 @ag.gov.au>; Constitutional Risk

<<u>Constitutional.Risk@protected.health.gov.au</u>>; \$22

<u>@Protected.Health.gov.au</u>>; s22 <u>@ag.gov.au</u>>

Subject: TRIM: RE: REVIEW REQUESTED BY MONDAY 6 DEC - REVIEW LIKELY TO BE REQUESTED EARLY NEXT WEEK - exco sch 1AB templates - mRNA vaccine manufacture [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege]

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His22

We'd appreciate seeing that document when changes have been made so that we can sign off on it.

Thanks,

s22

Attorney-General's Department

T: s22 @ag.gov.au

PROTECTED//CABINET Legal Privilege

From: \$22

Sent: Monday, 6 December 2021 1:49 PM

To: \$22

Cc: \$22 @ag.gov.au>; Constitutional Risk

<<u>Constitutional.Risk@protected.health.gov.au</u>>; s22

<u>@Protected.Health.gov.au</u>>; s22 <u>@ag.gov.au</u>>

Subject: RE: REVIEW REQUESTED BY MONDAY 6 DEC - REVIEW LIKELY TO BE REQUESTED EARLY NEXT WEEK - exco sch 1AB templates - mRNA vaccine manufacture [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege]

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Thank you<mark>s22</mark>

We really appreciate you reviewing the documents and in such a short time frame.

We will review and make some appropriate edits. Does OCL wish to review the final documents once we make those changes?

Kind regards, \$22 [PROTECTED] s22 From: S22 @ag.gov.au> Sent: Monday, 6 December 2021 1:44 PM @Protected.Health.gov.au>; OCL < OCL@ag.gov.au> @ag.gov.au>: Constitutional Risk Cc: \$22 <<u>Constitutional.Risk@protected.health.gov.au</u>>; s22 @Protected.Health.gov.au>: \$22 @ag.gov.au> Subject: RE: REVIEW REQUESTED BY MONDAY 6 DEC - REVIEW LIKELY TO BE REQUESTED EARLY NEXT WEEK - exco sch 1AB templates - mRNA vaccine manufacture [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege] PROTECTED//CABINET Legal Privilege Good afternoon \$22 Thank you for your assistance on Friday in relation to legal advices on mRNA manufacturing. Please see attached OCL's comments on the draft letter to the Finance Minister and the accompanying attachment. Please let me know should you wish to discuss, Kind regards, s22 Attorney-General's Department @ag.gov.au PROTECTED//CABINET Legal Privilege From: S22 @Protected.Health.gov.au> Sent: Friday, 3 December 2021 2:42 PM To: OCL <OCL@ag.gov.au>: \$22 @ag.gov.au> @ag.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>: s22 @Protected.Health.gov.au>; \$22 @ag.gov.au> Subject: REVIEW REQUESTED BY MONDAY 6 DEC - RE: REVIEW LIKELY TO BE REQUESTED EARLY NEXT WEEK - exco sch 1AB templates - mRNA vaccine manufacture [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege] Importance: High **CAUTION**: This email originated from outside of the organisation. Do not follow guidance, click links, or open attachments unless you recognise the sender and know the content is safe. Good afternoon \$22 Thank you for your time on the phone just now, \$34(3) s22 Second, as flagged in my email below, we have now prepared for your review the relevant

Second, as flagged in my email below, we have now prepared for your review the relevant sections of the draft schedule 1AB templates which the Department of Finance requires in order to progress a 1AB item at Exco. We have drafted the sections relating to constitutional heads of power, \$42 and draft schedule 1AB item. I understand the content of the templates is of course subject to change depending on \$34(3)

I also attach again for reference, \$42

We would be grateful if we could receive your review as soon as possible on **Monday, 6 December**. If there is anything you would like to discuss or clarify, please don't hesitate to contact us.

Kind regards, \$22 [PROTECTED]

s22

From: S22

Sent: Thursday, 2 December 2021 2:00 PM

To: \$22

Cc: \$22 @ag.gov.au>; Constitutional Risk

<Constitutional.Risk@protected.health.gov.au>; s22

@Protected.Health.gov.au>

Subject: REVIEW LIKELY TO BE REQUESTED EARLY NEXT WEEK - exco sch 1AB templates - mRNA vaccine manufacture [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege]

Importance: High

Dear OCL,

I just wanted to flag with you that Health is likely to have a \$34(3)

If there is agreement to the proposal, at this stage I understand it will be rushed through as an urgent amendment to schedule 1AB of the *Financial Framework (Supplementary Powers) Regulations 1997.* I expect to have some draft templates for your review either by the end of this week or early next week.

I will provide any updates as soon as I receive them. If you would like to discuss this further, please don't hesitate to contact our team.

Kindest regards,

[Protected]

A/g Senior Lawyer – Constitutional Risk Assessment Section

Legal and Assurance Division | Corporate Operations Group

Australian Government Department of Health

T: s22 protected.health.gov.au;

constitutional.risk@protected.health.gov.au

Location: s22

GPO Box 9848, Canberra ACT 2601, Australia

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From: S22

Cc: S22 Industry Section

Subject: RE: mRNA late letter [SEC=PROTECTED, CAVEAT=SH:CABINET]

Date: Thursday, 9 December 2021 1:32:41 PM

Attachments: image001.jpg

image002.jpg image004.jpg image005.png image006.jpg image007.jpg

SEC=PROTECTED. CAVEAT=SH:CABINET

Great – thanks \$22

SEC=PROTECTED, CAVEAT=SH:CABINET

From: \$22 @pmc.gov.au>

Sent: Thursday, 9 December 2021 1:31 PM

To: \$22 @finance.gov.au>

@finance.gov.au>; Industry Section <Industry@pmc.gov.au>

Subject: RE: mRNA late letter [SEC=PROTECTED, CAVEAT=SH:CABINET]

PROTECTED//CABINET

His22

Thanks for this. Can confirm we provided to PMO yesterday, requesting signature by tomorrow. PDMS reference is MS21-001956.

Will also send a copy of the letter once it come back from the office.

Cheers

s22 s22 | Adviser

Industry, Innovation, Science and Technology | Department of the Prime Minister and Cabinet

p. **s22**

Ngunnawal Country, One National Circuit Barton ACT 2600 | PO Box 6500 CANBERRA ACT 2600

e. **\$22** @pmc.gov.au w. pmc.gov.au

?

The Department acknowledges and pays respect to the past, present and emerging Elders and Traditional Custodians of Country, and the continuation of cultural, spiritual and educational practices of Aboriginal and Torres Strait Islander peoples.

From: S22 @finance.gov.au>

Sent: Thursday, 9 December 2021 1:28 PM

To: \$22

Cc: \$22 @finance.gov.au>; Industry Section < Industry@pmc.gov.au>

Subject: RE: mRNA late letter [SEC=PROTECTED, CAVEAT=SH:CABINET] **SEC=PROTECTED, CAVEAT=SH:CABINET**

His22

Just wanted to confirm the current status of your briefing to PM re late letter. I am drafting my brief and wanted to say something along the lines that the late letter is with the PMO and expected to be signed by Friday 10 December 2021. If you are able to advise your PDMS ref number that would be awesome, because then our office could follow up if necessary.

Cheers

s22

FOI 24-25/081 - Document 14 under the Freedom of Information Act 1982 SEC=PROTECTED. CAVEAT=SH:CABINET From: S22 @pmc.gov.au> Sent: Tuesday, 7 December 2021 1:22 PM To: \$22 @finance.gov.au> Cc: \$22 @finance.gov.au>; Industry Section <<u>Industry@pmc.gov.au</u>> **Subject:** RE: mRNA late letter [SEC=PROTECTED, CAVEAT=SH:CABINET] PROTECTED//CABINET His22 Many thanks for the chat and providing the sample letter. I've also had a chat to \$22 am preparing the PM letter and accompanying brief which will seek the GG's agreement to late lodgement of the papers to ExCo. Given the timeframes, will aim to get this up to the PMO by the end of today to ensure everything is in place prior to the Finance Minister approving the paperwork by the end of this week. Let me know if there's anything else you need, happy to discuss. Cheers s22 s22 | Adviser Industry, Innovation, Science and Technology | Department of the Prime Minister and Cabinet Ngunnawal Country, One National Circuit Barton ACT 2600 | PO Box 6500 CANBERRA ACT 2600 e. s22 @pmc.gov.au w. pmc.gov.au The Department acknowledges and pays respect to the past, present and emerging Elders and Traditional Custodians of Country, and the continuation of cultural, spiritual and educational practices of Aboriginal and Torres Strait Islander peoples. From: S22 @finance.gov.au> Sent: Tuesday, 7 December 2021 12:35 PM To: \$22 @pmc.gov.au> Cc: \$22 @finance.gov.au> **Subject:** mRNA late letter [SEC=PROTECTED, CAVEAT=SH:CABINET] SEC=PROTECTED, CAVEAT=SH:CABINET His22 Thank you for taking my call. As discussed, attached is an example of late letter which was provided to Health. This was prepared by the relevant PM&C advisers without the responsible Minister writing to the Prime Minister. We would be very grateful if you could help facilitate a late letter from the Prime Minister to Governor-General \$34(3)

This is because the timeframes for the lodgement of papers to Exco for the 16 December meeting are very tight, and we are hoping to get the papers signed by our Minister by the end of this week if we can. It would be ideal if the Prime Minister signed late letter to Governor-General by the end of this week too.

I also forgot to mention that I've given heads up regarding this late item to \$22 Secretariat. I am sure that \$22 would also be happy to provide further guidance regarding late letter as required.

Very happy to discuss.

Kind regards

\$22

| Director

Schedule 1AB | Financial Management Branch

Department of Finance

T: \$22

| M: \$22

E: \$22

@finance.gov.au | FFSPRegs@finance.gov.au

A: 1 Canberra Avenue, Forrest ACT 2603

SEC=PROTECTED, CAVEAT=SH:CABINET

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From: Financial Framework (Supplementary Powers) Regulations

To: S22

Subject: FW: UPDATE - Schedule 1AB: draft instrument for mRNA item [SEC=OFFICIAL:Sensitive, ACCESS=Legal-

Privilege]

Date: Thursday, 9 December 2021 9:15:00 AM

Attachments: S42

From: Financial Framework (Supplementary Powers) Regulations

Sent: Thursday, 9 December 2021 9:14:56 AM (UTC+10:00) Canberra, Melbourne, Sydney

To: \$22 Cc: \$22

; Constitutional Risk; Financial Framework (Supplementary Powers)

Regulations

Subject: RE: UPDATE - RE: Schedule 1AB: draft instrument for mRNA item

[SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

His22

Revised instrument is attached and in the process of being finalised by OPC.

Cheers

s22

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

From: \$22 @health.gov.au>

Sent: Wednesday, 8 December 2021 3:47 PM

To: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>; \$22

@finance.gov.au>

Cc: \$22 @health.gov.au>; Constitutional Risk

<Constitutional.Risk@protected.health.gov.au>; \$22 @Protected.Health.gov.au>

Subject: RE: UPDATE - RE: Schedule 1AB: draft instrument for mRNA item

[SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

Good afternoon, s22

The program area AS has now cleared the **attached** instrument, subject to the following.

There is a reference to 'unemployment benefits' which needs to be changed to 'pharmaceutical

benefits'. s42

The program area has requested a standard commencement of the day after registration (being 17 December), but with urgent same day registration of the instrument once made at ExCo.

We have also obtained OCL clearance of the final templates which I will forward to you in a few moments.

Thanks again for your patience on this and please don't hesitate to contact me should you have any questions at all.

Kind regards, **s22**

Constitutional Risk Assessment Section

s22

s22 @health.gov.au

constitutional.risk@protected.health.gov.au

From: Financial Framework (Supplementary Powers) Regulations < FFSPRegs@finance.gov.au>

Sent: Wednesday, 8 December 2021 8:52 AM

To: \$22 @Protected.Health.gov.au>; \$22

<u>@health.gov.au</u>>; Financial Framework (Supplementary Powers) Regulations

< FFSPRegs@finance.gov.au>

Cc: \$22 @health.gov.au>; Constitutional Risk

<Constitutional.Risk@protected.health.gov.au>

Subject: RE: UPDATE - RE: Schedule 1AB: draft instrument for mRNA item

[SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

Thanks \$22 — will get started on the ES asap. You and \$22 — are doing great ☺

Cheers

s22

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

From: S22 @Protected.Health.gov.au>

Sent: Wednesday, 8 December 2021 8:42 AM

To: \$22 @health.gov.au>; Financial Framework (Supplementary

Powers) Regulations < FFSPRegs@finance.gov.au>

Cc: \$22 @health.gov.au>; Constitutional Risk

<Constitutional.Risk@protected.health.gov.au>

Subject: RE: UPDATE - RE: Schedule 1AB: draft instrument for mRNA item

[SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

Dear s22

Please now find **attached** the cleared templates. I am going to provide these to OCL this morning, as well.

As I noted in my email below, I understood there was some talk of the item changing. I think that this has now been resolved, but will confirm with you as soon as I can this morning.

I will also aim to provide you with program area SES clearance of the instrument as soon as I can. Thank you again for all of your patience, support and guidance with this matter and I sincerely apologise for our delays.

Kind regards, \$22 [PROTECTED]

s22

From: \$22

Sent: Tuesday, 7 December 2021 4:38 PM

To: Financial Framework (Supplementary Powers) Regulations < FFSPRegs@finance.gov.au>

Cc: \$22 @health.gov.au>; Constitutional Risk

<Constitutional.Risk@protected.health.gov.au>

Subject: UPDATE - RE: Schedule 1AB: draft instrument for mRNA item [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

⊣ s22

I tried to call you as I wanted to leave a quick update message, but I believe you may have left already.

I am still waiting on the templates from the program area. I am hoping to be able to send them through today but if I don't receive them in time, it is going to have to be first thing in the morning.

I also understand that there are some issues with the draft instrument that need to be resolved so it is likely to change tonight/in the morning.

If I receive the templates before 5 today, I will send them through to you and OCL noting the item is likely to change. I will then provide you with the comments/clearance on the item as soon as I can tomorrow.

Thank you greatly for your assistance and your patience on this matter to date, and I apologise for the difficulty.

Kind regards, **s22**

Constitutional Risk Assessment Section

s22

s22 @health.gov.au

constitutional.risk@protected.health.gov.au

From: Financial Framework (Supplementary Powers) Regulations < FFSPRegs@finance.gov.au>

Sent: Tuesday, 7 December 2021 3:42 PM

To: S22 @health.gov.au>

Cc: \$22

 $(Supplementary\ Powers)\ Regulations < \underline{FFSPRegs@finance.gov.au} >;\ Constitutional\ Risk$

<Constitutional.Risk@protected.health.gov.au>

Subject: Schedule 1AB: draft instrument for mRNA item [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

Hi **s22**

Please find attached draft instrument for the mRNA item. OPC did not ask any questions. We do have one question regarding the commencement of the instrument – are you ok with standard commencement the day after registration? If this is very urgent, then we could ask OPC to make the instrument commence immediately after registration but this is only if you needed it to commence on 16 December.

In the interest of time, could you please seek SES clearance of the instrument by **tomorrow** (Wednesday 8 December)? Unless of course you have any comments or would like amendments made.

Kind regards s22

P.S. I will need to log off around 4.30pm, be back after 9pm. Please send through information for the ES as soon as you have it available.

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s42

Subject: FW: Schedule 1AB: draft ES for mRNA [SEC=OFFICIAL:Sensitive, ACCESS=Legal-

Privilege]

Attachments: Draft ES - Health No. 9.docx

From: s22

Sent: Thursday, 9 December 2021 2:47:48 PM (UTC+10:00) Canberra, Melbourne, Sydney

To: Financial Framework (Supplementary Powers) Regulations

Cc: Constitutional Risk; s22

Subject: RE: Schedule 1AB: draft ES for mRNA [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

His22

Thanks for sending this through. I really appreciate it and apologies that I have taken a while to reply with an acknowledgment of receipt.

The draft is currently with the program area for review. I understand they are still going to the 16 December exco?, but want to give you a heads up that I have been asked if it is possible to delay registering the instrument in case an announcement has not been made by 17 December. I will let you know once I hear anything further, but just wanted to flag it at this stage.

I really apologise for the difficulties and, as always, happy to discuss.

Kind regards, S22

Constitutional Risk Assessment Section

s22

s22 @health.gov.au

constitutional.risk@protected.health.gov.au

From: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>

Sent: Thursday, 9 December 2021 12:59 PM

To: S22 @health.gov.au>

Cc: Constitutional Risk < Constitutional.Risk@protected.health.gov.au >; \$22

@health.gov.au>; Financial Framework (Supplementary Powers) Regulations

< FFSPRegs@finance.gov.au >

Subject: Schedule 1AB: draft ES for mRNA [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

Importance: High

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

His22

Please find attached draft ES for mRNA vaccines and treatments.

Can you please:

- review and address our questions/comments highlighted in yellow;
- check that the ES does not include information that is not public/shouldn't be made public (noting that most
 of the content is necessary to meet the requirements of the Scrutiny of Delegated Legislation Committee);
 and

 obtain SES clearance of the ES (unless there are any comments/issues that you wish to discuss with us before clearance is obtained).

Please provide any edits/comments in <u>track changes</u>. It would be appreciated if you do not make any changes to the template or structure of the ES. Please note that Finance reserves final editorial rights to this document.

Please provide SES clearance for the ES today (Thursday, 9 December 2021). The Commercial Policy and Advice Branch of our department has requested an opportunity to review the ES. In the interest of time, I will provide it to them for review with the same timeframe.

Kind regards **s22**

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

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