From: s22
To:
Subject: FW: mRNA SUB - s42 [SEC=PROTECTED, CAVEAT=SH:CABINET]
Date: Tuesday, 30 November 2021 12:22:51 PM
Attachments: image001.jpg
Documents 1 and 2

SEC=PROTECTED, CAVEAT=SH:CABINET

Would you mind having a look at these for me please? s22

Thanks!
s22

SEC=PROTECTED, CAVEAT=SH:CABINET

From: s22 @Protected.Health.gov.au>
Sent: Tuesday, 30 November 2021 12:21 PM
To: s22 @finance.gov.au>
Cc: s22 @Protected.Health.gov.au>
Subject: RE: mRNA SUB - AGS s42 [SEC=PROTECTED, CAVEAT=SH:CABINET]

s22 – please find the s42 attached for your records.

Kind regards
s22

Principal Lawyer
Constitutional Risk Team
Legal Advice and Legislation Branch | Legal and Assurance Division
Australian Government Department of Health
P: s22
E: s22 @protected.health.gov.au
Please note that this email and attachments may contain confidential or legally privileged information. Please consult with Legal & Assurance Division before disclosing any part of this email, or attachment, outside the Department. If you receive this email in error, please delete it and contact the sender immediately.

From: s22 @finance.gov.au>
Sent: Tuesday, 30 November 2021 11:40 AM
To: s22 @Protected.Health.gov.au>
Cc: s22 @Protected.Health.gov.au>
Subject: RE: mRNA SUB - SEEKING URGENT 1AB [SEC=PROTECTED, CAVEAT=SH:CABINET]

SEC=PROTECTED, CAVEAT=SH:CABINET

Thanks s22 – a copy s42 would be appreciated.

SEC=PROTECTED, CAVEAT=SH:CABINET

From: s22 @Protected.Health.gov.au>
Sent: Tuesday, 30 November 2021 11:40 AM
To: s22 @finance.gov.au>
Cc: s22 @Protected.Health.gov.au>
Subject: RE: mRNA SUB - SEEKING URGENT 1AB [SEC=PROTECTED, CAVEAT=SH:CABINET]

Thanks s22
s42
s47C

The package is actually been taken forward by industry.
Regards
s22

From: s22 @finance.gov.au>
Sent: Tuesday, 30 November 2021 11:34 AM
To: s22 @Protected.Health.gov.au>
Cc: s22 @Protected.Health.gov.au>
Subject: RE: mRNA SUB - SEEKING URGENT 1AB [SEC=PROTECTED, CAVEAT=SH:CABINET]

SEC=PROTECTED, CAVEAT=SH:CABINET

s22 – one more thing, s42 so that there is no need for any additional correspondence/approvals afterwards.
s22

SEC=PROTECTED, CAVEAT=SH:CABINET

From: s22
Sent: Tuesday, 30 November 2021 11:23 AM
To: s22 @Protected.Health.gov.au>
Cc: s22 @Protected.Health.gov.au>
Subject: RE: mRNA SUB - SEEKING URGENT 1AB [SEC=PROTECTED, CAVEAT=SH:CABINET]

SEC=PROTECTED, CAVEAT=SH:CABINET

All good s22 ☺
That's what we are here for. Still hoping for some Christmas leave though lol
s22

SEC=PROTECTED, CAVEAT=SH:CABINET

From: s22 @Protected.Health.gov.au>
Sent: Tuesday, 30 November 2021 11:11 AM
To: s22 @finance.gov.au>
Cc: s22 @Protected.Health.gov.au>
Subject: RE: mRNA SUB - SEEKING URGENT 1AB [SEC=PROTECTED, CAVEAT=SH:CABINET]

s22 thank you so much.
We really appreciate your assistance with getting this over the line.
Thank YOU!
Kindest regards
s22

From: s22 @finance.gov.au>
Sent: Tuesday, 30 November 2021 11:00 AM
To: s22 @Protected.Health.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Cc: s22 @Protected.Health.gov.au>; s22 @protected.health.gov.au>; s22 @Protected.Health.gov.au>
Subject: RE: mRNA SUB - SEEKING URGENT 1AB [SEC=PROTECTED, CAVEAT=SH:CABINET]

SEC=PROTECTED, CAVEAT=SH:CABINET

Hi s22
I think you can have just one recommendation along the following lines that will take care of everything you have asked at (a), (b) and (c). No need to specify exact Exco meeting, we will

toward the one that is preferred.s47C

s34(2), s34(3)

Hope this makes sense. Happy to discuss.
Kind regards

s22

s22 | Director
Schedule 1AB | Financial Management Branch
Department of Finance
T: s22 | **M:** s22
E: s22 @finance.gov.au | FFSPRegs@finance.gov.au
A: 1 Canberra Avenue, Forrest ACT 2603

SEC=PROTECTED, CAVEAT=SH:CABINET

From: s22 @Protected.Health.gov.au>
Sent: Tuesday, 30 November 2021 10:14 AM
To: s22 @finance.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Cc: s22 @Protected.Health.gov.au>; s22 @protected.health.gov.au>; s22 @Protected.Health.gov.au>
Subject: mRNA SUB - SEEKING URGENT 1AB [SEC=PROTECTED, CAVEAT=SH:CABINET]

Hello my very good friend, I have another quick question for you!!
We are settling the sub s47C and I just want you to check our request for urgent passage of a new item to support the onshore vaccine proposals. Can you let me know what you think about the requests as they are set out below?
As you know, I don't operate in this area of governance and processes…but as you can see we are taking your sage advice in requesting express progression of an item to provide legislative authority.

s34(2), s34(3)

s34(2), s34(3) [redacted]

Thank yo

I look forward to your feedback.

Kindest regards

s22 [redacted]

Principal Lawyer
Constitutional Risk Team
Legal Advice and Legislation Branch | Legal and Assurance Division
Australian Government Department of Health
P: s22 [redacted]
E: s22 [redacted]@protected.health.gov.au

From: s22
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: s22
PO Box 9848, Canberra ACT 2601, Australia

From: s22 @finance.gov.au>
Sent: Friday, 3 December 2021 2:21 PM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @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: s22 @health.gov.au>
Sent: Friday, 3 December 2021 12:18 PM
To: s22 finance.gov.au>
Cc: s22 @health.gov.au>; s22 @finance.gov.au>
Subject: RE: Late letter and PM&C contact details [SEC=OFFICIAL]
Thanks again s22 – you have been so helpful.
We have just finished our meeting with the program area and they will be contacting s22 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

From: s22 @finance.gov.au>
Sent: Friday, 3 December 2021 11:34 AM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @finance.gov.au>
Subject: RE: Late letter and PM&C contact details [SEC=OFFICIAL]

SEC=OFFICIAL

No problem s22 – anything to get our job done ☺
The relevant adviser in PM&C for the mRNA onshore production issue is s22 on s22 I think that s22 is expecting to be contacted.
Kind regards

s22

SEC=OFFICIAL

From: s22 @health.gov.au>
Sent: Friday, 3 December 2021 11:25 AM
To: s22 @finance.gov.au>
Cc: s22 @health.gov.au>; s22 @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

From: s22 @finance.gov.au>
Sent: Friday, 3 December 2021 11:19 AM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @finance.gov.au>
Subject: Late letter and PM&C contact details [SEC=OFFICIAL]

SEC=OFFICIAL

Hi s22

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 s34(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 s22

Kind regards

s22

SEC=OFFICIAL

"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."

From: Financial Framework (Supplementary Powers) Regulations
To: s22
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: s22
Cc: Financial Framework (Supplementary Powers) Regulations; s22
Subject: RE: mRNA [SEC=PROTECTED]

SEC=PROTECTED

s22 I just spoke to s22 in PM&C and asked him to help progress the late letter without Minister Hunt having to write to Prime Minister s34(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 s22 that they don't need to prepare a letter from Minister Hunt.
Cheers
s22

From: s22
Sent: Tuesday, 7 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: s22 @Protected.Health.gov.au>; Financial Framework (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: s22 @Protected.Health.gov.au>
Sent: Tuesday, 7 December 2021 11:01 AM
To: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Subject: RE: mRNA [SEC=PROTECTED]

Hi s22

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: s22 @Protected.Health.gov.au>; s22 @Protected.Health.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>

Subject: mRNA [SEC=PROTECTED]

SEC=PROTECTED

Hi s22

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

SEC=PROTECTED

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).

s45, s47, s47D [redacted]

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) [redacted]). 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.

s45, s47, s47D

[redacted]

s42

[redacted]

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:

s45, 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 Budget Paper No. 2.

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;

- 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.

s42

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.

s34(3)

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.

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: 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]
Date: Wednesday, 8 December 2021 3:49:47 PM
Attachments: image001.png

Duplicate of 6 December emails below, Documents 9 and 10 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]

Hi s22
Below is the final clearance from OCL.
Thanks again!
Kind regards, s22 [PROTECTED]
s22

From: s22 @ag.gov.au>
Sent: Wednesday, 8 December 2021 2:49 PM
To: s22 @Protected.Health.gov.au>
Cc: s22 @ag.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>; s22 @Protected.Health.gov.au>; s22 @ag.gov.au>; 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]

PROTECTED//CABINET
Legal Privilege

Hi s22
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: s22 @Protected.Health.gov.au>
Sent: Wednesday, 8 December 2021 9:21 AM
To: s22 @ag.gov.au>; OCL <OCL@ag.gov.au>
Cc: s22 @ag.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>; s22 @Protected.Health.gov.au>; s22 @ag.gov.au>
Subject: FINAL TEMPLATES - RE: 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]

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 [redacted]

We would be grateful for your final advice as soon as possible this afternoon 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, s22 [PROTECTED]

s22 [redacted]

From: s22 [redacted] @ag.gov.au>
Sent: Monday, 6 December 2021 1:51 PM
To: s22 [redacted] @Protected.Health.gov.au>; OCL <OCL@ag.gov.au>
Cc: s22 [redacted] @ag.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>; s22 [redacted] @Protected.Health.gov.au>; s22 [redacted] @ag.gov.au>
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]

PROTECTED//CABINET
Legal Privilege

Hi s22 [redacted]

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

Thanks,

s22 [redacted] | Attorney-General's Department

T: s22 [redacted] @ag.gov.au

PROTECTED//CABINET
Legal Privilege

From: s22 [redacted] @Protected.Health.gov.au>
Sent: Monday, 6 December 2021 1:49 PM
To: s22 [redacted] @ag.gov.au>; OCL <OCL@ag.gov.au>
Cc: s22 [redacted] @ag.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>; s22 [redacted] @Protected.Health.gov.au>; s22 [redacted] @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]

Thank you s22 .

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, s22 [PROTECTED]
s22

From: s22 @ag.gov.au>
Sent: Monday, 6 December 2021 1:44 PM
To: s22 @Protected.Health.gov.au>; OCL <OCL@ag.gov.au>
Cc: s22 @ag.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>; s22 @Protected.Health.gov.au>; s22 @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 s22
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
T: s22 @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>; s22 @ag.gov.au>
Cc: s22 @ag.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>; s22 @Protected.Health.gov.au>; s22 @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

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Good afternoon s22
Thank you for your time on the phone just now, s47C

s22

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, s42 and draft schedule 1AB item. I understand the content of the templates is of course subject to change depending on s47C

I also **attach** again for reference, s42 .

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, s22 [PROTECTED]

s22

From: s22

Sent: Thursday, 2 December 2021 2:00 PM

To: s22 @ag.gov.au>; OCL <OCL@ag.gov.au>

Cc: s22 @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 s47C . 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,

s22 **[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

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

If you have received this transmission in error please notify us immediately by return e-mail and delete all copies. If this e-mail or any attachments have been sent to you in error, that error does not constitute waiver of any confidentiality, privilege or copyright in respect of information in the e-mail or attachments.

From: s22
To:
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 s22 !

SEC=PROTECTED, CAVEAT=SH:CABINET

From: s22 @pmc.gov.au>
Sent: Thursday, 9 December 2021 1:31 PM
To: s22 @finance.gov.au>
Cc: s22 @finance.gov.au>; Industry Section <Industry@pmc.gov.au>
Subject: RE: mRNA late letter [SEC=PROTECTED, CAVEAT=SH:CABINET]

PROTECTED//CABINET

Hi s22
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. 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: Thursday, 9 December 2021 1:28 PM
To: s22 @pmc.gov.au>
Cc: s22 @finance.gov.au>; Industry Section <Industry@pmc.gov.au>
Subject: RE: mRNA late letter [SEC=PROTECTED, CAVEAT=SH:CABINET]

SEC=PROTECTED, CAVEAT=SH:CABINET

Hi s22
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

SEC=PROTECTED, CAVEAT=SH:CABINET

From: s22 @pmc.gov.au>
Sent: Tuesday, 7 December 2021 1:22 PM
To: s22 @finance.gov.au>
Cc: s22 @finance.gov.au>; Industry Section <Industry@pmc.gov.au>
Subject: RE: mRNA late letter [SEC=PROTECTED, CAVEAT=SH:CABINET]

PROTECTED//CABINET

Hi s22

Many thanks for the chat and providing the sample letter. I've also had a chat to s22 and 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
p. s22
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: s22 @pmc.gov.au>
Cc: s22 @finance.gov.au>
Subject: mRNA late letter [SEC=PROTECTED, CAVEAT=SH:CABINET]

SEC=PROTECTED, CAVEAT=SH:CABINET

Hi s22

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 s34(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 s22 in Exco Secretariat. I am sure that s22 would also be happy to provide further guidance regarding late letter as required.

Very happy to discuss.
Kind regards

s22

s22 | Director
Schedule 1AB | Financial Management Branch
Department of Finance
T: s22 | **M:** s22
E: s22 @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: s22
Cc: s22 ; 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

Hi s22
Revised instrument is attached and in the process of being finalised by OPC.
Cheers
s22

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

From: s22 @health.gov.au>
Sent: Wednesday, 8 December 2021 3:47 PM
To: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>; s22 @finance.gov.au>
Cc: s22 @health.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>; s22 @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: s22 @Protected.Health.gov.au>; s22

s22 @health.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Cc: s22 @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 s22 – will get started on the ES asap. You and s22 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: s22 @health.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Cc: s22 @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, s22 [PROTECTED]
s22

From: s22 @health.gov.au>
Sent: Tuesday, 7 December 2021 4:38 PM
To: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Cc: s22 @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]

H 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: s22 @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

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.

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

s42

[redacted]

s42

[redacted]

s42

[redacted]

s42

From:	Financial Framework (Supplementary Powers) Regulations
To:	s22
Subject:	FW: Schedule 1AB: draft instrument and ES for mRNA vaccines and treatments (urgent Exco item) [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]
Date:	Friday, 10 December 2021 3:06:38 PM
Attachments:	image001.png image002.jpg Att D - Explanatory Statement - Health No. 9.docx

From: Financial Framework (Supplementary Powers) Regulations
Sent: Friday, 10 December 2021 3:06:31 PM (UTC+10:00) Canberra, Melbourne, Sydney
To: s22
Cc: Financial Framework (Supplementary Powers) Regulations
Subject: RE: Schedule 1AB: draft instrument and ES for mRNA vaccines and treatments (urgent Exco item) [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege] [SEC=PROTECTED, ACCESS=Legal-Privilege]

Error! Not a valid filename. Hi s22
The final version of the ES cleared by Health is attached. The brief has been submitted to FMO.
Kind regards

s22

Error! Not a valid filename.

From: s22 @finance.gov.au>
Sent: Friday, 10 December 2021 12:37 PM
To: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Subject: RE: Schedule 1AB: draft instrument and ES for mRNA vaccines and treatments (urgent Exco item) [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege] [SEC=PROTECTED, ACCESS=Legal-Privilege]

SEC=PROTECTED, ACCESS=Legal-Privilege

Hi s22
Health mentioned they have amended the wording of the measure. Are you able to flick me a copy please? (They are having huge issues with the server being down).
regards

s22 | Director
Commercial Investments Division
Department of Finance
T: s22
E: s22 @finance.gov.au
A: One Canberra Avenue, FORREST ACT 2603

SEC=PROTECTED, ACCESS=Legal-Privilege

From: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Sent: Friday, 10 December 2021 10:34 AM
To: Jose, Cameron <Cameron.Jose@finance.gov.au>; s22 @finance.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>; s22 @finance.gov.au>; s22 @finance.gov.au>
Cc: Schweizer, Chris <Chris.Schweizer@finance.gov.au>
Subject: RE: Schedule 1AB: draft instrument and ES for mRNA vaccines and treatments (urgent Exco item) [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege] [SEC=PROTECTED, ACCESS=Legal-

Privilege]

SEC=PROTECTED, ACCESS=Legal-Privilege

Thanks Cameron and s22
Kind regards
s22

SEC=PROTECTED, ACCESS=Legal-Privilege

From: Jose, Cameron <Cameron.Jose@finance.gov.au>
Sent: Friday, 10 December 2021 10:32 AM
To: s22 @finance.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>; s22 s22 @finance.gov.au>; s22 @finance.gov.au>
Cc: Schweizer, Chris <Chris.Schweizer@finance.gov.au>
Subject: RE: Schedule 1AB: draft instrument and ES for mRNA vaccines and treatments (urgent Exco item) [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege] [SEC=PROTECTED, ACCESS=Legal-Privilege]

SEC=PROTECTED, ACCESS=Legal-Privilege

Ok, great thanks.
Regards,
Cameron.

SEC=PROTECTED, ACCESS=Legal-Privilege

From: s22 @finance.gov.au>
Sent: Friday, 10 December 2021 10:31 AM
To: Jose, Cameron <Cameron.Jose@finance.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>; s22 @finance.gov.au>; s22 @finance.gov.au>
Cc: Schweizer, Chris <Chris.Schweizer@finance.gov.au>
Subject: RE: Schedule 1AB: draft instrument and ES for mRNA vaccines and treatments (urgent Exco item) [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege] [SEC=PROTECTED, ACCESS=Legal-Privilege]

SEC=PROTECTED, ACCESS=Legal-Privilege

Thanks Cameron.
s47C
s22

SEC=PROTECTED, ACCESS=Legal-Privilege

From: Jose, Cameron <Cameron.Jose@finance.gov.au>
Sent: Friday, 10 December 2021 10:26 AM
To: s22 @finance.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>; s22 @finance.gov.au>; s22 @finance.gov.au>
Cc: Schweizer, Chris <Chris.Schweizer@finance.gov.au>
Subject: RE: Schedule 1AB: draft instrument and ES for mRNA vaccines and treatments (urgent Exco item) [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege] [SEC=PROTECTED, ACCESS=Legal-Privilege]

SEC=PROTECTED, ACCESS=Legal-Privilege

Thanks s22
Some comments from/minor tracks from me.
Happy to discuss.
Regards,
Cameron.

SEC=PROTECTED, ACCESS=Legal-Privilege

From: s22 @finance.gov.au>
Sent: Friday, 10 December 2021 10:08 AM
To: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>; s22 @finance.gov.au>; s22 @finance.gov.au>
Cc: Schweizer, Chris <Chris.Schweizer@finance.gov.au>; Jose, Cameron <Cameron.Jose@finance.gov.au>
Subject: RE: Schedule 1AB: draft instrument and ES for mRNA vaccines and treatments (urgent Exco item) [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege] [SEC=PROTECTED, ACCESS=Legal-Privilege]

SEC=PROTECTED, ACCESS=Legal-Privilege

Hi s22
Please find attached suggested edits in track on the funding.
Thanks
s22

SEC=PROTECTED, ACCESS=Legal-Privilege

From: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Sent: Thursday, 9 December 2021 5:25 PM
To: s22 @finance.gov.au>; s22 @finance.gov.au>
Cc: Schweizer, Chris <Chris.Schweizer@finance.gov.au>; Jose, Cameron <Cameron.Jose@finance.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Subject: RE: Schedule 1AB: draft instrument and ES for mRNA vaccines and treatments (urgent Exco item) [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege] [SEC=PROTECTED, ACCESS=Legal-Privilege]

SEC=PROTECTED, ACCESS=Legal-Privilege

Thanks s22 for quickly getting back to me.
Attached is the draft brief for this item. Please let me know if you have any comments, and grateful if you could check the financials.
Your response **by 10am tomorrow on Friday, 10 December** would be much appreciated.
Kind regards
s22

SEC=PROTECTED, ACCESS=Legal-Privilege

From: s22 @finance.gov.au>
Sent: Thursday, 9 December 2021 3:00 PM
To: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>; s22 @finance.gov.au>

Cc: Schweizer, Chris <Chris.Schweizer@finance.gov.au>; Jose, Cameron <Cameron.Jose@finance.gov.au>
Subject: RE: Schedule 1AB: draft instrument and ES for mRNA vaccines and treatments (urgent Exco item) [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

Thanks s22
No general concerns as discussed, assuming this is consistent with the approach that Health has also taken with the payments to purchase existing COVID-19 vaccines.
Happy to look through the brief when available for checking.
Thanks
s22

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

From: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Sent: Thursday, 9 December 2021 1:10 PM
To: s22 @finance.gov.au>; s22 @finance.gov.au>
Cc: Schweizer, Chris <Chris.Schweizer@finance.gov.au>; Jose, Cameron <Cameron.Jose@finance.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Subject: Schedule 1AB: draft instrument and ES for mRNA vaccines and treatments (urgent Exco item) [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]
Importance: High

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

Hi s22
Attached are draft instrument and explanatory statement (ES) for the mRNA vaccines and treatments, which is a late item for consideration at the 16 December Exco meeting.

- The instrument has been SES cleared by Health and is being finalised by OPC.
- The content of the ES is based on the information provided by Health.

The ES is currently being reviewed by Health, who have been asked to provide SES clearance of the ES **today (9 December 2021)**.
I am providing these papers to you concurrently in the interest of time. Please let me know if there are any red-flag issues. The ES needs to be finalised today.
I will also shortly provide you with a draft brief again with a short turnaround. The brief is scheduled for our FAS clearance tomorrow morning, and same-day Deputy Secretary clearance will be sought, so we could submit to the office as soon as possible.
Kind regards
s22

s22 | Director
Schedule 1AB | Financial Management Branch
Department of Finance
T: s22 | **M:** s22
E: s22 @finance.gov.au | FFSPRegs@finance.gov.au
A: 1 Canberra Avenue, Forrest ACT 2603

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Finance

Financial Framework (Supplementary Powers) Act 1997

Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021

The *Financial Framework (Supplementary Powers) Act 1997* (the FF(SP) Act) confers on the Commonwealth, in certain circumstances, powers to make arrangements under which money can be spent; or to make grants of financial assistance; and to form, or otherwise be involved in, companies. The arrangements, grants, programs and companies (or classes of arrangements or grants in relation to which the powers are conferred) are specified in the *Financial Framework (Supplementary Powers) Regulations 1997* (the Principal Regulations). The powers in the FF(SP) Act to make, vary or administer arrangements or grants may be exercised on behalf of the Commonwealth by Ministers and the accountable authorities of non-corporate Commonwealth entities, as defined under section 12 of the *Public Governance, Performance and Accountability Act 2013*.

Section 65 of the FF(SP) Act provides that the Governor-General may make regulations prescribing matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Section 32B of the FF(SP) Act authorises the Commonwealth to make, vary and administer arrangements and grants specified in the Principal Regulations. Section 32B also authorises the Commonwealth to make, vary and administer arrangements for the purposes of programs specified in the Principal Regulations. Schedule 1AA and Schedule 1AB to the Principal Regulations specify the arrangements, grants and programs.

The *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021* (the Regulations) amend Schedule 1AB to the Principal Regulations to establish legislative authority for government spending on the development and maintenance of Australia's onshore capability to manufacture mRNA (Messenger Ribonucleic Acid) products.

The capability will be initially founded through a partnership with one or more suppliers. The partnership is expected to be underpinned by agreements commencing in 2021-22 that would establish a population-scale mRNA manufacturing capability and guarantee the supply of locally manufactured mRNA vaccines, including COVID-19 vaccines, as well as provide future pandemic readiness. The cost of the agreements will depend on the outcome of ongoing commercial negotiations, the timeframe for completing an mRNA manufacturing facility in Australia by one or more suppliers, the number of mRNA products to be manufactured, and domestic requirements for COVID-19 vaccines and any other mRNA products.

At this stage, the Commonwealth's final funding commitment is subject to ongoing commercial-in-confidence negotiations with one or more suppliers and potential state government funding partners. The Regulations will enable the Commonwealth to enter into agreements with one or more suppliers (including any other suppliers of locally manufactured mRNA products) within the total funding commitment, subject to future decisions by the Government.

Vaccines and therapeutics that use mRNA technology have been identified as a key growth opportunity in the Medical Products National Manufacturing Priority road map under the Government's *Modern Manufacturing Strategy*. The mRNA technology underpins the highly effective Pfizer-BioNTech and Moderna COVID-19 vaccines which have been embraced by Australians, accelerating the country's recovery from the pandemic. This technology could deliver step-change improvements in vaccine efficacy and individualised treatments for cancer and other diseases.

The Department of Health will be the head agency for establishing the partnership and providing the ongoing contract management and supplier engagement.

Details of the Regulations are set out at Attachment A. A Statement of Compatibility with Human Rights is at Attachment B.

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*. The Regulations commence on the day after the instrument is registered on the Federal Register of Legislation.

Consultation

In accordance with section 17 of the *Legislation Act 2003*, consultation has taken place with the Department of Health.

A regulation impact statement is not required as the Regulations only apply to non-corporate Commonwealth entities and do not adversely affect the private sector.

Attachment A

Details of the *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021*

Section 1 – Name

This section provides that the title of the Regulations is the *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021*.

Section 2 – Commencement

This section provides that the Regulations commence on the day after the instrument is registered on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the Regulations are made under the *Financial Framework (Supplementary Powers) Act 1997*.

Section 4 – Schedules

This section provides that the *Financial Framework (Supplementary Powers) Regulations 1997* are amended as set out in the Schedule to the Regulations.

Schedule 1 – Amendments

Financial Framework (Supplementary Powers) Regulations 1997

Item 1 – In the appropriate position in Part 4 of Schedule 1AB (table)

This item adds a new table item to Part 4 of Schedule 1AB to establish legislative authority for government spending on an activity that will be administered by the Department of Health (the department).

New **table item 531** establishes legislative authority for government spending on the development and maintenance of Australia's onshore capability to manufacture mRNA (Messenger Ribonucleic Acid) products.

Vaccines and therapeutics that use mRNA technology have been identified as a key growth opportunity in the Medical Products National Manufacturing Priority road map under the Government's *Modern Manufacturing Strategy*. The mRNA technology underpins the highly effective Pfizer-BioNTech and Moderna COVID-19 vaccines which have been embraced by Australians, accelerating the country's recovery from the pandemic. This technology could deliver step-change improvements in vaccine efficacy and individualised treatments for cancer and other diseases.

Establishing onshore mRNA vaccine manufacturing capability would provide priority access to breakthrough vaccines and treatments, strengthen Australia's preparedness for future pandemics, accelerate growth in Australia's mRNA research and commercialisation ecosystem, and position Australia as the regional hub for this emerging, high-potential technology.

The partnership is expected to be underpinned by agreements commencing in 2021-22 that would establish a population-scale mRNA manufacturing capability and guarantee the supply of locally manufactured mRNA vaccines, including COVID-19 vaccines, as well as provide future pandemic readiness. The construction of a facility is estimated to be completed by 2024, with the capacity to manufacture and supply up to 100 million doses per annum in a future pandemic.

Under final agreements, the Commonwealth is expected to:

- provide a financial contribution to keep the facility pandemic-ready such that it is capable of rapid manufacture at a population scale; and
- purchase mRNA vaccines (including COVID-19 vaccines) from the facility.

At this stage, the Commonwealth's final funding commitment is subject to ongoing commercial-in-confidence negotiations with one or more suppliers and potential state government funding partners. Some state governments have indicated their interest in co-investing in the onshore mRNA capability, including for the fill and finish aspects of the capability, as well as contributing to a research and development fund and a workforce and supply chain initiative.

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

The COVID-19 Vaccines and Treatments for Australia – Science and Industry Technical Advisory Group (SITAG) has also maintained support for onshore manufacturing, emphasising 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. The SITAG provides advice to the Government on the purchasing and manufacturing of COVID-19 vaccines and treatments.

A 2020 audit of Australia's manufacturing capability, followed by a March 2021 business case, identified a need for Australia to undertake onshore mRNA manufacturing. In the 2021-22 Budget, the Government provided funding to the Department of Industry, Science, Energy and Resources (DISER) to work with the department to develop an onshore mRNA vaccine manufacturing capability in Australia. On 21 May 2021, the then Minister for Industry, Science and Technology, the Hon Christian Porter MP, and the Minister for Health and Aged Care, the Hon Greg Hunt MP, jointly announced in a media release that the Government is developing a pathway to establish Australia's own sovereign manufacturing capability for mRNA vaccines. The media release is available at https://www.minister.industry.gov.au/ministers/porter/media-releases/australia-develop-onshore-mrna-manufacturing.

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

- ensure priority access to, and reliable delivery of, safe and effective prospective mRNA vaccines and any mRNA therapeutics to the Australian population as soon as they are available, on an ongoing basis;
- provide security of vaccine supply to address pandemics and other health emergencies into the future; and
- strengthen Australia's biopharmaceuticals sector, including through enabling potential translation and commercialisation paths for Australian-based research and development.

The overarching requirements in the development and maintenance 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; and
- participation in the broader mRNA ecosystem, including contribution to research and development.

It is expected that the department will be the head agency for entering into agreements and providing ongoing contract management and supplier engagement. The department will also work closely with DISER, which will provide policy support in relation to the research and development ecosystem and regional hub elements.

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, including the *Public Governance, Performance and Accountability Act 2013* (PGPA Act), the *Commonwealth Procurement Rules* (CPRs) and the department's Accountable Authority Instructions.

The expenditure is expected to be provided through an approved process, including but not limited to a procurement process. In this regard, the Secretary of the department (as the relevant Accountable Authority) has made a determination under paragraph 2.6 of the CPRs to disapply Divisions 1 and 2 of the CPRs to the proposed procurement of onshore mRNA manufacturing capability and supply of mRNA vaccines and treatments for both pandemic and non-pandemic purposes and all incidental or related matters (the procurement) on the basis that it is necessary to protect human health. Accordingly, the requirement to publish the details of the proposed procurement on AusTender as set out in the CPRs will not apply. However, the department will be required to table details relating to the proposed procurement, in accordance with the *Senate Procedural Orders of Continuing Effect No. 12* (Production of Indexed Lists of Departmental and Agency Files).

Irrespective of the exemption given under paragraph 2.6 of CPRs, any procurement decisions will nevertheless be based on value for money, including capability and capacity to deliver, and price and risk considerations. Provisional expenditure and supplier decisions were made by the Government, with the associated financial commitment for the relevant agreements to be approved by the Secretary of the department or an appropriate financial delegate at the SES level who has responsibility for the oversight of the procurement.

To ensure administrative accountability in relation to the procurement, the department will:

- execute and manage all procurement contracts for the term of the agreements;
- work collaboratively with DISER and the supplier(s) to meaningfully engage in ecosystem requirements to strengthen mRNA capability in Australia;
- report publicly on the performance and progress of the mRNA capability, including in its annual report; and
- monitor expenditure on the mRNA capability.

Decisions made in connection with the procurement 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 (ARC) 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 remaking 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, the procurement of onshore mRNA manufacturing capability and supply of mRNA vaccines and treatments is a financial decision with a significant public interest element. This 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 system and the national vaccination programs. The ARC 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, the context of a global pandemic is an extremely rare event.

The project work to develop an onshore mRNA manufacturing capability, including negotiations with existing manufacturers and approach to the Australian market, was conducted by a joint taskforce which comprised the department and DISER. During the project phase in 2020 and 2021 and up to the execution of agreements, the following governing bodies and agencies were consulted:

- Therapeutic Goods Administration (TGA);
- Department of Finance;
- Department of the Prime Minister and Cabinet;
- Department of Foreign Affairs and Trade;
- Australian Government Solicitor;
- Australian Technical Advisory Group on Immunisation (ATAGI);
- Pharmaceutical Benefits Advisory Committee (PBAC);
- SITAG;
- state governments; and
- an expert advisory group advising on the procurement process and supplier proposals.

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

- DISER;
- TGA;
- ATAGI;
- state governments;
- relevant industries; and
- the biotechnology research sector, particularly with regard to the development of the research and development ecosystem.

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 (section 51(xxix));
- the social welfare power (section 51(xxiiiA)); and
- the express incidental power and the executive power (sections 51(xxxix) and 61), including the nationhood aspect.

External affairs power

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

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 proposed measure 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, including the nationhood aspect

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 proposed measure 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.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011.*

Overview of the legislative instrument

Section 32B of the *Financial Framework (Supplementary Powers) Act 1997* (the FF(SP) Act) authorises the Commonwealth to make, vary and administer arrangements and grants specified in the *Financial Framework (Supplementary Powers) Regulations 1997* (the FF(SP) Regulations) and to make, vary and administer arrangements and grants for the purposes of programs specified in the Regulations. Schedule 1AA and Schedule 1AB to the FF(SP) Regulations specify the arrangements, grants and programs. The powers in the FF(SP) Act to make, vary or administer arrangements or grants may be exercised on behalf of the Commonwealth by Ministers and the accountable authorities of non-corporate Commonwealth entities, as defined under section 12 of the *Public Governance, Performance and Accountability Act 2013*.

The *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021* amend Schedule 1AB to the FF(SP) Regulations to establish legislative authority for government spending on the development and maintenance of Australia's onshore capability to manufacture mRNA (Messenger Ribonucleic Acid) products.

The capability will be initially founded through a partnership with one or more suppliers. The partnership is expected to be underpinned by agreements commencing in 2021-22 that would establish a population-scale mRNA manufacturing capability and guarantee the supply of locally manufactured mRNA vaccines, including COVID-19 vaccines, as well as provide future pandemic readiness. This disallowable legislative instrument will enable the Commonwealth to enter into agreements with one or more suppliers (including any other suppliers of locally manufactured mRNA products) within the total funding commitment, subject to future decisions by the Government.

Vaccines and therapeutics that use mRNA technology have been identified as a key growth opportunity in the Medical Products National Manufacturing Priority road map under the Government's *Modern Manufacturing Strategy*. The mRNA technology underpins the highly effective Pfizer-BioNTech and Moderna COVID-19 vaccines which have been embraced by Australians, accelerating the country's recovery from the pandemic. This technology could deliver step-change improvements in vaccine efficacy and individualised treatments for cancer and other diseases.

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

- ensure priority access to, and reliable delivery of, safe and effective prospective mRNA vaccines and any mRNA therapeutics to the Australian population as soon as they are available, on an ongoing basis;
- provide security of vaccine supply to address pandemics and other health emergencies into the future; and
- strengthen Australia's biopharmaceuticals sector, including through enabling potential translation and commercialisation paths for Australian-based research and development.

The overarching requirements in the development and maintenance 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; and
- participation in the broader mRNA ecosystem, including contribution to research and development.

The Department of Health will be the head agency for entering into agreements and providing ongoing contract management and supplier engagement.

Human rights implications

This disallowable legislative instrument engages the following right:

- 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. The 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

This disallowable legislative instrument is compatible with human rights because it promotes the protection of human rights.

Senator the Hon Simon Birmingham
Minister for Finance

Subject: FW: CLEARANCE | PDMS MC21-004258 Financial Framework (Supplementary Powers) Amendment (Health Measures No. 6) Regulations 2021 [SEC=OFFICIAL]

Attachments: MS21-001343 Draft brief to FAS.docx; Att A.pdf; Att B - Draft Exco minute - Health No. 9.docx; Att C - Draft EM - Health No. 9.docx; Att D - Explanatory Statement - Health No. 9.docx

OFFICIAL

From: Fox, Amy <Amy.Fox@finance.gov.au>
Sent: Friday, 10 December 2021 2:42 PM
To: s22 @finance.gov.au>
Cc: Tran, Chi <Chi.Tran@finance.gov.au>; FARM Exec <FARMexec@finance.gov.au>; s22 @finance.gov.au>; s22 @finance.gov.au>
Subject: RE: CLEARANCE | PDMS MC21-004258 Financial Framework (Supplementary Powers) Amendment (Health Measures No. 6) Regulations 2021 [SEC=UNOFFICIAL]

SEC=UNOFFICIAL

Hi s22, thanks for the below update and how annoying for you re the IT issues. Your comments make sense and are OK with me. I looked for a 'the department' up to the front of the ES but must have missed it, apologies for that. Amy

SEC=UNOFFICIAL

From: s22 @finance.gov.au>
Sent: Friday, 10 December 2021 2:40 PM
To: Fox, Amy <Amy.Fox@finance.gov.au>
Cc: Tran, Chi <Chi.Tran@finance.gov.au>; FARM Exec <FARMexec@finance.gov.au>; s22 @finance.gov.au>; s22 @finance.gov.au>
Subject: RE: CLEARANCE | PDMS MC21-004258 Financial Framework (Supplementary Powers) Amendment (Health Measures No. 6) Regulations 2021 [SEC=UNOFFICIAL]

Error! Not a valid filename. Hi Amy

You will probably get this email with a line saying 'Error. Not a valid file name'. I started having IT issues with my Outlook and Word after coming back from the appointment. And now I cannot open any Word documents. So I had to ask s22 to project them on her screen for me.

I have accepted all of your edits in the brief except for the comma in paragraph 7 because I wasn't sure why it's required there. It's a list of Ministers who need to finalise negotiations, and 'you' is the last Minister in that list. In relation to s22 edit in paragraph 5, I would prefer to leave the words 'some time' there because otherwise it could be interpreted that the committee will follow as soon as the regulations are tabled, which may not be factually correct.

Regarding your query in Attachment D, we have introduced reference to the Department of Health as 'the department' in the beginning and therefore keep using this reference throughout. This is our current practice for the ESs.

Hope this is ok. Now I have to figure out how to submit this brief to you in PDMS. It may come from s22

Thank you one more time
s22

Error! Not a valid filename.

From: Fox, Amy <Amy.Fox@finance.gov.au>
Sent: Friday, 10 December 2021 12:02 PM
To: s22 @finance.gov.au>
Cc: Tran, Chi <Chi.Tran@finance.gov.au>; FARM Exec <FARMexec@finance.gov.au>
Subject: RE: CLEARANCE | PDMS MC21-004258 Financial Framework (Supplementary Powers) Amendment (Health Measures No. 6) Regulations 2021 [SEC=UNOFFICIAL]
Importance: High

SEC=UNOFFICIAL

Hi s22 excellent brief as I am coming to really appreciate!
This is cleared by me subject to taking up / considering my edits.
My suggestions on the brief itself are very tiny, on Attachment D, my main question is in regard to way Health refers to themselves. Again minor.
This can be progressed in PDMS once you have considered.
Thanks, Amy

SEC=UNOFFICIAL

-----Original Appointment-----
From: s22 **On Behalf Of** Fox, Amy
Sent: Wednesday, 8 December 2021 1:45 PM
To: Fox, Amy; s22
Subject: CLEARANCE | PDMS MC21-004258 Financial Framework (Supplementary Powers) Amendment (Health Measures No. 6) Regulations 2021
When: Friday, 10 December 2021 11:30 AM-12:00 PM (UTC+10:00) Canberra, Melbourne, Sydney.
Where:

SEC=UNOFFICIAL

PDR Number:
MS21-001343

Australian Government
Department of Finance

MINISTERIAL SUBMISSION

Copies to:
Secretary
Ms Carroll
Mr Williamson
Ms Patterson
Ms Fox
Ms Hall
Mr Graham
Mr Jose
Ms Schweizer

Minister for Finance 10 December 2021

Financial Framework (Supplementary Powers) Regulations 1997 – Schedule 1AB – mRNA vaccines and treatments – late item for the Executive Council Meeting on 16 December 2021

Timing: Urgent – by Tuesday, 14 December 2021. To enable documentation to be submitted as a late item for consideration at the Federal Executive Council meeting on 16 December 2021.

Recommendations:

That you:

i. **agree** to request that the Governor-General make regulations which would amend Schedule 1AB to the *Financial Framework (Supplementary Powers) Regulations 1997* to include a new item for mRNA vaccines and treatments;

AGREED / NOT AGREED / PLEASE DISCUSS

ii. **sign**, but do not date, the proposed regulations at Attachment A;

SIGNED / PLEASE DISCUSS

iii. **sign**, but do not date, the Executive Council Minute for the regulations at Attachment B;

SIGNED / PLEASE DISCUSS

iv. **initial** the bottom right-hand corner of each page of the Explanatory Memorandum for the regulations at Attachment C; and

INITIALLED / PLEASE DISCUSS

v. **approve** the release of the Explanatory Statement for the regulations at Attachment D.

APPROVED / NOT APPROVED / PLEASE DISCUSS

Key Issues:

s34(3)

[redacted]

s42 [redacted]

s45, s47 [redacted]

6. The cut-off date for final papers for the 16 December 2021 Executive Council meeting was on 7 December 2021. This means that the Governor-General would only consider this late item on a written request from the Prime Minister. The Department of the Prime Minister and Cabinet has advised that the proposed late letter for this item has been submitted to the Prime Minister's office, with Prime Minister's signature sought by 10 December 2021 (MS21-001956 refers).

Financial Implications:

s34(3) [redacted]

Consultation:

9. Health, the Office of Constitutional Law, the Executive Council Secretariat, the Commercial Policy and Advice Branch in the Commercial and Government Services Group, and the Health Branch in the Budget and Financial Reporting Group have been consulted.

Approved for electronic transmission

Amy Fox
A/g First Assistant Secretary
Financial Analysis, Reporting and Management Division
02 6215 2036

Contact Officer: s22
Job Title/Level: Director/EL2
Telephone: s22
PDR Number MS21-001343

/ /

Simon Birmingham

Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021

I, General the Honourable David Hurley AC DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 2021

David Hurley
Governor-General

By His Excellency's Command

Simon Birmingham
Minister for Finance

Contents

1 Name

This instrument is the *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the *Financial Framework (Supplementary Powers) Act 1997*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Financial Framework (Supplementary Powers) Regulations 1997

1 In the appropriate position in Part 4 of Schedule 1AB (table)

Insert:

531	mRNA vaccines and treatments	To develop and maintain Australia's onshore capability to manufacture mRNA products, as a measure to give effect to Australia's obligations under the International Covenant on Economic, Social and Cultural Rights, particularly Articles 2 and 12. This objective also has the effect it would have if it were limited to measures: (a) for the provision of, or incidental to the provision of, pharmaceutical, sickness or hospital benefits or medical services (within the meaning of paragraph 51(xxiiiA) of the Constitution); or (b) that are peculiarly adapted to the government of a nation and cannot otherwise be carried on for the benefit of the nation.

MINISTER FOR FINANCE

Departmental No. 2021/72

Executive Council
Meeting No. .....

Approved in Council

.....

David Hurley
Governor-General

.....

Filed in the Records
of the Council

.....
Secretary to the Executive Council

Minute Paper for the Executive Council

Subject

Financial Framework (Supplementary Powers) Act 1997

Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021

Recommended for the approval of His Excellency the Governor-General in Council that he make Regulations in the attached form.

Simon Birmingham
Minister for Finance

EXPLANATORY MEMORANDUM

Minute No. 72 of 2021 – Minister for Finance

Subject - *Financial Framework (Supplementary Powers) Act 1997*

Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021

The purpose of this instrument is to provide legislative authority for the expenditure of Commonwealth funds.

The *Financial Framework (Supplementary Powers) Act 1997* (the Act) confers on the Commonwealth, in certain circumstances, powers to make arrangements under which money can be spent; or to make grants of financial assistance; and to form, or otherwise be involved in, companies. The Act applies to Ministers and the accountable authorities of non-corporate Commonwealth entities, as defined under section 12 of the *Public Governance, Performance and Accountability Act 2013*.

Section 65 of the Act provides that the Governor-General may make regulations prescribing matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Section 32B of the Act authorises the Commonwealth to make, vary and administer arrangements, programs and grants of financial assistance specified in the *Financial Framework (Supplementary Powers) Regulations 1997* (the Principal Regulations). Schedules 1AA and 1AB to the Principal Regulations specify the arrangements, grants and programs. The overall effect of section 32B is to provide legislative authority for Commonwealth expenditure on the arrangements, programs and grants specified in the Principal Regulations. This includes providing legislative authority for the Commonwealth to be able to enter into contracts or other arrangements for the specified programs and grants.

The *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021* (the proposed Regulations) would insert a new **table item 531** in Part 4 of Schedule 1AB to the Principal Regulations to establish legislative authority for government spending on the development and maintenance of Australia's onshore capability to manufacture mRNA (Messenger Ribonucleic Acid) products.

Vaccines and therapeutics that use mRNA technology have been identified as a key growth opportunity in the Medical Products National Manufacturing Priority road map under the Government's *Modern Manufacturing Strategy*. The mRNA technology underpins the highly effective Pfizer-BioNTech and Moderna COVID-19 vaccines which have been embraced by Australians, accelerating the country's recovery from the pandemic. This technology could deliver step-change improvements in vaccine efficacy and individualised treatments for cancer and other diseases.

Establishing onshore mRNA vaccine manufacturing capability would provide priority access to breakthrough vaccines and treatments, strengthen Australia's preparedness for future pandemics, accelerate growth in Australia's mRNA research and commercialisation

ecosystem, and position Australia as the regional hub for this emerging, high-potential technology.

The partnership is expected to be underpinned by agreements commencing in 2021-22 that would establish a population-scale mRNA manufacturing capability and guarantee the supply of locally manufactured mRNA vaccines, including COVID-19 vaccines, as well as provide future pandemic readiness. The construction of a facility is estimated to be completed by 2024, with the capacity to manufacture and supply up to 100 million doses per annum in a future pandemic.

Under final agreements, the Commonwealth would be expected to:

- provide a financial contribution to keep the facility pandemic-ready such that it is capable of rapid manufacture at a population scale; and
- purchase mRNA vaccines (including COVID-19 vaccines) from the facility.

At this stage, the Commonwealth's final funding commitment is subject to ongoing commercial-in-confidence negotiations with one or more suppliers and potential state government funding partners. Some state governments have indicated their interest in co-investing in the onshore mRNA capability, including for the fill and finish aspects of the capability, as well as contributing to a research and development fund and a workforce and supply chain initiative. The Department of Health would be the head agency for establishing the partnership and providing the ongoing contract management and supplier engagement.

The project work to develop an onshore mRNA manufacturing capability, including negotiations with existing manufacturers and approach to the Australian market, was conducted by a joint taskforce which comprised the Department of Health and the Department of Industry, Science, Energy and Resources. During the project phase in 2020 and 2021 and up to the execution of agreements, the following governing bodies and agencies were consulted: Therapeutic Goods Administration; Department of Finance; Department of the Prime Minister and Cabinet; Department of Foreign Affairs and Trade; Australian Government Solicitor; Australian Technical Advisory Group on Immunisation; Pharmaceutical Benefits Advisory Committee; Science and Industry Technical Advisory Group; state governments; and an expert advisory group advising on the procurement process and supplier proposals.

The Act specifies no conditions that need to be satisfied before the power to make the proposed Regulations may be exercised.

The proposed Regulations would be a legislative instrument for the purposes of the *Legislation Act 2003.*

The proposed Regulations would commence the day after it is registered on the Federal Register of Legislation.

The Minute recommends that the Regulations be made in the form proposed.

Authority: Section 65 of the *Financial Framework (Supplementary Powers) Act 1997*

EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Finance

Financial Framework (Supplementary Powers) Act 1997

Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021

The *Financial Framework (Supplementary Powers) Act 1997* (the FF(SP) Act) confers on the Commonwealth, in certain circumstances, powers to make arrangements under which money can be spent; or to make grants of financial assistance; and to form, or otherwise be involved in, companies. The arrangements, grants, programs and companies (or classes of arrangements or grants in relation to which the powers are conferred) are specified in the *Financial Framework (Supplementary Powers) Regulations 1997* (the Principal Regulations). The powers in the FF(SP) Act to make, vary or administer arrangements or grants may be exercised on behalf of the Commonwealth by Ministers and the accountable authorities of non-corporate Commonwealth entities, as defined under section 12 of the *Public Governance, Performance and Accountability Act 2013*.

Section 65 of the FF(SP) Act provides that the Governor-General may make regulations prescribing matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Section 32B of the FF(SP) Act authorises the Commonwealth to make, vary and administer arrangements and grants specified in the Principal Regulations. Section 32B also authorises the Commonwealth to make, vary and administer arrangements for the purposes of programs specified in the Principal Regulations. Schedule 1AA and Schedule 1AB to the Principal Regulations specify the arrangements, grants and programs.

The *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021* (the Regulations) amend Schedule 1AB to the Principal Regulations to establish legislative authority for government spending on the development and maintenance of Australia's onshore capability to manufacture mRNA (Messenger Ribonucleic Acid) products.

The capability will be initially founded through a partnership with one or more suppliers. The partnership is expected to be underpinned by agreements commencing in 2021-22 that would establish a population-scale mRNA manufacturing capability and guarantee the supply of locally manufactured mRNA vaccines, including COVID-19 vaccines, as well as provide future pandemic readiness. The cost of the agreements will depend on the outcome of ongoing commercial negotiations, the timeframe for completing an mRNA manufacturing facility in Australia by one or more suppliers, the number of mRNA products to be manufactured, and domestic requirements for COVID-19 vaccines and any other mRNA products.

At this stage, the Commonwealth's final funding commitment is subject to ongoing commercial-in-confidence negotiations with one or more suppliers and potential state government funding partners. The Regulations will enable the Commonwealth to enter into agreements with one or more suppliers (including any other suppliers of locally manufactured mRNA products) within the total funding commitment, subject to future decisions by the Government.

Vaccines and therapeutics that use mRNA technology have been identified as a key growth opportunity in the Medical Products National Manufacturing Priority road map under the Government's *Modern Manufacturing Strategy*. The mRNA technology underpins the highly effective Pfizer-BioNTech and Moderna COVID-19 vaccines which have been embraced by Australians, accelerating the country's recovery from the pandemic. This technology could deliver step-change improvements in vaccine efficacy and individualised treatments for cancer and other diseases.

The Department of Health will be the head agency for establishing the partnership and providing the ongoing contract management and supplier engagement.

Details of the Regulations are set out at Attachment A. A Statement of Compatibility with Human Rights is at Attachment B.

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*. The Regulations commence on the day after the instrument is registered on the Federal Register of Legislation.

Consultation

In accordance with section 17 of the *Legislation Act 2003*, consultation has taken place with the Department of Health.

A regulation impact statement is not required as the Regulations only apply to non-corporate Commonwealth entities and do not adversely affect the private sector.

Details of the *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021*

Section 1 – Name

This section provides that the title of the Regulations is the *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021*.

Section 2 – Commencement

This section provides that the Regulations commence on the day after the instrument is registered on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the Regulations are made under the *Financial Framework (Supplementary Powers) Act 1997*.

Section 4 – Schedules

This section provides that the *Financial Framework (Supplementary Powers) Regulations 1997* are amended as set out in the Schedule to the Regulations.

Schedule 1 – Amendments

Financial Framework (Supplementary Powers) Regulations 1997

Item 1 – In the appropriate position in Part 4 of Schedule 1AB (table)

This item adds a new table item to Part 4 of Schedule 1AB to establish legislative authority for government spending on an activity that will be administered by the Department of Health (the department).

New **table item 531** establishes legislative authority for government spending on the development and maintenance of Australia's onshore capability to manufacture mRNA (Messenger Ribonucleic Acid) products.

Vaccines and therapeutics that use mRNA technology have been identified as a key growth opportunity in the Medical Products National Manufacturing Priority road map under the Government's *Modern Manufacturing Strategy*. The mRNA technology underpins the highly effective Pfizer-BioNTech and Moderna COVID-19 vaccines which have been embraced by Australians, accelerating the country's recovery from the pandemic. This technology could deliver step-change improvements in vaccine efficacy and individualised treatments for cancer and other diseases.

Establishing onshore mRNA vaccine manufacturing capability would provide priority access to breakthrough vaccines and treatments, strengthen Australia's preparedness for future pandemics, accelerate growth in Australia's mRNA research and commercialisation ecosystem, and position Australia as the regional hub for this emerging, high-potential technology.

The partnership is expected to be underpinned by agreements commencing in 2021-22 that would establish a population-scale mRNA manufacturing capability and guarantee the supply of locally manufactured mRNA vaccines, including COVID-19 vaccines, as well as provide future pandemic readiness. The construction of a facility is estimated to be completed by 2024, with the capacity to manufacture and supply up to 100 million doses per annum in a future pandemic.

Under final agreements, the Commonwealth is expected to:

- provide a financial contribution to keep the facility pandemic-ready such that it is capable of rapid manufacture at a population scale; and
- purchase mRNA vaccines (including COVID-19 vaccines) from the facility.

At this stage, the Commonwealth's final funding commitment is subject to ongoing commercial-in-confidence negotiations with one or more suppliers and potential state government funding partners. Some state governments have indicated their interest in co-investing in the onshore mRNA capability, including for the fill and finish aspects of the capability, as well as contributing to a research and development fund and a workforce and supply chain initiative.

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

The COVID-19 Vaccines and Treatments for Australia – Science and Industry Technical Advisory Group (SITAG) has also maintained support for onshore manufacturing, emphasising 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. The SITAG provides advice to the Government on the purchasing and manufacturing of COVID-19 vaccines and treatments.

A 2020 audit of Australia's manufacturing capability, followed by a March 2021 business case, identified a need for Australia to undertake onshore mRNA manufacturing. In the 2021-22 Budget, the Government provided funding to the Department of Industry, Science, Energy and Resources (DISER) to work with the department to develop an onshore mRNA vaccine manufacturing capability in Australia. On 21 May 2021, the then Minister for Industry, Science and Technology, the Hon Christian Porter MP, and the Minister for Health and Aged Care, the Hon Greg Hunt MP, jointly announced in a media release that the Government is developing a pathway to establish Australia's own sovereign manufacturing capability for mRNA vaccines. The media release is available at https://www.minister.industry.gov.au/ministers/porter/media-releases/australia-develop-onshore-mrna-manufacturing.

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

- ensure priority access to, and reliable delivery of, safe and effective prospective mRNA vaccines and any mRNA therapeutics to the Australian population as soon as they are available, on an ongoing basis;
- provide security of vaccine supply to address pandemics and other health emergencies into the future; and
- strengthen Australia's biopharmaceuticals sector, including through enabling potential translation and commercialisation paths for Australian-based research and development.

The overarching requirements in the development and maintenance 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; and
- participation in the broader mRNA ecosystem, including contribution to research and development.

It is expected that the department will be the head agency for entering into agreements and providing ongoing contract management and supplier engagement. The department will also work closely with DISER, which will provide policy support in relation to the research and development ecosystem and regional hub elements.

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, including the *Public Governance, Performance and Accountability Act 2013* (PGPA Act), the *Commonwealth Procurement Rules* (CPRs) and the department's Accountable Authority Instructions.

The expenditure is expected to be provided through an approved process, including but not limited to a procurement process. In this regard, the Secretary of the department (as the relevant Accountable Authority) has made a determination under paragraph 2.6 of the CPRs to disapply Divisions 1 and 2 of the CPRs to the proposed procurement of onshore mRNA manufacturing capability and supply of mRNA vaccines and treatments for both pandemic and non-pandemic purposes and all incidental or related matters (the procurement) on the basis that it is necessary to protect human health. Accordingly, the requirement to publish the details of the proposed procurement on AusTender as set out in the CPRs will not apply. However, the department will be required to table details relating to the proposed procurement, in accordance with the *Senate Procedural Orders of Continuing Effect No. 12* (Production of Indexed Lists of Departmental and Agency Files).

Irrespective of the exemption given under paragraph 2.6 of CPRs, any procurement decisions will nevertheless be based on value for money, including capability and capacity to deliver, and price and risk considerations. Provisional expenditure and supplier decisions were made by the Government, with the associated financial commitment for the relevant agreements to be approved by the Secretary of the department or an appropriate financial delegate at the SES level who has responsibility for the oversight of the procurement.

To ensure administrative accountability in relation to the procurement, the department will:

- execute and manage all procurement contracts for the term of the agreements;
- work collaboratively with DISER and the supplier(s) to meaningfully engage in ecosystem requirements to strengthen mRNA capability in Australia;
- report publicly on the performance and progress of the mRNA capability, including in its annual report; and
- monitor expenditure on the mRNA capability.

Decisions made in connection with the procurement 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 (ARC) 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 remaking 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, the procurement of onshore mRNA manufacturing capability and supply of mRNA vaccines and treatments is a financial decision with a significant public interest element. This 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 system and the national vaccination programs. The ARC 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, the context of a global pandemic is an extremely rare event.

The project work to develop an onshore mRNA manufacturing capability, including negotiations with existing manufacturers and approach to the Australian market, was conducted by a joint taskforce which comprised the department and DISER. During the project phase in 2020 and 2021 and up to the execution of agreements, the following governing bodies and agencies were consulted:

- Therapeutic Goods Administration (TGA);
- Department of Finance;
- Department of the Prime Minister and Cabinet;
- Department of Foreign Affairs and Trade;
- Australian Government Solicitor;
- Australian Technical Advisory Group on Immunisation (ATAGI);
- Pharmaceutical Benefits Advisory Committee (PBAC);
- SITAG;
- state governments; and
- an expert advisory group advising on the procurement process and supplier proposals.

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

- DISER;
- TGA;
- ATAGI;
- state governments;
- relevant industries; and
- the biotechnology research sector, particularly with regard to the development of the research and development ecosystem.

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 (section 51(xxix));
- the social welfare power (section 51(xxiiiA)); and
- the express incidental power and the executive power (sections 51(xxxix) and 61), including the nationhood aspect.

External affairs power

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

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 proposed measure 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, including the nationhood aspect

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 proposed measure 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.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the legislative instrument

Section 32B of the *Financial Framework (Supplementary Powers) Act 1997* (the FF(SP) Act) authorises the Commonwealth to make, vary and administer arrangements and grants specified in the *Financial Framework (Supplementary Powers) Regulations 1997* (the FF(SP) Regulations) and to make, vary and administer arrangements and grants for the purposes of programs specified in the Regulations. Schedule 1AA and Schedule 1AB to the FF(SP) Regulations specify the arrangements, grants and programs. The powers in the FF(SP) Act to make, vary or administer arrangements or grants may be exercised on behalf of the Commonwealth by Ministers and the accountable authorities of non-corporate Commonwealth entities, as defined under section 12 of the *Public Governance, Performance and Accountability Act 2013*.

The *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021* amend Schedule 1AB to the FF(SP) Regulations to establish legislative authority for government spending on the development and maintenance of Australia's onshore capability to manufacture mRNA (Messenger Ribonucleic Acid) products.

The capability will be initially founded through a partnership with one or more suppliers. The partnership is expected to be underpinned by agreements commencing in 2021-22 that would establish a population-scale mRNA manufacturing capability and guarantee the supply of locally manufactured mRNA vaccines, including COVID-19 vaccines, as well as provide future pandemic readiness. This disallowable legislative instrument will enable the Commonwealth to enter into agreements with one or more suppliers (including any other suppliers of locally manufactured mRNA products) within the total funding commitment, subject to future decisions by the Government.

Vaccines and therapeutics that use mRNA technology have been identified as a key growth opportunity in the Medical Products National Manufacturing Priority road map under the Government's *Modern Manufacturing Strategy*. The mRNA technology underpins the highly effective Pfizer-BioNTech and Moderna COVID-19 vaccines which have been embraced by Australians, accelerating the country's recovery from the pandemic. This technology could deliver step-change improvements in vaccine efficacy and individualised treatments for cancer and other diseases.

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

- ensure priority access to, and reliable delivery of, safe and effective prospective mRNA vaccines and any mRNA therapeutics to the Australian population as soon as they are available, on an ongoing basis;
- provide security of vaccine supply to address pandemics and other health emergencies into the future; and
- strengthen Australia's biopharmaceuticals sector, including through enabling potential translation and commercialisation paths for Australian-based research and development.

The overarching requirements in the development and maintenance 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; and
- participation in the broader mRNA ecosystem, including contribution to research and development.

The Department of Health will be the head agency for entering into agreements and providing ongoing contract management and supplier engagement.

Human rights implications

This disallowable legislative instrument engages the following right:

- 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. The 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

This disallowable legislative instrument is compatible with human rights because it promotes the protection of human rights.

Senator the Hon Simon Birmingham
Minister for Finance

From: s22
To:
Cc: DLO - Finance; Carroll, Tracey; Fox, Amy; Tran, Chi; s22
Subject: RE: Heads up: urgent Schedule 1AB brief for 16 December Exco [SEC=PROTECTED]
Date: Monday, 13 December 2021 12:24:13 PM
Attachments: image001.jpg
doc00500720211213115022.pdf

SEC=PROTECTED

Hi s22

The Minister has signed this one (see attached).
Thanks
s22

SEC=PROTECTED

From: s22 @finance.gov.au>
Sent: Friday, 10 December 2021 2:41 PM
To: s22 @finance.gov.au>
Cc: DLO - Finance <DLO-Finance@finance.gov.au>; Carroll, Tracey <Tracey.Carroll@finance.gov.au>; Fox, Amy <Amy.Fox@finance.gov.au>; Tran, Chi <Chi.Tran@finance.gov.au>; s22 @finance.gov.au>; s22 @finance.gov.au>
Subject: RE: Heads up: urgent Schedule 1AB brief for 16 December Exco [SEC=PROTECTED]

Error! Not a valid filename. Hi s22

Please find attached an urgent Schedule 1AB brief for the 16 December Exco. Finance Minister's approval is sought by **Tuesday, 14 December** (or sooner if possible).
PM&C has advised that the late letter for the Prime Minister to send to the Governor-General is with the PMO, seeking the Prime Minister's signature by today Friday, 10 December (MS21-001956 refers).
Thank you very much in advance.
Kind regards
s22

Error! Not a valid filename.

From: s22
Sent: Tuesday, 7 December 2021 1:50 PM
To: s22 @finance.gov.au>
Cc: DLO - Finance <DLO-Finance@finance.gov.au>; Carroll, Tracey <Tracey.Carroll@finance.gov.au>; Fox, Amy <Amy.Fox@finance.gov.au>; Tran, Chi <Chi.Tran@finance.gov.au>; s22 @finance.gov.au>; Jose, Cameron <Cameron.Jose@finance.gov.au>; s22 @finance.gov.au>; s22 @finance.gov.au>
Subject: Heads up: urgent Schedule 1AB brief for 16 December Exco [SEC=PROTECTED]

SEC=PROTECTED

Hi s22
Just a heads-up that we are working on an urgent Schedule 1AB brief for mRNA vaccines onshore manufacturing capability for the 16 December Exco meeting. s34(3)

s34(3)

We are aiming to have the papers to you by the end of this week, seeking Finance Minister's approval by Tuesday 14 December (or sooner if possible). We are also working with PM&C on the letter from the Prime Minister to the Governor-General seeking acceptance of late papers for that Exco meeting (formal due date for papers is today).

Kind regards

s22

s22 | Director
Schedule 1AB | Financial Management Branch
Department of Finance
T: s22 | **M:** s22
E: s22 @finance.gov.au | FFSPRegs@finance.gov.au
A: 1 Canberra Avenue, Forrest ACT 2603

SEC=PROTECTED

PDR Number:
MS21-001343

Australian Government
Department of Finance

MINISTERIAL SUBMISSION

Copies to:
Secretary
Ms Carroll
Mr Williamson
Ms Patterson
Ms Fox
Ms Hall
Mr Graham
Mr Jose
Ms Schweizer

Minister for Finance 10 December 2021

Financial Framework (Supplementary Powers) Regulations 1997 – Schedule 1AB – mRNA vaccines and treatments – late item for the Executive Council Meeting on 16 December 2021

Timing: Urgent - by Tuesday, 14 December 2021. To enable documentation to be submitted as a late item for consideration at the Federal Executive Council meeting on 16 December 2021.

Recommendations:

That you:

i. **agree** to request that the Governor-General make regulations which would amend Schedule 1AB to the *Financial Framework (Supplementary Powers) Regulations 1997* to include a new item for mRNA vaccines and treatments;

AGREED / NOT AGREED / PLEASE DISCUSS

ii. **sign**, but do not date, the proposed regulations at Attachment A;

SIGNED / PLEASE DISCUSS

iii. **sign**, but do not date, the Executive Council Minute for the regulations at Attachment B;

SIGNED / PLEASE DISCUSS

iv. **initial** the bottom right-hand corner of each page of the Explanatory Memorandum for the regulations at Attachment C; and

INITIALLED / PLEASE DISCUSS

v. **approve** the release of the Explanatory Statement for the regulations at Attachment D.

APPROVED / NOT APPROVED / PLEASE DISCUSS

Key Issues:

s34(3) [redacted]

s42 [redacted]

s45, s47 [redacted]

6. The cut-off date for final papers for the 16 December 2021 Executive Council meeting was on 7 December 2021. This means that the Governor-General would only consider this late item on a written request from the Prime Minister. The Department of the Prime Minister and Cabinet has advised that the proposed late letter for this item has been submitted to the Prime Minister's office, with the Prime Minister's signature sought by 10 December 2021 (MS21-001956 refers).

Financial Implications:

s34(3) [redacted]

Consultation:

9. Health, the Office of Constitutional Law, the Executive Council Secretariat, the Commercial Policy and Advice Branch in the Commercial and Government Services Group, and the Health Branch in the Budget and Financial Reporting Group have been consulted.

Approved for electronic transmission

Amy Fox
A/g First Assistant Secretary
Financial Analysis, Reporting and Management Division
02 6215 2036

Contact Officer: s22
Job Title/Level: Director/EL2
Telephone: s22
PDR Number MS21-001343

13/12/24.

Simon Birmingham

Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021

I, General the Honourable David Hurley AC DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 2021

David Hurley
Governor-General

By His Excellency's Command

Simon Birmingham
Minister for Finance

Contents

1 Name

This instrument is the *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the *Financial Framework (Supplementary Powers) Act 1997*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Financial Framework (Supplementary Powers) Regulations 1997

1 In the appropriate position in Part 4 of Schedule 1AB (table)

Insert:

531	mRNA vaccines and treatments	To develop and maintain Australia's onshore capability to manufacture mRNA products, as a measure to give effect to Australia's obligations under the International Covenant on Economic, Social and Cultural Rights, particularly Articles 2 and 12. This objective also has the effect it would have if it were limited to measures: (a) for the provision of, or incidental to the provision of, pharmaceutical, sickness or hospital benefits or medical services (within the meaning of paragraph 51(xxiiiA) of the Constitution); or (b) that are peculiarly adapted to the government of a nation and cannot otherwise be carried on for the benefit of the nation.

MINISTER FOR FINANCE

Departmental No. 2021/72

Executive Council
Meeting No. .....

Approved in Council

.....

David Hurley
Governor-General

.....

Filed in the Records
of the Council

.....
Secretary to the Executive Council

Minute Paper for the Executive Council

Subject

Financial Framework (Supplementary Powers) Act 1997

Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021

Recommended for the approval of His Excellency the Governor-General in Council that he make Regulations in the attached form.

Simon Birmingham
Minister for Finance

EXPLANATORY MEMORANDUM

Minute No. 72 of 2021 – Minister for Finance

Subject - *Financial Framework (Supplementary Powers) Act 1997*

Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021

The purpose of this instrument is to provide legislative authority for the expenditure of Commonwealth funds.

The *Financial Framework (Supplementary Powers) Act 1997* (the Act) confers on the Commonwealth, in certain circumstances, powers to make arrangements under which money can be spent; or to make grants of financial assistance; and to form, or otherwise be involved in, companies. The Act applies to Ministers and the accountable authorities of non-corporate Commonwealth entities, as defined under section 12 of the *Public Governance, Performance and Accountability Act 2013*.

Section 65 of the Act provides that the Governor-General may make regulations prescribing matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Section 32B of the Act authorises the Commonwealth to make, vary and administer arrangements, programs and grants of financial assistance specified in the *Financial Framework (Supplementary Powers) Regulations 1997* (the Principal Regulations). Schedules 1AA and 1AB to the Principal Regulations specify the arrangements, grants and programs. The overall effect of section 32B is to provide legislative authority for Commonwealth expenditure on the arrangements, programs and grants specified in the Principal Regulations. This includes providing legislative authority for the Commonwealth to be able to enter into contracts or other arrangements for the specified programs and grants.

The *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021* (the proposed Regulations) would insert a new **table item 531** in Part 4 of Schedule 1AB to the Principal Regulations to establish legislative authority for government spending on the development and maintenance of Australia's onshore capability to manufacture mRNA (Messenger Ribonucleic Acid) products.

Vaccines and therapeutics that use mRNA technology have been identified as a key growth opportunity in the Medical Products National Manufacturing Priority road map under the Government's *Modern Manufacturing Strategy*. The mRNA technology underpins the highly effective Pfizer-BioNTech and Moderna COVID-19 vaccines which have been embraced by Australians, accelerating the country's recovery from the pandemic. This technology could deliver step-change improvements in vaccine efficacy and individualised treatments for cancer and other diseases.

Establishing onshore mRNA vaccine manufacturing capability would provide priority access to breakthrough vaccines and treatments, strengthen Australia's preparedness for future pandemics, accelerate growth in Australia's mRNA research and commercialisation

ecosystem, and position Australia as the regional hub for this emerging, high-potential technology.

The partnership is expected to be underpinned by agreements commencing in 2021-22 that would establish a population-scale mRNA manufacturing capability and guarantee the supply of locally manufactured mRNA vaccines, including COVID-19 vaccines, as well as provide future pandemic readiness. The construction of a facility is estimated to be completed by 2024, with the capacity to manufacture and supply up to 100 million doses per annum in a future pandemic.

Under final agreements, the Commonwealth would be expected to:

- provide a financial contribution to keep the facility pandemic-ready such that it is capable of rapid manufacture at a population scale; and
- purchase mRNA vaccines (including COVID-19 vaccines) from the facility.

At this stage, the Commonwealth's final funding commitment is subject to ongoing commercial-in-confidence negotiations with one or more suppliers and potential state government funding partners. Some state governments have indicated their interest in co-investing in the onshore mRNA capability, including for the fill and finish aspects of the capability, as well as contributing to a research and development fund and a workforce and supply chain initiative. The Department of Health would be the head agency for establishing the partnership and providing the ongoing contract management and supplier engagement.

The project work to develop an onshore mRNA manufacturing capability, including negotiations with existing manufacturers and approach to the Australian market, was conducted by a joint taskforce which comprised the Department of Health and the Department of Industry, Science, Energy and Resources. During the project phase in 2020 and 2021 and up to the execution of agreements, the following governing bodies and agencies were consulted: Therapeutic Goods Administration; Department of Finance; Department of the Prime Minister and Cabinet; Department of Foreign Affairs and Trade; Australian Government Solicitor; Australian Technical Advisory Group on Immunisation; Pharmaceutical Benefits Advisory Committee; Science and Industry Technical Advisory Group; state governments; and an expert advisory group advising on the procurement process and supplier proposals.

The Act specifies no conditions that need to be satisfied before the power to make the proposed Regulations may be exercised.

The proposed Regulations would be a legislative instrument for the purposes of the *Legislation Act 2003*.

The proposed Regulations would commence the day after it is registered on the Federal Register of Legislation.

The Minute recommends that the Regulations be made in the form proposed.

Authority: Section 65 of the *Financial Framework (Supplementary Powers) Act 1997*

EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Finance

Financial Framework (Supplementary Powers) Act 1997

Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021

The *Financial Framework (Supplementary Powers) Act 1997* (the FF(SP) Act) confers on the Commonwealth, in certain circumstances, powers to make arrangements under which money can be spent; or to make grants of financial assistance; and to form, or otherwise be involved in, companies. The arrangements, grants, programs and companies (or classes of arrangements or grants in relation to which the powers are conferred) are specified in the *Financial Framework (Supplementary Powers) Regulations 1997* (the Principal Regulations). The powers in the FF(SP) Act to make, vary or administer arrangements or grants may be exercised on behalf of the Commonwealth by Ministers and the accountable authorities of non-corporate Commonwealth entities, as defined under section 12 of the *Public Governance, Performance and Accountability Act 2013*.

Section 65 of the FF(SP) Act provides that the Governor-General may make regulations prescribing matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Section 32B of the FF(SP) Act authorises the Commonwealth to make, vary and administer arrangements and grants specified in the Principal Regulations. Section 32B also authorises the Commonwealth to make, vary and administer arrangements for the purposes of programs specified in the Principal Regulations. Schedule 1AA and Schedule 1AB to the Principal Regulations specify the arrangements, grants and programs.

The *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021* (the Regulations) amend Schedule 1AB to the Principal Regulations to establish legislative authority for government spending on the development and maintenance of Australia's onshore capability to manufacture mRNA (Messenger Ribonucleic Acid) products.

The capability will be initially founded through a partnership with one or more suppliers. The partnership is expected to be underpinned by agreements commencing in 2021-22 that would establish a population-scale mRNA manufacturing capability and guarantee the supply of locally manufactured mRNA vaccines, including COVID-19 vaccines, as well as provide future pandemic readiness. The cost of the agreements will depend on the outcome of ongoing commercial negotiations, the timeframe for completing an mRNA manufacturing facility in Australia by one or more suppliers, the number of mRNA products to be manufactured, and domestic requirements for COVID-19 vaccines and any other mRNA products.

At this stage, the Commonwealth's final funding commitment is subject to ongoing commercial-in-confidence negotiations with one or more suppliers and potential state government funding partners. The Regulations will enable the Commonwealth to enter into agreements with one or more suppliers (including any other suppliers of locally manufactured mRNA products) within the total funding commitment, subject to future decisions by the Government.

Vaccines and therapeutics that use mRNA technology have been identified as a key growth opportunity in the Medical Products National Manufacturing Priority road map under the Government's *Modern Manufacturing Strategy*. The mRNA technology underpins the highly effective Pfizer-BioNTech and Moderna COVID-19 vaccines which have been embraced by Australians, accelerating the country's recovery from the pandemic. This technology could deliver step-change improvements in vaccine efficacy and individualised treatments for cancer and other diseases.

The Department of Health will be the head agency for establishing the partnership and providing the ongoing contract management and supplier engagement.

Details of the Regulations are set out at Attachment A. A Statement of Compatibility with Human Rights is at Attachment B.

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*. The Regulations commence on the day after the instrument is registered on the Federal Register of Legislation.

Consultation

In accordance with section 17 of the *Legislation Act 2003*, consultation has taken place with the Department of Health.

A regulation impact statement is not required as the Regulations only apply to non-corporate Commonwealth entities and do not adversely affect the private sector.

Attachment A

Details of the *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021*

Section 1 – Name

This section provides that the title of the Regulations is the *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021*.

Section 2 – Commencement

This section provides that the Regulations commence on the day after the instrument is registered on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the Regulations are made under the *Financial Framework (Supplementary Powers) Act 1997*.

Section 4 – Schedules

This section provides that the *Financial Framework (Supplementary Powers) Regulations 1997* are amended as set out in the Schedule to the Regulations.

Schedule 1 – Amendments

Financial Framework (Supplementary Powers) Regulations 1997

Item 1 – In the appropriate position in Part 4 of Schedule 1AB (table)

This item adds a new table item to Part 4 of Schedule 1AB to establish legislative authority for government spending on an activity that will be administered by the Department of Health (the department).

New **table item 531** establishes legislative authority for government spending on the development and maintenance of Australia's onshore capability to manufacture mRNA (Messenger Ribonucleic Acid) products.

Vaccines and therapeutics that use mRNA technology have been identified as a key growth opportunity in the Medical Products National Manufacturing Priority road map under the Government's *Modern Manufacturing Strategy*. The mRNA technology underpins the highly effective Pfizer-BioNTech and Moderna COVID-19 vaccines which have been embraced by Australians, accelerating the country's recovery from the pandemic. This technology could deliver step-change improvements in vaccine efficacy and individualised treatments for cancer and other diseases.

Establishing onshore mRNA vaccine manufacturing capability would provide priority access to breakthrough vaccines and treatments, strengthen Australia's preparedness for future pandemics, accelerate growth in Australia's mRNA research and commercialisation ecosystem, and position Australia as the regional hub for this emerging, high-potential technology.

The partnership is expected to be underpinned by agreements commencing in 2021-22 that would establish a population-scale mRNA manufacturing capability and guarantee the supply of locally manufactured mRNA vaccines, including COVID-19 vaccines, as well as provide future pandemic readiness. The construction of a facility is estimated to be completed by 2024, with the capacity to manufacture and supply up to 100 million doses per annum in a future pandemic.

Under final agreements, the Commonwealth is expected to:

- provide a financial contribution to keep the facility pandemic-ready such that it is capable of rapid manufacture at a population scale; and
- purchase mRNA vaccines (including COVID-19 vaccines) from the facility.

At this stage, the Commonwealth's final funding commitment is subject to ongoing commercial-in-confidence negotiations with one or more suppliers and potential state government funding partners. Some state governments have indicated their interest in co-investing in the onshore mRNA capability, including for the fill and finish aspects of the capability, as well as contributing to a research and development fund and a workforce and supply chain initiative.

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

The COVID-19 Vaccines and Treatments for Australia – Science and Industry Technical Advisory Group (SITAG) has also maintained support for onshore manufacturing, emphasising 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. The SITAG provides advice to the Government on the purchasing and manufacturing of COVID-19 vaccines and treatments.

A 2020 audit of Australia's manufacturing capability, followed by a March 2021 business case, identified a need for Australia to undertake onshore mRNA manufacturing. In the 2021-22 Budget, the Government provided funding to the Department of Industry, Science, Energy and Resources (DISER) to work with the department to develop an onshore mRNA vaccine manufacturing capability in Australia. On 21 May 2021, the then Minister for Industry, Science and Technology, the Hon Christian Porter MP, and the Minister for Health and Aged Care, the Hon Greg Hunt MP, jointly announced in a media release that the Government is developing a pathway to establish Australia's own sovereign manufacturing capability for mRNA vaccines. The media release is available at https://www.minister.industry.gov.au/ministers/porter/media-releases/australia-develop-onshore-mrna-manufacturing.

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

- ensure priority access to, and reliable delivery of, safe and effective prospective mRNA vaccines and any mRNA therapeutics to the Australian population as soon as they are available, on an ongoing basis;
- provide security of vaccine supply to address pandemics and other health emergencies into the future; and
- strengthen Australia's biopharmaceuticals sector, including through enabling potential translation and commercialisation paths for Australian-based research and development.

The overarching requirements in the development and maintenance 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; and
- participation in the broader mRNA ecosystem, including contribution to research and development.

It is expected that the department will be the head agency for entering into agreements and providing ongoing contract management and supplier engagement. The department will also work closely with DISER, which will provide policy support in relation to the research and development ecosystem and regional hub elements.

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, including the *Public Governance, Performance and Accountability Act 2013* (PGPA Act), the *Commonwealth Procurement Rules* (CPRs) and the department's Accountable Authority Instructions.

The expenditure is expected to be provided through an approved process, including but not limited to a procurement process. In this regard, the Secretary of the department (as the relevant Accountable Authority) has made a determination under paragraph 2.6 of the CPRs to disapply Divisions 1 and 2 of the CPRs to the proposed procurement of onshore mRNA manufacturing capability and supply of mRNA vaccines and treatments for both pandemic and non-pandemic purposes and all incidental or related matters (the procurement) on the basis that it is necessary to protect human health. Accordingly, the requirement to publish the details of the proposed procurement on AusTender as set out in the CPRs will not apply. However, the department will be required to table details relating to the proposed procurement, in accordance with the *Senate Procedural Orders of Continuing Effect No. 12* (Production of Indexed Lists of Departmental and Agency Files).

Irrespective of the exemption given under paragraph 2.6 of CPRs, any procurement decisions will nevertheless be based on value for money, including capability and capacity to deliver, and price and risk considerations. Provisional expenditure and supplier decisions were made by the Government, with the associated financial commitment for the relevant agreements to be approved by the Secretary of the department or an appropriate financial delegate at the SES level who has responsibility for the oversight of the procurement.

To ensure administrative accountability in relation to the procurement, the department will:

- execute and manage all procurement contracts for the term of the agreements;
- work collaboratively with DISER and the supplier(s) to meaningfully engage in ecosystem requirements to strengthen mRNA capability in Australia;
- report publicly on the performance and progress of the mRNA capability, including in its annual report; and
- monitor expenditure on the mRNA capability.

Decisions made in connection with the procurement 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 (ARC) 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 remaking 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, the procurement of onshore mRNA manufacturing capability and supply of mRNA vaccines and treatments is a financial decision with a significant public interest element. This 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 system and the national vaccination programs. The ARC 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, the context of a global pandemic is an extremely rare event.

The project work to develop an onshore mRNA manufacturing capability, including negotiations with existing manufacturers and approach to the Australian market, was conducted by a joint taskforce which comprised the department and DISER. During the project phase in 2020 and 2021 and up to the execution of agreements, the following governing bodies and agencies were consulted:

- Therapeutic Goods Administration (TGA);
- Department of Finance;
- Department of the Prime Minister and Cabinet;
- Department of Foreign Affairs and Trade;
- Australian Government Solicitor;
- Australian Technical Advisory Group on Immunisation (ATAGI);
- Pharmaceutical Benefits Advisory Committee (PBAC);
- SITAG;
- state governments; and
- an expert advisory group advising on the procurement process and supplier proposals.

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

- DISER;
- TGA;
- ATAGI;
- state governments;
- relevant industries; and
- the biotechnology research sector, particularly with regard to the development of the research and development ecosystem.

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 (section 51(xxix));
- the social welfare power (section 51(xxiiiA)); and
- the express incidental power and the executive power (sections 51(xxxix) and 61), including the nationhood aspect.

External affairs power

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

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 proposed measure 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, including the nationhood aspect

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 proposed measure 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.

Attachment B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the legislative instrument

Section 32B of the *Financial Framework (Supplementary Powers) Act 1997* (the FF(SP) Act) authorises the Commonwealth to make, vary and administer arrangements and grants specified in the *Financial Framework (Supplementary Powers) Regulations 1997* (the FF(SP) Regulations) and to make, vary and administer arrangements and grants for the purposes of programs specified in the Regulations. Schedule 1AA and Schedule 1AB to the FF(SP) Regulations specify the arrangements, grants and programs. The powers in the FF(SP) Act to make, vary or administer arrangements or grants may be exercised on behalf of the Commonwealth by Ministers and the accountable authorities of non-corporate Commonwealth entities, as defined under section 12 of the *Public Governance, Performance and Accountability Act 2013*.

The *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021* amend Schedule 1AB to the FF(SP) Regulations to establish legislative authority for government spending on the development and maintenance of Australia's onshore capability to manufacture mRNA (Messenger Ribonucleic Acid) products.

The capability will be initially founded through a partnership with one or more suppliers. The partnership is expected to be underpinned by agreements commencing in 2021-22 that would establish a population-scale mRNA manufacturing capability and guarantee the supply of locally manufactured mRNA vaccines, including COVID-19 vaccines, as well as provide future pandemic readiness. This disallowable legislative instrument will enable the Commonwealth to enter into agreements with one or more suppliers (including any other suppliers of locally manufactured mRNA products) within the total funding commitment, subject to future decisions by the Government.

Vaccines and therapeutics that use mRNA technology have been identified as a key growth opportunity in the Medical Products National Manufacturing Priority road map under the Government's *Modern Manufacturing Strategy*. The mRNA technology underpins the highly effective Pfizer-BioNTech and Moderna COVID-19 vaccines which have been embraced by Australians, accelerating the country's recovery from the pandemic. This technology could deliver step-change improvements in vaccine efficacy and individualised treatments for cancer and other diseases.

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

- ensure priority access to, and reliable delivery of, safe and effective prospective mRNA vaccines and any mRNA therapeutics to the Australian population as soon as they are available, on an ongoing basis;
- provide security of vaccine supply to address pandemics and other health emergencies into the future; and
- strengthen Australia's biopharmaceuticals sector, including through enabling potential translation and commercialisation paths for Australian-based research and development.

The overarching requirements in the development and maintenance 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; and
- participation in the broader mRNA ecosystem, including contribution to research and development.

The Department of Health will be the head agency for entering into agreements and providing ongoing contract management and supplier engagement.

Human rights implications

This disallowable legislative instrument engages the following right:

- 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. The 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

This disallowable legislative instrument is compatible with human rights because it promotes the protection of human rights.

Senator the Hon Simon Birmingham
Minister for Finance

From: Financial Framework (Supplementary Powers) Regulations
To: s22
Subject: FW: LEX 48606 - (item 531) 1AB package for OCL clearance "Moderna's on shore manufacturing facility" - 24 October 2024 ExCo [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege]
Date: Tuesday, 6 August 2024 1:02:30 PM
Attachments: s42

s42

Letter to Minister for Finance - mRNA onsure (Aug 6).docx
s42

From: s22 @Protected.Health.gov.au>
Sent: Tuesday, August 6, 2024 12:28:46 PM (UTC+10:00) Canberra, Melbourne, Sydney
To: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Cc: s22 @Protected.Health.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>
Subject: LEX 48606 - (item 531) 1AB package for OCL clearance "Moderna's on shore manufacturing facility" - 24 October 2024 ExCo [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege]

Dear Schedule 1AB team

Please find **attached** the draft (item 531) Schedule 1AB package for comments. The Department of Health and Aged Care is aiming to make amendments to item 531 at the 24 October ExCo meeting s42

s42

For the undertaking to amend the explanatory statement to include the additional information requested by the committee, in relation to the *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations*, I am waiting for s22 to return from leave, and we will get back to you later this week.

Please let me know if there are any questions.

Kind regards,

s22
Senior Lawyer – Constitutional Risk Team

Legal Advice and Legislation Branch

Legal Division | Corporate Operations Group
Australian Government, Department of Health and Aged Care
T: s22 @protected.health.gov.au
Sirius Building s22
PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as 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 all Elders both past and present.

Attachment A1

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

Description of the proposed new or materially changed Commonwealth expenditure

The 10 year Moderna Partnership is supported through a Facility Establishment Agreement (FEA) with Moderna that commenced in March 2022 and will terminate in 2032. The funding amount paid to Moderna will depend on several factors including:

- Determining COVID-19 needs based on recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI);
- The number of Moderna mRNA vaccines approved by the Australian Therapeutic Goods Administration (TGA);
- The results of undertaking Health Technology Assessment (HTA) noting the onshore vaccines will not go through the Pharmaceutical Advisory Committee (PBAC) process and therefore will not be listed as designated vaccines on the National Immunisation Program (refer to section 9B of the *National Health Act 1953*); and
- The date by which the TGA will provide their Good Manufacturing Practice (cGMP) license for the facility, and approve manufacturing each vaccine at the facility.

Building on the success of breakthrough COVID-19 mRNA vaccines, the Commonwealth recognises that the 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 respiratory diseases.

In establishing an onshore mRNA manufacturing capability including product fill and finish facilities in Victoria, the Commonwealth's objective is to:

- Secure onshore population-scale mRNA vaccine manufacturing capability, supply and resilience to respond to future pandemics and other health emergencies;
- Provide priority access to mRNA COVID-19 vaccines and other respiratory vaccines should those vaccines obtain regulatory approval from the TGA;
- 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 establishing 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;
- Non-pandemic vaccine supply agreements to procure Australia's requirement for COVID-19 vaccines, respiratory syncytial virus (RSV), influenza and other mRNA vaccines should those vaccines be developed and approved;
- Ongoing pandemic preparedness fees to secure priority access to mRNA pandemic vaccines; and
- Pandemic vaccine advance purchase agreements if Moderna identifies and/or develops vaccine candidates for future pandemics.

The Department of Health and Aged Care (the Department) is the head agency for the FEA with Moderna and provides the ongoing contract management and supplier engagement. The Department will also work closely with:

- Department of Industry, Science, Energy and Resources (DISER) who provides policy support in relation to the research and development ecosystem and regional hub elements; and
- The Department of Jobs, Skills, Industry and Regions in Victoria (through mRNA Victoria) who provides support in relation to construction of the facility and development of the regional research and development centre in Victoria.

Background

- 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 was identified as a priority growth opportunity in the *Medical Products National Manufacturing Priority road map*, published by the DISER in February 2021, refer to Medical Products National Manufacturing Priority road map (https://www.mtaa.org.au/news/medical-products-national-manufacturing-priority-road-map).
- During the COVID-19 pandemic, there were some 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 equip Australia to deal with any new challenges for 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 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 the Department to develop an onshore mRNA vaccine manufacturing capability in Australia, refer to Budget Paper No. 2, page 134.

s42

[redacted]

Statement of the relevance and operation of constitutional heads of power

External affairs power (s 51(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.

Australia has international obligations under the International Covenant on Economic, Social and Cultural Rights (ICESCR). 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 2 requires each State Party to 'take steps…to the maximum of its available resources, with a view to achieving progressively the full realisation' of this right 'by all appropriate means, including particularly the adoption of legislative measures'.

The steps to be taken by State Parties to achieve full realisation of the right to health are specified in Article 12(2) and include steps necessary for:

a) The prevention, treatment and control of epidemic, endemic, occupational and other diseases (Article 12(2)(c)); and
b) The creation of conditions which would assure to all medical service and medical attention in the event of sickness (Article 12(2)(d)).

The Committee on Economic, Social and Cultural Rights has expressed the view these obligations require State parties to, among other matters, 'implement and enhance immunization programmes'.

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

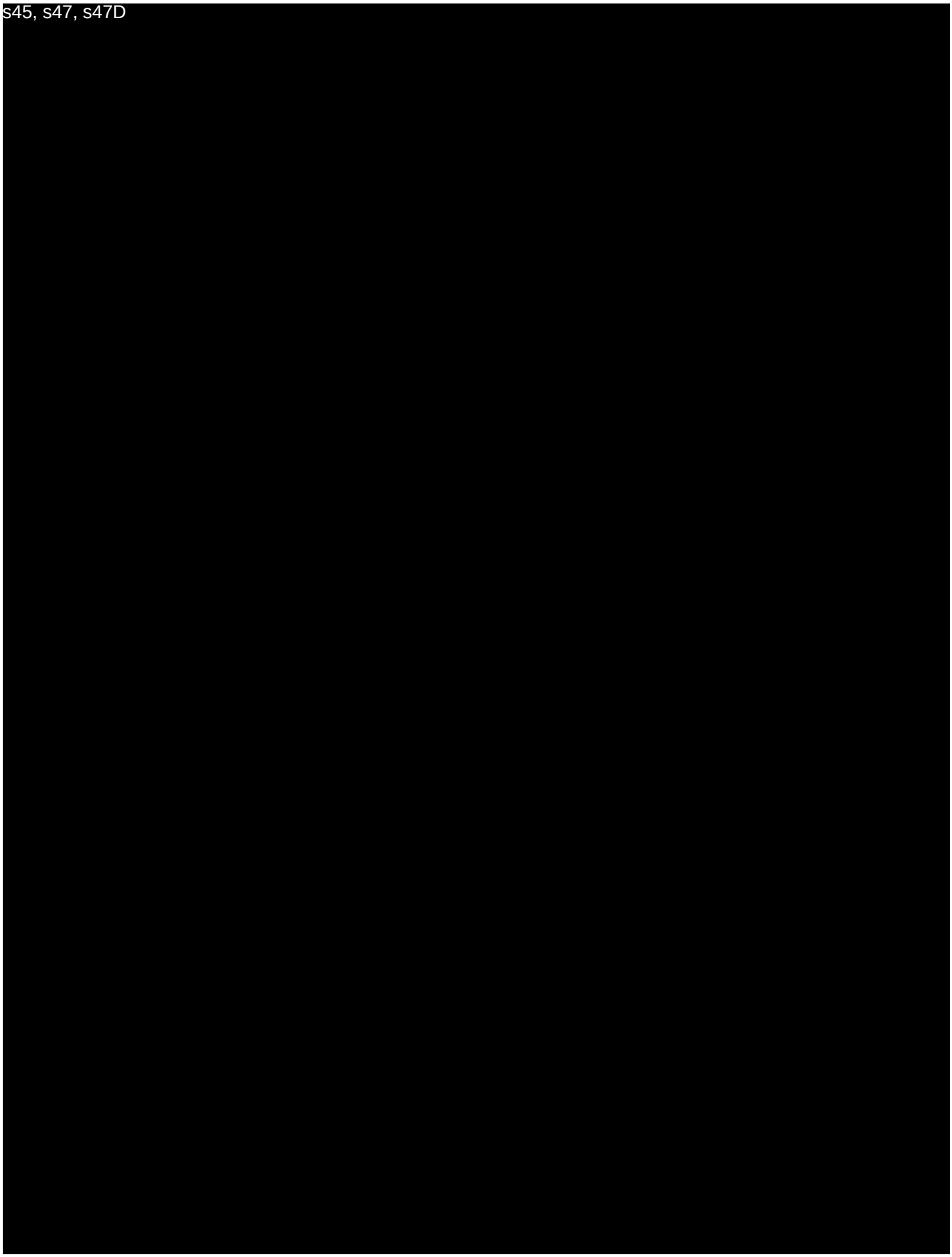
The proposed measure relates to the provision of pharmaceutical benefits and the manufacturing of vaccines and treatments in order to prevent and treat diseases and medical conditions using mRNA technology.

Executive power and express incidental power, including the nationhood aspect
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 proposed measure 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.

s45, s47, s47D

s45, s47, s47D



s45, s47, s47D [redacted]

Decisions about Commonwealth expenditure

The Department will provide the above mentioned funding to deliver the mRNA manufacturing capability and the purchased vaccines, 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.

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.

s34(3) [redacted] with the associated financial commitment for the relevant agreements approved by the Secretary of the Department (as the Accountable Authority of the Department) or an appropriate delegate.

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;
- ATAGI;
- TGA;
- 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.

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 as it promotes the protection of human rights.

s42

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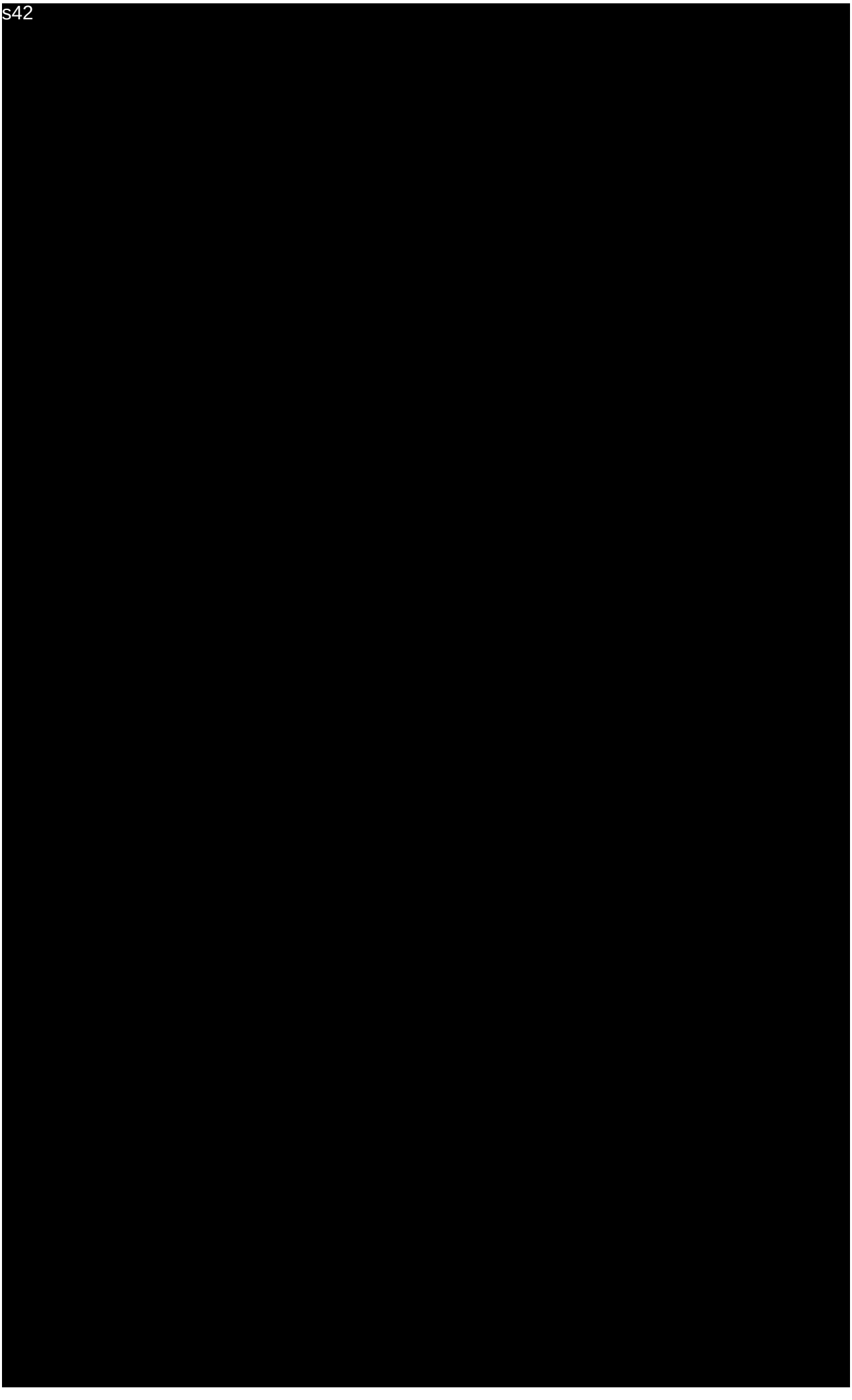
s42

s42



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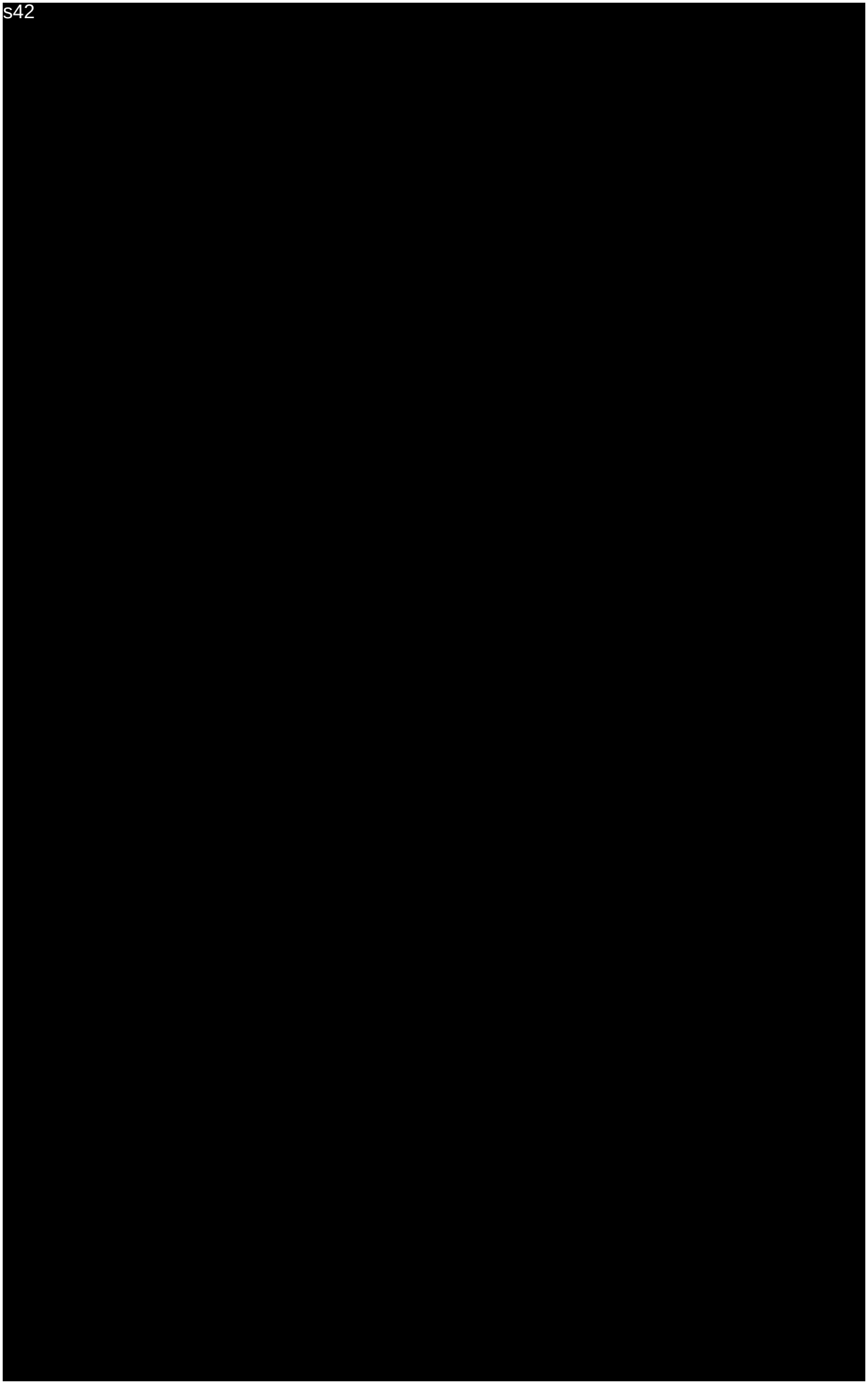

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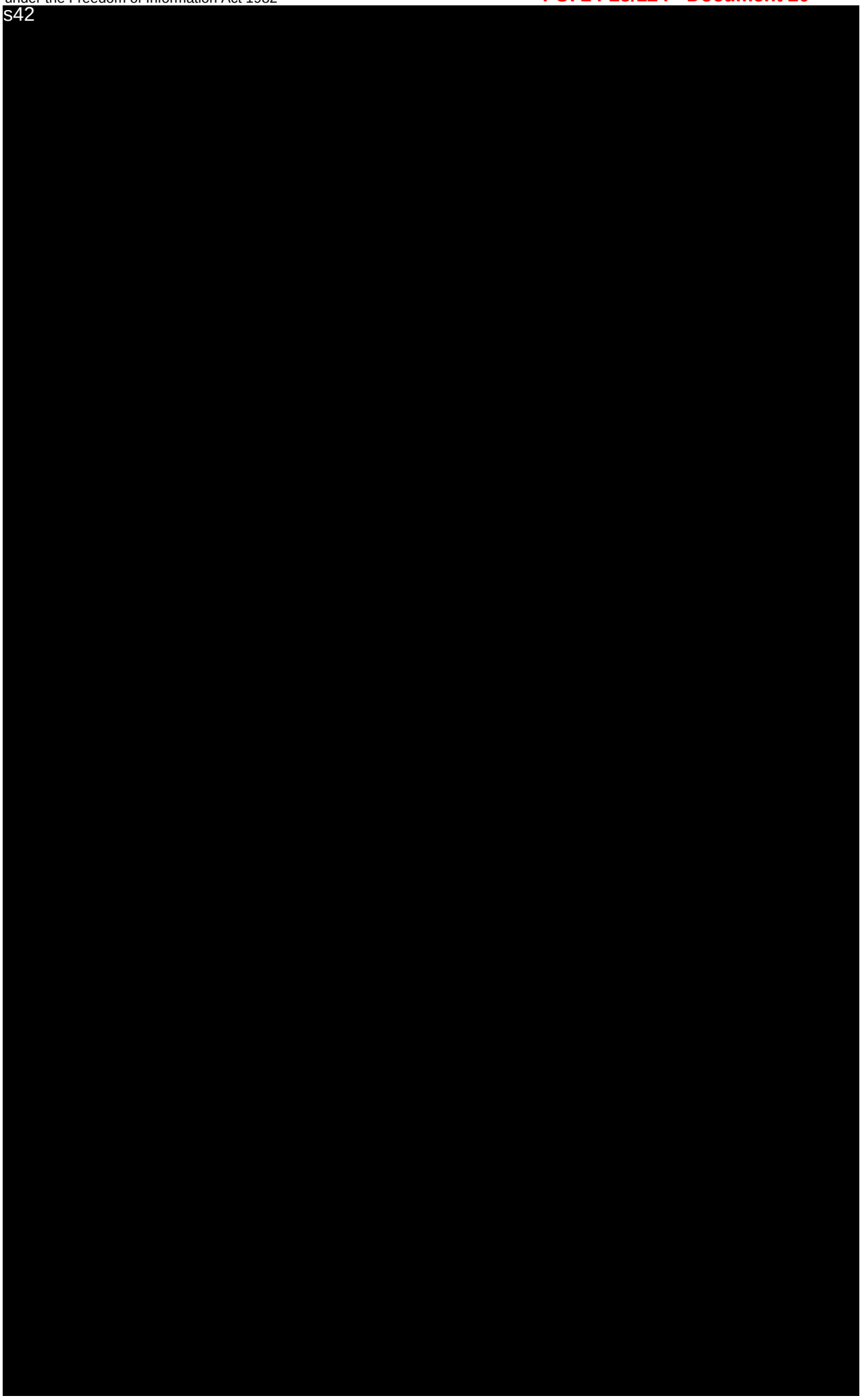

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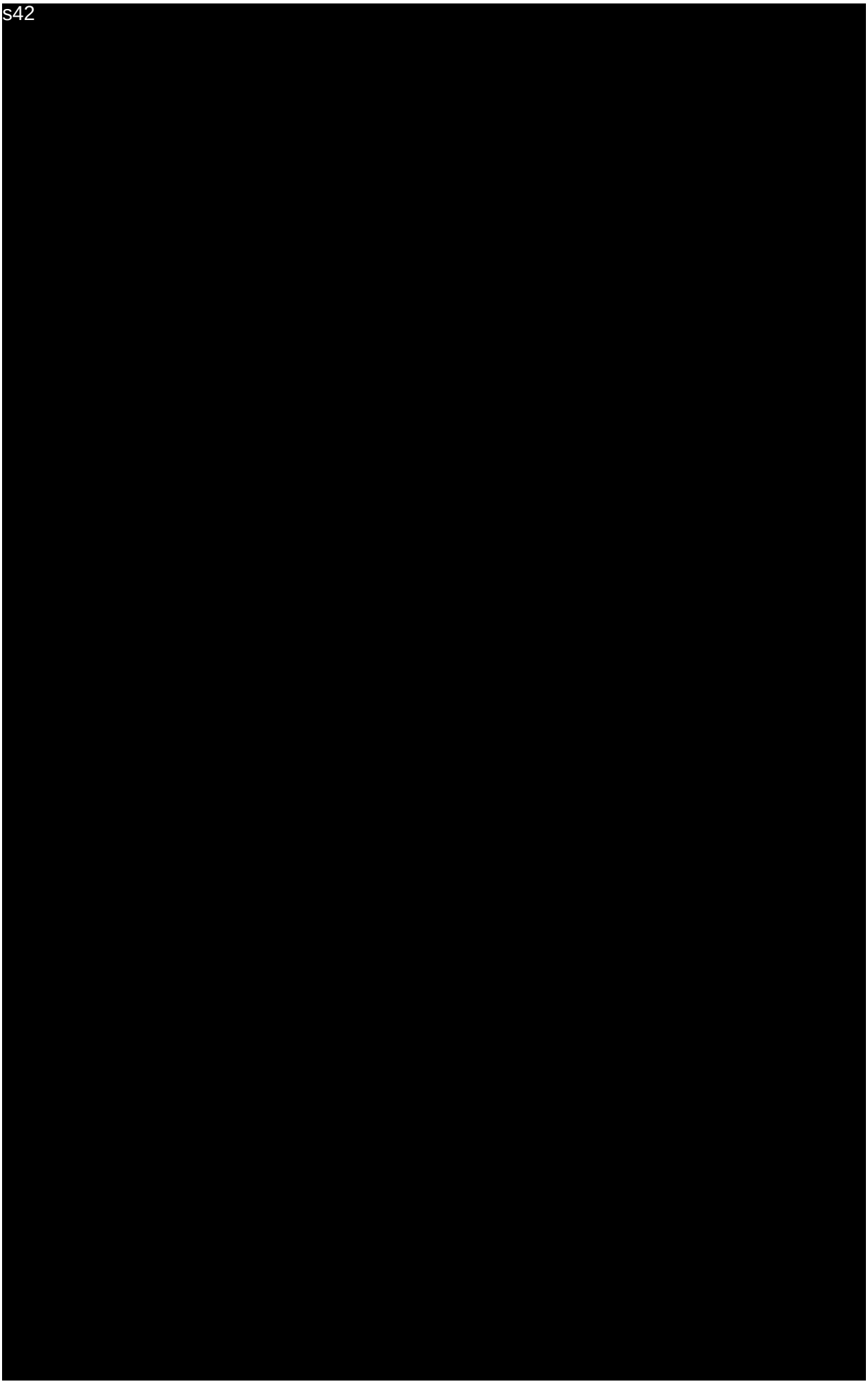

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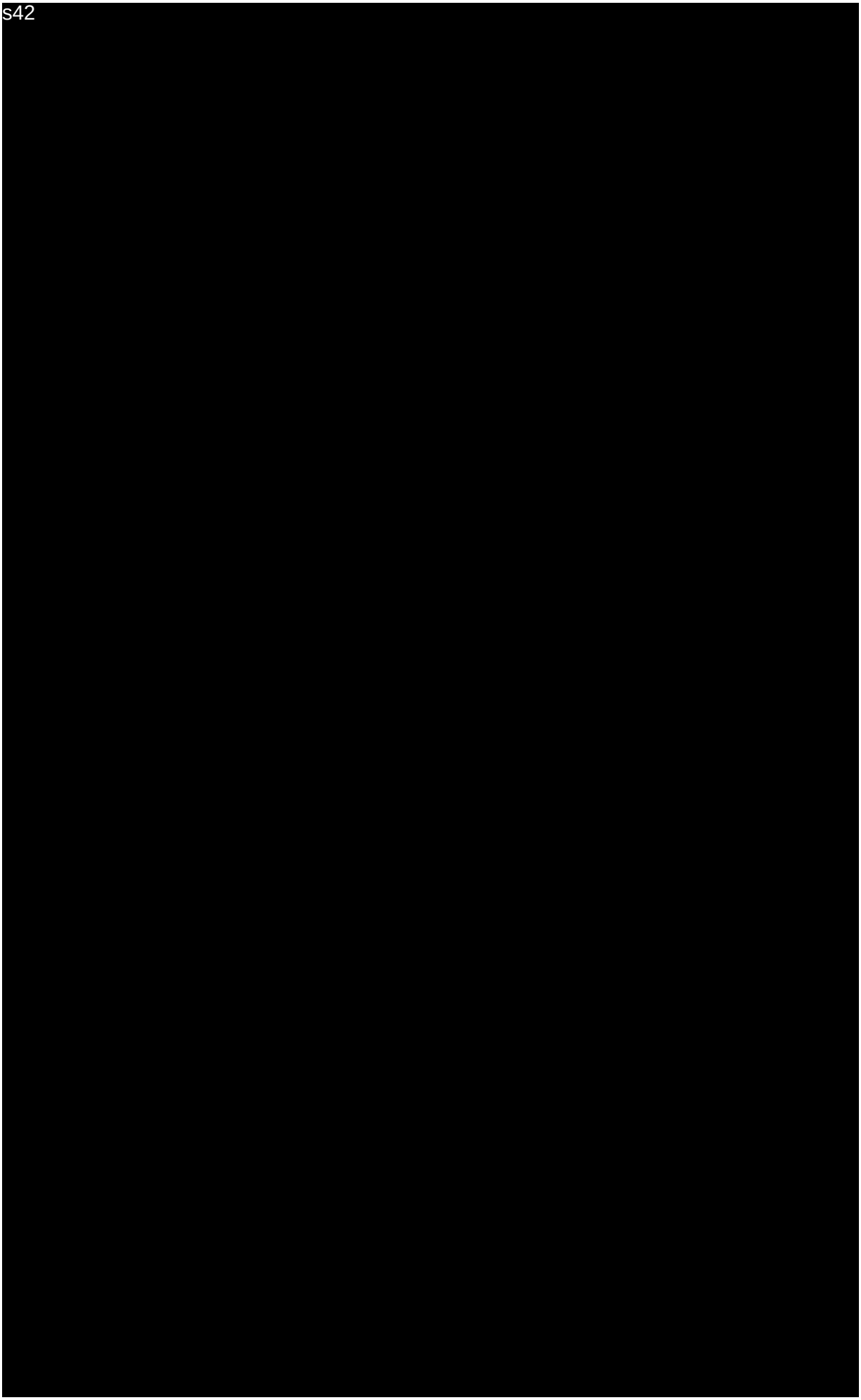

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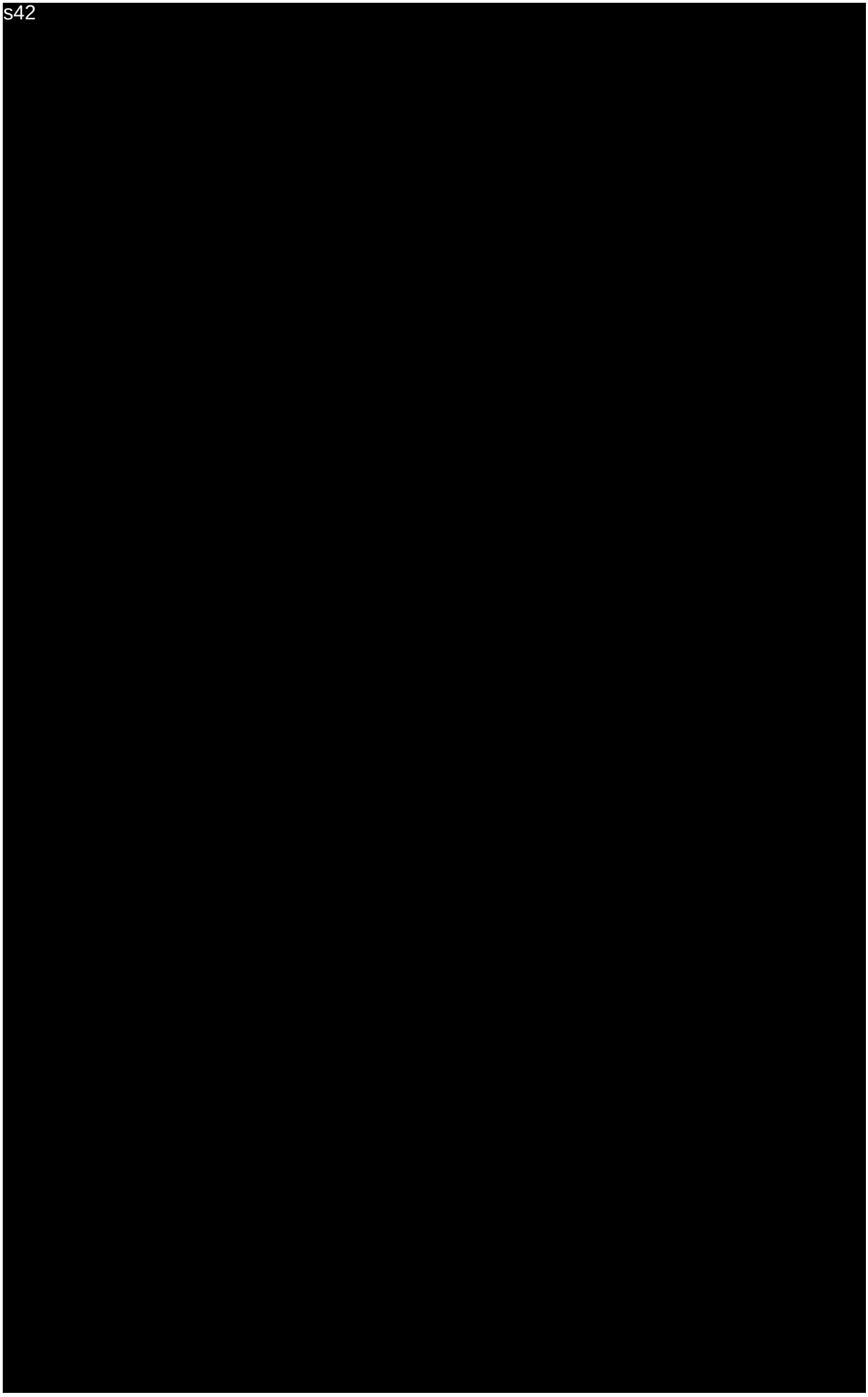

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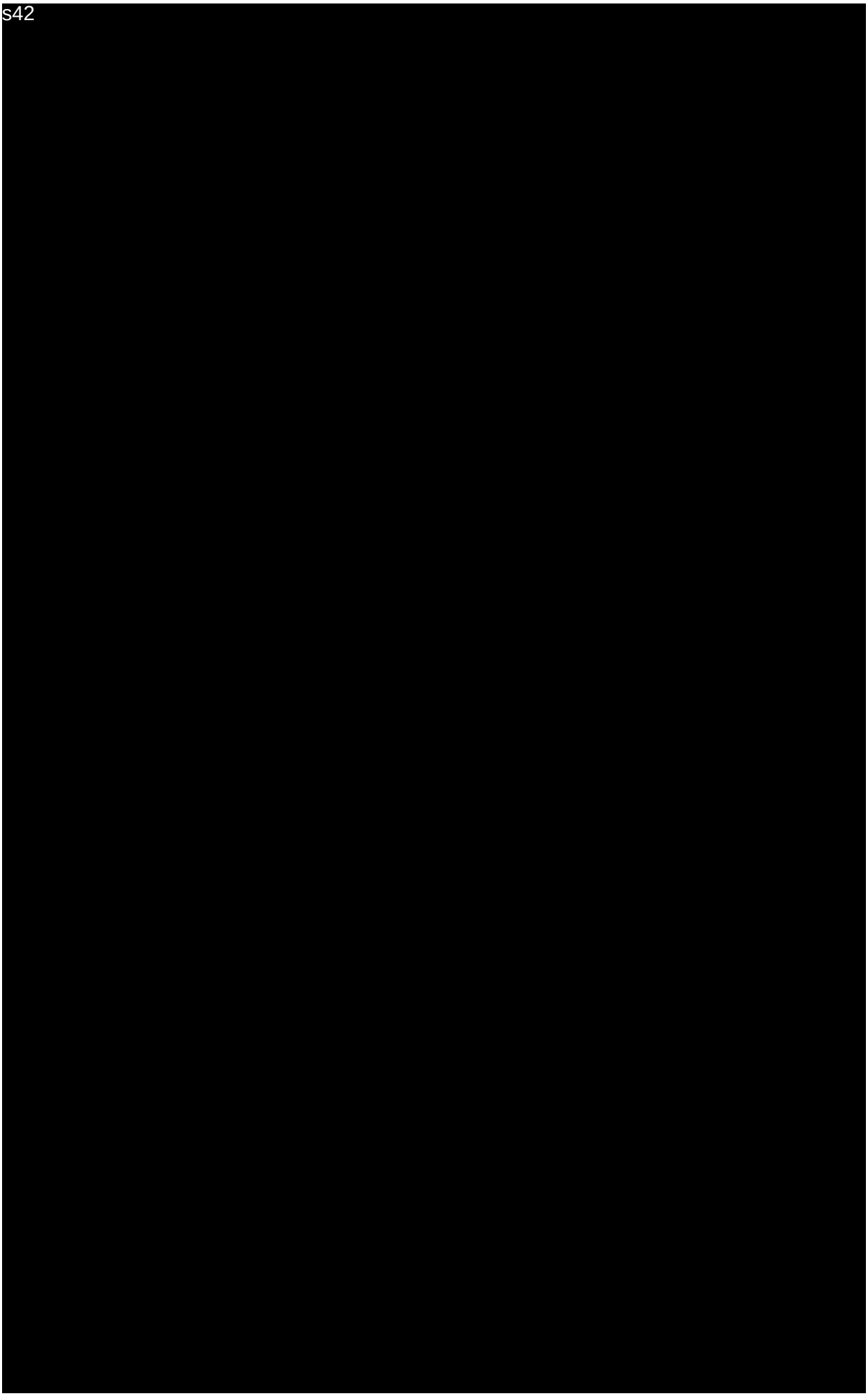

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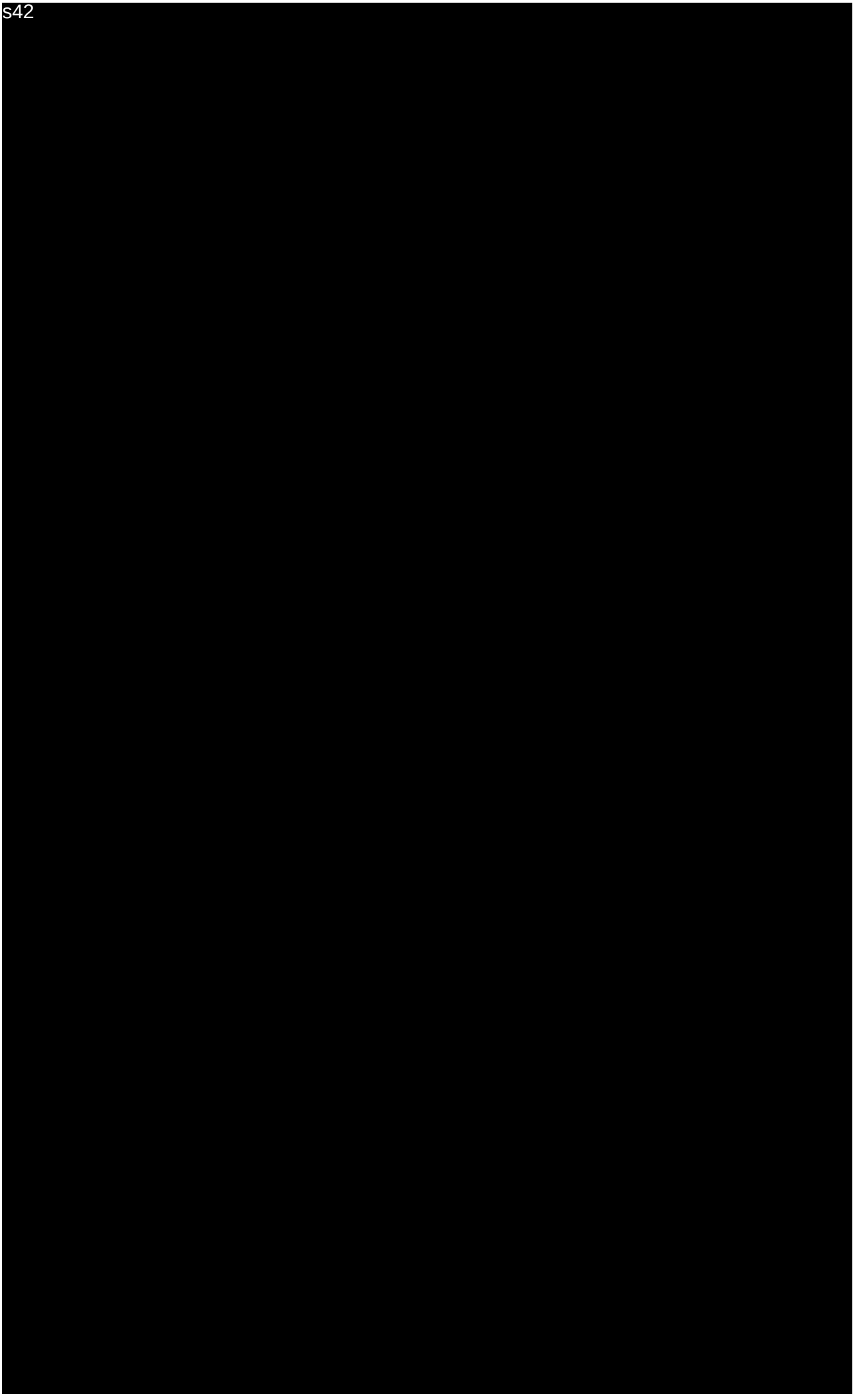
s42



Ref No: XX

Senator the Hon Katy Gallagher
Minister for Finance
Parliament House
CANBERRA ACT 2600

Dear Minister

Request to amend item 531 in Part 4 of Schedule 1AB to the *Financial Framework (Supplementary Powers) Regulation 1997*

I am writing to seek your agreement to amend item 531 in Part 4 of Schedule 1AB to the *Financial Framework (Supplementary Powers) Regulations 1997* (the FF(SP) Regulations), to establish legislative authority for government spending on the messenger Ribonucleic Acid (mRNA) vaccines program. This Schedule 1AB amendment is proposed for consideration by the Governor-General at the next Federal Executive Council meeting scheduled for 24 October 2024.

Summary of the proposed Commonwealth expenditure
In March 2022, the Australian Government executed a 10 year agreement with Moderna Australia Pty Ltd (Moderna) to establish a population-scale mRNA respiratory vaccine manufacturing facility and a regional research and development centre for respiratory medicines and tropical diseases in Melbourne, Victoria.

The Moderna Partnership includes a contribution from the Victorian Government. The Moderna Partnership will supply mRNA respiratory vaccines and provide Australia with priority access in case of pandemics. This initiative signals the Australian Government's support for onshore advanced technology manufacturing and sovereign capability, a commitment to pandemic readiness, and supporting Australia's world class capabilities to develop and produce the next generation of medical technology.

Moderna is the primary project lead to establish and operate the end-to-end mRNA manufacturing facility. However, the Commonwealth of Australia represented by my Department, the Department of Industry, Science, Energy and Research (DISER) and the Victorian Government (mRNA Victoria) have enabling roles, including the provision of funds towards the infrastructure build (via mRNA Victoria) and ongoing operational costs and purchase of the vaccines (via my Department).

Currently, the construction of the facility is underway and the facility is expected to be completed by December 2024. Pending successful trials, regulatory approvals by the Therapeutic Goods Administration (TGA) and Health Technology Assessments, Moderna envisages to manufacture the onshore vaccines in the first half of 2025.

The Australian Government will purchase the onshore vaccines outside the National Immunisation Program as per the Agreement with Moderna.

Policy authority

s34(3) [redacted]

Funding information

The Australian Government funding under the Facility Establishment Agreement includes financial commitments for an:

a) Annual Pandemic Preparedness Facility Fee (PPFF) which will provide Australia with priority access to vaccines in the event of future pandemics or local outbreaks; and
b) Annual Minimum Purchase Commitments of COVID-19 vaccines, plus other respiratory vaccines should they be approved by TGA.

The Victorian Government will make a financial contribution towards the Annual PPFF.

s42 [redacted]

To assist your department with drafting the proposed Schedule 1AB amendment and preparing explanatory materials, I have enclosed additional information about the program at Attachment A1.

Yours sincerely

Mark Butler

……/……/2024
Encl (Attachment A1)

From:	Financial Framework (Supplementary Powers) Regulations
To:	s22
Subject:	FW: LEX 48606 - (item 531) 1AB package for OCL clearance "Moderna's on shore manufacturing facility" - 24 October 2024 ExCo [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege]
Date:	Wednesday, 7 August 2024 5:21:01 PM
Attachments:	image001.png RE LEX 48606 - Seeking 1AB package for OCL clearance Modernas on shore manufacturing facility - 24 October 2024 ExCo SECPROTECTED CAVEATSHCABINET ACCESSLegal-Privilege.msg

From: s22 @Protected.Health.gov.au>
Sent: Wednesday, August 7, 2024 5:16:09 PM (UTC+10:00) Canberra, Melbourne, Sydney
To: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Cc: s22 @Protected.Health.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>
Subject: RE: LEX 48606 - (item 531) 1AB package for OCL clearance "Moderna's on shore manufacturing facility" - 24 October 2024 ExCo [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege]

Hi s22

Thank you for the heads up.

Please find **attached** the clearance email from OCL.

Kind regards,

s22
Senior Lawyer – Constitutional Risk Team
Legal Advice and Legislation Branch
Legal Division | Corporate Operations Group
Australian Government, Department of Health and Aged Care
T: s22 @protected.health.gov.au
Sirius Building s22
PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as 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 all Elders both past and present.

From: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Sent: Wednesday, 7 August 2024 5:01 PM
To: s22 @Protected.Health.gov.au>
Cc: s22 @Protected.Health.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>

Subject: RE: LEX 48606 - (item 531) 1AB package for OCL clearance "Moderna's on shore manufacturing facility" - 24 October 2024 ExCo [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege]

PROTECTED//CABINET
Legal Privilege

Hi s22

Thanks for providing the draft pack for the mRNA onshore item.

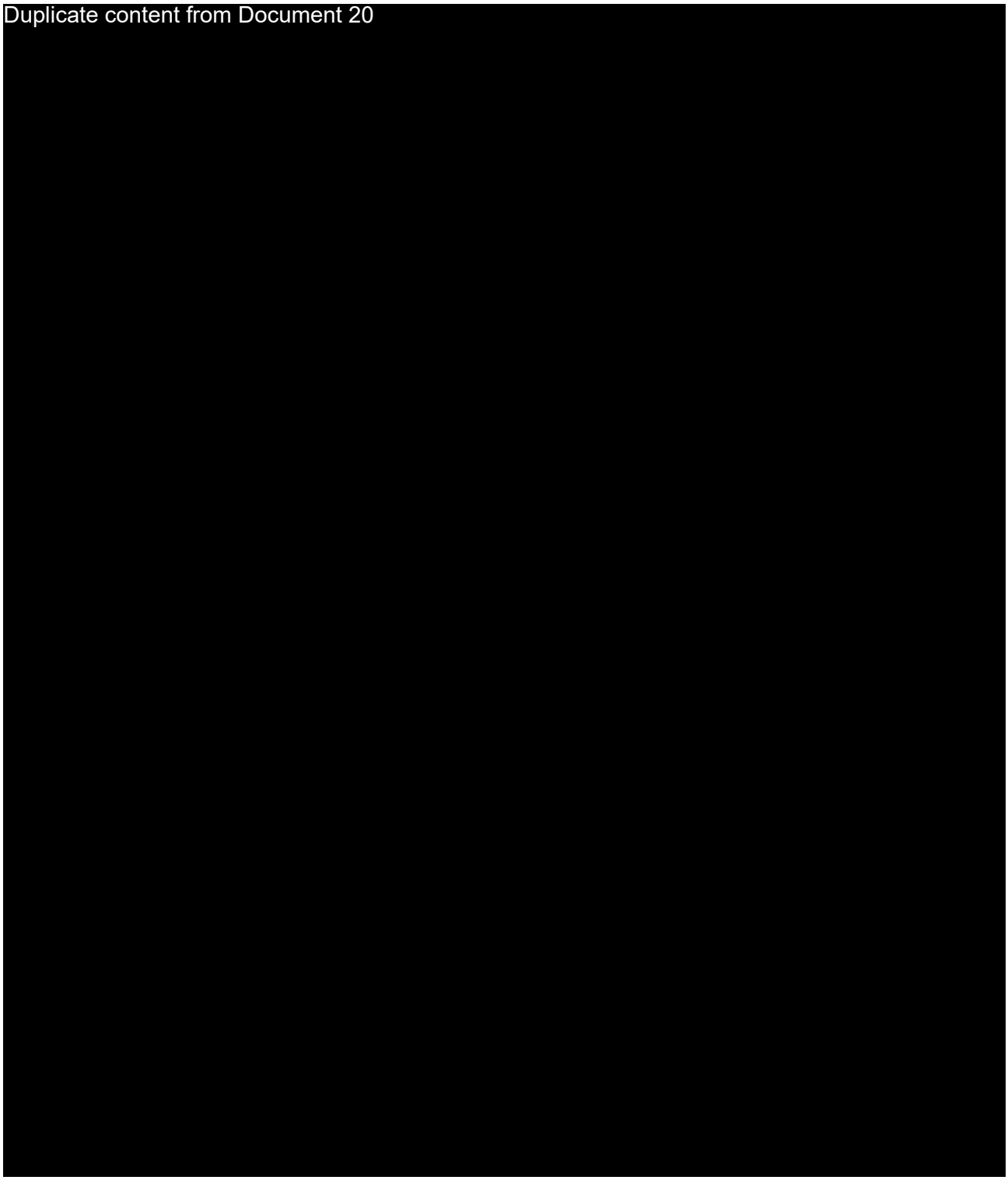
We will engage with the AAU shortly to seek their view on policy position, including the status of costings and will come back with our comments. As a heads up and noting SDLC has their eyes on this item since 2021, I would be looking for updated activities since item 531 was inserted. This is because the information provided appeared the same as the original item, ie using COVID-19 as one of the key drivers and that the Government has to respond rapidly to uphold public confidence in the health system.

We will await your further response on the outstanding undertaking. Finally, can you provide us the email clearance from OCL for the letter and attachment.

Thanks s22
s22

Duplicate content from Document 20

Duplicate content from Document 20



From: s22
To:
Cc: s22 ; Constitutional Risk; s22 ; OCL
Subject: RE: LEX 48606 - Seeking 1AB package for OCL clearance "Moderna's on shore manufacturing facility" - 24 October 2024 ExCo [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege]
Date: Tuesday, 6 August 2024 11:33:49 AM
Attachments: Duplicate attachments from Document 20

PROTECTED//CABINET

Legal Privilege

Dear s22

Thank you for sending the revised documents and for consulting AGS on our questions. OCL provides clearance of the letter and attachment.

Kind regards

s22
Legal Officer
Office of Constitutional Law
Attorney-General's Department
Ph: s22 @ag.gov.au

Indigenous banner Signature Block three.

PROTECTED//CABINET

Legal Privilege

From: s22
Sent: Tuesday, 6 August 2024 11:03 AM
To: s22
Cc: s22 ; Constitutional Risk ; s22 ; OCL
Subject: RE: LEX 48606 - Seeking 1AB package for OCL clearance "Moderna's on shore manufacturing facility" - 24 October 2024 ExCo [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege]

Dear s22

Thank you for providing OCL's comments.

AGS have clarified the points raised by OCL and please find **attached** their response. Please find **attached** the draft letter and Attachment A1 for re-review. The comments raised by OCL have been accepted and further changes by the Department have been kept in track changes.

Please let me know if there are any questions.

Kind regards,

s22
Senior Lawyer – Constitutional Risk Team
Legal Advice and Legislation Branch
Legal Division | Corporate Operations Group
Australian Government, Department of Health and Aged Care
T: s22 @protected.health.gov.au
Sirius Building s22
PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as 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 all Elders both past and present.

From: s22 @ag.gov.au>
Sent: Wednesday, 31 July 2024 5:53 PM
To: s22 @Protected.Health.gov.au>
Cc: s22 @Protected.Health.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>; s22 @ag.gov.au>; s22 @ag.gov.au>; OCL <OCL@ag.gov.au>
Subject: RE: LEX 48606 - Seeking 1AB package for OCL clearance "Moderna's on shore manufacturing facility" - 24 October 2024 ExCo [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege]

PROTECTED//CABINET

Legal Privilege

Dear s22

Thank you for consulting OCL on the Schedule 1AB letter and attachment regarding *Moderna's on shore manufacturing facility*. Please see attached OCL's comments. In our comments we have suggested you consult AGS further, could we please re-review after you have consulted them.

Kind regards

s22

Legal Officer
Office of Constitutional Law
Attorney-General's Department
Ph: s22 @ag.gov.au

Indigenous banner Signature Block three.

PROTECTED//CABINET

Legal Privilege

From: s22 @Protected.Health.gov.au>
Sent: Friday, 19 July 2024 3:15 PM
To: OCL <OCL@ag.gov.au>
Cc: s22 @Protected.Health.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>
Subject: LEX 48606 - Seeking 1AB package for OCL clearance "Moderna's on shore manufacturing facility" - 24 October 2024 ExCo [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege]

Dear OCL

We are progressing a proposed item for consideration at the 24 October ExCo meeting s42

We would be grateful to get OCL's comments by **31 July 2024** in relation to the **attached** Schedule 1AB package:

- the program completed draft letter to the Minister for Finance; and
- the program completed attachment to the letter to the Minister for Finance

Please find **attached** the:

s42

s42 [redacted]

Please let me know if there are any questions.

Kind regards,

s22 [redacted]
Senior Lawyer – Constitutional Risk Team
Legal Advice and Legislation Branch

Legal Division | Corporate Operations Group
Australian Government, Department of Health and Aged Care
T: s22 [redacted] @protected.health.gov.au
Sirius Building s22 [redacted]
PO Box 9848, Canberra ACT 2601, Australia

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From: Financial Framework (Supplementary Powers) Regulations
To: s22
Subject: FW: LEX 48606 - (item 531) 1AB package for OCL clearance "Moderna's on shore manufacturing facility" - 24 October 2024 ExCo [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege]
Date: Wednesday, 21 August 2024 6:07:46 PM
Attachments: image001.png
Attachment A 1- mRNA onshore (Aug 16).docx
Letter to Minister for Finance - mRNA onsure (Aug 16).docx

From: s22 @Protected.Health.gov.au>
Sent: Wednesday, August 21, 2024 6:01:56 PM (UTC+10:00) Canberra, Melbourne, Sydney
To: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Cc: s22 @Protected.Health.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>
Subject: RE: LEX 48606 - (item 531) 1AB package for OCL clearance "Moderna's on shore manufacturing facility" - 24 October 2024 ExCo [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege]

Hi s22

Many thanks to you and your team for your assistance amending item 531. Please find **attached** the updated letter and attachment. The updates include an update to the activities since COVID which I have left in tracked changes for ease of identifying the changes. The program area also confirmed that the figures on pages 4 to 6 are commercial in confidence and are only provided to the Department of Finance (and Minister for Finance) to be transparent with the costs (which are still be negotiated) and therefore should not be in the Explanatory Statement. As mentioned in the meeting on Monday, it is the intention of the Department to provide an amount to the Committee that does not breach any confidentiality after the negations have been completed.

Kind regards,

s22
Senior Lawyer – Constitutional Risk Team
Legal Advice and Legislation Branch
Legal Division | Corporate Operations Group
Australian Government, Department of Health and Aged Care
T: s22 @protected.health.gov.au
Sirius Building s22
PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as 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 all Elders both past and present.

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Attachment A1

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

Description of the proposed new or materially changed Commonwealth expenditure

The 10 year Moderna Partnership is supported through a Facility Establishment Agreement (FEA) with Moderna that commenced in March 2022 and will terminate in 2032. The funding amount paid to Moderna will depend on several factors including:

- Determining COVID-19 needs based on recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI);
- The number of Moderna mRNA vaccines approved by the Australian Therapeutic Goods Administration (TGA);
- The results of undertaking Health Technology Assessment (HTA) noting the onshore vaccines will not go through the Pharmaceutical Advisory Committee (PBAC) process and therefore will not be listed as designated vaccines on the National Immunisation Program (refer to section 9B of the *National Health Act 1953*); and
- The date by which the TGA will provide their Good Manufacturing Practice (cGMP) license for the facility, and approve manufacturing each vaccine at the facility.

Building on the success of breakthrough COVID-19 mRNA vaccines, the Commonwealth recognises that the 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 respiratory diseases.

In establishing an onshore mRNA manufacturing capability including product fill and finish facilities in Victoria, the Commonwealth's objective is to:

- Secure onshore population-scale mRNA vaccine manufacturing capability, supply and resilience to respond to future pandemics and other health emergencies;
- Provide priority access to mRNA COVID-19 vaccines and other respiratory vaccines should those vaccines obtain regulatory approval from the TGA;
- 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 establishing 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;
- Non-pandemic vaccine supply agreements to procure Australia's requirement for COVID-19 vaccines, respiratory syncytial virus (RSV), influenza and other mRNA vaccines should those vaccines be developed and approved;
- Ongoing pandemic preparedness fees to secure priority access to mRNA pandemic vaccines; and
- Pandemic vaccine advance purchase agreements if Moderna identifies and/or develops vaccine candidates for future pandemics.

The Department of Health and Aged Care (the Department) is the head agency for the FEA with Moderna and provides the ongoing contract management and supplier engagement. The Department will also work closely with:

- Department of Industry, Science, and Resources (DISR) who provides policy support in relation to the research and development ecosystem and regional hub elements; and
- The Department of Jobs, Skills, Industry and Regions in Victoria (through mRNA Victoria) who provides support in relation to construction of the facility and development of the regional research and development centre in Victoria.

Background

- 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 was identified as a priority growth opportunity in the *Medical Products National Manufacturing Priority road map*, published by the DISR in February 2021, refer to Medical Products National Manufacturing Priority road map (https://www.mtaa.org.au/news/medical-products-national-manufacturing-priority-road-map).
- During the COVID-19 pandemic, there were some 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 equip Australia to deal with any new challenges for 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 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 DISR to work with the Department to develop an onshore mRNA vaccine manufacturing capability in Australia, refer to Budget Paper No. 2, page 134.

s42

[redacted]

Statement of the relevance and operation of constitutional heads of power

External affairs power (s 51(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.

Australia has international obligations under the International Covenant on Economic, Social and Cultural Rights (ICESCR). 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 2 requires each State Party to 'take steps…to the maximum of its available resources, with a view to achieving progressively the full realisation' of this right 'by all appropriate means, including particularly the adoption of legislative measures'.

The steps to be taken by State Parties to achieve full realisation of the right to health are specified in Article 12(2) and include steps necessary for:

a) The prevention, treatment and control of epidemic, endemic, occupational and other diseases (Article 12(2)(c)); and
b) The creation of conditions which would assure to all medical service and medical attention in the event of sickness (Article 12(2)(d)).

The Committee on Economic, Social and Cultural Rights has expressed the view these obligations require State parties to, among other matters, 'implement and enhance immunization programmes'.

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

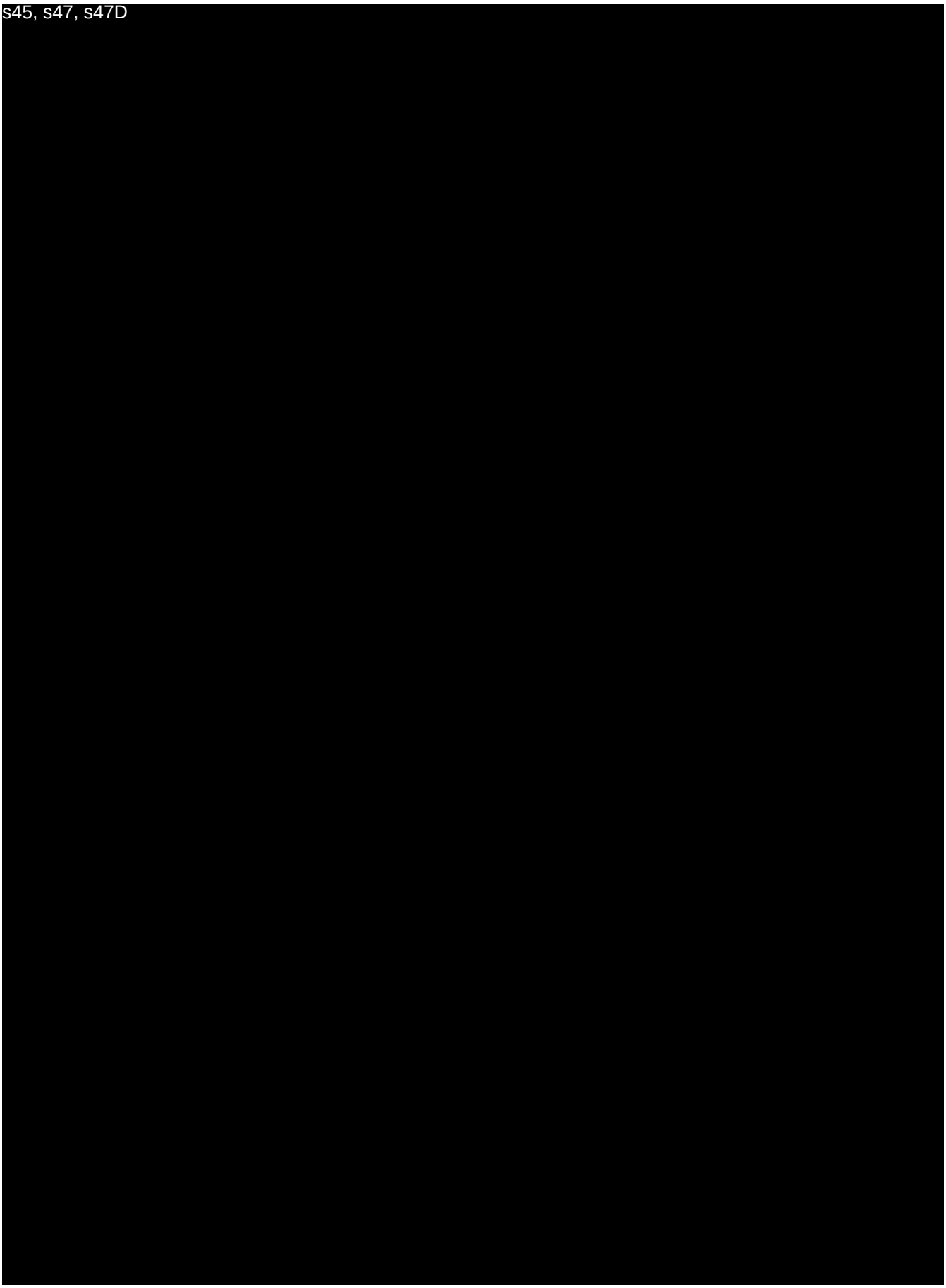
The proposed measure relates to the provision of pharmaceutical benefits and the manufacturing of vaccines and treatments in order to prevent and treat diseases and medical conditions using mRNA technology.

Executive power and express incidental power, including the nationhood aspect
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 proposed measure 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.

s45, s47, s47D

s45, s47, s47D



s45, s47, s47D

[redacted]

Decisions about Commonwealth expenditure

The Department will provide the above mentioned funding to deliver the mRNA manufacturing capability and the purchased vaccines, 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.

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.

s34(3) [redacted], with the associated financial commitment for the relevant agreements approved by the Secretary of the Department (as the Accountable Authority of the Department) or an appropriate delegate.

The Department would propose to:

- Execute and manage all contracts for the above services for the term of the agreements;
- Work collaboratively with DISR 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, DISR 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;
- ATAGI;
- TGA;
- 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.

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

- State Governments;
- DISR;
- 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 as it promotes the protection of human rights.

The Hon Mark Butler MP
Minister for Health and Aged Care

Ref No: XX

Senator the Hon Katy Gallagher
Minister for Finance
Parliament House
CANBERRA ACT 2600

Dear Minister

Request to amend item 531 in Part 4 of Schedule 1AB to the *Financial Framework (Supplementary Powers) Regulation 1997*

I am writing to seek your agreement to amend item 531 in Part 4 of Schedule 1AB to the *Financial Framework (Supplementary Powers) Regulations 1997* (the FF(SP) Regulations), to establish legislative authority for government spending on the messenger Ribonucleic Acid (mRNA) vaccines program. This Schedule 1AB amendment is proposed for consideration by the Governor-General at the next Federal Executive Council meeting scheduled for 24 October 2024.

Summary of the proposed Commonwealth expenditure
In March 2022, the Australian Government executed a 10 year agreement with Moderna Australia Pty Ltd (Moderna) to establish a population-scale mRNA respiratory vaccine manufacturing facility and a regional research and development centre for respiratory medicines and tropical diseases in Melbourne, Victoria.

The Moderna Partnership includes a contribution from the Victorian Government. The Moderna Partnership will supply mRNA respiratory vaccines and provide Australia with priority access in case of pandemics. This initiative signals the Australian Government's support for onshore advanced technology manufacturing and sovereign capability, a commitment to pandemic readiness, and supporting Australia's world class capabilities to develop and produce the next generation of medical technology.

Moderna is the primary project lead to establish and operate the end-to-end mRNA manufacturing facility. However, the Commonwealth of Australia represented by my Department, the Department of Industry, Science, Energy and Research (DISER) and the Victorian Government (mRNA Victoria) have enabling roles, including the provision of funds towards the infrastructure build (via mRNA Victoria) and ongoing operational costs and purchase of the vaccines (via my Department).

Currently, the construction of the facility is underway and the facility is expected to be completed by December 2024. Pending successful trials, regulatory approvals by the Therapeutic Goods Administration (TGA) and Health Technology Assessments, Moderna envisages to manufacture the onshore vaccines in the first half of 2025.

The Australian Government will purchase the onshore vaccines outside the National Immunisation Program as per the Facility Establishment Agreement (Agreement)with Moderna.

Policy authority

s34(2), s34(3) [redacted]

Funding information

The Australian Government funding under the Agreement includes financial commitments for an:

a) Annual Pandemic Preparedness Facility Fee (PPFF) which is the annual fee paid to Moderna for the up keep of the facility and commences on the date that drug manufacturing and fill/finish facilities have TGA approval to commence manufacturing mRNA vaccines.; and
b) Annual Minimum Purchase Commitments of COVID-19 vaccines, plus other respiratory vaccines should they be approved by TGA. The Commonwealth's commitment to purchasing minimum number of vaccines for delivery in each financial year

The Victorian Government will make a financial contribution towards the Annual PPFF.

s45, s47, s47D [redacted]

s42 [redacted]

To assist your department with drafting the proposed Schedule 1AB amendment and preparing explanatory materials, I have enclosed additional information about the program at Attachment A1.

Yours sincerely

Mark Butler

……/……/2024
Encl (Attachment A1)

From: Financial Framework (Supplementary Powers) Regulations
To: s22
Subject: FW: AAU consult: Health Schedule 1AB item - mRNA vaccines and treatments - 24 Oct Exco meeting [SEC=PROTECTED, CAVEAT=SH:CABINET]
Date: Monday, 26 August 2024 5:28:15 PM
Attachments: image001.png

From: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Sent: Monday, August 26, 2024 5:28:08 PM (UTC+10:00) Canberra, Melbourne, Sydney
To: PBS Team <PBSTeam@finance.gov.au>
Cc: s22 @finance.gov.au>; s22 @finance.gov.au>; s22 @finance.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Subject: RE: AAU consult: Health Schedule 1AB item - mRNA vaccines and treatments - 24 Oct Exco meeting [SEC=PROTECTED, CAVEAT=SH:CABINET]

PROTECTED//CABINET

Thanks s22 perfect timing.

I will incorporate your comments to Health shortly.

Will also reach out if I have further questions.

Have a good night.

Cheers,
s22

From: PBS Team <PBSTeam@finance.gov.au>
Sent: Monday, August 26, 2024 5:21:00 PM (UTC+10:00) Canberra, Melbourne, Sydney
To: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Cc: PBS Team <PBSTeam@finance.gov.au>; s22 @finance.gov.au>; s22 @finance.gov.au>; s22 @finance.gov.au>
Subject: RE: AAU consult: Health Schedule 1AB item - mRNA vaccines and treatments - 24 Oct Exco meeting [SEC=PROTECTED, CAVEAT=SH:CABINET]

PROTECTED//CABINET
Legal Privilege

H s22 ,

Thanks for sharing the draft letter with us.

Please be advised we have minor comments and suggestions in track in the attached. Kindly let us know if you would like to discuss on anything further.

Many thanks
s22

s22
Assistant Director • PBS, Vaccines and Emergency Response AAU
Health Branch • Social Policy Division
Department of Finance

T: s22 • E: s22 @finance.gov.au

From: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Sent: Thursday, August 22, 2024 9:47 AM
To: s22 @finance.gov.au>; s22 @finance.gov.au>; s22 @finance.gov.au>
Cc: PBS Team <PBSTeam@finance.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Subject: AAU consult: Health Schedule 1AB item - mRNA vaccines and treatments - 24 Oct Exco meeting [SEC=PROTECTED, CAVEAT=SH:CABINET, ACCESS=Legal-Privilege]

PROTECTED//CABINET
Legal Privilege

Hi s22 and team,

Further to our meeting on Monday, please now find attached the draft letter of request to amend legislative authority for the mRNA vaccines and treatments – item 531. The amendment is necessary to support the purchase of vaccines from April 2025. s42

As you are aware, the commitment to enter into a ten-year partnership with Moderna was agreed by the previous Government s34(3)). I've also attached our brief to the FM at the time when the item was inserted in December 2021 for visibility and context.

Grateful if you can review and let us know (from a policy and costings perspective) if there is anything we need to flag with the FM.

Can we please have your response by Monday, 26 August 2024 (or earlier if possible) to ensure we incorporate your comments back to Health.

Happy to also discuss if you have any questions or concerns.

Thanks,
s22

From: Financial Framework (Supplementary Powers) Regulations
To: s22
Subject: FW: DoHAC - Responses to OPC Questions - Instrument first draft - Health Measures No. 4 - 24 Oct Exco [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]
Date: Thursday, 5 September 2024 11:37:54 AM
Attachments: image001.png

From: s22 @Protected.Health.gov.au>
Sent: Thursday, September 5, 2024 11:37:32 AM (UTC+10:00) Canberra, Melbourne, Sydney
To: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Cc: Constitutional Risk <Constitutional.Risk@protected.health.gov.au>; s22 @Protected.Health.gov.au>
Subject: RE: DoHAC - Responses to OPC Questions - Instrument first draft - Health Measures No. 4 - 24 Oct Exco [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

Hi s22

Your interpretation is correct!

Kind regards
s22

s22
Principal Lawyer
Constitutional Risk Team

Legal Division
Corporate Operations Group
Australian Government Department of Health and Aged Care
T: s22 @protected.health.gov.au
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.

From: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Sent: Thursday, 5 September 2024 11:27 AM
To: s22 @Protected.Health.gov.au>
Cc: Constitutional Risk <Constitutional.Risk@protected.health.gov.au>; s22 @Protected.Health.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>

Subject: RE: DoHAC - Responses to OPC Questions - Instrument first draft - Health Measures No. 4 - 24 Oct Exco [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

OFFICIAL:Sensitive
Legal Privilege

Thanks s22

s22

Can I confirm your rationale for item 531 – just to be crystal clear.

s42

Subject to your confirmation today, I will provide our consolidated responses back to OPC for a revised draft.

Cheers,
s22

From: s22 @Protected.Health.gov.au>
Sent: Thursday, September 5, 2024 10:48:35 AM (UTC+10:00) Canberra, Melbourne, Sydney
To: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Cc: Constitutional Risk <Constitutional.Risk@protected.health.gov.au>; s22 @Protected.Health.gov.au>
Subject: DoHAC - Responses to OPC Questions - Instrument first draft - Health Measures No. 4 - 24 Oct Exco [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

Dear s22

s22 is not in the office today, so I am responding to your email of 30 August 2024.

To identify our additional instructions s22 to the queries raised by OPC we have used yellow highlight and bold green text – ***for example***.

s22

Always a pleasure working with you.
If you require any further assistance, please don't hesitate to contact.

Kind regards,
s22

Principal Lawyer
Constitutional Risk Team

Legal Division
Corporate Operations Group
Australian Government Department of Health and Aged Care
T: s22 @protected.health.gov.au
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.

From: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Sent: Friday, 30 August 2024 11:28 AM
To: s22 @Protected.Health.gov.au>
Cc: s22 @Protected.Health.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Subject: For review: Instrument first draft - Health Measures No. 4 - 24 Oct Exco
[SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

OFFICIAL:Sensitive
Legal Privilege

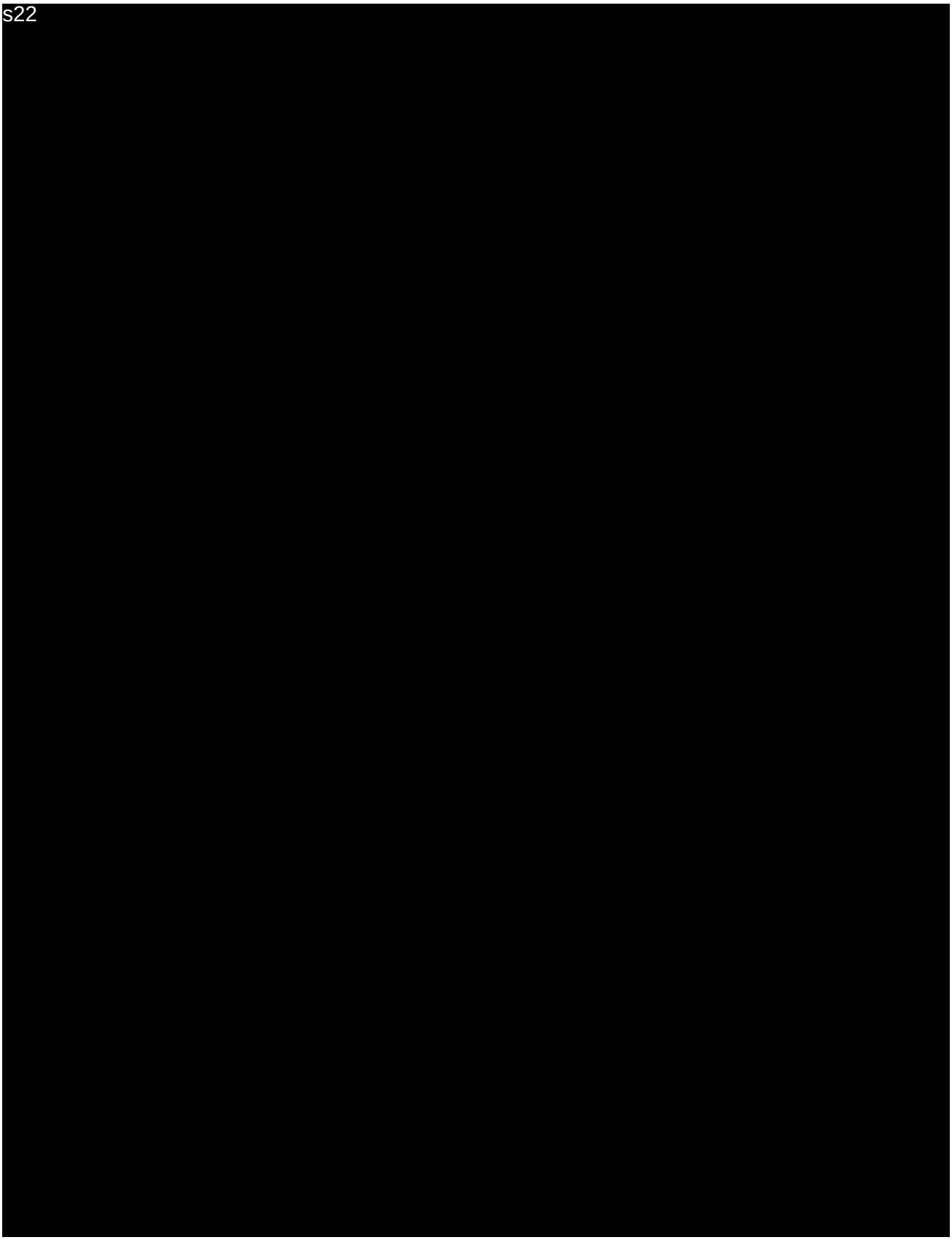
Hi s22

Please find attached Health's first draft Regulations for your consideration.

OPC raised a few queries for each amended item which are extracted below for ease of comments – please read them together with the instrument. We also provide our view where relevant.

s22

s22



s42

s42 [redacted]

We are currently drafting the ES for the amended items and will send it across for your review shortly. In the interest of time, are you able to work with your clients and address all queries above, including seeking further AGS view (where necessary) to ensure we resolve any issues promptly.

Grateful if you can respond by **Thursday, 5 September 2024**.

Please reach out if you wish to discuss.

Thanks,

s22 [redacted]

From: Financial Framework (Supplementary Powers) Regulations
To: s22
Subject: FW: REVISED: For AS clearance: draft Regulations and Explanatory Statement (Health Measures No. 4) - 24 Oct Exco [SEC=OFFICIAL]
Date: Friday, 6 September 2024 4:42:45 PM
Attachments: ES - Health No. 4 - 6 Sept 24.docx
I24AE104.v03.docx
I24AE104.V03.V02.docx

From: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Sent: Friday, September 6, 2024 4:41:14 PM (UTC+10:00) Canberra, Melbourne, Sydney
To: s22 @Protected.Health.gov.au <s22 @Protected.Health.gov.au>
Cc: s22 @Protected.Health.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Subject: REVISED: For AS clearance: draft Regulations and Explanatory Statement (Health Measures No. 4) - 24 Oct Exco [SEC=OFFICIAL]

OFFICIAL

Hi s22

Please disregard my request for the revised Regs below.

s22

All other requests regarding the ES remain unchanged.

Thanks s22
s22

From: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Sent: Friday, September 6, 2024 3:32:14 PM (UTC+10:00) Canberra, Melbourne, Sydney
To: s22 @Protected.Health.gov.au <s22 @Protected.Health.gov.au>
Cc: s22 @Protected.Health.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Subject: For AS clearance: draft Regulations and Explanatory Statement (Health Measures No. 4) - 24 Oct Exco [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

OFFICIAL:Sensitive
Legal Privilege

Hi s22

Please find attached the revised draft regulations (Regs) and draft explanatory statement (ES) relating to all three Health amended items for your review and consideration.

In relation to the ES, can you please:

- review and address our comments highlighted in Yellow, in s22 [redacted]
- check that the ES does not contain any 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 (unless there are any comments/issues that you wish to discuss with us before clearance is obtained).

Please provide any edits/comments in track changes. Please note that Finance reserves final editorial rights to this document.

In relation to the revised Regs, while OPC has no further queries, please let us know if you have any comments.

If you don't have concerns or significant issues in the ES and Regs, could you please obtain SES clearance by **Thursday, 12 September 2024** to assist with the remaining drafting of the explanatory memorandum.

If you do have any significant issues or concerns to be addressed in either document before obtaining SES clearance, please revert as soon as possible to allow us time to address the issues.

As always, happy to chat.

With thanks,

s22 [redacted]

EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Finance

Financial Framework (Supplementary Powers) Act 1997

Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024

The *Financial Framework (Supplementary Powers) Act 1997* (the FFSP Act) confers on the Commonwealth, in certain circumstances, powers to make arrangements under which money can be spent; or to make grants of financial assistance; and to form, or otherwise be involved in, companies. The arrangements, grants, programs and companies (or classes of arrangements or grants in relation to which the powers are conferred) are specified in the *Financial Framework (Supplementary Powers) Regulations 1997* (the Principal Regulations). The powers in the FFSP Act to make, vary or administer arrangements or grants may be exercised on behalf of the Commonwealth by Ministers and the accountable authorities of non-corporate Commonwealth entities, as defined under section 12 of the *Public Governance, Performance and Accountability Act 2013*.

The Principal Regulations are exempt from sunsetting under section 12 of the *Legislation (Exemptions and Other Matters) Regulation 2015* (item 28A). If the Principal Regulations were subject to the sunsetting regime under the *Legislation Act 2003*, this would generate uncertainty about the continuing operation of existing contracts and funding agreements between the Commonwealth and third parties (particularly those extending beyond 10 years), as well as the Commonwealth's legislative authority to continue making, varying or administering arrangements, grants and programs.

Additionally, the Principal Regulations authorise a number of activities that form part of intergovernmental schemes. It would not be appropriate for the Commonwealth to unilaterally sunset an instrument that provides authority for Commonwealth funding for activities that are underpinned by an intergovernmental arrangement. To ensure that the Principal Regulations continue to reflect government priorities and remain up to date, the Principal Regulations are subject to periodic review to identify and repeal items that are redundant or no longer required.

Section 32B of the FFSP Act authorises the Commonwealth to make, vary and administer arrangements and grants specified in the Principal Regulations. Section 32B also authorises the Commonwealth to make, vary and administer arrangements for the purposes of programs specified in the Principal Regulations. Section 32D of the FFSP Act confers powers of delegation on Ministers and the accountable authorities of non-corporate Commonwealth entities, including subsection 32B(1) of the Act. Schedule 1AA and Schedule 1AB to the Principal Regulations specify the arrangements, grants and programs.

Section 65 of the FFSP Act provides that the Governor-General may make regulations prescribing matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024* (the Regulations) amend Schedule 1AB to the Principal Regulations to establish legislative authority for Government spending on activities administered by the Department of Health and Aged Care.

Existing funding is allocated for the:

s22 [redacted]

- messenger Ribonucleic Acid (mRNA) vaccines and treatments program to develop and maintain Australia's onshore capability to manufacture mRNA vaccines and products, including by purchasing mRNA vaccines and products manufactured onshore (financial implications for this element are not for publication due to commercial-in-confidence sensitivities. It is the intention of the Australian Government to disclose the funding allocated for the program once the agreements are finalised).

Details of the Regulations are set out at Attachment A. A Statement of Compatibility with Human Rights is at Attachment B.

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence on the day after registration on the Federal Register of Legislation.

Consultation

In accordance with section 17 of the *Legislation Act 2003*, consultation has taken place with the Department of Health and Aged Care.

A regulatory impact analysis is not required as the Regulations only apply to non-corporate Commonwealth entities and do not adversely affect the private sector.

Attachment A

Details of the *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024*

Section 1 – Name

This section provides that the title of the Regulations is the *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024.*

Section 2 – Commencement

This section provides that the Regulations commence on the day after registration on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the Regulations are made under the *Financial Framework (Supplementary Powers) Act 1997*.

Section 4 – Schedules

This section provides that the *Financial Framework (Supplementary Powers) Regulations 1997* are amended as set out in the Schedule to the Regulations.

Schedule 1 – Amendments

Financial Framework (Supplementary Powers) Regulations 1997

Amended Table item 306 – Quality Use of Diagnostic, Therapeutics and Pathology Program

s22

s22

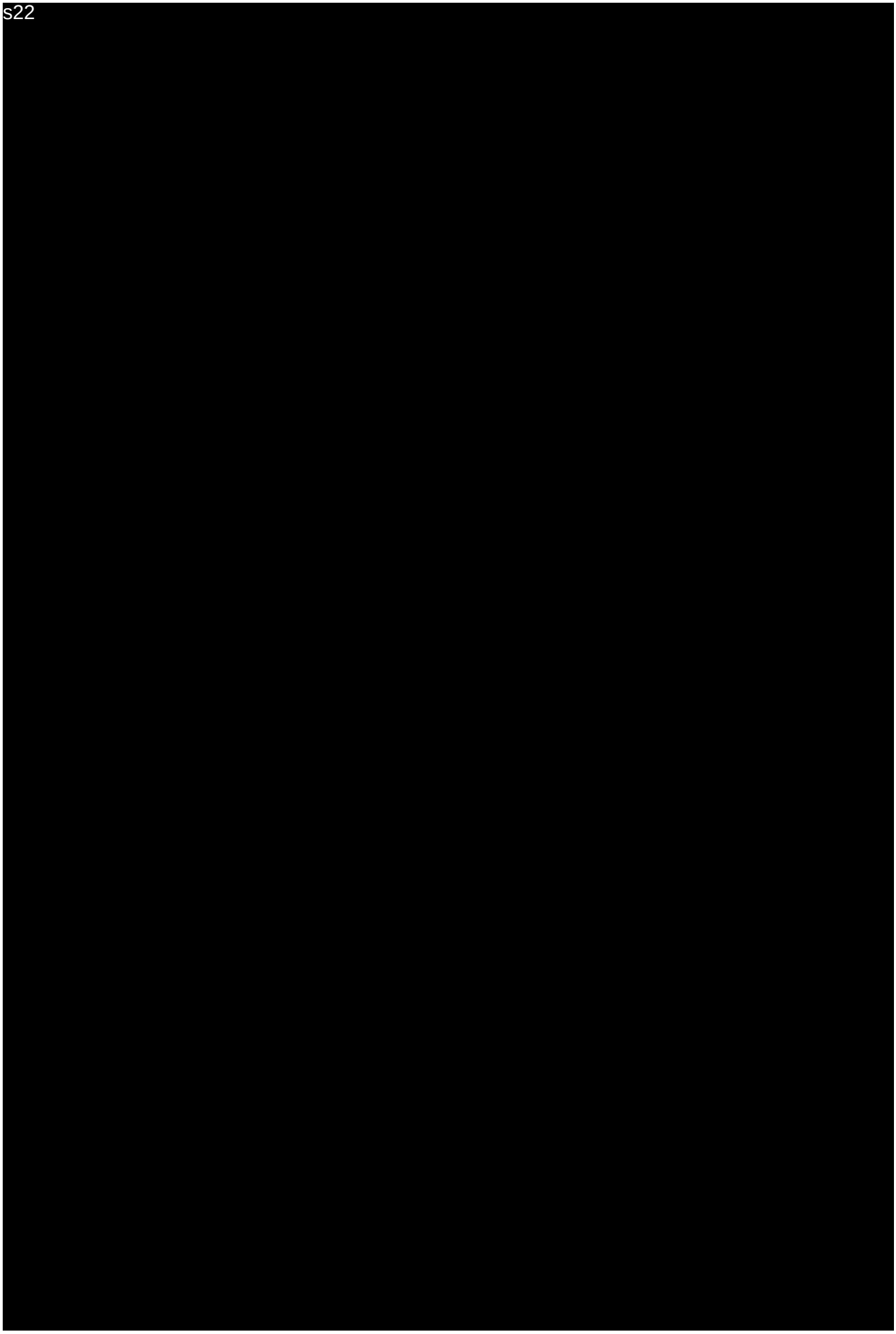
s22

[redacted]

s22

[redacted]

s22

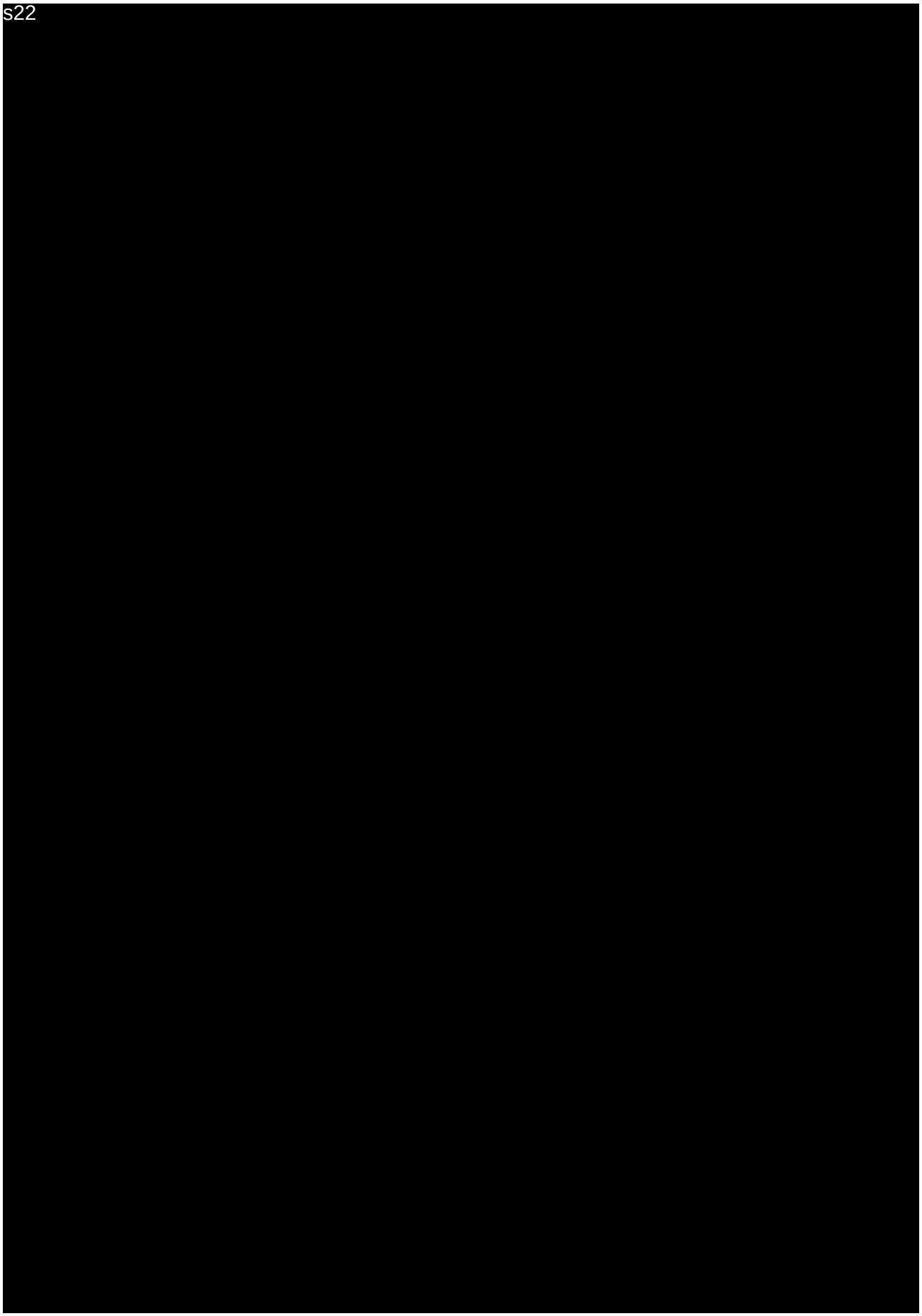


s22

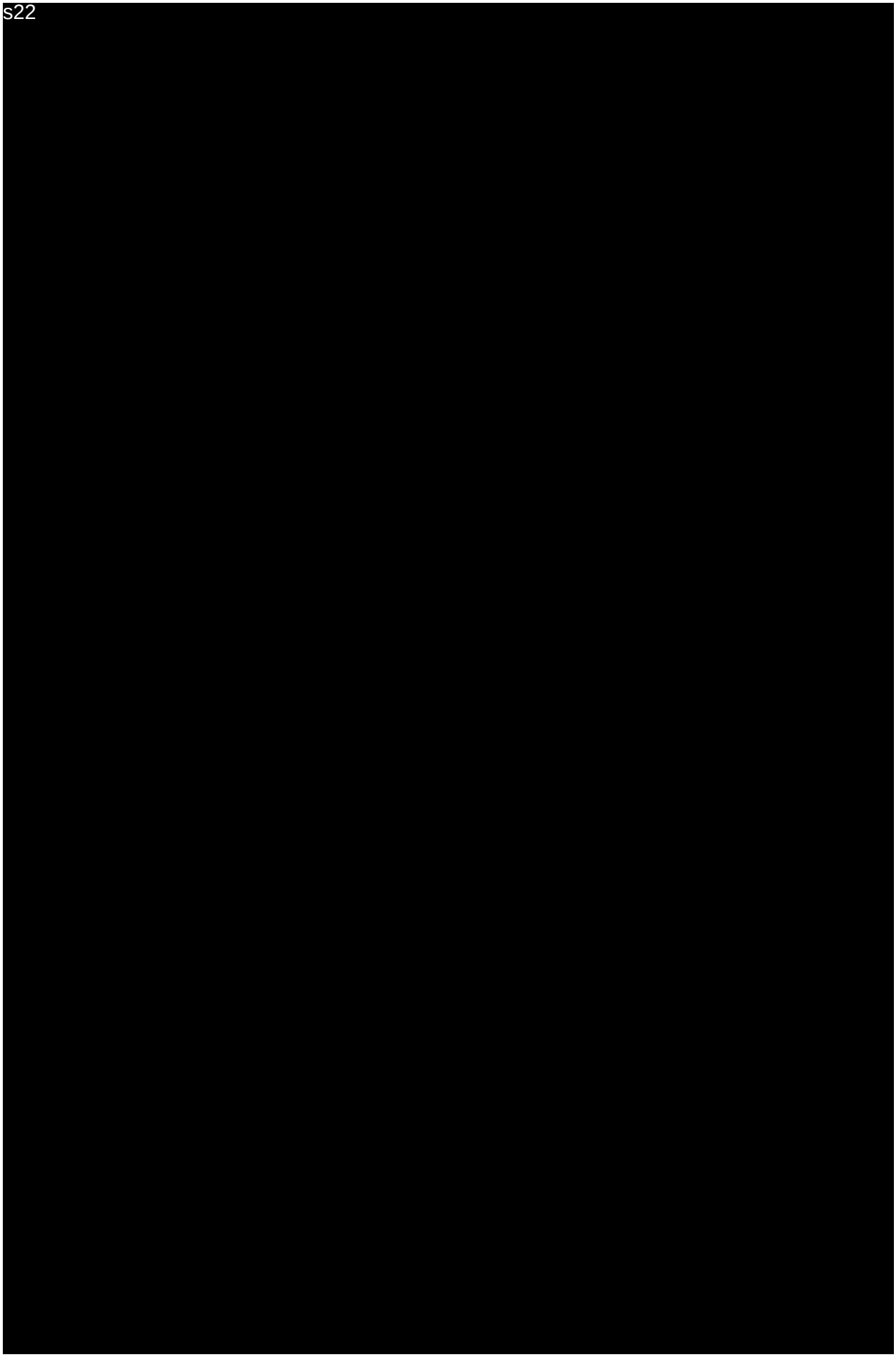
[redacted]

s22

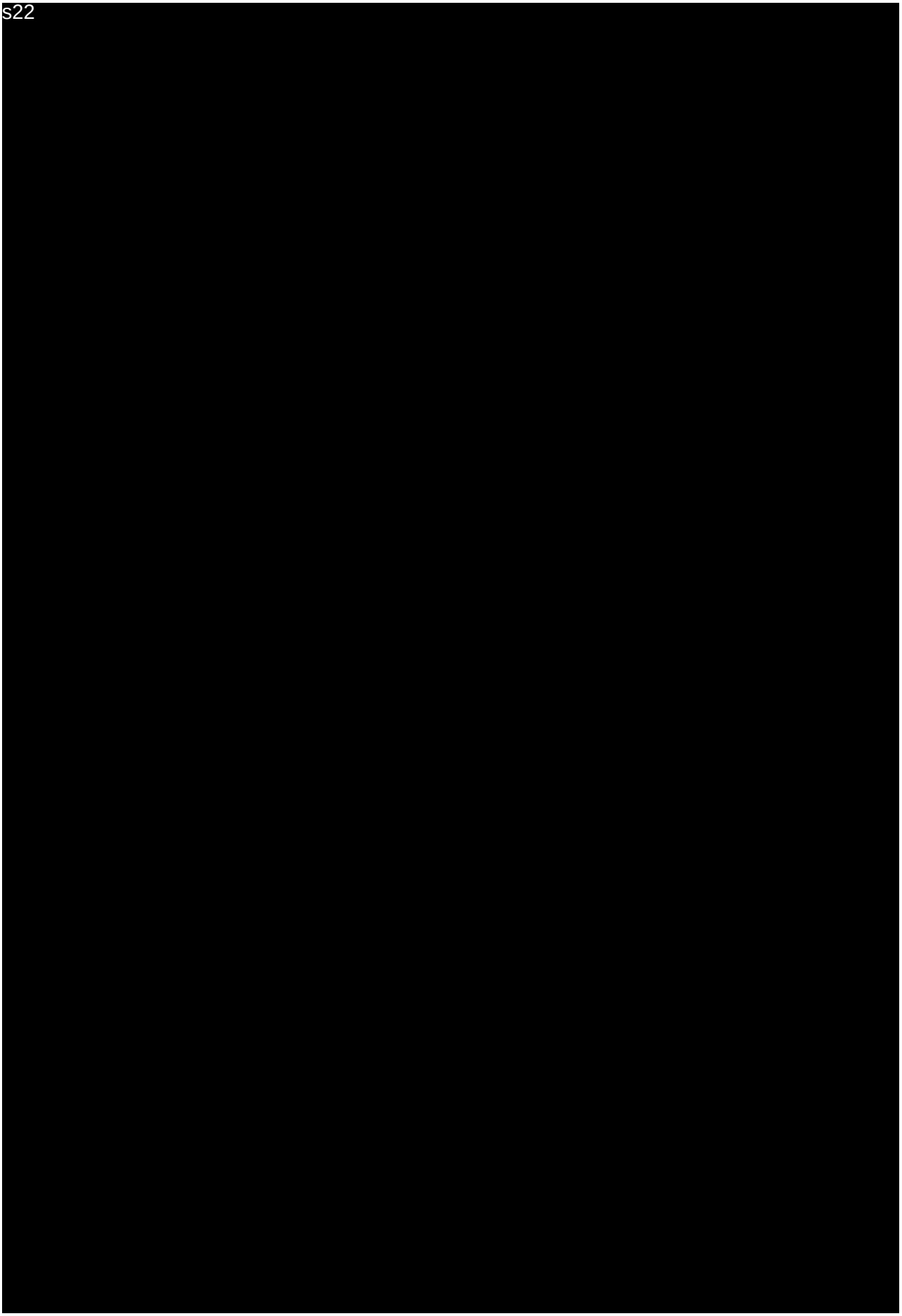
s22



s22



s22



s22

s22

[redacted]

Amended Table item 531 – mRNA vaccines and treatments

Item 12 – Part 4 of Schedule 1AB (table item 531, column headed "Objective(s)")

Table item 531 in Part 4 of Schedule 1AB establishes legislative authority for government spending on the messenger Ribonucleic Acid (mRNA) vaccines and treatments program (the program), which is administered by the department.

Item 12 amends table item 531 by omitting "mRNA products" and substituting "mRNA vaccines and products, including by purchasing mRNA vaccines and products manufactured onshore" in the column headed "Objective(s)". The amendment clarifies the effect of item 531 to establish and maintain the Moderna facility in anticipation of it manufacturing mRNA respiratory vaccines for purchase by the Commonwealth.

In the 2021-22 Budget, the Government agreed to establish an onshore end-to-end, population-scale mRNA manufacturing capability in Australia under a ten-year partnership with Moderna Australia Pty Ltd (Moderna) (the Moderna Partnership). The Moderna Partnership is supported through a Facility Establishment Agreement (FEA) that commenced in March 2022 and will terminate in June 2032.

The Moderna Partnership includes the establishment of a population-scale mRNA respiratory vaccine manufacturing facility and a regional research and development centre for respiratory medicines and tropical diseases in Melbourne, Victoria. The Moderna Partnership also includes financial contribution from the Victorian Government.

The Moderna Partnership will supply mRNA respiratory vaccines and provide Australia with priority access in case of pandemics. The initiative signals the Australian Government's support for onshore advanced technology manufacturing and sovereign capability, a commitment to pandemic readiness, and supporting Australia's world class capabilities to develop and produce the next generation of medical technology.

The construction of the facility is currently underway and expected to be completed by December 2024. Pending successful trials, regulatory approvals by the Therapeutic Goods Administration (TGA) and Health Technology Assessments (HTA), Moderna envisages to manufacture the onshore vaccines in the first half of 2025. The Australian Government will purchase the onshore vaccines outside the National Immunisation Program as per the FEA with Moderna.

The Australian Government funding commitments under the FEA include:

- an Annual Pandemic Preparedness Facility Fee which is the annual fee paid to Moderna for the up keep of the facility and commences on the date that drug manufacturing and fill/finish facilities have TGA approval to commence manufacturing mRNA vaccines; and
- an Annual Minimum Purchase Commitments of COVID-19 vaccines, plus other respiratory vaccines should they be approved by TGA. The Commonwealth's commitment to purchasing minimum number of vaccines for delivery in each financial year.

The final funding amount paid to Moderna will depend on several factors including:

- determining COVID-19 needs based on recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI);
- the number of Moderna mRNA vaccines approved by the TGA;
- the results of undertaking HTA noting the onshore vaccines will not go through the Pharmaceutical Advisory Committee (PBAC) process and therefore will not be listed as designated vaccines on the National Immunisation Program (refer to section 9B of the *National Health Act 1953*); and
- the date by which the TGA will provide their Good Manufacturing Practice (GMP) license for the facility, and approve manufacturing each vaccine at the facility.

Building on the success of breakthrough COVID-19 mRNA vaccines, the Commonwealth recognises that the 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, other respiratory disease vaccines including respiratory syncytial virus (RSV) and Influenza, as well as future pandemics.

In establishing an onshore mRNA manufacturing capability including product fill and finish facilities in Victoria, the Commonwealth's objective is to:

- secure onshore population-scale mRNA vaccine manufacturing capability, supply and resilience to respond to future pandemics and other health emergencies;
- provide priority access to mRNA COVID-19 vaccines and other respiratory vaccines should those vaccines obtain regulatory approval from the TGA;
- 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 establishing 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;
- non-pandemic vaccine supply agreements to procure Australia's requirement for COVID-19 vaccines, RSV, influenza and other mRNA vaccines should those vaccines be developed and approved;
- ongoing pandemic preparedness fees to secure priority access to mRNA pandemic vaccines; and
- pandemic vaccine advance purchase agreements if Moderna identifies and/or develops vaccine candidates for future pandemics.

Moderna is the primary project lead to establish and operate the end-to-end mRNA manufacturing facility. However, the Commonwealth represented by the department is the head agency for the FEA with Moderna and provides the ongoing contract management and supplier engagement. The department will also work closely with the Department of Industry, Science, and Resources (DISR) who provides policy support in relation to the research and development ecosystem and regional hub elements; and the Department of Jobs, Skills, Industry and Regions in Victoria (through mRNA Victoria), who provides support in relation to construction of the facility and development of the regional research and development centre in Victoria.

Funding amount and arrangements, merits review and consultation

Under the FEA between Moderna and Australia for establishing onshore capability to manufacture mRNA products, procurement of vaccines is yet to occur. The procurement will be represented under sub-agreements with Moderna, which upon finalisation will provide greater clarity around the amount of funding allocated to the program.

To ensure confidential commercial information in the agreements between Australia and Moderna is maintained and to ensure that disclosure of financial implications is in line with the final contract terms, it is the intention of the Australian Government to disclose the funding allocated for the program once the agreements are finalised.

The department will procure the goods and services with Moderna in accordance with applicable legislative requirements and the Commonwealth resource management framework under the PGPA Act, the PGPA Rule, the CPRs and the department's Accountable Authority Instructions.

The expenditure will be provided through an approved process, including a procurement process. In this regard, the Secretary of the department (as the relevant Accountable Authority) has made a determination under paragraph 2.6 of the CPRs to disapply Divisions 1 and 2 of the CPRs to the proposed procurement of onshore mRNA manufacturing capability and supply of mRNA vaccines and treatments for both pandemic and non-pandemic purposes and all incidental or related matters (the procurement) on the basis that it is necessary to protect human health. Accordingly, the requirement to publish the details of the proposed procurement on AusTender as set out in the CPRs will not apply. However, the department will be required to table details relating to the proposed procurement, in accordance with the *Senate Procedural Orders of Continuing Effect No. 12* (Production of Indexed Lists of Departmental and Agency Files).

[Finance comment: we include the exemption under Div 1 and 2 of the CPRs here, please check that you are still ok with the description.

Irrespective of the exemption given under paragraph 2.6 of CPRs, 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.

Vaccine purchase decisions will be made following a thorough HTA process, similar to that for the Pharmaceutical Benefits Advisory Committee. The department will make a recommendation on purchases to the Minister for Health and Aged Care, and should agreement be given, the delegate, at the Senior Executive Service (Band 2 level) who has responsibility for the oversight of the procurement will be the final decision maker. Purchase decisions will be exercised in accordance with the PGPA Act, Moderna contract, and department policies.

The department would propose to:

- execute and manage all contracts for the above services for the term of the agreements;
- work collaboratively with DISR 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.

Procurement decisions made in connection with the program 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 ARC 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 ARC guide).

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. The *Government Procurement (Judicial Review) Act 2018* enables suppliers to challenge some procurement processes for alleged breaches of certain procurement rules. This legislation might provide an additional avenue of redress (compensation or injunction) for dissatisfied providers or potential providers, depending on the circumstances.

Furthermore, procurement for onshore mRNA manufacturing is a financial policy decision with a significant public interest element. The program is a response to the COVID-19 pandemic and would enhance sovereign capability and readiness for future pandemics. Arrangements are required to be entered into to uphold public confidence in the health systems and the national vaccination programs.

The ARC has acknowledged that it is justifiable to exclude merits review in relation to decisions of this nature (see paragraph 4.34 of the ARC guide,). While it is acknowledged that reliance on this justification for the exclusion of merits review is rare (see paragraph 4.36 of the ARC guide), the context of a global pandemic is an extremely rare situation.

The project was a joint Taskforce activity between the department, DISR and the Department of Finance. Across 2020 and 2021, the following governing bodies and agencies were consulted during the project phase, up to execution of agreements in March 2022:

- state governments;
- ATAGI;
- TGA;
- PBAC;
- COVID-19 Vaccines and Treatments for Australia – Science and Industry Technical Advisory Group;
- the Department of Foreign Affairs and Trade;
- the Department of the Prime Minister and Cabinet;
- an Expert Advisory Group advising on the Approach to Market process and the Moderna proposal; and
- the Australian Government Solicitor.

DISR lead this process, and broadly the intention to establish an onshore mRNA respiratory vaccine manufacturing capability was met with a consensus to proceed.

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

- state governments;
- DISR;
- TGA;
- ATAGI;
- relevant industries; and
- the biotechnology research sector, particularly with regard to the development of the research and development ecosystem.

Constitutional considerations

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

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

External affairs power

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.

Australia has international obligations under the ICESCR. 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 2 requires each State Party to ‘take steps…to the maximum of its available resources, with a view to achieving progressively the full realisation’ of this right ‘by all appropriate means, including particularly the adoption of legislative measures’.

The steps to be taken by States Parties to achieve full realisation of the right to health are specified in Article 12(2) and include steps necessary for:

(a) The prevention, treatment and control of epidemic, endemic, occupational and other diseases (Article 12(2)(c)); and
(b) The creation of conditions which would assure to all medical service and medical attention in the event of sickness (Article 12(2)(d)).

The Committee on Economic, Social and Cultural Rights has expressed the view these obligations require States parties to, among other matters, 'implement and enhance immunization programmes'.

The program 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 program 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 program 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

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

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

Executive power and express incidental power, including the nationhood aspect

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 program relates to the onshore production of mRNA vaccines and treatments, in order to enhance Australia's immunisation programs. The program 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.

Attachment B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the legislative instrument

Section 32B of the *Financial Framework (Supplementary Powers) Act 1997* (the FFSP Act) authorises the Commonwealth to make, vary and administer arrangements and grants specified in the *Financial Framework (Supplementary Powers) Regulations 1997* (the FFSP Regulations) and to make, vary and administer arrangements and grants for the purposes of programs specified in the Regulations. Schedule 1AA and Schedule 1AB to the FFSP Regulations specify the arrangements, grants and programs. The powers in the FFSP Act to make, vary or administer arrangements or grants may be exercised on behalf of the Commonwealth by Ministers and the accountable authorities of non-corporate Commonwealth entities, as defined under section 12 of the *Public Governance, Performance and Accountability Act 2013*.

The *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024* (the Regulations) amend Schedule 1AB to the FFSP Regulations to establish legislative authority for Government spending on activities administered by the Department of Health and Aged Care (the department).

This disallowable legislative instrument makes the following amendments to Part 4 of Schedule 1AB:

- amends table item 306 ‘Quality Use of Diagnostics, Therapeutics and Pathology Program’;
- amends table item 429 ‘Sport and Recreation Program’; and
- amends table item 531 ‘mRNA vaccines and treatments’.

Amended table item 306 – Quality Use of Diagnostics, Therapeutics and Pathology Program

The amended table item 306 establishes legislative authority for government spending on the Quality Use of Diagnostic, Therapeutics and Pathology (QUDTP) Program to reflect changes to the program design.

The QUDTP Program was established in 1999 and aimed to:

- improve the quality use of therapeutics, diagnostics and pathology for Australian consumers;
- improve the quality use of therapeutics, diagnostics and pathology for Australian health professionals;

- facilitate free access to information to support appropriate use of therapeutics, diagnostics and pathology; and
- support the effectiveness and efficiency of the health system.

The QUDTP Program was redesigned in 2022, with the subsequent arrangements initiating from 1 January 2023. The redesign primarily resulted in the responsibility for delivery of the QUDTP moving from NPS MedicineWise to the department in collaboration with the Australian Commission on Safety and Quality in Health Care (ACSQHC). The QUDTP Program supports the optimal use of medicines and diagnostics and enhances the ACSQHC's ability to co-ordinate and drive quality and safety improvements related to medicine and diagnostic use across the Australian health system.

Under the QUDTP Program, the department will also deliver targeted Quality Use of Medicines educational activities for health professionals and consumers through competitive grants and procurement processes to support the optimal use of therapeutics and diagnostics.

Funding of $22.3 million annually is available for the QUDTP Program.

Human rights implications

The amended table item 306 engages the following right:

- 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.

Right of everyone to the enjoyment of the highest attainable standard of physical and mental health

Article 2 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 realisation of the rights in the ICESCR by all appropriate means, including particularly the adoption of legislative measures.

Article 12(2) of the ICESCR requires that each State Party to the Covenant takes steps to achieve the full realization of the right shall include for:

(a) the provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
(b) the improvement of all aspects of environmental and industrial hygiene;
(c) the prevention, treatment and control of epidemic, endemic, occupational and other diseases;
(d) the creation of conditions which would assure to all medical service and medical attention in the event of sickness.

The QUDTP Program will advance the prevention, treatment and control of health issues and optimise health outcomes for Australians, through supporting health professionals, service providers and consumers with evidenced based education and support resources.

The amended table item 306 is compatible with human rights as the ongoing delivery of the QUDTP Program promotes quality use of medicine create conditions which assure to all medical service and medical attention in the event of sickness.

Amended table item 429 – Sport and Recreation Program

The amended table item 429 establishes legislative authority for government spending for the Sport and Recreation Program (the Program), which include a range of activities undertaken by the department through Program 4.1: Sport and Physical Activity, which is part of Outcome 4.

The Program aims to increase participation in sport and physical activity by all Australians and foster excellence in Australia's high-performance athletes. Further Australia's national interests by supporting the Australian sport sector, showcasing Australia as a premier host of major international sporting events, and developing sport policy and programs.

Table item 429 is amended to support the 2027 Men's Rugby World Cup and 2029 Women's Rugby World Cup (collectively known as the Legacy Program).

The purpose of the Legacy Program is to grow the sport of rugby and maximise health, well-being and social outcomes across Australia and the Pacific region. It is proposed to include activities involving club development, infrastructure, equipment and workforce support, developing states and territories, national programs, school competitions, women and girls' participation, and inclusion programs.

Funding of $90.0 million over five years from 2024-25 will be available for the Legacy Program.

Human rights implications

The amended table item 429 engages the following rights:

- the right to enjoy and benefit from culture – Articles 12 and 15 of the ICESCR, read with Article 2;
- the right of persons with disabilities to participate on an equal basis in cultural life, creation, leisure and sport – Article 30 of the Convention on the Rights of Persons with Disability (CRPD), read with Article 4;
- the right of women to the exercise and enjoyment of human rights and fundamental freedoms, in particular in the political, social, economic and cultural fields – Article 10 of the *Convention on the Elimination of All Forms of Discrimination against Women* (CEDAW), read with Article 2; and
- the rights of every child to engage freely in cultural life and the arts, as well as playing and recreational activities appropriate to his or her age – Articles 24 and 31 of the *Convention on the Rights of the Child* (CRC), read with Article 4.

Right to enjoy and benefit from culture

Article 2(2) of the ICESCR recognises the right to culture be exercised without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status. According to the United Nations Committee on Economic, Social and Cultural Rights, the right to culture includes sports and games.

Article 12(1) recognises the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. Sport and physical activity play an important role in both physical and mental wellbeing.

Article 15(1)(a) of the ICESCR recognises the right of everyone to take part in cultural life. According to the United Nations Committee on Economic, Social and Cultural Rights, the right to culture includes sports and games. This right encompasses access to culture, which includes the availability of mainstream sporting activities at all levels and sporting events hosted in Australia, in which everyone can participate.

Rights of persons with disabilities

Article 4 of the CPRD obliges each State Party to ensure and promote the full realisation of all human rights and fundamental freedoms for all persons with disabilities without discrimination of any kind on the basis of disability. This right includes elimination of discrimination in the field of employment, which includes occupations in the sport and physical activity sector.

Article 30 of the CPRD recognises the right of persons with disabilities to participate on an equal basis with others in cultural life, recreation, leisure and sport. This right encompasses the encouragement and promotion of participation, to the fullest extent possible, of persons with disabilities in mainstream sporting activities at all levels. It also encompasses access to sport, which includes the availability of sporting events (including those specifically for persons with disabilities) hosted in Australia.

Rights of women

Article 2 of the CEDAW condemns the discrimination of women in all its forms.

Article 10 of the CEDAW recognises the right of women to the same opportunities to participate in education as men. This right encompasses the encouragement and promotion of participation, to the fullest extent possible, of women in sport and physical activity education at all levels.

Rights of the child

Article 4 of the CRC obliges each State Party to undertake measures regarding economic, social and cultural rights of children to the maximum extent of their available resources. According to the United Nations Committee on Economic, Social and Cultural Rights, the right to culture includes sports and games.

Article 24 of the CRC obliges each State Party to ensure the rights of children to the highest attainable standard of health. This includes measures to combat disease and malnutrition, provide access to health education and develop preventive health care. Sport and physical activity have recognised physical and mental health benefits, and can aid in the prevention of an array of diseases.

Article 31(1) of the CRC recognises the right of every child to rest and leisure and to engage freely in cultural life and the arts, as well as playing and recreational activities appropriate to

his or her age. This right encompasses the encouragement and promotion of participation, to the fullest extent possible, of children in mainstream sporting activities at all levels.

The amended table item 429 is compatible with human rights because the item will promote and protect human rights through the outcomes achieved to enhance sport and physical activity from the delivery of the Legacy Program.

Amended table item 531 – mRNA vaccines and treatments

The amended table item 531 establishes legislative authority for government spending on the messenger Ribonucleic Acid (mRNA) vaccines and treatments program (the program) to clarify the effect of item 531 to establish and maintain the Moderna facility in anticipation of it manufacturing mRNA respiratory vaccines for purchase by the Commonwealth.

In the 2021-22 Budget, the Government agreed to establish an onshore end-to-end, population-scale mRNA manufacturing capability in Australia and a regional research and development centre for respiratory medicines and tropical diseases in Melbourne, Victoria under a ten-year partnership with Moderna Australia Pty Ltd (Moderna) (the Moderna Partnership). The Moderna Partnership is supported through a Facility Establishment Agreement (FEA) that commenced in March 2022 and will terminate in June 2032.

The Moderna Partnership will supply mRNA respiratory vaccines and provide Australia with priority access in case of pandemics. The initiative signals the Australian Government's support for onshore advanced technology manufacturing and sovereign capability, a commitment to pandemic readiness, and supporting Australia's world class capabilities to develop and produce the next generation of medical technology.

The Australian Government funding commitments under the FEA include:

- an Annual Pandemic Preparedness Facility Fee which is the annual fee paid to Moderna for the up keep of the facility and commences on the date that drug manufacturing and fill/finish facilities have Therapeutic Goods Administration approval to commence manufacturing mRNA vaccines; and
- an Annual Minimum Purchase Commitments of COVID-19 vaccines, plus other respiratory vaccines should they be approved by TGA. The Commonwealth's commitment to purchasing minimum number of vaccines for delivery in each financial year.

Human rights implications

The amended table item 531 engages the following right:

- the right of everyone to the enjoyment of the highest attainable standard of physical and mental health – Article 12 of ICESCR, read with Article 2.

Right of everyone to the enjoyment of the highest attainable standard of physical and mental health

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 program 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 program 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, the amended table item 531 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

This disallowable legislative instrument is compatible with human rights because it promotes the protection of human rights.

Senator the Hon Katy Gallagher
Minister for Finance

s42

[redacted]

s42

s42

[redacted]

s42

[redacted]

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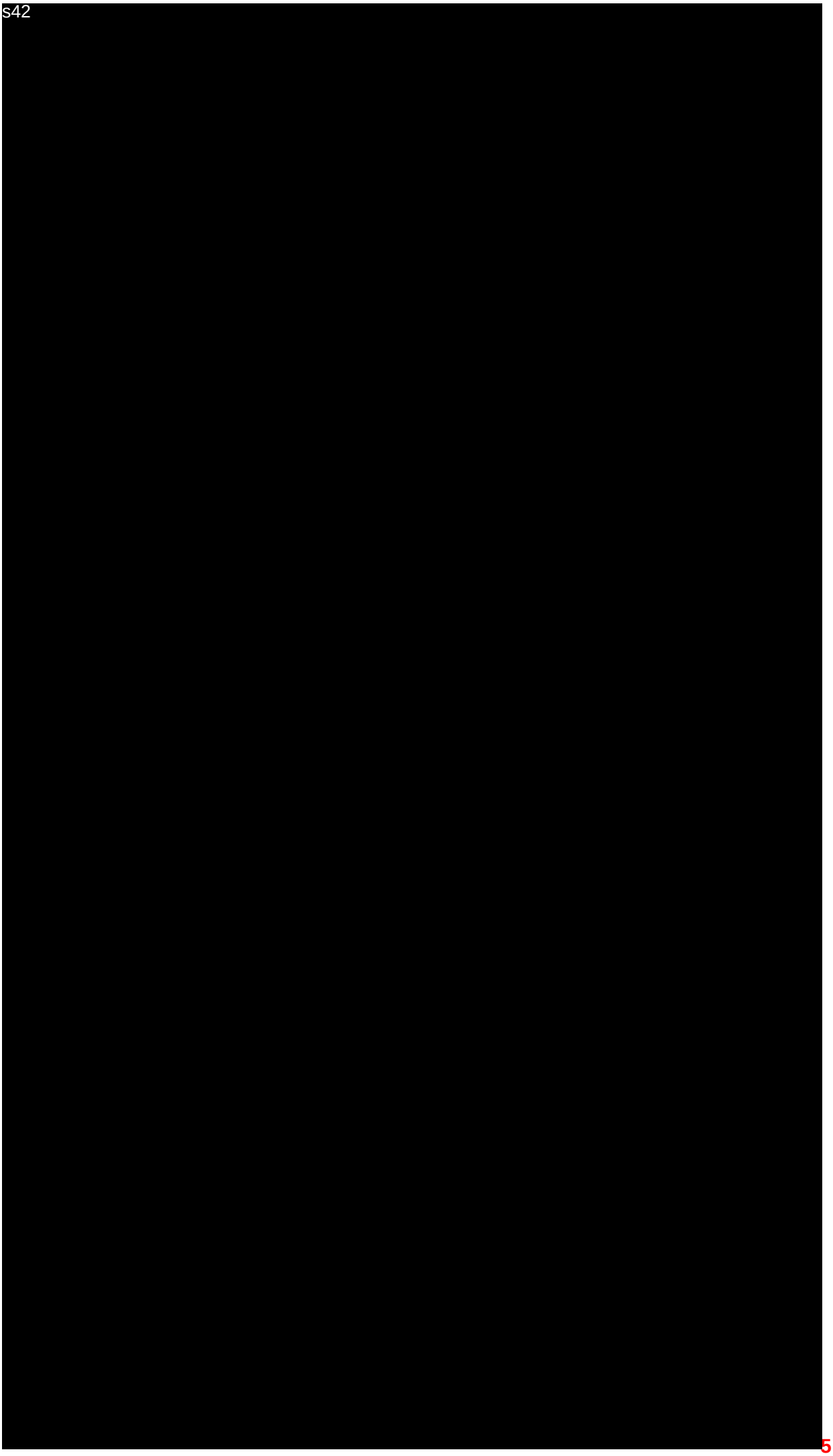

From: Financial Framework (Supplementary Powers) Regulations
To: s22
Subject: FW: Incoming Corro - Butler to Gallagher - Seeking agreement to amend Schedule 1AB of the Financial Framework (Supplementary Powers) Regulation 1997 - Messenger Ribonucleic Acid (mRNA) [SEC=PROTECTED, CAVEAT=SH:CABINET]
Date: Tuesday, 10 September 2024 9:23:02 AM
Attachments: MS24-900343 - Letter from Minister Butler to Minister Gallagher.pdf
Attachment to the letter to the Minister for Finance (mRNA vaccines program).pdf
image002.jpg
image003.jpg
image004.jpg

From: DLO - Finance <DLOFinance@finance.gov.au>
Sent: Tuesday, September 10, 2024 9:22:42 AM (UTC+10:00) Canberra, Melbourne, Sydney
To: PDMS <PDMS@finance.gov.au>
Cc: s22 @finance.gov.au>; s22 @finance.gov.au>; GRM - EXEC TEAM <GRM-ExecTeam@finance.gov.au>; FARM Exec <FARMexec@finance.gov.au>; Tran, Chi <Chi.Tran@finance.gov.au>; s22 @finance.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Subject: Incoming Corro - Butler to Gallagher - Seeking agreement to amend Schedule 1AB of the Financial Framework (Supplementary Powers) Regulation 1997 - Messenger Ribonucleic Acid (mRNA) [SEC=PROTECTED, CAVEAT=SH:CABINET]

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Ministerial correspondence form

Subject	Butler to Gallagher - Seeking agreement to amend Schedule 1AB of the Financial Framework (Supplementary Powers) Regulation 1997 - Messenger Ribonucleic Acid (mRNA)	
Division/Agency responsible	G&RM - Financial Analysis Reporting & Management	
Associated Division/Agency 1	Choose an item.	
Associated Division/Agency 2	Choose an item.	
Date received in Minister's Office 10/09/2024	**Action (Reply type):** For appropriate action	**Timeframe** 20 Days
Comments (instructions for PLC) Click or tap here to enter text. **Processing Instructions (to be provided to line area)** Click or tap here to enter text.		

Ministerial Submission = submission drafted by department for Ministerial approval
Reply by Minister = response drafted by Department, provide to the Minister for signature
Reply by Department = response drafted by Department and sent to initiator by line area
Appropriate Action = Department/Agency to determine action required
For information – no reply necessary = for noting purposes only before closing
If drafting officer has been copied into the email form – it is for early visibility

s22 | Departmental Liaison Officer
Office of Senator the Hon Katy Gallagher
Minister for Finance | Minister for Women | Minister for the Public Service
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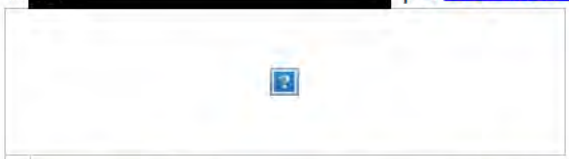


Please consider the environment before printing this email

The Hon Mark Butler MP
Minister for Health and Aged Care

Ref No: MS24-900343

Senator the Hon Katy Gallagher
Minister for Finance
Parliament House
CANBERRA ACT 2600

Dear Minister Katy

Request to amend item 531 in Part 4 of Schedule 1AB to the *Financial Framework (Supplementary Powers) Regulation 1997*

I am writing to seek your agreement to amend item 531 in Part 4 of Schedule 1AB to the *Financial Framework (Supplementary Powers) Regulations 1997* (the FF(SP) Regulations), which establishes legislative authority for government spending on the messenger Ribonucleic Acid (mRNA) vaccines program. This Schedule 1AB amendment is proposed for consideration by the Governor-General at the next Federal Executive Council meeting scheduled for 24 October 2024.

The initial wording for item 531 gave effect to establish and maintain the Moderna Australia Pty Ltd (Moderna) facility in anticipation of it manufacturing mRNA respiratory vaccines for purchase by the Commonwealth. s42 [redacted]

[redacted]

Summary of the proposed Commonwealth expenditure
In March 2022, the Australian Government executed a 10 year agreement with Moderna to establish a population-scale mRNA respiratory vaccine manufacturing facility and a regional research and development centre for respiratory medicines and tropical diseases in Melbourne, Victoria.

The Moderna Partnership includes a contribution from the Victorian Government. The Moderna Partnership will supply mRNA respiratory vaccines and provide Australia with priority access in case of pandemics. This initiative signals the Australian Government's support for onshore advanced technology manufacturing and sovereign capability, a commitment to pandemic readiness, and supporting Australia's world class capabilities to develop and produce the next generation of medical technology.

Moderna is the primary project lead to establish and operate the end-to-end mRNA manufacturing facility. However, the Commonwealth of Australia represented by the DHAC, the Department of Industry, Science and Research and the Victorian Government (mRNA Victoria) have enabling roles, including the provision of funds towards the infrastructure build (via mRNA Victoria) and ongoing operational costs and purchase of the vaccines (via the DHAC).

Currently, the construction of the facility is underway and the facility is expected to be completed by December 2024. Pending successful trials, regulatory approvals by the Therapeutic Goods Administration (TGA) and Health Technology Assessments, Moderna envisages to manufacture the onshore vaccines in the first half of 2025. The purchase of the onshore vaccines will occur outside the National Immunisation Program as per the Facility Establishment Agreement (Agreement) with Moderna.

Policy authority

s34(3) [redacted]

Funding information

The Australian Government funding under the Agreement includes financial commitments for an:

a) Annual Pandemic Preparedness Facility Fee (PPFF) which is the annual fee paid to Moderna for the up keep of the facility and commences on the date that drug manufacturing and fill/finish facilities have TGA approval to commence manufacturing mRNA vaccines; and
b) Annual Minimum Purchase Commitments of COVID-19 vaccines, plus other respiratory vaccines should they be approved by TGA. The Commonwealth's commitment to purchasing minimum number of vaccines for delivery in each financial year.

The Victorian Government will make a financial contribution towards the Annual PPFF.

s45, s47, s47D [redacted]

s45, s47, s47D

[redacted]

s42

[redacted]

To assist your department with progressing the proposed Schedule 1AB amendment and preparing explanatory materials, I have enclosed additional information about the program at **Attachment A**.

Yours sincerely

Mark Butler

09 / 09 / 2024

Encl (1) Attachment A - mRNA vaccines program

Attachment A

Attachment to the letter to the Minister for Finance (mRNA vaccines program)

Description of the proposed mRNA vaccines program

The 10 year Moderna Partnership is supported through a Facility Establishment Agreement with Moderna that commenced in March 2022 and will terminate in June 2032. The funding amount paid to Moderna will depend on several factors including:

- Determining COVID-19 needs based on recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI);
- The number of Moderna mRNA vaccines approved by the Australian Therapeutic Goods Administration (TGA);
- The results of undertaking Health Technology Assessment (HTA) noting the onshore vaccines will not go through the Pharmaceutical Advisory Committee (PBAC) process and therefore will not be listed as designated vaccines on the National Immunisation Program (refer to section 9B of the *National Health Act 1953*); and
- The date by which the TGA will provide their Good Manufacturing Practice (GMP) license for the facility, and approve manufacturing each vaccine at the facility.

Building on the success of breakthrough COVID-19 mRNA vaccines, the Commonwealth recognises that the 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, other respiratory disease vaccines including respiratory syncytial virus (RSV) and Influenza, as well as future pandemics.

In establishing an onshore mRNA manufacturing capability including product fill and finish facilities in Victoria, the Commonwealth's objective is to:

- Secure onshore population-scale mRNA vaccine manufacturing capability, supply and resilience to respond to future pandemics and other health emergencies;
- Provide priority access to mRNA COVID-19 vaccines and other respiratory vaccines should those vaccines obtain regulatory approval from the TGA;
- 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 establishing 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;
- Non-pandemic vaccine supply agreements to procure Australia's requirement for COVID-19 vaccines, RSV, influenza and other mRNA vaccines should those vaccines be developed and approved;
- Ongoing pandemic preparedness fees to secure priority access to mRNA pandemic vaccines; and
- Pandemic vaccine advance purchase agreements if Moderna identifies and/or develops vaccine candidates for future pandemics.

The Department of Health and Aged Care (DHAC) is the head agency for a Facility Establishment Agreement with Moderna and provides the ongoing contract management and supplier engagement. The DHAC will also work closely with:

- the Department of Industry, Science, and Resources (DISR) who provides policy support in relation to the research and development ecosystem and regional hub elements; and
- the Department of Jobs, Skills, Industry and Regions in Victoria (through mRNA Victoria) who provides support in relation to construction of the facility and development of the regional research and development centre in Victoria.

Background

- 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 was identified as a priority growth opportunity in the *Medical Products National Manufacturing Priority road map*, published by the DISR in February 2021, refer to Medical Products National Manufacturing Priority road map (https://www.mtaa.org.au/news/medical-products-national-manufacturing-priority-road-map).
- During the COVID-19 pandemic, there were some 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 equip Australia to deal with any new challenges for 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.
- 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 DISR to work with the DHAC to develop an onshore mRNA vaccine manufacturing capability in Australia, refer to Budget Paper No. 2, page 134.

s42

[redacted]

Statement of the relevance and operation of constitutional heads of power

External affairs power (s 51(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.

Australia has international obligations under the *International Covenant on Economic, Social and Cultural Rights* (ICESCR). 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 2 requires each State Party to 'take steps…to the maximum of its available resources, with a view to achieving progressively the full realisation' of this right 'by all appropriate means, including particularly the adoption of legislative measures'.

The steps to be taken by State Parties to achieve full realisation of the right to health are specified in Article 12(2) and include steps necessary for:

a) The prevention, treatment and control of epidemic, endemic, occupational and other diseases (Article 12(2)(c)); and
b) The creation of conditions which would assure to all medical service and medical attention in the event of sickness (Article 12(2)(d)).

The Committee on Economic, Social and Cultural Rights has expressed the view these obligations require State parties to, among other matters, 'implement and enhance immunization programmes'.

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

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

The proposed measure relates to the provision of pharmaceutical benefits and the manufacturing of vaccines and treatments in order to prevent and treat diseases and medical conditions using mRNA technology.

Executive power and express incidental power, including the nationhood aspect

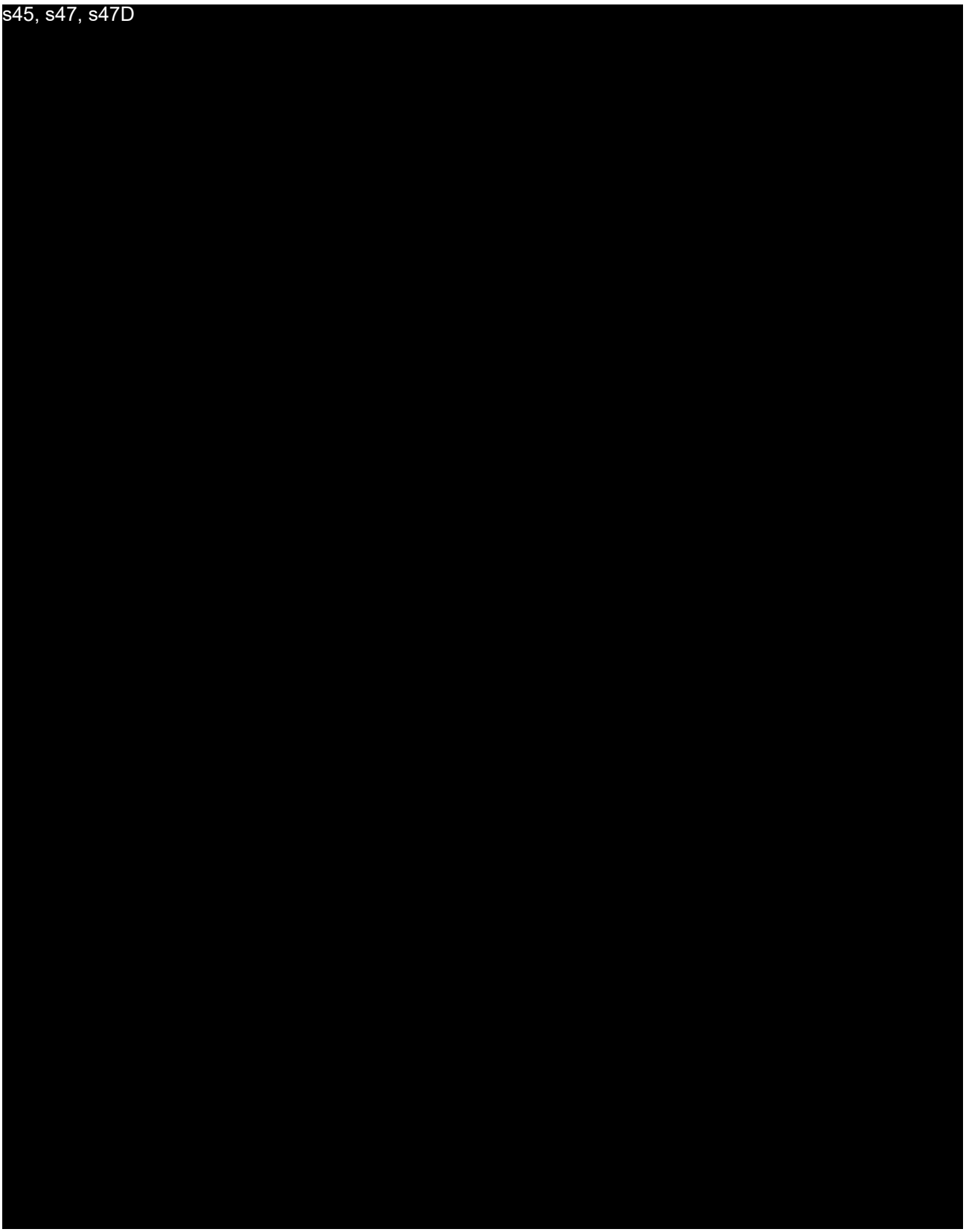
The express incidental power in section 51(xxxix) of the Constitution empowers the Parliament to make laws with respect to matters incidental to the execution of any power vested in the Parliament, the executive or the courts by the Constitution. Section 61 of the Constitution supports activities that 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 proposed measure 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.

Proposed Commonwealth expenditure

When specific conditions are met, the Australian Government will pay the following fees to Moderna. The amounts here under are not for further disclosure as they are commercial in confidence. The amounts here under are provided to the Minister for Finance and the Department of Finance by way of an update and are not for further disclosure as they are commercial in confidence.

s45, s47, s47D



s45, s47, s47D [redacted]

Decisions about Commonwealth expenditure

The DHAC will provide the above mentioned funding to deliver the mRNA manufacturing capability and the purchased vaccines, 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* and the DHAC's Accountable Authority Instructions.

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.

s34(3) [redacted] with the associated financial commitment for the relevant agreements approved by the Secretary of the Department (as the Accountable Authority of the DHAC) or the appropriate delegate.

Vaccine purchase decisions will be made following a thorough Health Technology Assessment process, similar to that for the Pharmaceutical Benefits Advisory Committee. The DHAC will make a recommendation on purchases to the Minister of Health and Aged Care. Subject to agreement, delegation of the decision would be at the SES Band 2 level. Purchase decisions will be exercised in accordance with the PGPA Act, Moderna contract, and the DHAC's policies.

The DHAC propose to:

- Execute and manage all contracts for the above services for the term of the agreements;
- Work collaboratively with DISR 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. The *Government Procurement (Judicial Review) Act 2018* enables suppliers to challenge some procurement processes for alleged breaches of certain procurement rules. This legislation might provide an additional avenue of redress (compensation or injunction) for dissatisfied providers or potential providers, depending on the circumstances.

Furthermore, procurement for onshore mRNA manufacturing is a financial policy decision with a significant public interest element. The proposed measure is a response to the COVID-19 pandemic and would enhance sovereign capability and readiness for future pandemics. Arrangements are required to be entered into 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 DHAC, DISR 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;
- ATAGI;
- TGA;
- PBAC;

- COVID-19 Vaccines and Treatments for Australia – Science and Industry Technical Advisory Group;
- The Department of Foreign Affairs and Trade;
- The Department of the Prime Minister and Cabinet;
- An Expert Advisory Group advising on the Approach to Market process and the Moderna proposal; and
- AGS.

DISR lead this process, and broadly the intention to establish an onshore mRNA respiratory vaccine manufacturing capability was met with a consensus to proceed.

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

- State Governments;
- DISR;
- 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 proposed amendment to item 531 in Part 4 of Schedule 1AB to the FF(SP) Regulations 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 amendment would allow purchase of vaccines from Australia's onshore mRNA manufacturing and assist in maintaining the facility. 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.

The proposed amendment is compatible with human rights as it promotes the protection of human rights.

From:	Financial Framework (Supplementary Powers) Regulations
To:	s22
Subject:	FW: 371: Draft papers: Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024 - 24 Oct Exco [SEC=UNOFFICIAL]
Date:	Tuesday, 17 September 2024 5:18:46 PM
Attachments:	I24AE104.v06.docx Draft EM - Health No. 4 (Exco consults) - 16 Sept 24.docx Exco minute - Health No. 4.docx

From: Exco <Exco@pmc.gov.au>
Sent: Tuesday, September 17, 2024 5:15:45 PM (UTC+10:00) Canberra, Melbourne, Sydney
To: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>; Exco <Exco@pmc.gov.au>
Subject: RE: 371: Draft papers: Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024 - 24 Oct Exco [SEC=UNOFFICIAL]

OFFICIAL: Sensitive
Legal privilege

Dear s22

Attached are some minor formatting edits to the EM. Your departmental number is 371. Please consider these papers cleared for signature.

Kind regards

s22

s22 | Director
Legal Information Integrity | Cabinet Division
Department of the Prime Minister and Cabinet
p. s22
Ngunnawal Country, One National Circuit Barton ACT 2600 PO Box 6500 CANBERRA ACT 2600
e s22 @pmc.gov.au w: www.pmc.gov.au

From: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Sent: Monday, 16 September 2024 3:33 PM
To: Exco <Exco@pmc.gov.au>
Cc: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Subject: 371: Draft papers: Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024 - 24 Oct Exco [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

OFFICIAL:Sensitive
Legal Privilege

Hi Exco team,

Please find attached draft papers relating to the *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024* for your review. We don't anticipate any further changes to the instrument, which is proposed for consideration at the 24 October 2024 Exco meeting.

Grateful for your comments on the papers by Thursday, 19 September 2024.

Below is a summary on the status of the proposed measures for your reference.

Instrument	**Minute Number**	**Status**
s22 [redacted]		
Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024	371	Provided with this email
s22 [redacted]		

Please let me know if you have any questions.

With thanks,
s22 [redacted]

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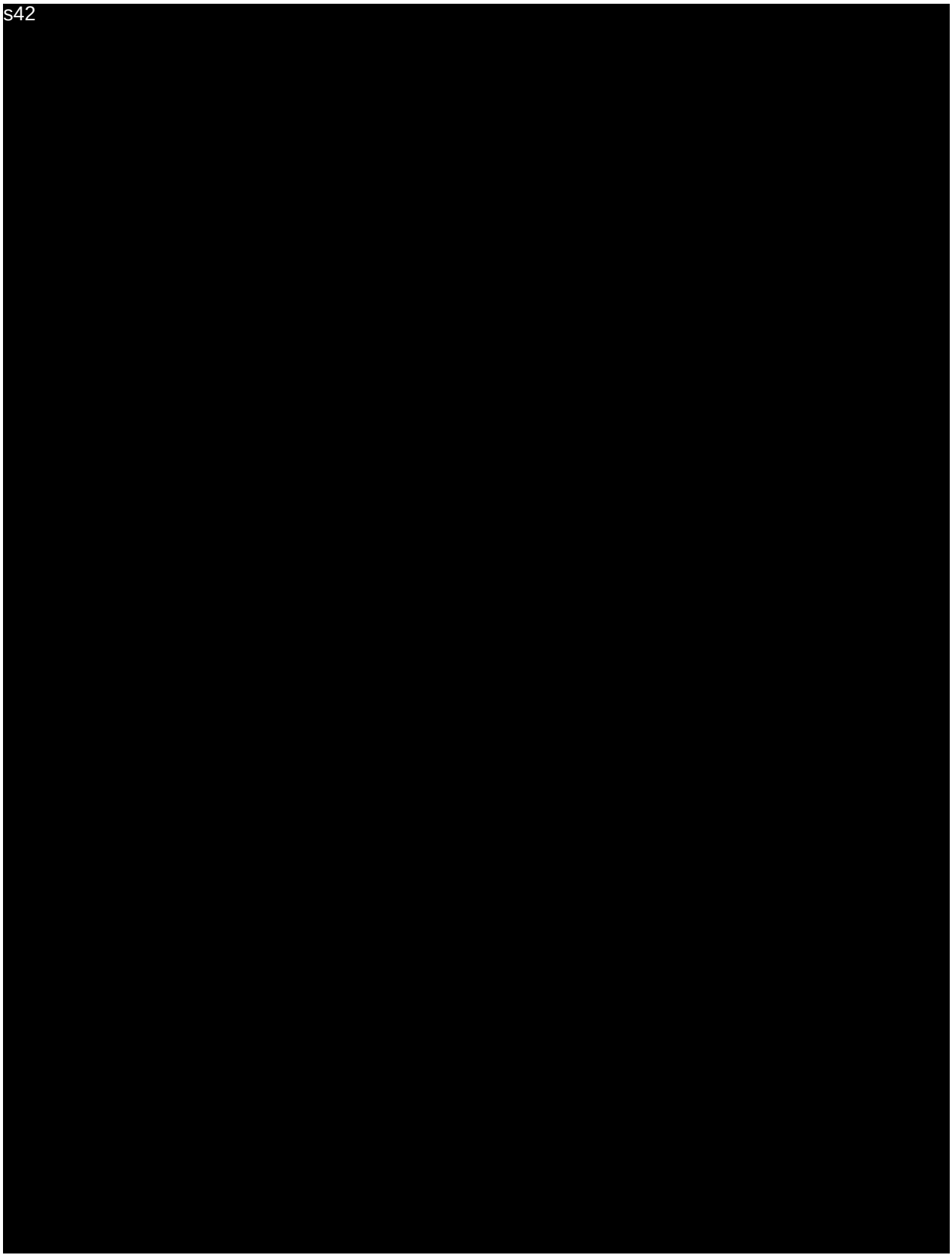
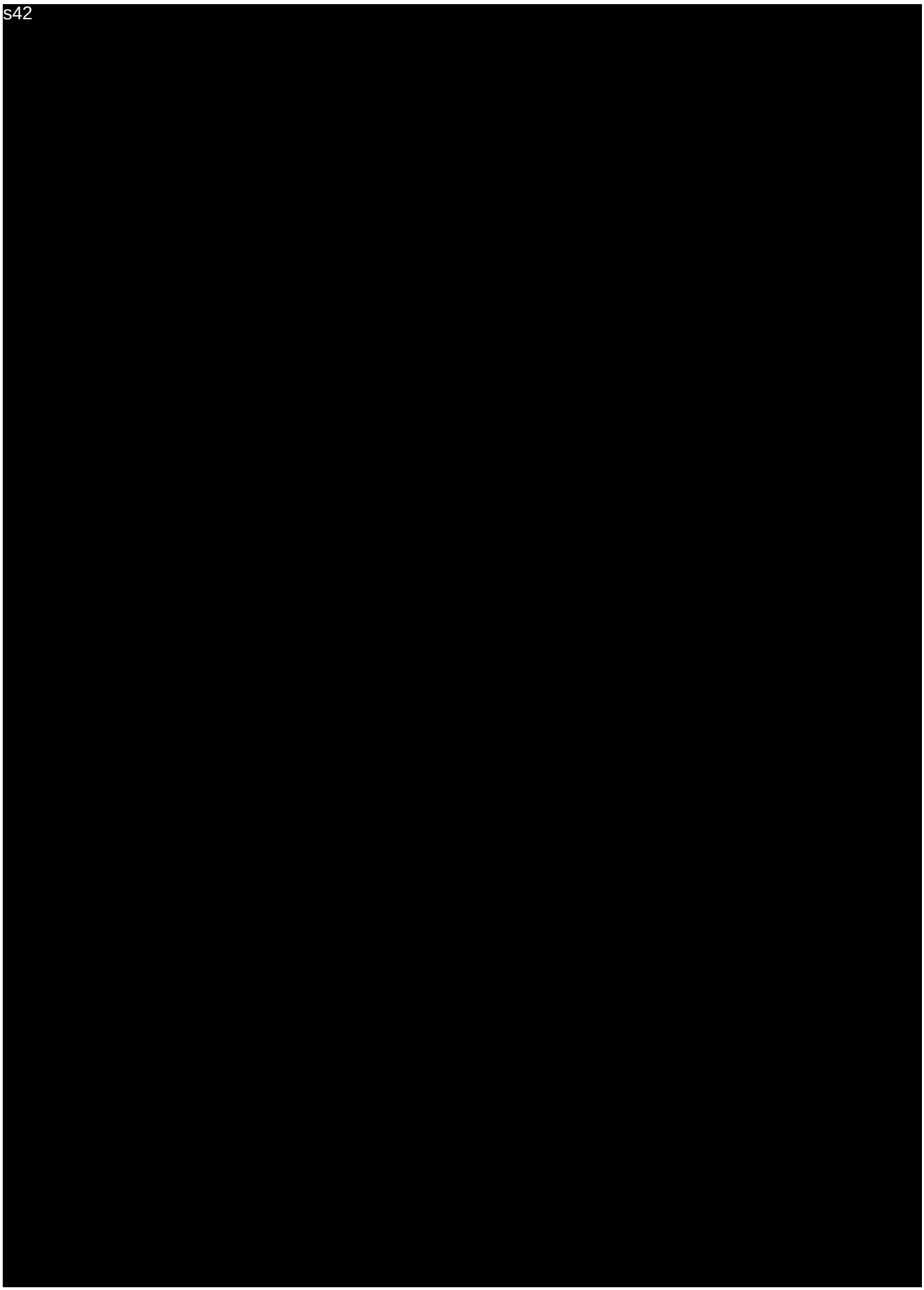
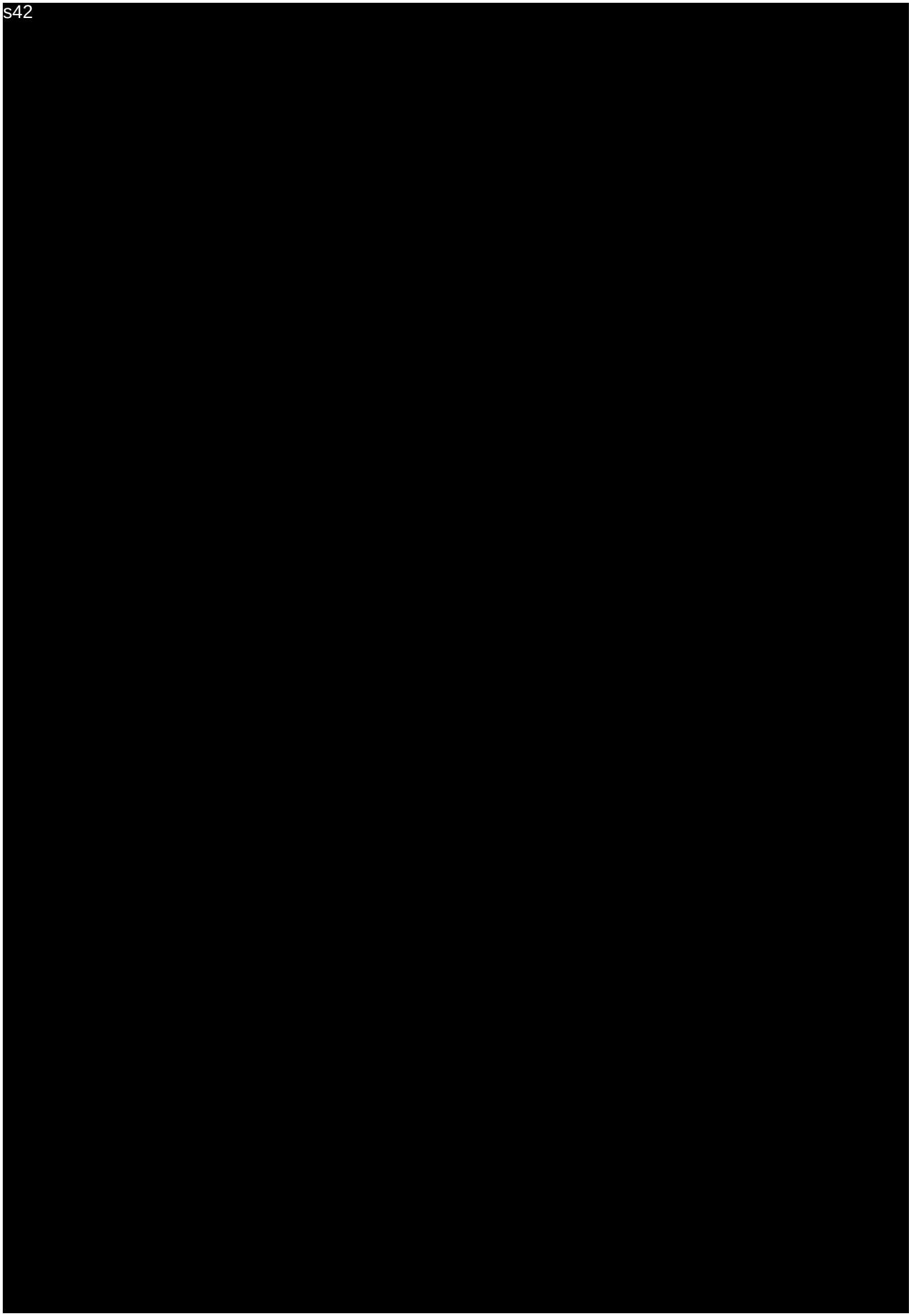
s42

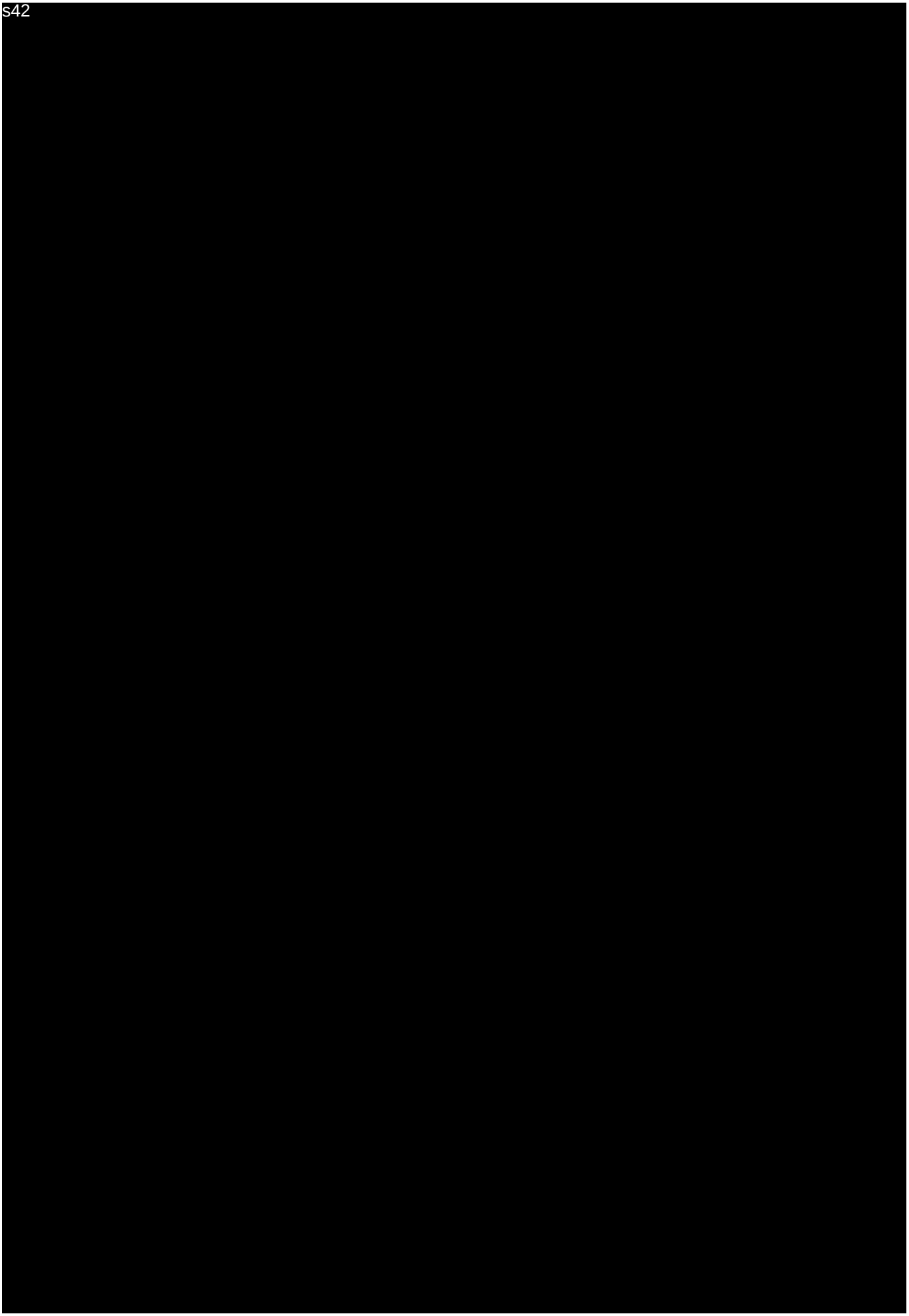


s42





s42



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[redacted]

EXPLANATORY MEMORANDUM

Minute No. 371 of 2024 – Minister for Finance

Subject - *Financial Framework (Supplementary Powers) Act 1997*

Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024

The purpose of this instrument is to provide legislative authority for the expenditure of Commonwealth funds.

The *Financial Framework (Supplementary Powers) Act 1997* (the Act) confers on the Commonwealth, in certain circumstances, powers to make arrangements under which money can be spent; or to make grants of financial assistance; and to form, or otherwise be involved in, companies. The Act applies to Ministers and the accountable authorities of non-corporate Commonwealth entities, as defined under section 12 of the *Public Governance, Performance and Accountability Act 2013*.

Section 65 of the Act provides that the Governor-General may make regulations prescribing matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Section 32B of the Act authorises the Commonwealth to make, vary and administer arrangements, programs and grants of financial assistance specified in the *Financial Framework (Supplementary Powers) Regulations 1997* (the Principal Regulations). Schedules 1AA and 1AB to the Principal Regulations specify the arrangements, grants and programs. The overall effect of section 32B is to provide legislative authority for Commonwealth expenditure on the arrangements, programs and grants specified in the Principal Regulations. This includes providing legislative authority for the Commonwealth to be able to enter into contracts or other arrangements for the specified programs and grants.

The *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024* (the proposed Regulations) would amend Schedule 1AB to the Principal Regulations to establish legislative authority for government spending on activities administered by the Department of Health and Aged Care.

Existing funding is allocated for the:

- Quality Use of Diagnostics Therapeutic and Pathology Program to improve the way in which health technologies, medicines and medical tests are prescribed and used (up to $34.4 million per year from 2024-25);
- Sport and Recreation Program to support activities directed at Australia hosting major international sporting events; promote access to, and participation in, sporting or recreation activities; and support the achievement of excellence in Australia's representative athletes ($30.0 million over six years from 2024-25 was provided to support the Legacy programs for Domestic and Pacific for Rugby World Cup events in 2027 and 2029); and
- messenger Ribonucleic Acid (mRNA) vaccines and treatments program to develop and maintain Australia's onshore capability to manufacture mRNA vaccines and products,

including by purchasing mRNA vaccines and products manufactured onshore (financial implications for this element are not for publication due to commercial-in-confidence sensitivities. It is the intention of the Australian Government to disclose the funding allocated for the program once the agreements are finalised).

In accordance with section 17 of the *Legislation Act 2003*, consultation has taken place with the department responsible for administering the spending activities. Details of the proposed Regulations and consultation undertaken with key stakeholders within the affected industry during their development are set out in the Attachment.

The Act specifies no conditions that need to be satisfied before the power to make the proposed Regulations may be exercised.

The proposed Regulations would be a legislative instrument for the purposes of the *Legislation Act 2003.*

The proposed Regulations would commence on the day after registration on the Federal Register of Legislation.

The Minute recommends that Regulations be made in the form proposed.

Authority: Section 65 of the *Financial Framework (Supplementary Powers) Act 1997*

ATTACHMENT

Details of the proposed *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024*

Section 1 – Name

This section would provide that the title of the Regulations would be the *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024.*

Section 2 – Commencement

This section would provide that the Regulations would commence on the day after registration on the Federal Register of Legislation.

Section 3 – Authority

This section would provide that the Regulations would be made under the *Financial Framework (Supplementary Powers) Act 1997*.

Section 4 – Schedules

This section would provide that the *Financial Framework (Supplementary Powers) Regulations 1997* would be amended as set out in the Schedule to the Regulations.

Schedule 1 – Amendments

Financial Framework (Supplementary Powers) Regulations 1997

The Regulations would amend three table items in Part 4 of Schedule 1AB to the Principal Regulations to establish legislative authority for government spending on activities to be administered by the Department of Health and Aged Care (the department).

Amended Table item 306 – Quality Use of Diagnostic, Therapeutics and Pathology Program

Item [1] – Part 4 of Schedule 1AB (table item 306, column headed "Objective(s)")

Table item 306 in Part 4 of Schedule 1AB establishes legislative authority for government spending on the Quality Use of Diagnostic, Therapeutics and Pathology (QUDTP) Program.

Item 1 would amend table item 306 by omitting "to NPS Medicine Wise" in the column headed "Objective(s)". The amendment would reflect the QUDTP Program redesigned which resulted in the transfer of responsibility for delivery of the QUDTP from NPS MedicineWise to the department.

Item [2] – Part 4 of Schedule 1AB (table item 306, column headed "Objective(s)", after paragraph (d))

Item 2 would amend table item 306 by inserting "; and (e) to provide education and awareness activities, events, conferences and symposiums on the safe and appropriate use of

medicines." in the column headed "Objective(s)" after paragraph (d). The amendment would reflect the expanded responsibility of the department to deliver targeted Quality Use of Medicines educational activities to health professions and consumers.

Item [3] – Part 4 of Schedule 1AB (table item 306, column headed "Objective(s)")

Item 3 would amend table item 306 by omitting the word "also" in the column headed "Objective(s)". The effect of this technical amendment to the operational provision would be to align table item 306 with the current approach to referring to constitutional heads of power in table items in Schedule 1AB.

Item [4] – Part 4 of Schedule 1AB (table item 306, column headed "Objective(s)", paragraph (a) (second occurring))

Item 4 would amend table item 306 by repealing and substituting paragraph "(a) for the provision of, or incidental to the provision of, pharmaceutical benefits, sickness benefits or medical services (within the meaning of paragraph 51(xxiiiA) of the Constitution); or" in the column headed "Objective(s)" at paragraph (a) (second occurring). The effect of this technical amendment to the operational provision would be to align table item 306 with the current approach to referring to constitutional heads of power in table items in Schedule 1AB.

Item [5] – Part 4 of Schedule 1AB (at the end of table item 306, column headed "Objective(s)")

Item 5 would amend table item 306 by adding "; or (c) with respect to postal, telegraphic, telephonic, and other like services (within the meaning of paragraph 51(v) of the Constitution)." in the column headed "Objective(s)". The amendment would reflect that spending activities under the QUDTP Program are also supported by the communications power as there are activities which utilise phone and internet services to achieve the objectives of the program.

The QUDTP Program was established in 1999 to support Quality Use of Medicines (QUM) in Australia. The QUDTP Program contributes to the implementation of Australia's National Medicines Policy (NMP) and the National Strategy for Quality Use of Medicines (NSQUM) by fostering cross sector collaboration and partnerships, collecting data, providing information, raising awareness and educating health professionals and consumers about the quality use of medicines and diagnostics.

QUM objectives must be achieved within a complex and crowded QUM ecosystem. This complexity underscores the need for the QUDTP Program to be implemented in a manner consistent with the NSQUM's five principles: primacy of the consumer; partnership; consultative, collaborative, multi-disciplinary activity; support for existing activity; and system-based approaches.

The objectives of the QUDTP Program are to:

- improve the quality use of therapeutics, diagnostics and pathology for Australian consumers;
- improve the quality use of therapeutics, diagnostics and pathology for Australian health professionals;
- facilitate free access to information to support appropriate use of therapeutics, diagnostics and pathology; and

- support the effectiveness and efficiency of the health system.

The intended outcomes of the QUDTP Program are for:

- improved use of health technologies to optimise health outcomes for Australians, through independent, evidence-based information and education;
- improved health literacy of Australians, through education of health professionals and consumer groups;
- reduced misuse of medicines and other health technologies; and
- improved sustainability of the Pharmaceutical Benefits Scheme (PBS) and Medicare Benefits Schedule (MBS).

Following an independent review, conducted by Deloitte in July/August 2022, the Government confirmed the agreement to redesign the QUDTP Program, which resulted in responsibility for the program delivery transferred to the department, working in collaboration with the Australian Commission on Safety and Quality in Health Care (ACSQHC). The QUDTP supports the optimal use of medicines and diagnostics and enhances the ACSQHC's ability to co-ordinate and drive quality and safety improvements related to medicine and diagnostic use across the Australian health system.

The redesign also included incorporating the Quality Use in Pathology Program (QUPP) into the QUDTP Program and provide for a dedicated quality use of pathology project stream to be administered alongside two existing QUDTP streams: the Health Professional Education and the Consumer Health Literacy. The quality use of pathology project stream would support innovative pathology practice and contribute to the evidence base of the national pathology accreditation program. It is intended that the quality use of pathology project stream under the QUDTP Program would fund the same scope of activity the QUPP has traditionally supported.

The Government has consulted with relevant parties regarding the QUDTP Program's redesign, these included NPS MedicineWise, the Royal Australian College of General Practitioners (RACGP), the Pharmaceutical Society of Australia, Consumers Health Forum, the National Aboriginal Community Controlled Health Organisation (NACCHO) and the ACSQHC. NPS MedicineWise and ACSQHC were heavily involved as part of the independent review process which was completed in August 2022.

The consultation supported the program's redesign which removed NPS MedicineWise as the program delivered partner. Other stakeholders such as RACGP welcomed the opportunity to compete for the grants and other activities and NACCHO welcomed the opportunities presented in the program's redesign.

The department continues to engage with interested parties through Grant Forums and other avenues as the opportunities present and as relates to the QUDTP Program's objectives.

Amended Table item 429 – Sport and Recreation Program

Item [6] – Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", paragraph (b) (first occurring))

Table item 429 in Part 4 of Schedule 1AB establishes legislative authority for government spending on the Sport and Recreation Program (the Program).

Item 6 would amend table item 429 by omitting "by members of the community" in the column headed "Objective(s)" at paragraph (b) (first occurring). The amendment would reflect the alignment of the Program's objective to promote access to, and participation in, sporting or recreation activities across Australia and the Pacific region.

Item [7] – Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", subparagraph (b)(i))

Item 7 would amend table item 429 by inserting "by members of the community" before "who are", in the column headed "Objective(s)" at subparagraph (b)(i). The amendment would reflect the alignment of the Program's objective to promote access to, and participation in, sporting or recreation activities by members of the community who are Indigenous Australians, children, women, non-citizens, immigrants or people with disabilities.

Item [8] – Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", subparagraph (b)(ii))

Item 8 would amend table item 429 by inserting "by members of the community," before "to promote" in the column headed "Objective(s)" at subparagraph (b)(ii). The amendment would reflect the alignment of the Program's objective to promote access to, and participation in, sporting or recreation activities by members of the community to promote physical and mental health and prevent disease.

Item [9] – Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", subparagraph (b)(iii))

Item 9 would amend table item 429 by inserting "by members of the community," before "to eliminate" in the column headed "Objective(s)" at subparagraph (b)(iii). The amendment would reflect the alignment of the Program's objective to promote access to, and participation in, sporting or recreation activities by members of the community to eliminate racial, cultural or ethnic discrimination and promote social cohesion within the community.

Item [10] – Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", after subparagraph (b)(iii))

Item 10 would amend table item 429 by inserting "; or (iv) in Pacific Island countries;" in the column headed "Objective(s)" after paragraph (e). The amendment would reflect the expanded scope of the Program's objective to promote access to, and participation in, sporting or recreation activities into the Pacific region.

Item [11] – Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", after paragraph (e))

Item 11 would amend table item 429 by inserting "(ea) with respect to places, persons, matters or things external to Australia; or (eb) with respect to Australia's relations with the islands of the Pacific; or" in the column headed "Objective(s)" after paragraph (e). The amendment would reflect that spending activities under the Program are also supported by the external affairs power with respect to matters or things outside the geographical limits of Australia, including matters concerning Australia's relations with other nations.

The Program provides comprehensive legislative authority for a range of activities delivered by the department through Program 4.1: Sport and Physical Activity, which is part of Outcome 4. The Program aims to increase participation in sport and physical activity by all Australians and foster excellence in Australia's high-performance athletes. Further Australia's national interests by supporting the Australian sport sector, showcasing Australia as a premier host of major international sporting events, and developing sport policy and programs.

The amendment to table item 429 would support additional funding activities for the 2027 Men's Rugby World Cup (MRWC2027) Pacific Legacy Program and the 2029 Women's Rugby World Cup (WRWC2029) Pacific Legacy Program (both referred to as the Legacy Program).

The overall purpose of the Legacy Program would be to grow the sport of rugby and maximise health, well-being and social outcomes across Australia and the Pacific region. It is proposed to include activities involving club development, facilities, equipment and workforce support, developing states and territories, national programs, school competitions, women and girls' participation, and inclusion programs.

The Rugby World Cups 2027 and 2029 and associated Legacy Program funding are part of the Government's commitment to hosting major international sporting events in the lead-up to the Brisbane 2032 Olympic and Paralympic Games (the 'green and gold decade'). The 'green and gold decade' of major sporting events would provide a platform to showcase Australia on the global stage and inspire the next generation of healthier Australians. Hosting the MRWC2027 and WRWC2029 is projected to generate more than $2.0 billion in economic benefits to Australia. The WRWC2029 would promote gender equality and social inclusion in sport and drive increased physical activity from women and girls.

The Pacific aspects of the Legacy Program would aim to make a lasting impact on Pacific rugby by investing in the capacity and capability of the Pacific national unions and teams. It would provide vital investment for Pacific rugby in the lead-up to the MRWC2027 and WRWC2029, resulting in more competitive Pacific national teams and stronger national unions. The Legacy Program would see Rugby Australia partner with World Rugby, Oceania Rugby, and the Pacific Unions to maximise high performance, management, well-being, and social outcomes across the Pacific region.

The department, through the Office for Sport, has consulted with the Department of Foreign Affairs and Trade and Australian Sports Commission in the design of the Legacy Program.

The Office for Sport further consulted with Rugby Australia on the development of a detailed plan for the Legacy Program, taking into consideration consultations Rugby Australia had had with World Rugby and the Pacific Unions. The consultations with Rugby Australia focused on ensuring the Legacy Program was fit for purpose and suitable to the Government's objectives. Rugby Australia has been consulting with World Rugby and the Pacific Unions on developing the detailed legacy plan for the Pacific legacy funding.

Amended Table item 531 – mRNA vaccines and treatments

Item [12] – Part 4 of Schedule 1AB (table item 531, column headed "Objective(s)")

Table item 531 in Part 4 of Schedule 1AB establishes legislative authority for government spending on the messenger Ribonucleic Acid (mRNA) vaccines and treatments program (the program).

Item 12 would amend table item 531 by omitting "mRNA products" and substituting "mRNA vaccines and products, including by purchasing mRNA vaccines and products manufactured onshore" in the column headed "Objective(s)". The amendment would clarify the effect of table item 531 to establish and maintain the Moderna facility in anticipation of it manufacturing mRNA respiratory vaccines for purchase by the Commonwealth.

In the 2021-22 Budget, the Government agreed to establish an onshore end-to-end, population-scale mRNA manufacturing capability in Australia under a ten-year partnership with Moderna Australia Pty Ltd (Moderna) (the Moderna Partnership). The Moderna Partnership is supported through a Facility Establishment Agreement (FEA) that commenced in March 2022 and terminates in June 2032.

The Moderna Partnership includes the establishment of a population-scale mRNA respiratory vaccine manufacturing facility and a regional research and development centre for respiratory medicines and tropical diseases in Melbourne, Victoria. The Moderna Partnership also includes financial contribution from the Victorian Government.

The Moderna Partnership would supply mRNA respiratory vaccines and provide Australia with priority access in case of pandemics. The initiative signals the Australian Government's support for onshore advanced technology manufacturing and sovereign capability, a commitment to pandemic readiness, and supporting Australia's world class capabilities to develop and produce the next generation of medical technology.

The construction of the facility is currently underway and expected to be completed by December 2024. Pending successful trials, regulatory approvals by the Therapeutic Goods Administration (TGA) and Health Technology Assessments, Moderna envisages to manufacture the onshore vaccines in the first half of 2025. The Australian Government would purchase the onshore vaccines outside the National Immunisation Program as per the FEA with Moderna.

The Australian Government funding commitments under the FEA include:

- an Annual Pandemic Preparedness Facility Fee which is the annual fee paid to Moderna for the up keep of the facility and commences on the date that drug manufacturing and fill/finish facilities have TGA approval to commence manufacturing mRNA vaccines; and
- an Annual Minimum Purchase Commitments of COVID-19 vaccines, plus other respiratory vaccines should they be approved by TGA. The Commonwealth's commitment to purchasing minimum number of vaccines for delivery in each financial year.

In establishing an onshore mRNA manufacturing capability including product fill and finish facilities in Victoria, the Commonwealth's objectives are to:

- secure onshore population-scale mRNA vaccine manufacturing capability, supply and resilience to respond to future pandemics and other health emergencies;
- provide priority access to mRNA COVID-19 vaccines and other respiratory vaccines should those vaccines obtain regulatory approval from the TGA;
- 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 establishing 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;
- non-pandemic vaccine supply agreements to procure Australia's requirement for COVID-19 vaccines, RSV, influenza and other mRNA vaccines should those vaccines be developed and approved;
- ongoing pandemic preparedness fees to secure priority access to mRNA pandemic vaccines; and
- pandemic vaccine advance purchase agreements if Moderna identifies and/or develops vaccine candidates for future pandemics.

The project was a joint Taskforce activity between the department, the Department of Industry, Science, and Resources (DISR) and the Department of Finance. Across 2020 and 2021, the following governing bodies and agencies were consulted during the project phase, up to execution of agreements in March 2022:

- state governments;
- Australian Technical Advisory Group on Immunisation (ATAGI);
- TGA;
- Pharmaceutical Advisory Committee;
- COVID-19 Vaccines and Treatments for Australia – Science and Industry Technical Advisory Group;
- the Department of Foreign Affairs and Trade and the Department of the Prime Minister and Cabinet; and
- an Expert Advisory Group advising on the Approach to Market process and the Moderna proposal.

DISR lead this process, and broadly the intention to establish an onshore mRNA respiratory vaccine manufacturing capability was met with a consensus to proceed.

Beyond the implementation phase to the end of the agreements, consultation will continue with state governments, DISR, TGA, ATAGI, relevant industries and the biotechnology research sector, particularly with regard to the development of the research and development ecosystem.

MINISTER FOR FINANCE

Departmental No. 371 of 2024

Executive Council
Meeting No. .....

Approved in Council

.....

Sam Mostyn AC
Governor-General

.....

Filed in the Records
of the Council

.....
Secretary to the Executive Council

Minute Paper for the Executive Council

Subject

Financial Framework (Supplementary Powers) Act 1997

Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024

Recommended for the approval of Her Excellency the Governor-General in Council that she make Regulations in the attached form.

Katy Gallagher
Minister for Finance

Subject: FW: PDMS Notification - Record Assigned : MS24-000856 Financial Framework (Supplementary Powers) Regulations 1997 – Schedule 1AB – various portfolios – Federal Executive Council Meeting on 24 October 2024 [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

Attachments: MS24-000856.docx; Att A - Summary - Description of Schedule 1AB.docx; Att I - Regs - Health No. 4.DOCX; Att I1 - Exco minute - Health No. 4.docx; Att I2 - EM - Health No. 4.docx; Att I3 - ES - Health No. 4.docx; Att U - Letter to Minister Butler.docx

OFFICIAL:Sensitive
Legal Privilege

From: noreply@pws.gov.au <noreply@pws.gov.au>
Sent: Thursday, 3 October 2024 4:06 PM
To: Fox, Amy <Amy.Fox@finance.gov.au>; s22 @finance.gov.au>; s22 @finance.gov.au>
Subject: PDMS Notification - Record Assigned : MS24-000856 Financial Framework (Supplementary Powers) Regulations 1997 – Schedule 1AB – various portfolios – Federal Executive Council Meeting on 24 October 2024 [SEC=OFFICIAL:Sensitive,ACCESS=Legal-privilege]

SEC=OFFICIAL:Sensitive,ACCESS=Legal-privilege

SUBJECT: Financial Framework (Supplementary Powers) Regulations 1997 – Schedule 1AB – various portfolios – Federal Executive Council Meeting on 24 October 2024

This is for your Information Only as the record was CC'ed to you by s22 .

This record can be viewed via the following link: **MS24-000856**

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Record Details **please note if any of the fields below are empty, the associated field is not populated in the record*	
PDR Number	MS24-000856
PDR Subject	Financial Framework (Supplementary Powers) Regulations 1997 – Schedule 1AB – various portfolios – Federal Executive Council Meeting on 24 October 2024
Status	Cleared
Processing Instructions	Please progress to FMO. Hard copies will be delivered to FMO tomorrow morning.
Milestones	Due for Clearance: 30/09/2024 5:00:00 PM Due to Parliamentary: 30/09/2024 5:00:00 PM

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s22 @finance.gov.au)

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Amendments to the *Financial Framework (Supplementary Powers) Regulations 1997*
24 October 2024 Federal Executive Council Meeting

Summary of requests by responsible Ministers and proposed amendments:

s22

[redacted]

<table>
<tr><th colspan="3">Amended table item 531 in Part 4: mRNA vaccines and treatments</th></tr>
<tr><td>Policy authority:</td><td>Cabinet</td><td rowspan="4">Description: Table item 531 establishes legislative authority for government spending on the messenger Ribonucleic Acid (mRNA) vaccines and treatments program (the program).

In March 2022, the Australian Government executed a 10-year agreement with Moderna Australia Pty Ltd (Moderna) to establish a population-scale mRNA respiratory vaccine manufacturing facility and a regional research and development centre for respiratory medicines and tropical diseases in Melbourne, Victoria.

The amendment clarifies the effect of item 531 to establish and maintain the Moderna facility in anticipation of it manufacturing mRNA respiratory vaccines for purchase by the Commonwealth.

Moderna is the primary project led to establish and operate the end-to-end mRNA manufacturing facility. The construction of the facility is underway and is expected to be completed by December 2024. Pending successful trials, regulatory approvals by the Therapeutic Goods Administration (TGA) and Health Technology Assessments, Moderna envisages to manufacture the onshore vaccines in the first half of 2025.

The Government has committed to the following components:
• Annual Pandemic Preparedness Facility Fee, which is the annual fee paid to Moderna for the upkeep of the facility and commences on the date that drug manufacturing and fill/finish facilities have TGA approval to commence manufacturing mRNA vaccines; and
• Annual Minimum Purchase Commitments of COVID-19 vaccines, plus other respiratory vaccines should they be approved by TGA. The Commonwealth's commitment to purchasing minimum number of vaccines for delivery in each financial year.</td></tr>
<tr><td>Funding:</td><td>s45, s47 [redacted]</td></tr>
<tr><td>Constitutional risk:</td><td>Medium</td></tr>
<tr><td>Constitutional powers:</td><td>• External Affairs power
• Social welfare power
• Executive power and express incidental power, including the nationhood aspect</td></tr>
</table>

Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024

I, the Honourable Sam Mostyn AC, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 2024

Sam Mostyn AC
Governor-General

By Her Excellency's Command

Katy Gallagher
Minister for Finance

Contents

1 Name

This instrument is the *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the *Financial Framework (Supplementary Powers) Act 1997*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Financial Framework (Supplementary Powers) Regulations 1997

1 Part 4 of Schedule 1AB (table item 306, column headed "Objective(s)")

Omit "to NPS MedicineWise".

2 Part 4 of Schedule 1AB (table item 306, column headed "Objective(s)", after paragraph (d))

Insert:

; and (e) to provide education and awareness activities, events, conferences and symposiums on the safe and appropriate use of medicines.

3 Part 4 of Schedule 1AB (table item 306, column headed "Objective(s)")

Omit "also".

4 Part 4 of Schedule 1AB (table item 306, column headed "Objective(s)", paragraph (a) (second occurring))

Repeal the paragraph, substitute:

(a) for the provision of, or incidental to the provision of, pharmaceutical benefits, sickness benefits or medical services (within the meaning of paragraph 51(xxiiiA) of the Constitution); or

5 Part 4 of Schedule 1AB (at the end of table item 306, column headed "Objective(s)")

Add:

; or (c) with respect to postal, telegraphic, telephonic, and other like services (within the meaning of paragraph 51(v) of the Constitution).

6 Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", paragraph (b) (first occurring))

Omit "by members of the community".

7 Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", subparagraph (b)(i))

Before "who are", insert "by members of the community".

8 Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", subparagraph (b)(ii))

Before "to promote", insert "by members of the community,".

9 Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", subparagraph (b)(iii))

Before "to eliminate", insert "by members of the community,".

10 Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", after subparagraph (b)(iii))

Insert:

or (iv) in Pacific Island countries;

11 Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", after paragraph (e))

Insert:

(ea) with respect to places, persons, matters or things external to Australia; or

(eb) with respect to the relations of the Commonwealth with the islands of the Pacific; or

12 Part 4 of Schedule 1AB (table item 531, column headed "Objective(s)")

Omit "mRNA products", substitute "mRNA vaccines and products, including by purchasing mRNA vaccines and products manufactured onshore".

MINISTER FOR FINANCE

Departmental No. 371 of 2024

Executive Council
Meeting No. .....

Approved in Council

.....

Sam Mostyn AC
Governor-General

.....

Filed in the Records
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Secretary to the Executive Council

Minute Paper for the Executive Council

Subject

Financial Framework (Supplementary Powers) Act 1997

Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024

Recommended for the approval of Her Excellency the Governor-General in Council that she make Regulations in the attached form.

Katy Gallagher
Minister for Finance

EXPLANATORY MEMORANDUM

Minute No. 371 of 2024 – Minister for Finance

Subject - *Financial Framework (Supplementary Powers) Act 1997*

Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024

The purpose of this instrument is to provide legislative authority for the expenditure of Commonwealth funds.

The *Financial Framework (Supplementary Powers) Act 1997* (the Act) confers on the Commonwealth, in certain circumstances, powers to make arrangements under which money can be spent; or to make grants of financial assistance; and to form, or otherwise be involved in, companies. The Act applies to Ministers and the accountable authorities of non-corporate Commonwealth entities, as defined under section 12 of the *Public Governance, Performance and Accountability Act 2013*.

Section 65 of the Act provides that the Governor-General may make regulations prescribing matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Section 32B of the Act authorises the Commonwealth to make, vary and administer arrangements, programs and grants of financial assistance specified in the *Financial Framework (Supplementary Powers) Regulations 1997* (the Principal Regulations). Schedules 1AA and 1AB to the Principal Regulations specify the arrangements, grants and programs. The overall effect of section 32B is to provide legislative authority for Commonwealth expenditure on the arrangements, programs and grants specified in the Principal Regulations. This includes providing legislative authority for the Commonwealth to be able to enter into contracts or other arrangements for the specified programs and grants.

The *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024* (the proposed Regulations) would amend Schedule 1AB to the Principal Regulations to establish legislative authority for government spending on activities administered by the Department of Health and Aged Care.

Existing funding is allocated for the:

- Quality Use of Diagnostics Therapeutic and Pathology Program to improve the way in which health technologies, medicines and medical tests are prescribed and used (up to $34.4 million per year from 2024-25);
- Sport and Recreation Program to support activities directed at Australia hosting major international sporting events; promote access to, and participation in, sporting or recreation activities; and support the achievement of excellence in Australia's representative athletes ($30.0 million over six years from 2024-25 was provided to support the Legacy programs for Domestic and Pacific for Rugby World Cup events in 2027 and 2029); and
- messenger Ribonucleic Acid (mRNA) vaccines and treatments program to develop and maintain Australia's onshore capability to manufacture mRNA vaccines and products,

including by purchasing mRNA vaccines and products manufactured onshore (financial implications for this element are not for publication due to commercial-in-confidence sensitivities. It is the intention of the Australian Government to disclose the funding allocated for the program once the agreements are finalised).

In accordance with section 17 of the *Legislation Act 2003*, consultation has taken place with the department responsible for administering the spending activities. Details of the proposed Regulations and consultation undertaken with key stakeholders within the affected industry during their development are set out in the Attachment.

The Act specifies no conditions that need to be satisfied before the power to make the proposed Regulations may be exercised.

The proposed Regulations would be a legislative instrument for the purposes of the *Legislation Act 2003.*

The proposed Regulations would commence on the day after registration on the Federal Register of Legislation.

The Minute recommends that the Regulations be made in the form proposed.

Authority: Section 65 of the *Financial Framework (Supplementary Powers) Act 1997*

ATTACHMENT

Details of the proposed *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024*

Section 1 – Name

This section would provide that the title of the Regulations would be the *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024.*

Section 2 – Commencement

This section would provide that the Regulations would commence on the day after registration on the Federal Register of Legislation.

Section 3 – Authority

This section would provide that the Regulations would be made under the *Financial Framework (Supplementary Powers) Act 1997*.

Section 4 – Schedules

This section would provide that the *Financial Framework (Supplementary Powers) Regulations 1997* would be amended as set out in the Schedule to the Regulations.

Schedule 1 – Amendments

Financial Framework (Supplementary Powers) Regulations 1997

The Regulations would amend three table items in Part 4 of Schedule 1AB to the Principal Regulations to establish legislative authority for government spending on activities to be administered by the Department of Health and Aged Care (the department).

Item [1] – Part 4 of Schedule 1AB (table item 306, column headed "Objective(s)")

Amended Table item 306 – Quality Use of Diagnostic, Therapeutics and Pathology Program

Table item 306 in Part 4 of Schedule 1AB establishes legislative authority for government spending on the Quality Use of Diagnostic, Therapeutics and Pathology (QUDTP) Program.

Item 1 would amend table item 306 by omitting "to NPS Medicine Wise" in the column headed "Objective(s)". The amendment would reflect the redesigned QUDTP Program which resulted in the transfer of responsibility for delivery of the QUDTP from NPS MedicineWise to the department.

Item [2] – Part 4 of Schedule 1AB (table item 306, column headed "Objective(s)", after paragraph (d))

Item 2 would amend table item 306 by inserting "; and (e) to provide education and awareness activities, events, conferences and symposiums on the safe and appropriate use of

medicines." in the column headed "Objective(s)" after paragraph (d). The amendment would reflect the expanded responsibility of the department to deliver targeted Quality Use of Medicines educational activities to health professions and consumers.

Item [3] – Part 4 of Schedule 1AB (table item 306, column headed "Objective(s)")

Item 3 would amend table item 306 by omitting the word "also" in the column headed "Objective(s)". The effect of this technical amendment to the operational provision would be to align table item 306 with the current approach to referring to constitutional heads of power in table items in Schedule 1AB.

Item [4] – Part 4 of Schedule 1AB (table item 306, column headed "Objective(s)", paragraph (a) (second occurring))

Item 4 would amend table item 306 by repealing and substituting paragraph "(a) for the provision of, or incidental to the provision of, pharmaceutical benefits, sickness benefits or medical services (within the meaning of paragraph 51(xxiiiA) of the Constitution); or" in the column headed "Objective(s)" at paragraph (a) (second occurring). The effect of this technical amendment to the operational provision would be to align table item 306 with the current approach to referring to constitutional heads of power in table items in Schedule 1AB.

Item [5] – Part 4 of Schedule 1AB (at the end of table item 306, column headed "Objective(s)")

Item 5 would amend table item 306 by adding "; or (c) with respect to postal, telegraphic, telephonic, and other like services (within the meaning of paragraph 51(v) of the Constitution)." in the column headed "Objective(s)". The amendment would reflect that spending activities under the QUDTP Program are also supported by the communications power as there are activities which utilise phone and internet services to achieve the objectives of the program.

The QUDTP Program was established in 1999 to support Quality Use of Medicines (QUM) in Australia. The QUDTP Program contributes to the implementation of Australia's National Medicines Policy (NMP) and the National Strategy for Quality Use of Medicines (NSQUM) by fostering cross sector collaboration and partnerships, collecting data, providing information, raising awareness and educating health professionals and consumers about the quality use of medicines and diagnostics.

QUM objectives must be achieved within a complex and crowded QUM ecosystem. This complexity underscores the need for the QUDTP Program to be implemented in a manner consistent with the NSQUM's five principles: primacy of the consumer; partnership; consultative, collaborative, multi-disciplinary activity; support for existing activity; and system-based approaches.

The objectives of the QUDTP Program are to:

- improve the quality use of therapeutics, diagnostics and pathology for Australian consumers;
- improve the quality use of therapeutics, diagnostics and pathology for Australian health professionals;
- facilitate free access to information to support appropriate use of therapeutics, diagnostics and pathology; and

- support the effectiveness and efficiency of the health system.

The intended outcomes of the QUDTP Program are for:

- improved use of health technologies to optimise health outcomes for Australians, through independent, evidence-based information and education;
- improved health literacy of Australians, through education of health professionals and consumer groups;
- reduced misuse of medicines and other health technologies; and
- improved sustainability of the Pharmaceutical Benefits Scheme (PBS) and Medicare Benefits Schedule (MBS).

Following an independent review, conducted by Deloitte in July/August 2022, the Government confirmed the agreement to redesign the QUDTP Program, which resulted in responsibility for the program delivery transferred to the department, working in collaboration with the Australian Commission on Safety and Quality in Health Care (ACSQHC). The QUDTP supports the optimal use of medicines and diagnostics and enhances the ACSQHC's ability to co-ordinate and drive quality and safety improvements related to medicine and diagnostic use across the Australian health system.

The redesign also included incorporating the Quality Use in Pathology Program (QUPP) into the QUDTP Program and provide for a dedicated quality use of pathology project stream to be administered alongside two existing QUDTP streams: the Health Professional Education and the Consumer Health Literacy. The quality use of pathology project stream would support innovative pathology practice and contribute to the evidence base of the national pathology accreditation program. It is intended that the quality use of pathology project stream under the QUDTP Program would fund the same scope of activity the QUPP has traditionally supported.

The Government has consulted with relevant parties regarding the QUDTP Program's redesign, these included NPS MedicineWise, the Royal Australian College of General Practitioners (RACGP), the Pharmaceutical Society of Australia, Consumers Health Forum, the National Aboriginal Community Controlled Health Organisation (NACCHO) and the ACSQHC. NPS MedicineWise and ACSQHC were heavily involved as part of the independent review process which was completed in August 2022.

The consultation supported the program's redesign which removed NPS MedicineWise as the program delivered partner. Other stakeholders such as RACGP welcomed the opportunity to compete for the grants and other activities and NACCHO welcomed the opportunities presented in the program's redesign.

The department continues to engage with interested parties through Grant Forums and other avenues as the opportunities present and as relates to the QUDTP Program's objectives.

Amended Table item 429 – Sport and Recreation Program

Item [6] – Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", paragraph (b) (first occurring))

Table item 429 in Part 4 of Schedule 1AB establishes legislative authority for government spending on the Sport and Recreation Program (the Program).

Item 6 would amend table item 429 by omitting "by members of the community" in the column headed "Objective(s)" at paragraph (b) (first occurring). The amendment would reflect the alignment of the Program's objective to promote access to, and participation in, sporting or recreation activities across Australia and the Pacific region.

Item [7] – Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", subparagraph (b)(i))

Item 7 would amend table item 429 by inserting "by members of the community" before "who are", in the column headed "Objective(s)" at subparagraph (b)(i). The amendment would reflect the alignment of the Program's objective to promote access to, and participation in, sporting or recreation activities by members of the community who are Indigenous Australians, children, women, non-citizens, immigrants or people with disabilities.

Item [8] – Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", subparagraph (b)(ii))

Item 8 would amend table item 429 by inserting "by members of the community," before "to promote" in the column headed "Objective(s)" at subparagraph (b)(ii). The amendment would reflect the alignment of the Program's objective to promote access to, and participation in, sporting or recreation activities by members of the community to promote physical and mental health and prevent disease.

Item [9] – Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", subparagraph (b)(iii))

Item 9 would amend table item 429 by inserting "by members of the community," before "to eliminate" in the column headed "Objective(s)" at subparagraph (b)(iii). The amendment would reflect the alignment of the Program's objective to promote access to, and participation in, sporting or recreation activities by members of the community to eliminate racial, cultural or ethnic discrimination and promote social cohesion within the community.

Item [10] – Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", after subparagraph (b)(iii))

Item 10 would amend table item 429 by inserting "; or (iv) in Pacific Island countries;" in the column headed "Objective(s)" after paragraph (e). The amendment would reflect the expanded scope of the Program's objective to promote access to, and participation in, sporting or recreation activities into the Pacific region.

Item [11] – Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", after paragraph (e))

Item 11 would amend table item 429 by inserting "(ea) with respect to places, persons, matters or things external to Australia; or (eb) with respect to Australia's relations with the islands of the Pacific; or" in the column headed "Objective(s)" after paragraph (e). The amendment would reflect that spending activities under the Program are also supported by the external affairs power with respect to matters or things outside the geographical limits of Australia, including matters concerning Australia's relations with other nations.

The Program provides comprehensive legislative authority for a range of activities delivered by the department through Program 4.1: Sport and Physical Activity, which is part of Outcome 4. The Program aims to increase participation in sport and physical activity by all Australians and foster excellence in Australia's high-performance athletes. Further Australia's national interests by supporting the Australian sport sector, showcasing Australia as a premier host of major international sporting events, and developing sport policy and programs.

The amendment to table item 429 would support additional funding activities for the 2027 Men's Rugby World Cup (MRWC2027) Pacific Legacy Program and the 2029 Women's Rugby World Cup (WRWC2029) Pacific Legacy Program (both referred to as the Legacy Program).

The overall purpose of the Legacy Program would be to grow the sport of rugby and maximise health, well-being and social outcomes across Australia and the Pacific region. It is proposed to include activities involving club development, facilities, equipment and workforce support, developing states and territories, national programs, school competitions, women and girls' participation, and inclusion programs.

The Rugby World Cups 2027 and 2029 and associated Legacy Program funding are part of the Government's commitment to hosting major international sporting events in the lead-up to the Brisbane 2032 Olympic and Paralympic Games (the 'green and gold decade'). The 'green and gold decade' of major sporting events would provide a platform to showcase Australia on the global stage and inspire the next generation of healthier Australians. Hosting the MRWC2027 and WRWC2029 is projected to generate more than $2.0 billion in economic benefits to Australia. The WRWC2029 would promote gender equality and social inclusion in sport and drive increased physical activity from women and girls.

The Pacific aspects of the Legacy Program would aim to make a lasting impact on Pacific rugby by investing in the capacity and capability of the Pacific national unions and teams. It would provide vital investment for Pacific rugby in the lead-up to the MRWC2027 and WRWC2029, resulting in more competitive Pacific national teams and stronger national unions. The Legacy Program would see Rugby Australia partner with World Rugby, Oceania Rugby, and the Pacific Unions to maximise high performance, management, well-being, and social outcomes across the Pacific region.

The department, through the Office for Sport, has consulted with the Department of Foreign Affairs and Trade and Australian Sports Commission in the design of the Legacy Program. The Office for Sport further consulted with Rugby Australia on the development of a detailed plan for the Legacy Program, taking into consideration consultations Rugby Australia had had with World Rugby and the Pacific Unions. The consultations with Rugby Australia focused on ensuring the Legacy Program was fit for purpose and suitable to the Government's objectives. Rugby Australia has been consulting with World Rugby and the Pacific Unions on developing the detailed legacy plan for the Pacific legacy funding.

Amended Table item 531 – mRNA vaccines and treatments

Item [12] – Part 4 of Schedule 1AB (table item 531, column headed "Objective(s)")

Table item 531 in Part 4 of Schedule 1AB establishes legislative authority for government spending on the messenger Ribonucleic Acid (mRNA) vaccines and treatments program (the program).

Item 12 would amend table item 531 by omitting "mRNA products" and substituting "mRNA vaccines and products, including by purchasing mRNA vaccines and products manufactured onshore" in the column headed "Objective(s)". The amendment would clarify the effect of table item 531 to establish and maintain the Moderna facility in anticipation of it manufacturing mRNA respiratory vaccines for purchase by the Commonwealth.

In the 2021-22 Budget, the Government agreed to establish an onshore end-to-end, population-scale mRNA manufacturing capability in Australia under a ten-year partnership with Moderna Australia Pty Ltd (Moderna) (the Moderna Partnership). The Moderna Partnership is supported through a Facility Establishment Agreement (FEA) that commenced in March 2022 and terminates in June 2032.

The Moderna Partnership includes the establishment of a population-scale mRNA respiratory vaccine manufacturing facility and a regional research and development centre for respiratory medicines and tropical diseases in Melbourne, Victoria. The Moderna Partnership also includes financial contribution from the Victorian Government.

The Moderna Partnership would supply mRNA respiratory vaccines and provide Australia with priority access in case of pandemics. The initiative signals the Australian Government's support for onshore advanced technology manufacturing and sovereign capability, a commitment to pandemic readiness, and supporting Australia's world class capabilities to develop and produce the next generation of medical technology.

The construction of the facility is currently underway and expected to be completed by December 2024. Pending successful trials, regulatory approvals by the Therapeutic Goods Administration (TGA) and Health Technology Assessments, Moderna envisages to manufacture the onshore vaccines in the first half of 2025. The Australian Government would purchase the onshore vaccines outside the National Immunisation Program as per the FEA with Moderna.

The Australian Government funding commitments under the FEA include:

- an Annual Pandemic Preparedness Facility Fee which is the annual fee paid to Moderna for the up keep of the facility and commences on the date that drug manufacturing and fill/finish facilities have TGA approval to commence manufacturing mRNA vaccines; and
- an Annual Minimum Purchase Commitments of COVID-19 vaccines, plus other respiratory vaccines should they be approved by TGA. The Commonwealth's commitment to purchasing minimum number of vaccines for delivery in each financial year.

In establishing an onshore mRNA manufacturing capability including product fill and finish facilities in Victoria, the Commonwealth's objectives are to:

- secure onshore population-scale mRNA vaccine manufacturing capability, supply and resilience to respond to future pandemics and other health emergencies;
- provide priority access to mRNA COVID-19 vaccines and other respiratory vaccines should those vaccines obtain regulatory approval from the TGA;
- 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 establishing 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;
- non-pandemic vaccine supply agreements to procure Australia's requirement for COVID-19 vaccines, RSV, influenza and other mRNA vaccines should those vaccines be developed and approved;
- ongoing pandemic preparedness fees to secure priority access to mRNA pandemic vaccines; and
- pandemic vaccine advance purchase agreements if Moderna identifies and/or develops vaccine candidates for future pandemics.

The project was a joint Taskforce activity between the department, the Department of Industry, Science, and Resources (DISR) and the Department of Finance. Across 2020 and 2021, the following governing bodies and agencies were consulted during the project phase, up to execution of agreements in March 2022:

- state governments;
- Australian Technical Advisory Group on Immunisation (ATAGI);
- TGA;
- Pharmaceutical Advisory Committee;
- COVID-19 Vaccines and Treatments for Australia – Science and Industry Technical Advisory Group;
- the Department of Foreign Affairs and Trade and the Department of the Prime Minister and Cabinet; and
- an Expert Advisory Group advising on the Approach to Market process and the Moderna proposal.

DISR lead this process, and broadly the intention to establish an onshore mRNA respiratory vaccine manufacturing capability was met with a consensus to proceed.

Beyond the implementation phase to the end of the agreements, consultation will continue with state governments, DISR, TGA, ATAGI, relevant industries and the biotechnology research sector, particularly with regard to the development of the research and development ecosystem.

EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Finance

Financial Framework (Supplementary Powers) Act 1997

Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024

The *Financial Framework (Supplementary Powers) Act 1997* (the FFSP Act) confers on the Commonwealth, in certain circumstances, powers to make arrangements under which money can be spent; or to make grants of financial assistance; and to form, or otherwise be involved in, companies. The arrangements, grants, programs and companies (or classes of arrangements or grants in relation to which the powers are conferred) are specified in the *Financial Framework (Supplementary Powers) Regulations 1997* (the Principal Regulations). The powers in the FFSP Act to make, vary or administer arrangements or grants may be exercised on behalf of the Commonwealth by Ministers and the accountable authorities of non-corporate Commonwealth entities, as defined under section 12 of the *Public Governance, Performance and Accountability Act 2013*.

The Principal Regulations are exempt from sunsetting under section 12 of the *Legislation (Exemptions and Other Matters) Regulation 2015* (item 28A). If the Principal Regulations were subject to the sunsetting regime under the *Legislation Act 2003*, this would generate uncertainty about the continuing operation of existing contracts and funding agreements between the Commonwealth and third parties (particularly those extending beyond 10 years), as well as the Commonwealth's legislative authority to continue making, varying or administering arrangements, grants and programs.

Additionally, the Principal Regulations authorise a number of activities that form part of intergovernmental schemes. It would not be appropriate for the Commonwealth to unilaterally sunset an instrument that provides authority for Commonwealth funding for activities that are underpinned by an intergovernmental arrangement. To ensure that the Principal Regulations continue to reflect government priorities and remain up to date, the Principal Regulations are subject to periodic review to identify and repeal items that are redundant or no longer required.

Section 32B of the FFSP Act authorises the Commonwealth to make, vary and administer arrangements and grants specified in the Principal Regulations. Section 32B also authorises the Commonwealth to make, vary and administer arrangements for the purposes of programs specified in the Principal Regulations. Section 32D of the FFSP Act confers powers of delegation on Ministers and the accountable authorities of non-corporate Commonwealth entities, including subsection 32B(1) of the Act. Schedule 1AA and Schedule 1AB to the Principal Regulations specify the arrangements, grants and programs.

Section 65 of the FFSP Act provides that the Governor-General may make regulations prescribing matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024* (the Regulations) amend Schedule 1AB to the Principal Regulations to establish legislative authority for Government spending on activities administered by the Department of Health and Aged Care.

Existing funding is allocated for the:

- Quality Use of Diagnostics Therapeutic and Pathology Program to improve the way in which health technologies, medicines and medical tests are prescribed and used (up to $34.4 million per year from 2024-25);
- Sport and Recreation Program to support activities directed at Australia hosting major international sporting events; promote access to, and participation in, sporting or recreation activities; and support the achievement of excellence in Australia's representative athletes ($30.0 million over six years from 2024-25 was provided to support the Legacy programs for Domestic and Pacific for Rugby World Cup events in 2027 (men) and 2029 (women)); and
- messenger Ribonucleic Acid (mRNA) vaccines and treatments program to develop and maintain Australia's onshore capability to manufacture mRNA vaccines and products, including by purchasing mRNA vaccines and products manufactured onshore (financial implications for this element are not for publication due to commercial-in-confidence sensitivities. It is the intention of the Australian Government to disclose the funding allocated for the program once the agreements are finalised).

Details of the Regulations are set out at Attachment A. A Statement of Compatibility with Human Rights is at Attachment B.

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence on the day after registration on the Federal Register of Legislation.

Consultation

In accordance with section 17 of the *Legislation Act 2003*, consultation has taken place with the Department of Health and Aged Care.

A regulatory impact analysis is not required as the Regulations only apply to non-corporate Commonwealth entities and do not adversely affect the private sector.

Attachment A

Details of the *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024*

Section 1 – Name

This section provides that the title of the Regulations is the *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024.*

Section 2 – Commencement

This section provides that the Regulations commence on the day after registration on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the Regulations are made under the *Financial Framework (Supplementary Powers) Act 1997*.

Section 4 – Schedules

This section provides that the *Financial Framework (Supplementary Powers) Regulations 1997* are amended as set out in the Schedule to the Regulations.

Schedule 1 – Amendments

Financial Framework (Supplementary Powers) Regulations 1997

The items in Schedule 1 amend Schedule 1AB to the Principal Regulations to provide legislative authority for government spending on activities administered by the Department of Health and Aged Care (the department).

Item 1 – Part 4 of Schedule 1AB (table item 306, column headed "Objective(s)")

Amended table item 306 – Quality Use of Diagnostic, Therapeutics and Pathology Program

Table item 306 in Part 4 of Schedule 1AB establishes legislative authority for government spending on the Quality Use of Diagnostic, Therapeutics and Pathology (QUDTP) Program.

Item 1 amends table item 306 by omitting "to NPS Medicine Wise" in the column headed "Objective(s)". The amendment reflects the redesigned QUDTP Program which resulted in the transfer of responsibility for delivery of the QUDTP from NPS MedicineWise to the department.

Item 2 – Part 4 of Schedule 1AB (table item 306, column headed "Objective(s)", after paragraph (d))

Item 2 amends table item 306 by inserting "; and (e) to provide education and awareness activities, events, conferences and symposiums on the safe and appropriate use of medicines." in the column headed "Objective(s)" after paragraph (d). The amendment reflects the expanded responsibility of the department to deliver targeted Quality Use of Medicines educational activities to health professions and consumers.

Item 3 – Part 4 of Schedule 1AB (table item 306, column headed "Objective(s)")

Item 3 amends table item 306 by omitting the word "also" in the column headed "Objective(s)". The effect of this technical amendment to the operational provision is to align table item 306 with the current approach to referring to constitutional heads of power in table items in Schedule 1AB.

Item 4 – Part 4 of Schedule 1AB (table item 306, column headed "Objective(s)", paragraph (a) (second occurring))

Item 4 amends table item 306 by repealing and substituting paragraph "(a) for the provision of, or incidental to the provision of, pharmaceutical benefits, sickness benefits or medical services (within the meaning of paragraph 51(xxiiiA) of the Constitution); or" in the column headed "Objective(s)" at paragraph (a) (second occurring). The effect of this technical amendment to the operational provision is to align table item 306 with the current approach to referring to constitutional heads of power in table items in Schedule 1AB.

Item 5 – Part 4 of Schedule 1AB (at the end of table item 306, column headed "Objective(s)")

Item 5 amends table item 306 by adding "; or (c) with respect to postal, telegraphic, telephonic, and other like services (within the meaning of paragraph 51(v) of the Constitution)." in the column headed "Objective(s)". The amendment reflects that spending activities under the QUDTP Program are also supported by the communications power as there are activities which utilise phone and internet services to achieve the objectives of the program.

The QUDTP Program was established in 1999 to support Quality Use of Medicines (QUM) in Australia. The QUDTP Program contributes to the implementation of Australia's National Medicines Policy (NMP) and the National Strategy for Quality Use of Medicines (NSQUM) by fostering cross sector collaboration and partnerships, collecting data, providing information, raising awareness and educating health professionals and consumers about the quality use of medicines and diagnostics.

QUM objectives must be achieved within a complex and crowded QUM ecosystem. This complexity underscores the need for the QUDTP Program to be implemented in a manner consistent with the NSQUM's five principles: primacy of the consumer; partnership; consultative, collaborative, multi-disciplinary activity; support for existing activity; and system-based approaches.

The objectives of the QUDTP Program are to:

- improve the quality use of therapeutics, diagnostics and pathology for Australian consumers;
- improve the quality use of therapeutics, diagnostics and pathology for Australian health professionals;
- facilitate free access to information to support appropriate use of therapeutics, diagnostics and pathology; and
- support the effectiveness and efficiency of the health system.

The intended outcomes of the QUDTP Program are:

- improved use of health technologies to optimise health outcomes for Australians, through independent, evidence-based information and education;
- improved health literacy of Australians, through education of health professionals and consumer groups;
- reduced misuse of medicines and other health technologies; and
- improved sustainability of the Pharmaceutical Benefits Scheme (PBS) and Medicare Benefits Schedule (MBS).

Following an independent review, conducted by Deloitte in July/August 2022, the Government confirmed the agreement to redesign the QUDTP Program, which resulted in responsibility for the program delivery transferred to the department, working in collaboration with the Australian Commission on Safety and Quality in Health Care (ACSQHC). The QUDTP supports the optimal use of medicines and diagnostics and enhances the ACSQHC's ability to co-ordinate and drive quality and safety improvements related to medicine and diagnostic use across the Australian health system.

The redesign also included incorporating the Quality Use in Pathology Program (QUPP) into the QUDTP Program and provide for a dedicated quality use of pathology project stream to be administered alongside two existing QUDTP streams: Health Professional Education and Consumer Health Literacy. The quality use of pathology project stream will support innovative pathology practice and contribute to the evidence base of the national pathology accreditation program. It is intended that the quality use of pathology project stream under the QUDTP Program will fund the same scope of activity the QUPP has traditionally supported.

Spending activities under the QUDTP Program are currently delivered by ACSQHC and the department.

Activities delivered by ACSQHC include:

- National Medicines Symposium – an annual, cross-disciplinary event bringing together leading organisations, experts, clinicians, consumers and policymakers to lead discussion on improving quality use of medicines in Australia;
- Practice Reviews (PBS/MBS Feedback Letters) – aim to deliver savings for the PBS and MBS, through targeting overused items which do not represent best practice;
- MedicineInsight – a data program, used by General Practices to improve medication management and support research and policy decisions in relation to primary care data;
- Online applications – MedicineWise, a free medicine and health management tool that assists consumers and their families or carers manage their medication, medical

conditions and provides important health information; and Doctor's Bag, a free application designed to assist Australian health professionals with medication related to the PBS Doctor's Bag during emergencies;

- QUM Stewardship and Indicator Development – supports and facilitates collaboration across the health systems, raises awareness of QUM issues. QUM indicators are to be developed in consultation with key stakeholders for integration across the health system and monitor the impact of changes related to medicines; and
- former NPS MedicineWise resources for health professionals and consumers, including websites (choosing wisely, nps.org.au, learning platform), on-line training modules, and RADAR (newsletter publication).

Activities under the department's responsibility are delivered through a range of procurement and grant processes. Procurement activities include:

- Consumer Phone Lines – 1300 Medicines Line, which accepts general medication phone enquires and is staffed by pharmacists, and Adverse Medicines Events Line, which enables consumers to log adverse events to medicines to the Therapeutic Goods Administration by phone with the support of health professionals, who can support care options for the consumer;
- Australian prescriber and support for communications relating to the PBS;
- QUM Horizon scanning, priority setting and program evaluations – horizon scanning provides an analysis of current and emerging issues, priorities and policies on quality use of medicines in Australia to inform future activities;
- National Prescribing Competencies Framework (NPCF) – describes the competencies that health professionals require to prescribe medicines judiciously, appropriately, safely and effectively in the Australian healthcare system. It is used by health professional regulation, health professionals, and those developing education and training programs to support QUM; and
- National Prescribing Curriculum – online modules aim to support student/new prescriber's confidence and capabilities to prescribe in a consumer focused context and aligned to the NPCF.

Grant activities include:

- Health Professional Educational Programs – targeted towards supporting the QUM educational needs of health professionals. The grant opportunity can also support quality use of diagnostics and pathology which leads to improved QUM outcomes. The programs support synergies across the healthcare system, leveraging the grant funding to achieve shared QUM goals through the provision of evidence-based QUM initiatives;
- Consumer Health Literacy – targeted towards improving and supporting medication health literacy for Australians. The grants can also support quality use of diagnostics and pathology which leads to improved QUM outcomes. The grants require high levels of collaboration and cooperation between relevant QUM stakeholders to achieve the intended grant outcomes; and
- The QUPP, comprising three initiatives:
  - Quality Pathology Practice to support professional practice standards that meet consumer and referral needs and provide evidence-based, best practice, quality-assured services that are safe, efficient and cost effective;
  - Quality Referrals (Requesting/Ordering) to support referral practices that are informed and facilitated by best practice professional relationships and protocols

between referrers and providers, informed by evidence, maximise health benefits, and inform and engage consumers; and

- Quality Consumer Services to develop and improve consumer-focussed, accessible and coordinated services that promote informed choice and meet consumer needs.

Funding amount and arrangements, merits review and consultation

Funding of up to $34.4 million annually for the item comes from Program 1.1: Safety and Quality in Health Care (available to ACSQHC), Program 2.3: Pharmaceutical Benefits and Program 2.1: Medical Benefits, which are all part of Outcome 2. Details are set out in the *Portfolio Budget Statements 2024-25, Budget Related Paper No. 1.9, Health and Aged Care Portfolio* at pages 25, 78, 80, 82, 149, 150, 154, 155.

The QUDTP Program is delivered in accordance with the Commonwealth resource management framework, including the *Public Governance, Performance and Accountability Act 2013* (the PGPA Act), the *Public Governance, Performance and Accountability Rule 2014* (PGPA Rule) and the department's Accountable Authority Instructions.

The department uses a number of procurement processes for some activities and does so in line with the *Commonwealth Procurement Rules* (CPRs). These include open tenders for the delivery of specific activities (such as Australian Prescriber, National Prescribing Curriculum), the Management Advisory Service Panel, and other panels as relevant to the activity. The department also undertakes direct sourcing where appropriate and in line with the CPRs (such as engaging in contracts with other Government entities, including ACSQHC and to fund unsolicited proposals such as the engagement of the Australian Health Practitioner Regulation Agency to deliver the National Prescribing Competencies Framework) where these have aligned to the relevant programs objectives and represent value for money.

Procurement decisions will be made in accordance with the Commonwealth resource management framework, including the PGPA Act, the PGPA Rule and the CPRs. A delegate of the Secretary of the department under the *Financial Framework (Supplementary Powers) Act 1997* (FFSP Act) will be responsible for approving Commonwealth funding provided for all procurement. The delegate is the Assistant Secretary for Pricing & PBS Policy, Technology Assessment and Access Division (except for QUPP activities) and the Assistant Secretary for Diagnostic Imaging and Pathology Branch, Medicare Benefits and Digital Health Division (for QUPP activities only). These positions are the executives responsible for policies and programs the QUDTP Program supports and have the appropriate skills and experience to understand the medical and health detail of a tender. Where required, further technical expertise is available to support their decision making, including medical officers and specialist advisors and advisory groups.

The department will provide an opportunity for suppliers and tenderers to make complaints if they wish, and to receive feedback. These complaints and inquiries can be made at any time during the procurement process, and will be handled in accordance with probity requirements. Information about the tender and the resultant contracts will be made available on AusTender (www.tenders.gov.au) once the contracts are signed. Procurement decisions will be based on value for money, including capability and capacity to deliver, and price and risk considerations.

Grant activities delivered under the QUDTP Program are run as open competitive processes in line with the *Commonwealth Grants Rules and Principles 2024* (CGRPs) to support innovation and achieving value for money. Consistent with the CGRPs, the department will develop grant opportunity guidelines where necessary and have regard to the nine key principles in administering the grant.

Grant applications are assessed against the nominated selection criteria with an assessment panel making recommendations to the decision maker. Grant opportunity guidelines and information about the grants will be made available on the GrantConnect website (http://www.grants.gov.au). The grants will be administered by the Community Grants Hub, which is part of the Department of Social Services.

The Minister for Health and Aged Care's delegates, the Assistant Secretary, Pricing & PBS Policy Branch, Technology Assessment & Access Division, and the Assistant Secretary for Diagnostic Imaging and Pathology Branch, Medicare Benefits and Digital Health Division are responsible for approving Commonwealth funding for grant activities. They have the appropriate skills and experience to understand the medical and health detail provided within a grant application to assess how it would meet the program's objectives.

Funding decisions made in connection with the QUDTP Program, whether through grants or procurements are not considered suitable for independent merits review, as they are decisions relating to the allocation of a finite resource, from which all potential claims for a share of the resource cannot be met. In addition, any funding that has already been allocated would be affected if the original decision was overturned. The Administrative Review Council (ARC) 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?* (ARC guide)).

The remaking of a decision after entry into a contractual arrangement with a successful provider is legally complex, impractical, and could result in delays to providing services to platform users. The *Government Procurement (Judicial Review) Act 2018* enables suppliers to challenge some procurement processes for alleged breaches of certain procurement rules. This legislation might provide an additional avenue of redress (compensation or injunction) for dissatisfied or potential providers, depending on the circumstances.

Further, the right to review under section 75(v) of the Constitution and review under section 39B of the *Judiciary Act 1903* may be available. Persons affected by spending decisions would also have recourse to the Commonwealth Ombudsman where appropriate.

The Government has consulted with relevant parties regarding the QUDTP Program's redesign, these included NPS MedicineWise, the Royal Australian College of General Practitioners (RACGP), the Pharmaceutical Society of Australia, Consumers Health Forum, the National Aboriginal Community Controlled Health Organisation (NACCHO) and the ACSQHC. NPS MedicineWise and ACSQHC were heavily involved as part of the independent review process which was completed in August 2022.

The program redesign resulted in the transfer of responsibility for delivery of the QUDTP from NPS MedicineWise to the department. Other stakeholders such as RACGP welcomed the opportunity to compete for the grants and other activities and NACCHO welcomed the opportunities presented in the program's redesign.

The department continues to engage with interested parties through Grant Forums and other avenues as the opportunities present and as relates to the QUDTP Program's objectives.

Constitutional considerations

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

- the social welfare power (section 51(xxiiiA));
- the external affairs power (section 51(xxix)); and
- the communications power (section 51(v)).

Social Welfare Power

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

The QUDTP Program is directed at promoting better practice in the provision of pharmaceutical medicines under the PBS and diagnostic, therapeutic and pathology medical services provided under the MBS.

External affairs power

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.

Australia is a party to the *International Covenant on Economic, Social and Cultural Rights* [1976] ATS 5 (ICESCR). Article 2 provides the general obligation of States Parties to undertake steps, including the adoption of legislative measures, to achieve the full realisation of the rights recognised in the Covenant. Article 12(2)(c) requires achievement of the full realisation of the 'prevention, treatment and control of epidemic, endemic, occupational and other diseases' and Article 12(2)(d) requires 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness'.

The QUDTP Program enhances the quality use of medicines and reduces adverse drug events (e.g. incorrect taking of medicines), including by ensuring information is made available about the judicious, appropriate, safe and effective use of medicines.

Communications power

Section 51(v) of the Constitution empowers the Parliament to make laws with respect to 'postal, telegraphic, telephonic and other like services'.

Aspects of the QUDTP Program utilise phone and internet services to achieve the objectives of the program.

Amended table item 429 – Sport and Recreation Program

Item 6 – Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", paragraph (b) (first occurring))

Table item 429 in Part 4 of Schedule 1AB establishes legislative authority for government spending on the Sport and Recreation Program (the Program).

Item 6 amends table item 429 by omitting "by members of the community" in the column headed "Objective(s)" at paragraph (b) (first occurring). The amendment reflects the alignment of the Program's objective to promote access to, and participation in, sporting or recreation activities across Australia and the Pacific region.

Item 7 – Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", subparagraph (b)(i))

Item 7 amends table item 429 by inserting "by members of the community" before "who are", in the column headed "Objective(s)" at subparagraph (b)(i). The amendment reflects the alignment of the Program's objective to promote access to, and participation in, sporting or recreation activities by members of the community who are Indigenous Australians, children, women, non-citizens, immigrants or people with disabilities.

Item 8 – Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", subparagraph (b)(ii))

Item 8 amends table item 429 by inserting "by members of the community," before "to promote" in the column headed "Objective(s)" at subparagraph (b)(ii). The amendment reflects the alignment of the Program's objective to promote access to, and participation in, sporting or recreation activities by members of the community to promote physical and mental health and prevent disease.

Item 9 – Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", subparagraph (b)(iii))

Item 9 amends table item 429 by inserting "by members of the community," before "to eliminate" in the column headed "Objective(s)" at subparagraph (b)(iii). The amendment reflects the alignment of the Program's objective to promote access to, and participation in, sporting or recreation activities by members of the community to eliminate racial, cultural or ethnic discrimination and promote social cohesion within the community.

Item 10 – Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", after subparagraph (b)(iii))

Item 10 amends table item 429 by inserting "; or (iv) in Pacific Island countries;" in the column headed "Objective(s)" after paragraph (e). The amendment reflects the expanded scope of the Program's objective to promote access to, and participation in, sporting or recreation activities into the Pacific region.

Item 11 – Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", after paragraph (e))

Item 11 amends table item 429 by inserting new paragraphs "(ea) with respect to places, persons, matters or things external to Australia; or (eb) with respect to Australia's relations with the islands of the Pacific; or" in the column headed "Objective(s)" after paragraph (e). The amendment reflects that spending activities under the Program are also supported by the external affairs power with respect to matters or things outside the geographical limits of Australia, including matters concerning Australia's relations with other nations.

The Program provides legislative authority for a range of activities delivered by the department through Program 4.1: Sport and Physical Activity, which is part of Outcome 4. The Program aims to increase participation in sport and physical activity by all Australians and foster excellence in Australia's high-performance athletes. It also aims to further Australia's national interests by supporting the Australian sport sector, showcasing Australia as a premier host of major international sporting events, and developing sport policy and programs.

Funding under the Program supports activities across three streams:

- major international sporting events, to showcase Australia as a premier host of international sporting events through the bidding for and staging of major international sporting events in Australia;
- achieving excellence in Australia's representative athletes, to foster and supporting excellence in Australia's high performance or elite athletes; improve Australia's ability to identify and develop high performance and elite athletes including para-athletes to compete internationally; enable and empower sports to achieve sustained sporting success on domestic and international sporting stages; and promote gender equality in professional sport by supporting female athletes and women in leadership in sport; and
- increase participation in sport and recreation activities, to promote participation by all Australians in sporting and recreational activities in order to improve physical and mental health and prevent disease; promote participation in sporting and recreational activities in order to increase social cohesion and eliminate racial, cultural or ethnic discrimination within the community; and increase participation in sport and recreation among targeted community groups, including Indigenous Australians, children, women, non-citizens, immigrants and people with disabilities.

Table item 429 is amended to support the 2027 Men's Rugby World Cup (MRWC2027) Pacific Legacy Program and the 2029 Women's Rugby World Cup (WRWC2029) Pacific Legacy Program (both referred to as the Legacy Program), which form part of the third funding stream under the Program.

The overall purpose of the Legacy Program is to develop the sport of rugby and maximise health, well-being and social outcomes across Australia and the Pacific region. It is proposed to include activities involving club development, facilities, equipment and workforce support, developing states and territories, national programs, school competitions, women and girls' participation, and inclusion programs.

The Rugby World Cups 2027 and 2029 and associated Legacy Program funding are part of the Government's commitment to hosting major international sporting events in the lead up to the Brisbane 2032 Olympic and Paralympic Games (the 'green and gold decade'). The 'green and gold decade' of major sporting events provides a platform to showcase Australia on the global stage and inspire the next generation of healthier Australians. Hosting the MRWC2027 and WRWC2029 is projected to generate more than $2.0 billion in economic benefits to Australia. The WRWC2029 will promote gender equality and social inclusion in sport and drive increased physical activity from women and girls.

The Pacific aspects of the Legacy Program aim to make a lasting impact on Pacific rugby by investing in the capacity and capability of the Pacific national unions and teams. It will provide vital investment for Pacific rugby in the lead-up to the MRWC2027 and WRWC2029, resulting in more competitive Pacific national teams and stronger national unions. The Legacy Program will see Rugby Australia partner with World Rugby, Oceania Rugby, and the Pacific Unions to maximise high performance, management, well-being, and social outcomes across the Pacific region.

The Pacific aspects of the Legacy Program funding is aligned with the Government's policy objectives outlined in the Major Sport Events Legacy Framework (the Framework), in particular through diplomacy and building stronger communities in the region, and is complementary to the Department of Foreign Affairs and Trade's PacificAus Sports programs.

The Framework, developed by the Australian Government, through the Office for Sport and in consultation with relevant Government agencies, provides an overview of the Australian Government policy objectives that can be achieved through hosting major sporting events.

The Framework's vision is to attract, deliver and leverage world class major sporting events to provide the greatest social, sporting and economic benefits for all Australians. The five pillars that support the vision are:

- Promoting gender equality and a more inclusive society;
- Building a healthy and connected community;
- Showcasing Australia to the world;
- Strengthening our future; and
- Achieving sporting success.

Sport is one of the most powerful and influential social institutions. Hosting a major sporting event has the potential to provide economic, social, cultural, environmental and sporting benefits to Australia and enhance Australia international reputation.

Funding amount and arrangements, merits review and consultation

Funding of $30.0 million over six years from 2024-25 for the Legacy Program will come from Program 4.1: Sport and Physical Activity, which is part of Outcome 4. Details are set out in the *Portfolio Budget Statements 2024-25, Budget Related Paper No. 1.9, Health and Aged Care Portfolio* at page 103.

The department will provide funding for the Legacy Program to Rugby Australia as a non-competitive grant process. The grant will be administered in accordance with the Commonwealth resource management framework, including the PGPA Act, the PGPA Rule and the CGRPs.

In line with the CGRPs, the department will develop grant opportunity guidelines and will have regard to the nine key principles in administering the grant.

Grant opportunity guidelines and information about the grant will be made available on the GrantConnect website (www.grants.gov.au), and the grant will be administered by the Community Grants Hub, which is part of the Department of Social Services.

The delegate of the Secretary of the department, the Assistant Secretary, Major Events Branch will be responsible for approving Commonwealth funding provided to Rugby Australia acting in accordance with the FFSP Act. The Assistant Secretary has extensive experience in overseeing delivery of major sporting events and related legacy programs hosted in Australia, from grant development and assessment, event delivery and event evaluation.

Funding decisions in relation to the Legacy Program will not be suitable for independent merits review because the funding will be delivered through a closed non-competitive grant to Rugby Australia, as the only suitable organisation to facilitate the program. The decision for funding is not directed towards the circumstances of particular persons, but rather applies generally to the community, and is therefore considered to be unsuitable for review. This event, by its nature is unlikely to affect the interests of any one person.

Further, decisions relating to the allocation of a finite resource, from which all potential claims for a share of the resource cannot be met, have been recognised by the ARC as justifiable to exclude merits review (see paragraphs 4.11 to 4.19 of the ARC guide).

In any case, the right to review under section 75(v) of the Constitution and review under section 39B of the *Judiciary Act 1903* may be available. Persons affected by spending decisions would also have recourse to the Commonwealth Ombudsman where appropriate.

The department, through the Office for Sport, has consulted with the Department of Foreign Affairs and Trade and Australian Sports Commission in the design of the Legacy Program.

The Office for Sport further consulted with Rugby Australia on the development of a detailed plan for the Legacy Program, taking into consideration consultations Rugby Australia had had with World Rugby and the Pacific Unions. The consultations with Rugby Australia focused on ensuring the Legacy Program was fit for purpose and suitable to the Government’s objectives. Rugby Australia has been consulting with World Rugby and the Pacific Unions on developing the detailed legacy plan for the Pacific legacy funding.

Constitutional considerations

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

- the communications power (section 51(v));
- the aliens power (section 51(xix));
- the race power (section 51(xxvi));
- the immigration power (section 51(xxvii));
- the external affairs power (section 51(xxix));
- the Pacific Islands power (section 51(xxx));
- the executive power and express incidental power (section 61 and section 51(xxxix)), including the nationhood aspect; and
- the Territories power (section 122).

Communications power

Section 51(v) of the Constitution empowers the Parliament to make laws with respect to 'postal, telegraphic, telephonic and other like services'. The Legacy Program will assist with improvements to ICT infrastructure or may be conducted through the internet, telephone or broadcast media (such as publishing information and analysis about the Legacy Program over the internet).

Aliens power

Section 51(xix) of the Constitution empowers the Parliament to make laws with respect to 'naturalization and aliens'. The Legacy Program aims to increase and promote participation in sport and recreation amongst different groups in Australia and in Pacific nations, including to benefit persons born outside Australia, whose parents were not Australians, and who has not been naturalised as an Australian.

Race power

Section 51(xxvi) of the Constitution empowers the Parliament to make laws with respect to 'the people of any race for whom it is deemed necessary to make special laws'. The Legacy Program aims to increase and promote participation in sport and recreation to different groups in society, including activities specifically directed at Indigenous Australians and persons of other particular races.

Immigration power

Section 51(xxvii) of the Constitution empowers the Parliament to make laws with respect to 'immigration and emigration'. The Legacy Program aims to increase and promote participation in sport and recreation to different groups in society, including activities specifically directed at new migrants.

External affairs power

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

The external affairs power supports legislation with respect to matters or things outside the geographical limits of Australia. The Pacific aspects of the Legacy Program will involve the delivery of activities to increase and promote participation in sport and recreation in the Pacific region.

The external affairs power also supports legislation with respect to matters concerning Australia's relations with other nations. The Pacific aspects of the Legacy Program aim to strengthen relations between Australia and Pacific Island countries.

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

Convention on the Rights of the Child (CRC)

Australia is a party to the CRC [1991] ATS 4. Under Article 4, Australia is under an obligation as a party to the CRC to 'undertake all appropriate legislative, administrative, and other measures for the implementation of rights recognized' in the CRC. This includes the right under Article 24 to pursue the full implementation of 'the rights of the child to the enjoyment of the highest attainable standard of health', including by 'develop[ing] preventive health care' and 'guidance for parents'. This also includes the right under Article 31 to respect and promote the 'right of the child to participate fully in cultural and artistic life' and 'encourage the provision of appropriate and equal opportunities for cultural, artistic, recreational and leisure activity'.

The Legacy Program aims to increase and promote participation in sport and recreation to different groups in society, including children.

Convention on the Elimination of All Forms of Discrimination against Women (CEDAW)

Australia is a party to the CEDAW [1983] ATS 9. The Legacy Program is particularly relevant to Articles 2 and 10 of the CEDAW.

Article 2 requires States Parties to:

1. …condemn discrimination against women in all its forms, agree to pursue by all appropriate means and without delay a policy of eliminating discrimination against women and, to this end, undertake…

   (b) To adopt appropriate legislative and other measures, including sanctions where appropriate, prohibiting all discrimination against women…

   (e) To take all appropriate measures to eliminate discrimination against women by all persons, organisation or enterprise;

   (f) To take all appropriate measures, including legislation, to modify or abolish existing laws, regulations, customs and practices which constitute discrimination against women;

Article 10 requires States Parties to:

1. …take all appropriate measures to eliminate discrimination against women in order to ensure to them equal rights with men in the field of education and in particular to ensure, on a basis of equality of men and women…

    (g) The same Opportunities to participate actively in sports and physical education.

The Legacy Program aims to increase and promote participation in sport and recreation to different groups in society, including specifically to women.

Convention on the Rights of Persons with Disability (CRPD)

Australia is a party to the CRPD [2008] ATS 12. Parties to the CRPD are required to ensure and promote the full realisation of all human rights and fundamental freedoms for all persons with disabilities without discrimination of any kind on the basis of disability (Art 4(1)). Parties to the CRPD are also required to 'recognize the right of persons with disabilities to take part on an equal basis with others in cultural life' (Article 30(1)). This includes to 'enable persons with disabilities to participate on an equal basis with others in recreational, leisure and sporting activities' (Article 30(5)).

In particular, Article 30(5) requires States Parties to take appropriate measures:

(a) To encourage and promote the participation, to the fullest extent possible, of persons with disabilities in mainstream sporting activities at all levels;
(b) To ensure that persons with disabilities have an opportunity to organize, develop and participate in disability-specific sporting and recreational activities and, to this end, encourage the provision, on an equal basis with others, of appropriate instruction, training and resources;
(c) To ensure that persons with disabilities have access to sporting, recreational and tourism venues;
(d) To ensure that children with disabilities have equal access with other children to participation in play, recreation and leisure and sporting activities, including those activities in the school system;
(e) To ensure that persons with disabilities have access to services from those involved in the organization of recreational, tourism, leisure and sporting activities.

The Legacy Program aims to increase and promote participation in sport and recreation to different groups in society, including specifically to people with disabilities.

International Covenant on Economic, Social and Cultural Rights (ICESCR)

Australia is a party to the ICESCR. 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 15(1) of the ICESCR recognises the 'right of everyone to take part in cultural life'. Article 2 requires each State Party to 'take steps…to the maximum of its available resources, with a view to achieving progressively the full realisation' of this right 'by all appropriate means, including particularly the adoption of legislative measures'.

The steps to be taken by States Parties to achieve full realisation of the right to health are specified in Article 12(2) and include steps necessary for:

(a) The prevention, treatment and control of epidemic, endemic, occupational and other diseases (Article 12(2)(c)); and
(b) The creation of conditions which would assure to all medical service and medical attention in the event of sickness (Article 12(2)(d)).

The steps to be taken by States Parties to achieve full realisation of the right to take part in cultural life are specified in Article 15 and include steps necessary for 'full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture'.

The Legacy Program aims to promote participation in sporting and recreational activities in order to improve physical and mental health and prevent disease. The Legacy Program also promotes participation in sporting and recreational activities in order to increase social cohesion and eliminate racial, cultural or ethnic discrimination within the community.

Pacific Islands power

Section 51(xxx) of the Constitution empowers the Parliament to make laws with respect to 'the relations of the Commonwealth with the islands of the Pacific'. The Pacific aspects of the Legacy Program aim to strengthen relations between Australia and Pacific Island countries.

Executive power and express incidental power, including the nationhood aspect

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.

Aspects of the Legacy Program are aimed at reducing racial, cultural and religious intolerance and strengthening social cohesion, community harmony and cross-cultural understanding for the benefit of the nation, particularly where promoting the program can be demonstrably linked to addressing national security risks).

Territories power

Section 122 of the Constitution empowers the Parliament to 'make laws for the government of any territory'.

The Legacy Program aims to promote participation in sporting and recreational activities in Australia, including the delivery of activities in the Territories.

Amended table item 531 – mRNA vaccines and treatments

Item 12 – Part 4 of Schedule 1AB (table item 531, column headed "Objective(s)")

Table item 531 in Part 4 of Schedule 1AB establishes legislative authority for government spending on the messenger Ribonucleic Acid (mRNA) vaccines and treatments program (the program).

Item 12 amends table item 531 by omitting "mRNA products" and substituting "mRNA vaccines and products, including by purchasing mRNA vaccines and products manufactured onshore" in the column headed "Objective(s)". The amendment clarifies the effect of table item 531 to establish and maintain the Moderna facility in anticipation of it manufacturing mRNA respiratory vaccines for purchase by the Commonwealth.

In the 2021-22 Budget, the Government agreed to establish an onshore end-to-end, population-scale mRNA manufacturing capability in Australia under a ten-year partnership with Moderna Australia Pty Ltd (Moderna) (the Moderna Partnership). The Moderna Partnership is supported through a Facility Establishment Agreement (FEA) that commenced in March 2022 and will terminate in June 2032.

The Moderna Partnership includes the establishment of a population-scale mRNA respiratory vaccine manufacturing facility and a regional research and development centre for respiratory medicines and tropical diseases in Melbourne, Victoria. The Moderna Partnership also includes financial contribution from the Victorian Government.

The Moderna Partnership will supply mRNA respiratory vaccines and provide Australia with priority access in case of pandemics. The initiative signals the Australian Government's support for onshore advanced technology manufacturing and sovereign capability, a commitment to pandemic readiness, and supporting Australia's world class capabilities to develop and produce the next generation of medical technology.

The construction of the facility is currently underway and expected to be completed by December 2024. Pending successful trials, regulatory approvals by the Therapeutic Goods Administration (TGA) and Health Technology Assessments (HTA), Moderna envisages to manufacture the onshore vaccines in the first half of 2025. The Australian Government will purchase the onshore vaccines outside the National Immunisation Program as per the FEA with Moderna.

The Australian Government funding commitments under the FEA include:

- an Annual Pandemic Preparedness Facility Fee which is the annual fee paid to Moderna for the up keep of the facility and commences on the date that drug manufacturing and fill/finish facilities have TGA approval to commence manufacturing mRNA vaccines; and
- an Annual Minimum Purchase Commitments of COVID-19 vaccines, plus other respiratory vaccines should they be approved by TGA. The Commonwealth's commitment to purchasing minimum number of vaccines for delivery in each financial year.

The final funding amount paid to Moderna will depend on several factors including:

- determining COVID-19 needs based on recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI);
- the number of Moderna mRNA vaccines approved by the TGA;
- the results of undertaking HTA noting the onshore vaccines will not go through the Pharmaceutical Advisory Committee (PBAC) process and therefore will not be listed as designated vaccines on the National Immunisation Program (refer to section 9B of the *National Health Act 1953*); and
- the date by which the TGA will provide their Good Manufacturing Practice (GMP) license for the facility, and approve manufacturing each vaccine at the facility.

Building on the success of breakthrough COVID-19 mRNA vaccines, the Commonwealth recognises that the 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, other respiratory disease vaccines including respiratory syncytial virus (RSV) and influenza, as well as future pandemics.

In establishing an onshore mRNA manufacturing capability including product fill and finish facilities in Victoria, the Commonwealth's objectives are to:

- secure onshore population-scale mRNA vaccine manufacturing capability, supply and resilience to respond to future pandemics and other health emergencies;
- provide priority access to mRNA COVID-19 vaccines and other respiratory vaccines should those vaccines obtain regulatory approval from the TGA;
- 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 establishing 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;
- non-pandemic vaccine supply agreements to procure Australia's requirement for COVID-19 vaccines, RSV, influenza and other mRNA vaccines should those vaccines be developed and approved;
- ongoing pandemic preparedness fees to secure priority access to mRNA pandemic vaccines; and
- pandemic vaccine advance purchase agreements if Moderna identifies and/or develops vaccine candidates for future pandemics.

Moderna is the primary project lead to establish and operate the end-to-end mRNA manufacturing facility. However, the Commonwealth represented by the department is the head agency for the FEA with Moderna and provides the ongoing contract management and supplier engagement. The department will also work closely with the Department of Industry, Science, and Resources (DISR) which provides policy support in relation to the research and

development ecosystem and regional hub elements; and the Department of Jobs, Skills, Industry and Regions in Victoria (through mRNA Victoria), which provides support in relation to construction of the facility and development of the regional research and development centre in Victoria.

Funding amount and arrangements, merits review and consultation

Under the FEA between Moderna and Australia for establishing onshore capability to manufacture mRNA products, procurement of vaccines is yet to occur. The procurement will be represented under sub-agreements with Moderna, which upon finalisation will provide greater clarity around the amount of funding allocated to the program.

To ensure confidentiality of commercial information in the agreements between Australia and Moderna is maintained and to ensure that disclosure of financial implications is in line with the final contract terms, it is the intention of the Australian Government to disclose the funding allocated for the program once the agreements are finalised.

The department will procure the goods and services with Moderna in accordance with applicable legislative requirements and the Commonwealth resource management framework under the PGPA Act, the PGPA Rule, the CPRs and the department's Accountable Authority Instructions.

The expenditure will be provided through an approved process, including a procurement process. In this regard, the Secretary of the department (as the relevant Accountable Authority) has made a determination under paragraph 2.6 of the CPRs to disapply Divisions 1 and 2 of the CPRs to the proposed procurement of onshore mRNA manufacturing capability and supply of mRNA vaccines and treatments for both pandemic and non-pandemic purposes and all incidental or related matters (the procurement) on the basis that it is necessary to protect human health. Accordingly, the requirement to publish the details of the proposed procurement on AusTender as set out in the CPRs will not apply. However, the department will be required to table details relating to the proposed procurement, in accordance with the *Senate Procedural Orders of Continuing Effect No. 12* (Production of Indexed Lists of Departmental and Agency Files).

Irrespective of the exemption given under paragraph 2.6 of CPRs, 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.

Vaccine purchase decisions will be made following a thorough HTA process, similar to that for the Pharmaceutical Benefits Advisory Committee. The department will make a recommendation on purchases to the Minister for Health and Aged Care, and should agreement be given, the delegate, at the Senior Executive Service (Band 2 level) who has responsibility for the oversight of the procurement will be the final decision maker. Purchase decisions will be exercised in accordance with the PGPA Act, Moderna contract, and department policies.

The department would propose to:

- execute and manage all contracts for the above services for the term of the agreements;
- work collaboratively with DISR 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.

Procurement decisions made in connection with the program 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 ARC 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 ARC guide).

The remaking 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. The *Government Procurement (Judicial Review) Act 2018* enables suppliers to challenge some procurement processes for alleged breaches of certain procurement rules. This legislation might provide an additional avenue of redress (compensation or injunction) for dissatisfied providers or potential providers, depending on the circumstances.

Furthermore, procurement for onshore mRNA manufacturing is a financial policy decision with a significant public interest element. The program is a response to the COVID-19 pandemic and would enhance sovereign capability and readiness for future pandemics. Arrangements are required to be entered into to uphold public confidence in the health systems and the national vaccination programs.

The ARC has acknowledged that it is justifiable to exclude merits review in relation to decisions of this nature (see paragraph 4.34 of the ARC guide,). While it is acknowledged that reliance on this justification for the exclusion of merits review is rare (see paragraph 4.36 of the ARC guide), the context of a global pandemic is an extremely rare situation.

The project was a joint Taskforce activity between the department, DISR and the Department of Finance. Across 2020 and 2021, the following governing bodies and agencies were consulted during the project phase, up to execution of agreements in March 2022:

- state governments;
- ATAGI;
- TGA;
- PBAC;
- COVID-19 Vaccines and Treatments for Australia – Science and Industry Technical Advisory Group;
- the Department of Foreign Affairs and Trade;
- the Department of the Prime Minister and Cabinet; and
- an Expert Advisory Group advising on the Approach to Market process and the Moderna proposal.

DISR lead this process, and broadly the intention to establish an onshore mRNA respiratory vaccine manufacturing capability was met with a consensus to proceed.

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

- state governments;
- DISR;
- TGA;
- ATAGI;
- relevant industries; and
- the biotechnology research sector, particularly with regard to the development of the research and development ecosystem.

Constitutional considerations

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

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

External affairs power

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.

Australia has international obligations under the ICESCR. 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 2 requires each State Party to 'take steps…to the maximum of its available resources, with a view to achieving progressively the full realisation' of this right 'by all appropriate means, including particularly the adoption of legislative measures'.

The steps to be taken by States Parties to achieve full realisation of the right to health are specified in Article 12(2) and include steps necessary for:

(a) The prevention, treatment and control of epidemic, endemic, occupational and other diseases (Article 12(2)(c)); and
(b) The creation of conditions which would assure to all medical service and medical attention in the event of sickness (Article 12(2)(d)).

The Committee on Economic, Social and Cultural Rights has expressed the view these obligations require States parties to, among other matters, 'implement and enhance immunization programmes'.

The program 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 program 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 program 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

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

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

Executive power and express incidental power, including the nationhood aspect

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 program relates to the onshore production of mRNA vaccines and treatments, in order to enhance Australia's immunisation programs. The program 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.

Attachment B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the legislative instrument

Section 32B of the *Financial Framework (Supplementary Powers) Act 1997* (the FFSP Act) authorises the Commonwealth to make, vary and administer arrangements and grants specified in the *Financial Framework (Supplementary Powers) Regulations 1997* (the Principal Regulations) and to make, vary and administer arrangements and grants for the purposes of programs specified in the Regulations. Schedule 1AA and Schedule 1AB to the Principal Regulations specify the arrangements, grants and programs. The powers in the FFSP Act to make, vary or administer arrangements or grants may be exercised on behalf of the Commonwealth by Ministers and the accountable authorities of non-corporate Commonwealth entities, as defined under section 12 of the *Public Governance, Performance and Accountability Act 2013*.

The *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024* (the Regulations) amend Schedule 1AB to the Principal Regulations to establish legislative authority for Government spending on activities administered by the Department of Health and Aged Care (the department).

This disallowable legislative instrument makes the following amendments to Part 4 of Schedule 1AB:

- amends table item 306 ‘Quality Use of Diagnostics, Therapeutics and Pathology Program’;
- amends table item 429 ‘Sport and Recreation Program’; and
- amends table item 531 ‘mRNA vaccines and treatments’.

Amended table item 306 – Quality Use of Diagnostics, Therapeutics and Pathology Program

The amended table item 306 establishes legislative authority for government spending on the Quality Use of Diagnostic, Therapeutics and Pathology (QUDTP) Program to reflect changes to the program design.

The QUDTP Program was established in 1999 and aimed to:

- improve the quality use of therapeutics, diagnostics and pathology for Australian consumers;
- improve the quality use of therapeutics, diagnostics and pathology for Australian health professionals;

- facilitate free access to information to support appropriate use of therapeutics, diagnostics and pathology; and
- support the effectiveness and efficiency of the health system.

The QUDTP Program was redesigned in 2022, with the subsequent arrangements operating from 1 January 2023. The redesign primarily resulted in the responsibility for delivery of the QUDTP moving from NPS MedicineWise to the department in collaboration with the Australian Commission on Safety and Quality in Health Care (ACSQHC). The QUDTP Program supports the optimal use of medicines and diagnostics and enhances the ACSQHC's ability to co-ordinate and drive quality and safety improvements related to medicine and diagnostic use across the Australian health system.

Under the QUDTP Program, the department will also deliver targeted Quality Use of Medicines educational activities for health professionals and consumers through competitive grants and procurement processes to support the optimal use of therapeutics and diagnostics.

Funding of up to $34.4 million annually is available for the QUDTP Program.

Human rights implications

The amended table item 306 engages the following right:

- 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.

Right of everyone to the enjoyment of the highest attainable standard of physical and mental health

Article 2 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 realisation of the rights in the ICESCR by all appropriate means, including particularly the adoption of legislative measures.

Article 12(2) of the ICESCR requires that each State Party to the ICESCR takes steps to achieve the full realisation of the right shall include for:

(a) the provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
(b) the improvement of all aspects of environmental and industrial hygiene;
(c) the prevention, treatment and control of epidemic, endemic, occupational and other diseases;
(d) the creation of conditions which would assure to all medical service and medical attention in the event of sickness.

The QUDTP Program will advance the prevention, treatment and control of health issues and optimise health outcomes for Australians, through supporting health professionals, service providers and consumers with evidenced based education and support resources.

The amended table item 306 is compatible with human rights as the ongoing delivery of the QUDTP Program promotes quality use of medicine create conditions which assure to all medical service and medical attention in the event of sickness.

Amended table item 429 – Sport and Recreation Program

The amended table item 429 establishes legislative authority for government spending for the Sport and Recreation Program (the Program), which include a range of activities undertaken by the department through Program 4.1: Sport and Physical Activity, which is part of Outcome 4.

The Program aims to increase participation in sport and physical activity by all Australians and foster excellence in Australia's high-performance athletes. It also aims to further Australia's national interests by supporting the Australian sport sector, showcasing Australia as a premier host of major international sporting events, and developing sport policy and programs.

Table item 429 is amended to support the 2027 Men's Rugby World Cup Pacific Legacy Program and the 2029 Women's Rugby World Cup Pacific Legacy Program (both referred to as the Legacy Program).

The purpose of the Legacy Program is to expand the sport of rugby and maximise health, well-being and social outcomes across Australia and the Pacific region. It is proposed to include activities involving club development, infrastructure, equipment and workforce support, developing states and territories, national programs, school competitions, women and girls' participation, and inclusion programs.

Funding of $30.0 million over six years from 2024-25 will be available for the Legacy Program.

Human rights implications

The amended table item 429 engages the following rights:

- the right to enjoy and benefit from culture – Articles 12 and 15 of the ICESCR, read with Article 2;
- the right of persons with disabilities to participate on an equal basis in cultural life, creation, leisure and sport – Article 30 of the *Convention on the Rights of Persons with Disability* (CRPD), read with Article 4;
- the right of women to the exercise and enjoyment of human rights and fundamental freedoms, in particular in the political, social, economic and cultural fields – Article 10 of the *Convention on the Elimination of All Forms of Discrimination against Women* (CEDAW), read with Article 2; and
- the rights of every child to engage freely in cultural life and the arts, as well as playing and recreational activities appropriate to his or her age – Articles 24 and 31 of the *Convention on the Rights of the Child* (CRC), read with Article 4.

Right to enjoy and benefit from culture

Article 2(2) of the ICESCR requires States Parties to undertake to guarantee the right to culture be exercised without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status. According to the United Nations Committee on Economic, Social and Cultural Rights, the right to culture includes sports and games.

Article 12(1) recognises the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. Sport and physical activity play an important role in both physical and mental wellbeing.

Article 15(1)(a) of the ICESCR recognises the right of everyone to take part in cultural life. According to the United Nations Committee on Economic, Social and Cultural Rights, the right to culture includes sports and games. This right encompasses access to culture, which includes the availability of mainstream sporting activities at all levels and sporting events hosted in Australia, in which everyone can participate.

Rights of persons with disabilities

Article 4 of the CPRD obliges each State Party to ensure and promote the full realisation of all human rights and fundamental freedoms for all persons with disabilities without discrimination of any kind on the basis of disability. This right includes elimination of discrimination in the field of employment, which includes occupations in the sport and physical activity sector.

Article 30 of the CPRD recognises the right of persons with disabilities to participate on an equal basis with others in cultural life, recreation, leisure and sport. This right encompasses the encouragement and promotion of participation, to the fullest extent possible, of persons with disabilities in mainstream sporting activities at all levels. It also encompasses access to sport, which includes the availability of sporting events (including those specifically for persons with disabilities) hosted in Australia.

Rights of women

Article 2 of the CEDAW condemns the discrimination of women in all its forms.

Article 10 of the CEDAW recognises the right of women to the same opportunities to participate in education as men. This right encompasses the encouragement and promotion of participation, to the fullest extent possible, of women in sport and physical activity education at all levels.

Rights of the child

Article 4 of the CRC obliges each State Party to undertake measures regarding economic, social and cultural rights of children to the maximum extent of their available resources. According to the United Nations Committee on Economic, Social and Cultural Rights, the right to culture includes sports and games.

Article 24 of the CRC obliges each State Party to ensure the rights of children to the highest attainable standard of health. This includes measures to combat disease and malnutrition, provide access to health education and develop preventive health care. Sport and physical activity have recognised physical and mental health benefits, and can aid in the prevention of an array of diseases.

Article 31(1) of the CRC recognises the right of every child to rest and leisure and to engage freely in cultural life and the arts, as well as playing and recreational activities appropriate to his or her age. This right encompasses the encouragement and promotion of participation, to the fullest extent possible, of children in mainstream sporting activities at all levels.

The amended table item 429 is compatible with human rights because the item will promote and protect human rights through the outcomes achieved to enhance sport and physical activity from the delivery of the Legacy Program.

Amended table item 531 – mRNA vaccines and treatments

The amended table item 531 establishes legislative authority for government spending on the messenger Ribonucleic Acid (mRNA) vaccines and treatments program (the program) to clarify the effect of item 531 to establish and maintain the Moderna facility in anticipation of it manufacturing mRNA respiratory vaccines for purchase by the Commonwealth.

In the 2021-22 Budget, the Government agreed to establish an onshore end-to-end, population-scale mRNA manufacturing capability in Australia and a regional research and development centre for respiratory medicines and tropical diseases in Melbourne, Victoria under a ten-year partnership with Moderna Australia Pty Ltd (Moderna) (the Moderna Partnership). The Moderna Partnership is supported through a Facility Establishment Agreement (FEA) that commenced in March 2022 and will terminate in June 2032.

The Moderna Partnership will supply mRNA respiratory vaccines and provide Australia with priority access in case of pandemics. The initiative signals the Australian Government's support for onshore advanced technology manufacturing and sovereign capability, a commitment to pandemic readiness, and supporting Australia's world class capabilities to develop and produce the next generation of medical technology.

The Australian Government funding commitments under the FEA include:

- an Annual Pandemic Preparedness Facility Fee which is the annual fee paid to Moderna for the up keep of the facility and commences on the date that drug manufacturing and fill/finish facilities have Therapeutic Goods Administration approval to commence manufacturing mRNA vaccines; and
- an Annual Minimum Purchase Commitments of COVID-19 vaccines, plus other respiratory vaccines should they be approved by TGA. The Commonwealth's commitment to purchasing minimum number of vaccines for delivery in each financial year.

Human rights implications

The amended table item 531 engages the following right:

- the right of everyone to the enjoyment of the highest attainable standard of physical and mental health – Article 12 of ICESCR, read with Article 2.

Right of everyone to the enjoyment of the highest attainable standard of physical and mental health

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 program 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 program 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, the amended table item 531 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

This disallowable legislative instrument is compatible with human rights because it promotes the protection of human rights.

Senator the Hon Katy Gallagher
Minister for Finance

Senator the Hon Katy Gallagher

Minister for Finance
Minister for Women
Minister for the Public Service
Senator for the Australian Capital Territory

REF: MS24-000856

The Hon Mark Butler MP
Minister for Health and Aged Care
Parliament House
CANBERRA ACT 2600

Dear Minister

Thank you for your letters of 9 September 2024 seeking my agreement to amend Schedule 1AB to the *Financial Framework (Supplementary Powers) Regulations 1997* (FFSP Regulations).

I agree to your requests to amend Schedule 1AB to the FFSP Regulations to establish legislative authority for government spending relating to the Quality Use of Diagnostics, Therapeutics and Pathology Program and the messenger Ribonucleic Acid (mRNA) vaccines and treatments program, as set out in your letters.

s42 [redacted]

The necessary documentation will be submitted to the Governor-General for consideration at the Executive Council meeting currently scheduled for 24 October 2024. Once the matter has been considered by the Governor-General, my Department will advise your Department of the outcome.

Yours sincerely

Katy Gallagher

PDR Number: MS24-000856
Date sent to MO: 3 October 2024

Australian Government
Department of Finance

MINISTERIAL SUBMISSION

Copies to:
Secretary
Mr Williamson
Ms Patterson
Mr Windeyer
Ms Fox
Mr Webster
Ms Harmer
Mr Sorbello
Ms Cole
Ms Carroll
Ms Tran

Minister for Finance

***Financial Framework (Supplementary Powers) Regulations 1997* – Schedule 1AB – various portfolios – Federal Executive Council Meeting on 24 October 2024**

Minister's action due by: 15 October 2024, to enable documentation to be submitted by the cut-off date for the Federal Executive Council (ExCo) meeting scheduled for 24 October 2024.

Recommendations:

That you:

i. **agree** to request that the Governor-General make 11 regulations to amend the *Financial Framework (Supplementary Powers) Regulations 1997* (the FFSP Regulations) as outlined at Attachment A;

AGREED / NOT AGREED / PLEASE DISCUSS

s22 [redacted]

NOTED / PLEASE DISCUSS

s42 [redacted]

NOTED / PLEASE DISCUSS

iv. **sign**, but do not date, the proposed regulations at Attachments B to L;

SIGNED / PLEASE DISCUSS

v. **sign**, but do not date, the Executive Council Minutes for each of the proposed regulations at Attachments B1 to L1;

SIGNED / PLEASE DISCUSS

vi. **initial** the bottom right-hand corner of each page of the Explanatory Memoranda for each of the proposed regulations at Attachments B2 to L2;

INITIALLED / PLEASE DISCUSS

vii. **approve** the release of the Explanatory Statements for each of the proposed regulations at Attachments B3 to L3;

APPROVED / NOT APPROVED / PLEASE DISCUSS

s22 [redacted]

APPROVED / NOT APPROVED / PLEASE DISCUSS

ix. **sign** the reply letters to the responsible Ministers at Attachments N to X.

SIGNED / PLEASE DISCUSS

/ /

Katy Gallagher

Key Issues:

Schedule 1AB amendments to the FFSP Regulations

1. Requests have been received from the following Ministers (Attachment Y) for amendments to Schedule 1AB to the FFSP Regulations to establish legislative authority for 19 spending activities in their portfolios:

s22 [redacted]

vii. Minister for Health and Aged Care, the Hon Mark Butler MP (2 items);

s22 [redacted]

s22 [redacted]

4. A summary of the proposed amendments to be considered at the 24 October 2024 ExCo meeting is included in Attachment A.

s42 [redacted]

8. Subject to your approval, all proposed regulations will be submitted for consideration by the Governor-General at the ExCo meeting scheduled for 24 October 2024.

Senate Standing Committee for the Scrutiny of Delegated Legislation (the Committee)

s22 [redacted]

Financial Implications:

14. Funding details for the Schedule 1AB items in the proposed regulations are set out at Attachment A.

Consultation:

15. Budget Group, Commercial Group, the responsible entities, the Office of Constitutional Law in the Attorney-General's Department and the Executive Council Secretariat were consulted.

Attachments:
Att A – Summary of the items contained in each of the regulations
Att B to L – Proposed regulations
Att B1 to L1 – Executive Council Minute Papers for each of the regulations
Att B2 to L2 – Explanatory Memoranda for each of the regulations
Att B3 to L3 – Explanatory Statements for each of the regulations
Att M – Replacement Explanatory Statement to the Finance Regulations
Att N to X – Letters to responsible Ministers, approving proposed Schedule 1AB amendments
Att Y – Letters from responsible Ministers requesting approval for amendments

Approved for electronic transmission

s22
A/g Assistant Secretary
Financial Management Branch
Financial Analysis, Reporting and Management Division
s22

Contact Officer: s22
Job Title/Level: Director/EL2
Telephone: s22
PDR Number MS24-000856

Subject: FW: PDMS Notification - Record Assigned : MS24-000856 Financial Framework (Supplementary Powers) Regulations 1997 – Schedule 1AB – various portfolios – Federal Executive Council Meeting on 24 October 2024 [SEC=PROTECTED, CAVEAT=SH:CABINET]

Attachments: MS24-000856 - MF signed.pdf

From: noreply@pws.gov.au <noreply@pws.gov.au>
Sent: Thursday, 10 October 2024 5:24 PM
To: s22 @finance.gov.au>; s22 @finance.gov.au>; s22 @finance.gov.au>; s22 @finance.gov.au>; s22 @finance.gov.au>; s22 @finance.gov.au>
Subject: PDMS Notification - Record Assigned : MS24-000856 Financial Framework (Supplementary Powers) Regulations 1997 – Schedule 1AB – various portfolios – Federal Executive Council Meeting on 24 October 2024 [SEC=PROTECTED,CAVEAT=SH:CABINET]

SEC=PROTECTED,CAVEAT=SH:CABINET

SUBJECT: Financial Framework (Supplementary Powers) Regulations 1997 – Schedule 1AB – various portfolios – Federal Executive Council Meeting on 24 October 2024

This is for your Information Only as the record was CC'ed to you by s22

This record can be viewed via the following link: **MS24-000856**

s22 has assigned MS24-000856 to Parliamentary Coordinator MS with the following details of the PDR

Record Details **please note if any of the fields below are empty, the associated field is not populated in the record*	
PDR Number	MS24-000856
PDR Subject	Financial Framework (Supplementary Powers) Regulations 1997 – Schedule 1AB – various portfolios – Federal Executive Council Meeting on 24 October 2024
Status	Ready For Publication
Processing Instructions	Signed by Minister. Letters dispatched from FMO via email. Hard copies of ExCo papers retained in DLO safe.
Milestones	Due for Clearance: 30/09/2024 5:00:00 PM Due to Parliamentary: 30/09/2024 5:00:00 PM

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For assistance please call s22 or email pdms@finance.gov.au

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PDR Number: MS24-000856
Date sent to MO: 3 October 2024

Australian Government
Department of Finance

MINISTERIAL SUBMISSION

Copies to:
Secretary
Mr Williamson
Ms Patterson
Mr Windeyer
Ms Fox
Mr Webster
Ms Harmer
Mr Sorbello
Ms Cole
Ms Carroll
Ms Tran

Minister for Finance

***Financial Framework (Supplementary Powers) Regulations 1997* – Schedule 1AB – various portfolios – Federal Executive Council Meeting on 24 October 2024**

Minister's action due by: 15 October 2024, to enable documentation to be submitted by the cut-off date for the Federal Executive Council (ExCo) meeting scheduled for 24 October 2024.

Recommendations:

That you:

i. **agree** to request that the Governor-General make 11 regulations to amend the *Financial Framework (Supplementary Powers) Regulations 1997* (the FFSP Regulations) as outlined at Attachment A;

AGREED / NOT AGREED / PLEASE DISCUSS

s22 [redacted]

NOTED / PLEASE DISCUSS

s42 [redacted]

NOTED / PLEASE DISCUSS

iv. **sign**, but do not date, the proposed regulations at Attachments B to L;

SIGNED / PLEASE DISCUSS

v. **sign**, but do not date, the Executive Council Minutes for each of the proposed regulations at Attachments B1 to L1;

SIGNED / PLEASE DISCUSS

vi. **initial** the bottom right-hand corner of each page of the Explanatory Memoranda for each of the proposed regulations at Attachments B2 to L2;

INITIALLED / PLEASE DISCUSS

vii. **approve** the release of the Explanatory Statements for each of the proposed regulations at Attachments B3 to L3;

APPROVED / NOT APPROVED / PLEASE DISCUSS

s22 [redacted]

APPROVED / NOT APPROVED / PLEASE DISCUSS

ix. **sign** the reply letters to the responsible Ministers at Attachments N to X.

SIGNED / PLEASE DISCUSS

Katy Gallagher 8/10/24

Katy Gallagher

Key Issues:

Schedule 1AB amendments to the FFSP Regulations

1. Requests have been received from the following Ministers (Attachment Y) for amendments to Schedule 1AB to the FFSP Regulations to establish legislative authority for 19 spending activities in their portfolios:

s22 [redacted]

vii. Minister for Health and Aged Care, the Hon Mark Butler MP (2 items);

s22 [redacted]

s22 [redacted]

4. A summary of the proposed amendments to be considered at the 24 October 2024 ExCo meeting is included in Attachment A.

s42 [redacted]

8. Subject to your approval, all proposed regulations will be submitted for consideration by the Governor-General at the ExCo meeting scheduled for 24 October 2024.

s22 [redacted]

Financial Implications:

14. Funding details for the Schedule 1AB items in the proposed regulations are set out at Attachment A.

Consultation:

15. Budget Group, Commercial Group, the responsible entities, the Office of Constitutional Law in the Attorney-General's Department and the Executive Council Secretariat were consulted.

Attachments:

Att A – Summary of the items contained in each of the regulations
Att B to L – Proposed regulations
Att B1 to L1 – Executive Council Minute Papers for each of the regulations
Att B2 to L2 – Explanatory Memoranda for each of the regulations
Att B3 to L3 – Explanatory Statements for each of the regulations
Att M – Replacement Explanatory Statement to the Finance Regulations
Att N to X – Letters to responsible Ministers, approving proposed Schedule 1AB amendments
Att Y – Letters from responsible Ministers requesting approval for amendments

Approved for electronic transmission

s22

A/g Assistant Secretary
Financial Management Branch
Financial Analysis, Reporting and Management Division
s22

Contact Officer:	s22
Job Title/Level:	Director/EL2
Telephone:	s22
PDR Number	MS24-000856