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

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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]

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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 27

Duplicate content from Document 27

[redacted]

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 27

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

s42
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

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
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.

Start of Document 28 - duplicate removed

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.

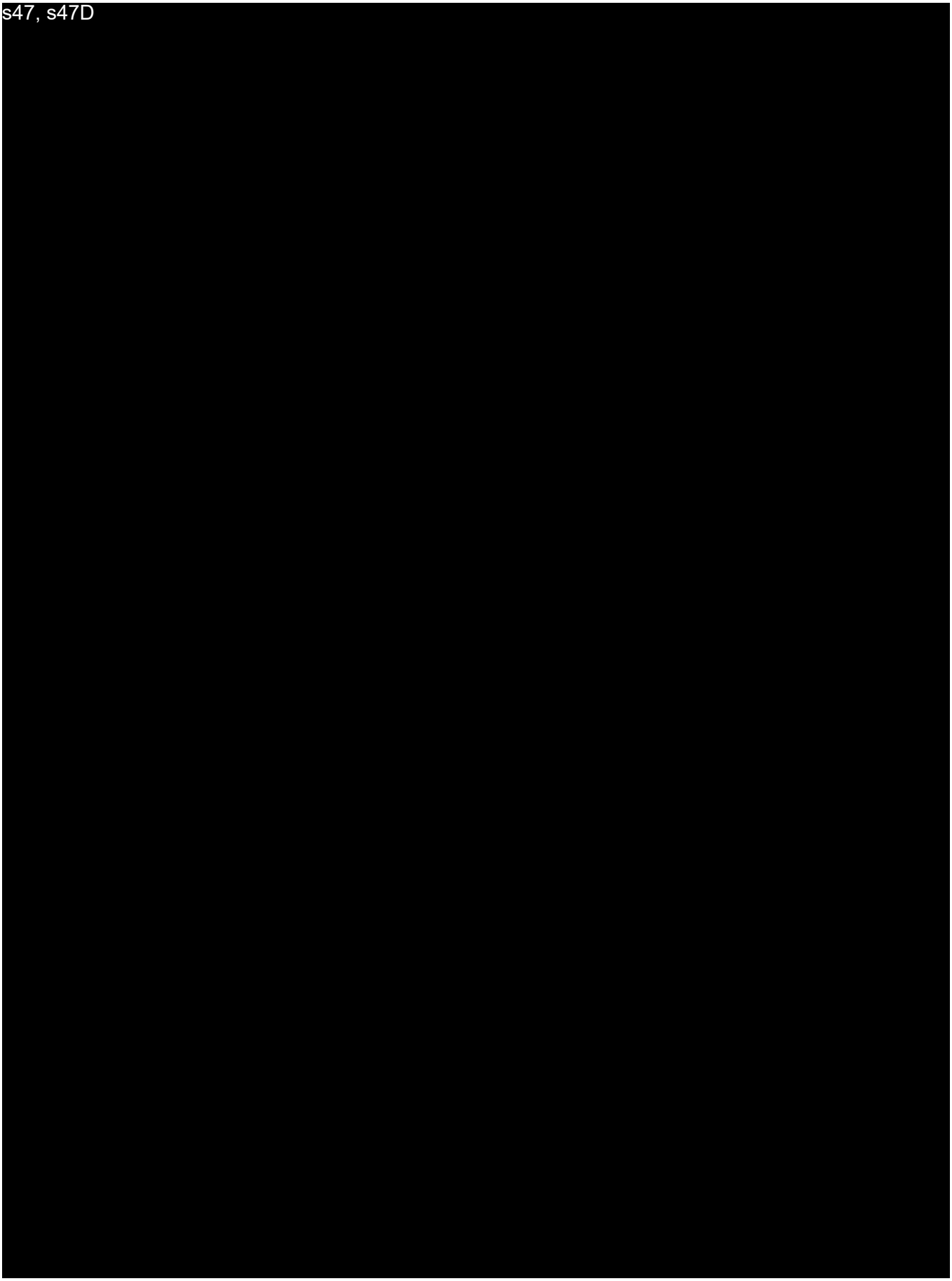
Social welfare power
The social welfare power in section 51(xxiiiA) of the Constitution empowers the Parliament to make laws with respect to the provision of certain social welfare benefits including pharmaceutical benefits, sickness and hospital benefits and medical services.

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.

s47, s47D



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(2) [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.

PROTECTED: CABINET

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) [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.

s47C, 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, s47C

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

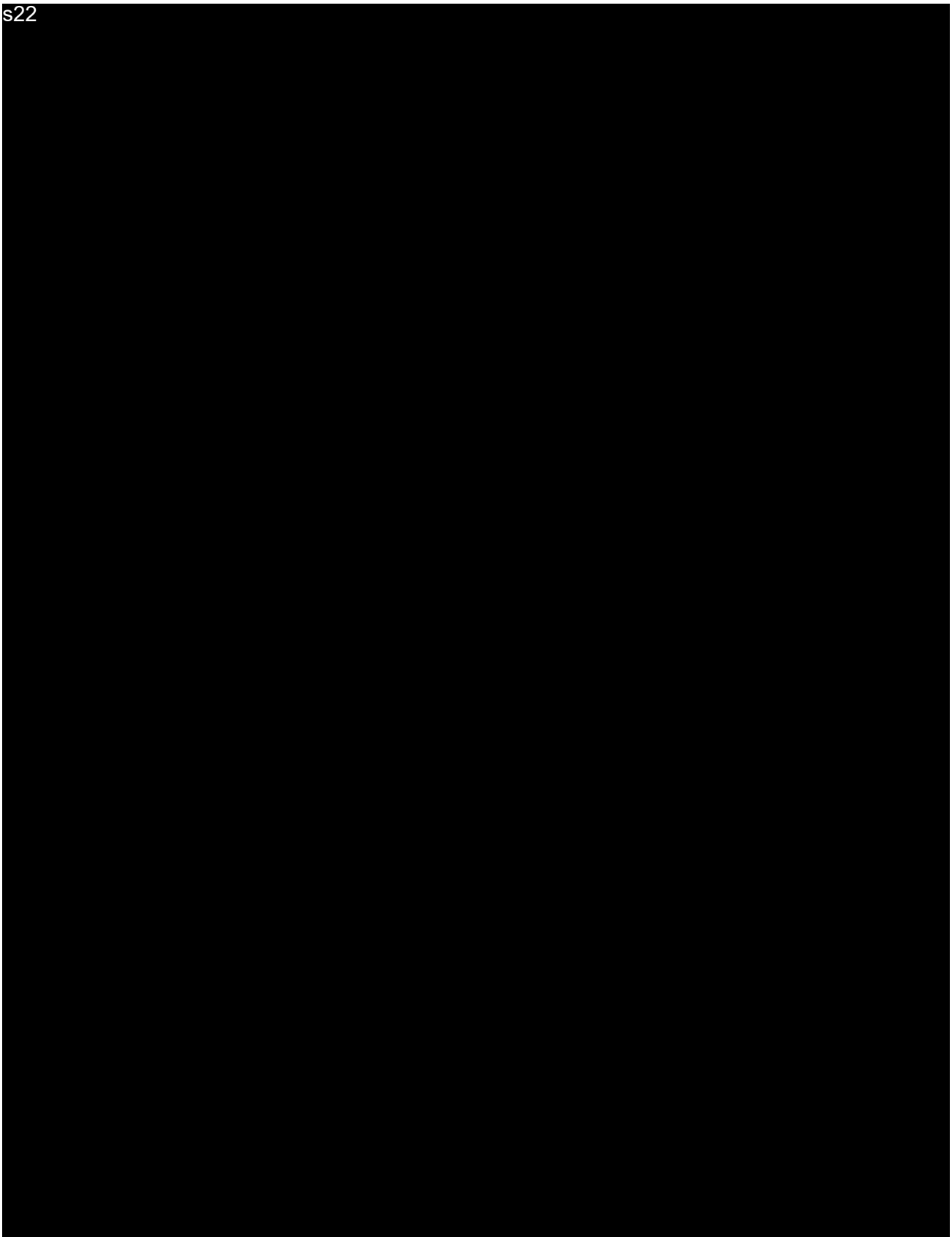
Hi s22

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]

s47C [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: DoHAC - Responses to OPC Questions - Instrument first draft - Health Measures No. 4 - 24 Oct Exco [SEC=UNOFFICIAL]
Date: Friday, 6 September 2024 11:57:14 AM
Attachments: image002.png
image003.png
s22
Finalised duplicates at Document 37
s22

Finalised duplicates at Document 37

From: s22 @Protected.Health.gov.au>
Sent: Friday, September 6, 2024 11:51:10 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=UNOFFICIAL]

Hi s22

Please find **attached** the final version of the letters and attachment to the letters for the:

- s22
- mRNA vaccines program; and
- s22

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 Buildings22
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: Thursday, 5 September 2024 11:39 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

Amazing – thanks s22

Cheers,
s22

Duplicate content from Document 33

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.

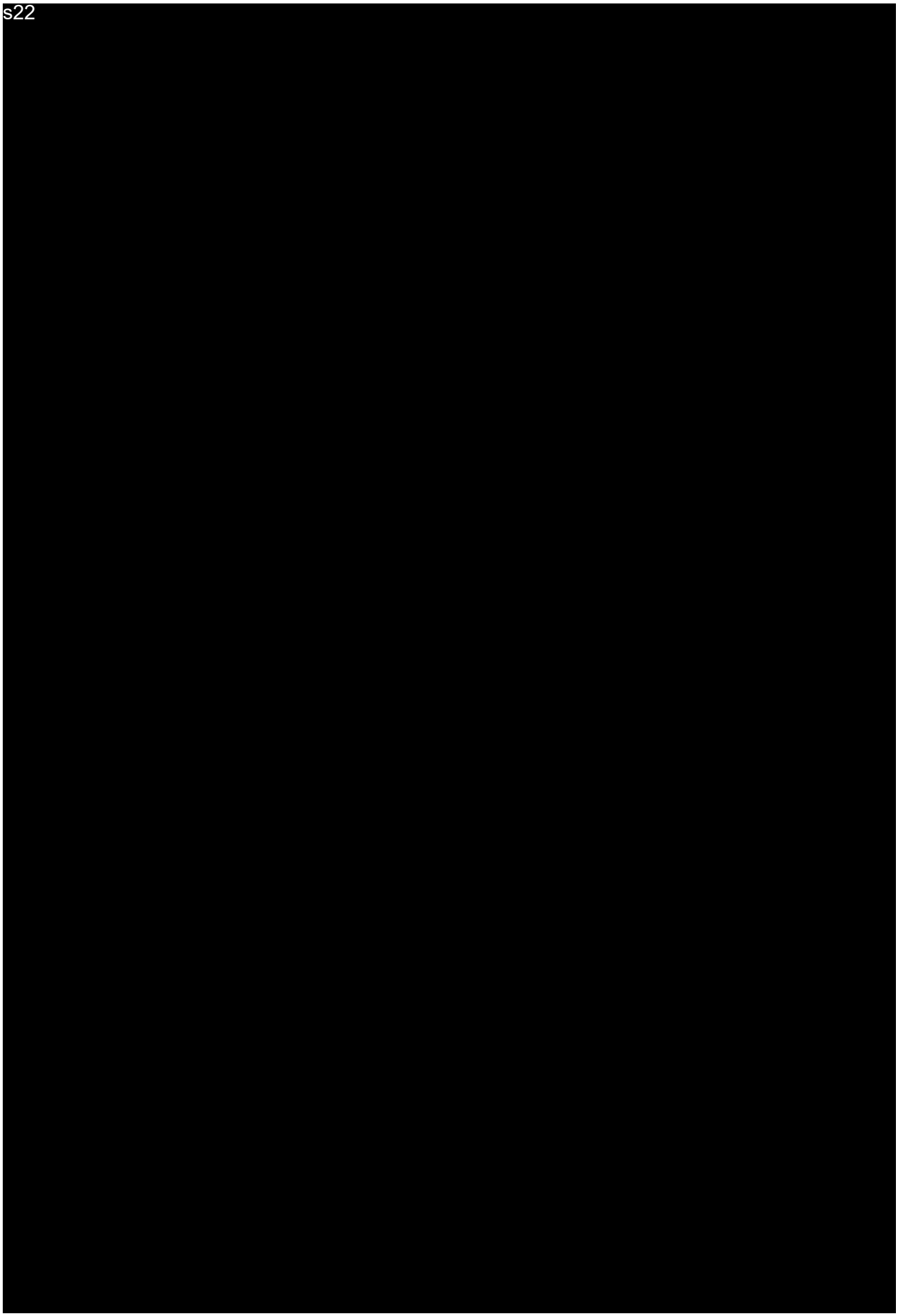
Schedule 1 – Amendments

Financial Framework (Supplementary Powers) Regulations 1997

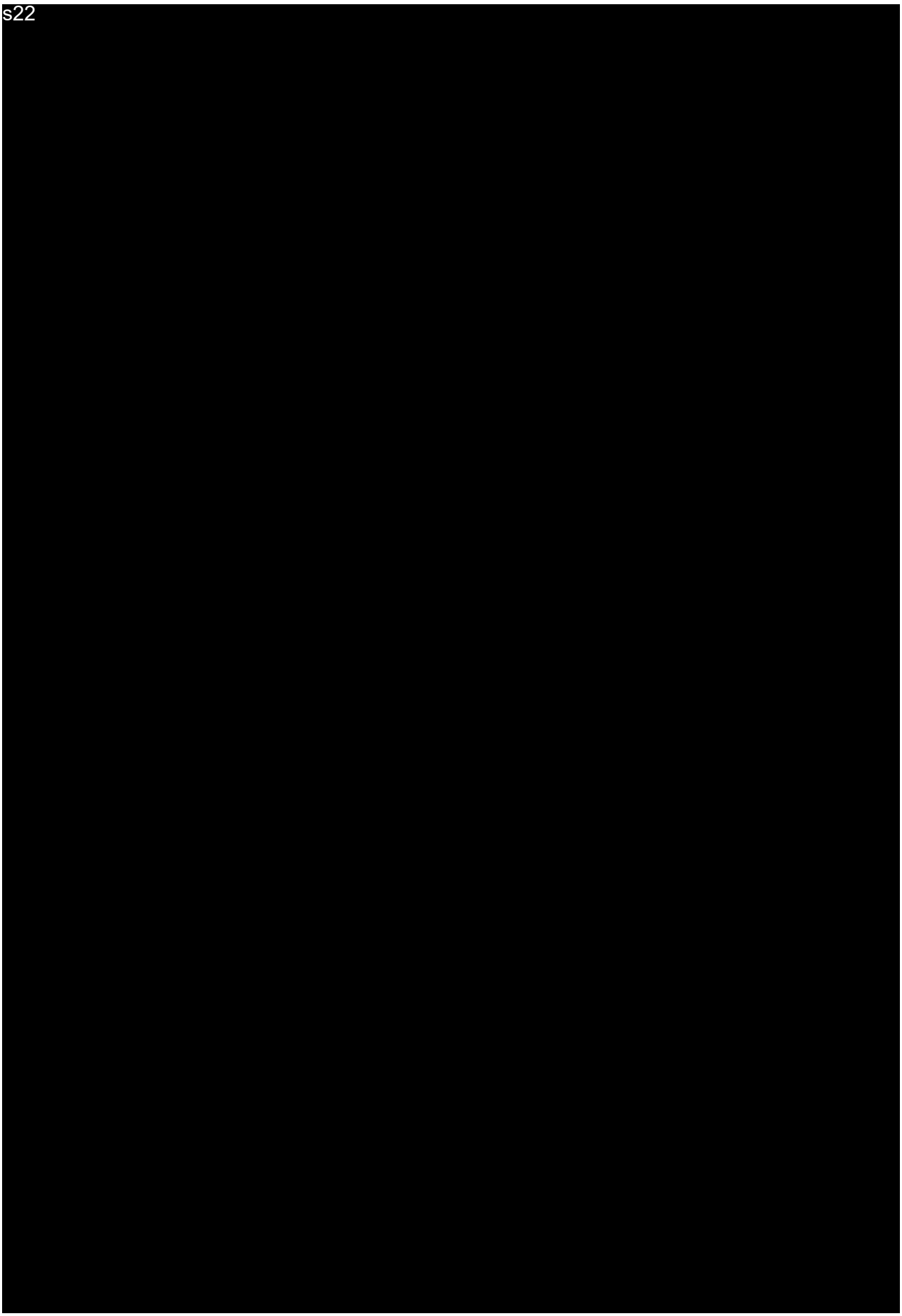
Amended Table item 306 – Quality Use of Diagnostic, Therapeutics and Pathology Program

s22

s22



s22



s22

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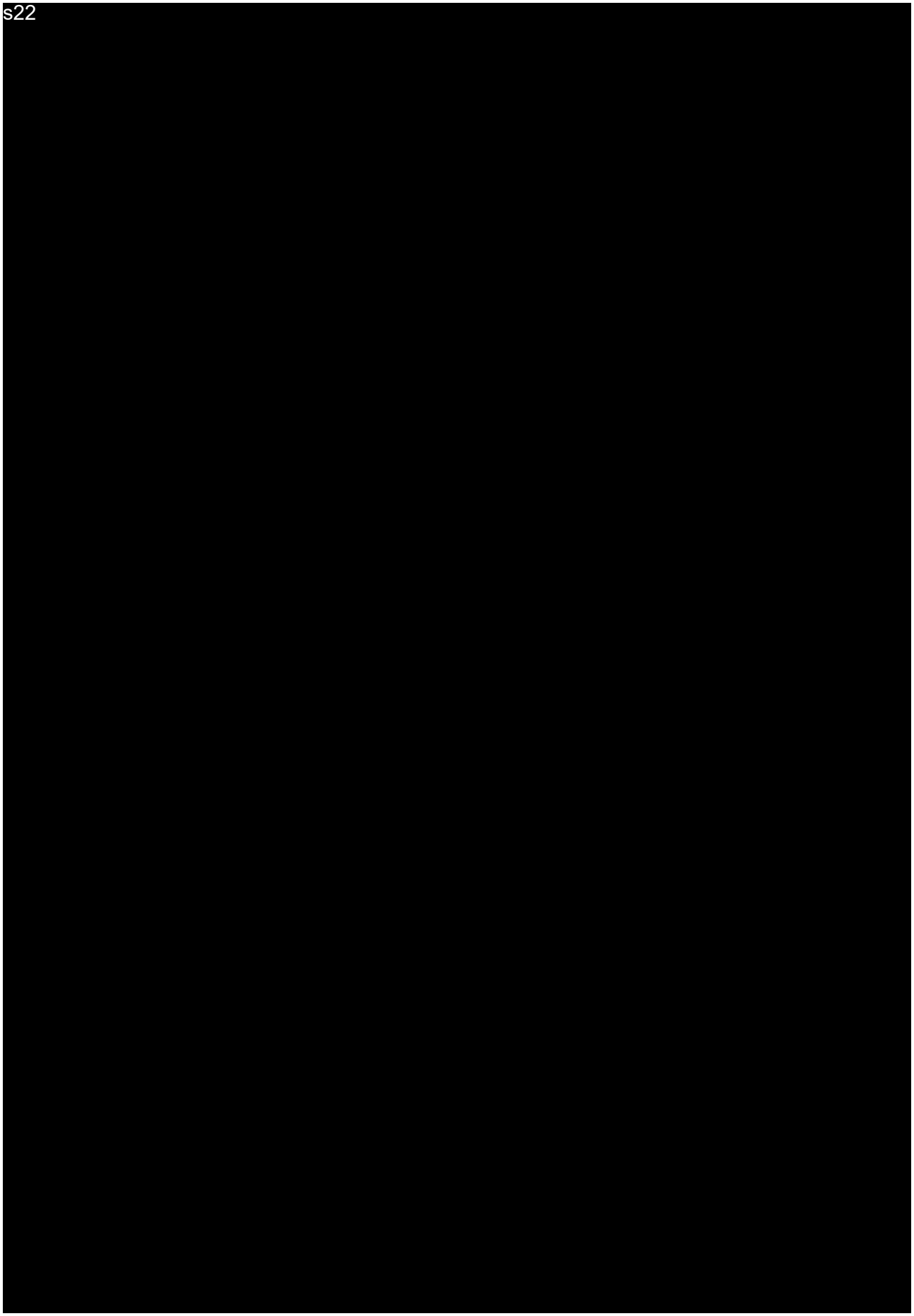
s22



s22

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s22

[redacted]

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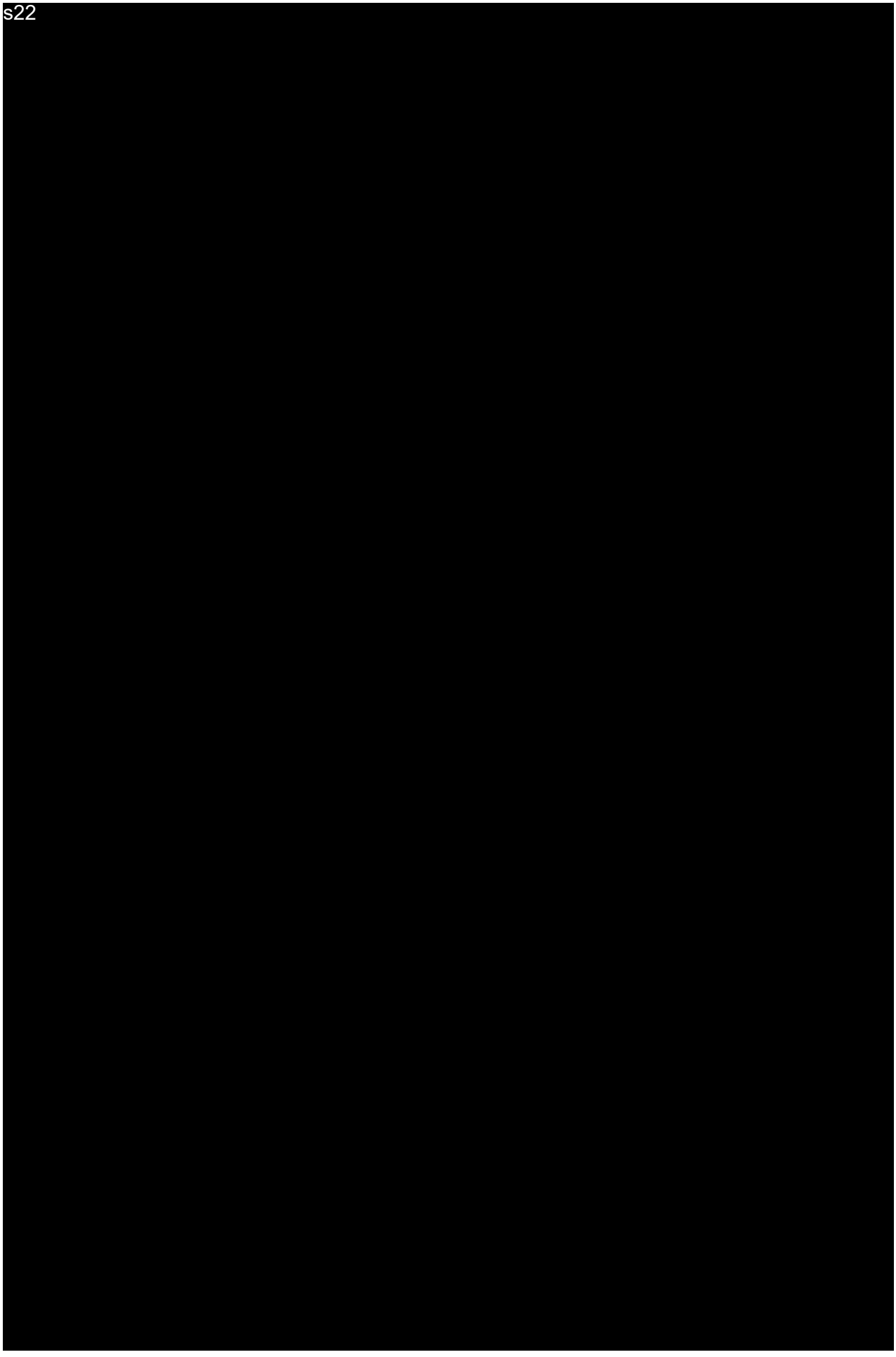

s22

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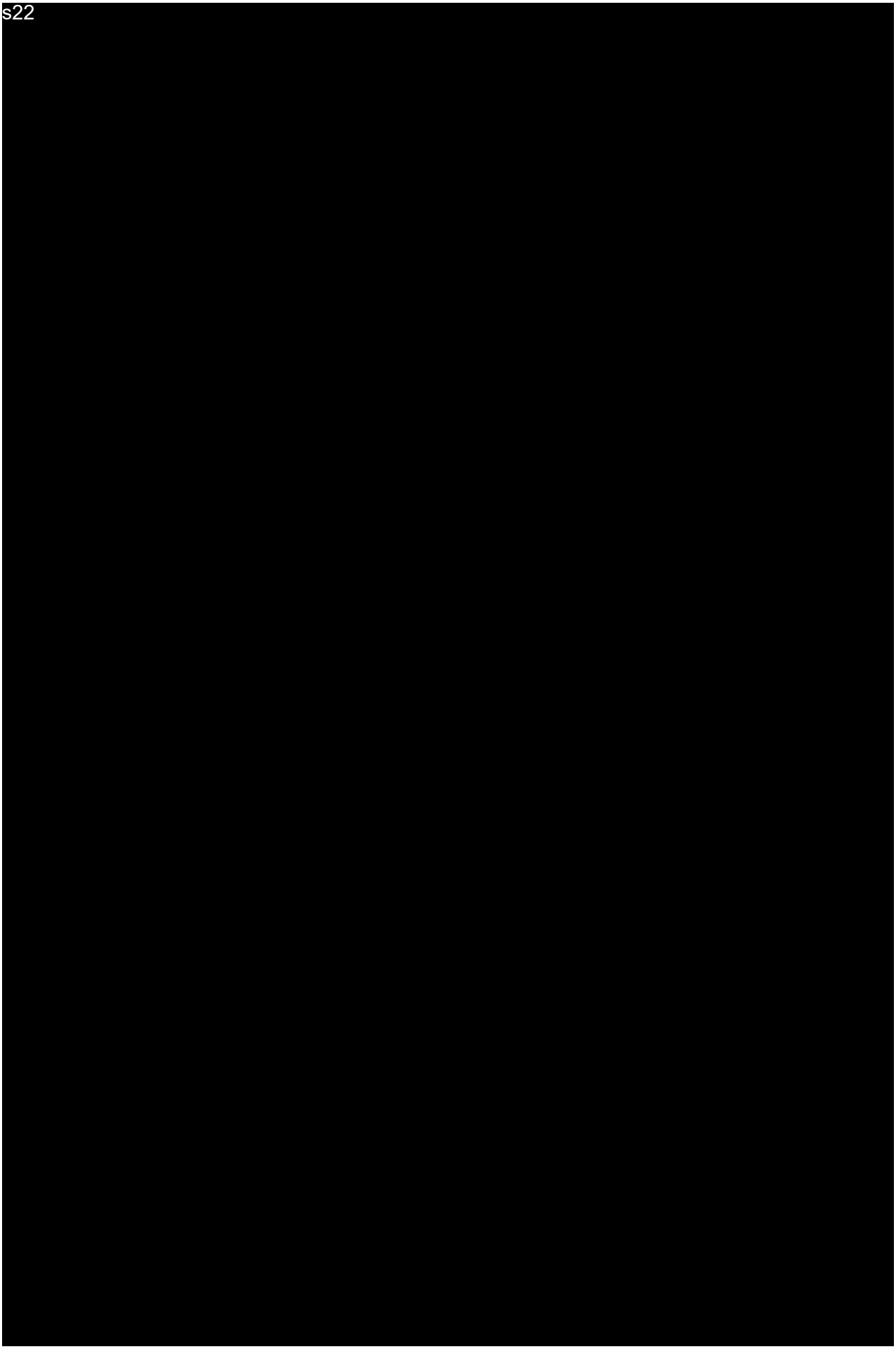
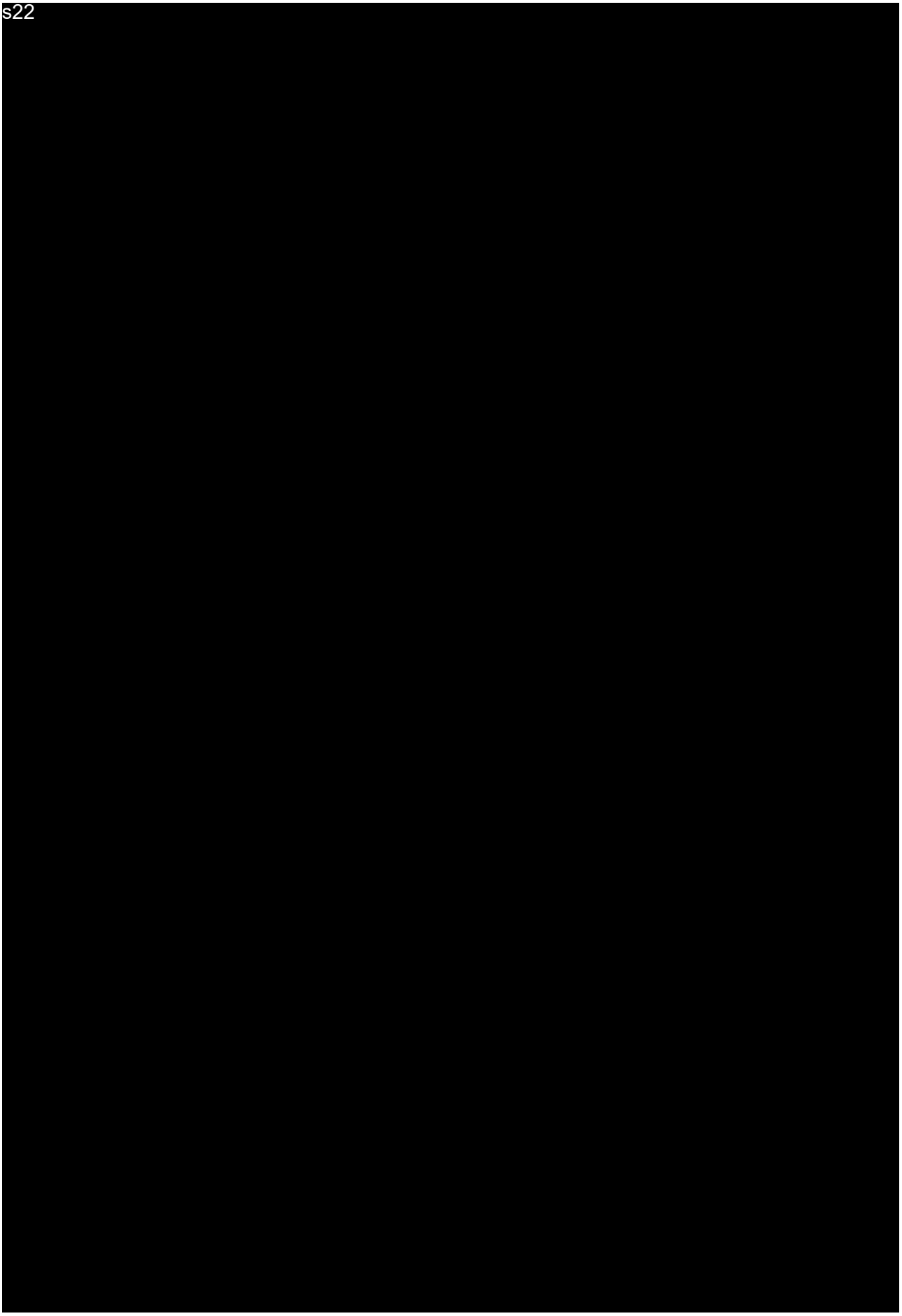


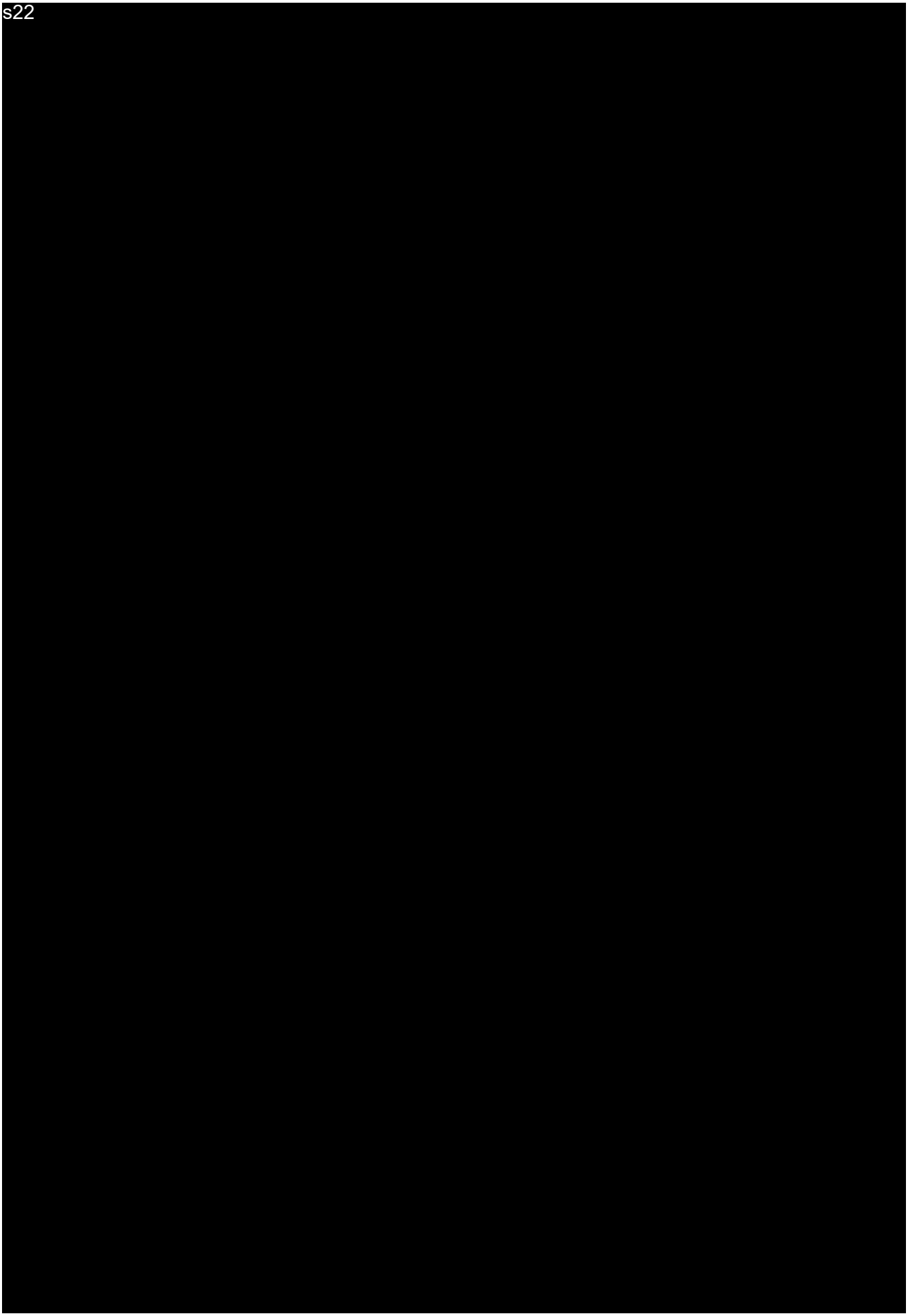
s22

[redacted]

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.

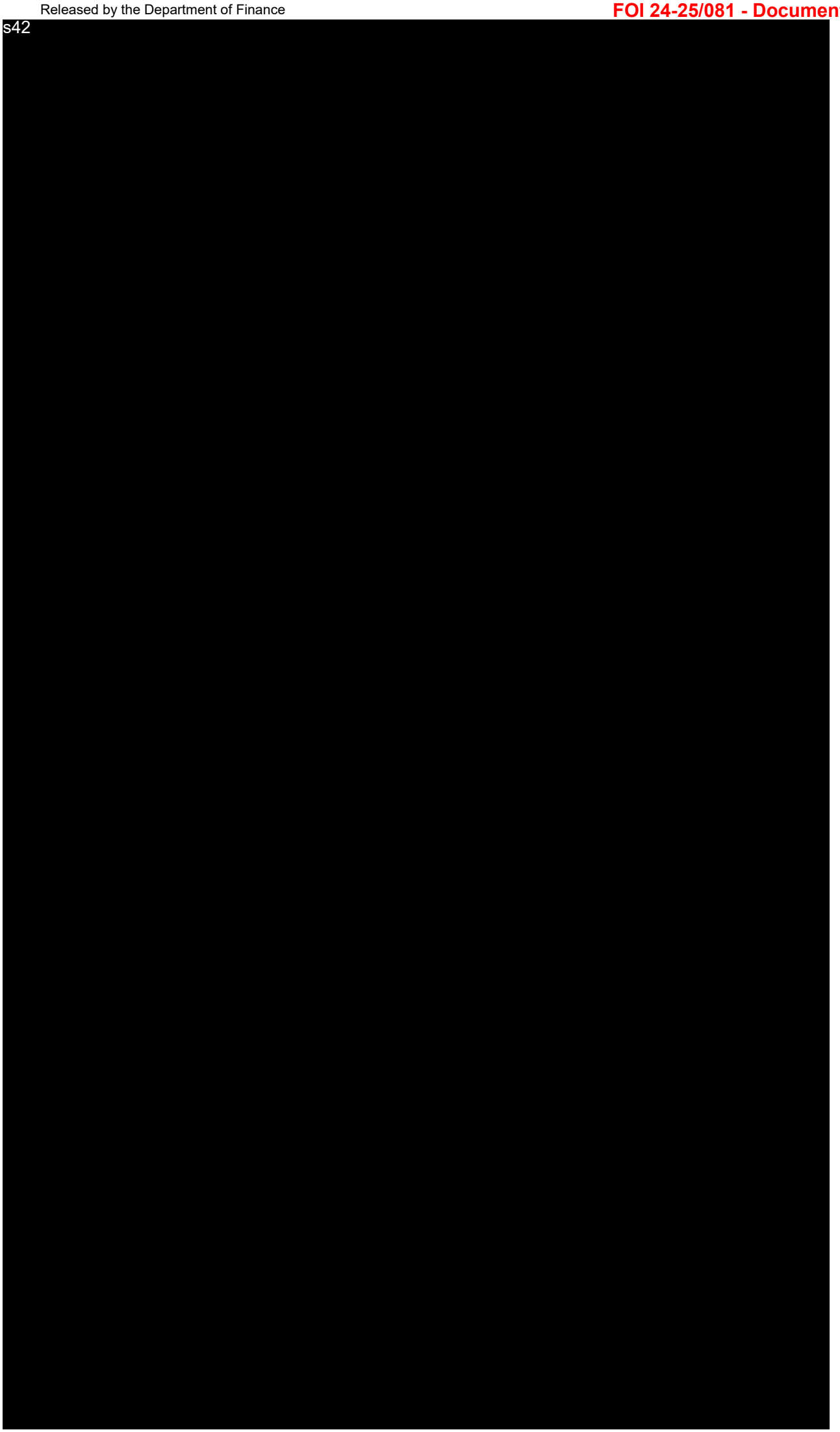
The program would promote the right to health by ensuring that Australia is well prepared to prevent, treat and control diseases and other medical conditions using mRNA technology. Having mRNA manufacturing capability onshore would also ensure that Australia is not subject to potential supply and delivery 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


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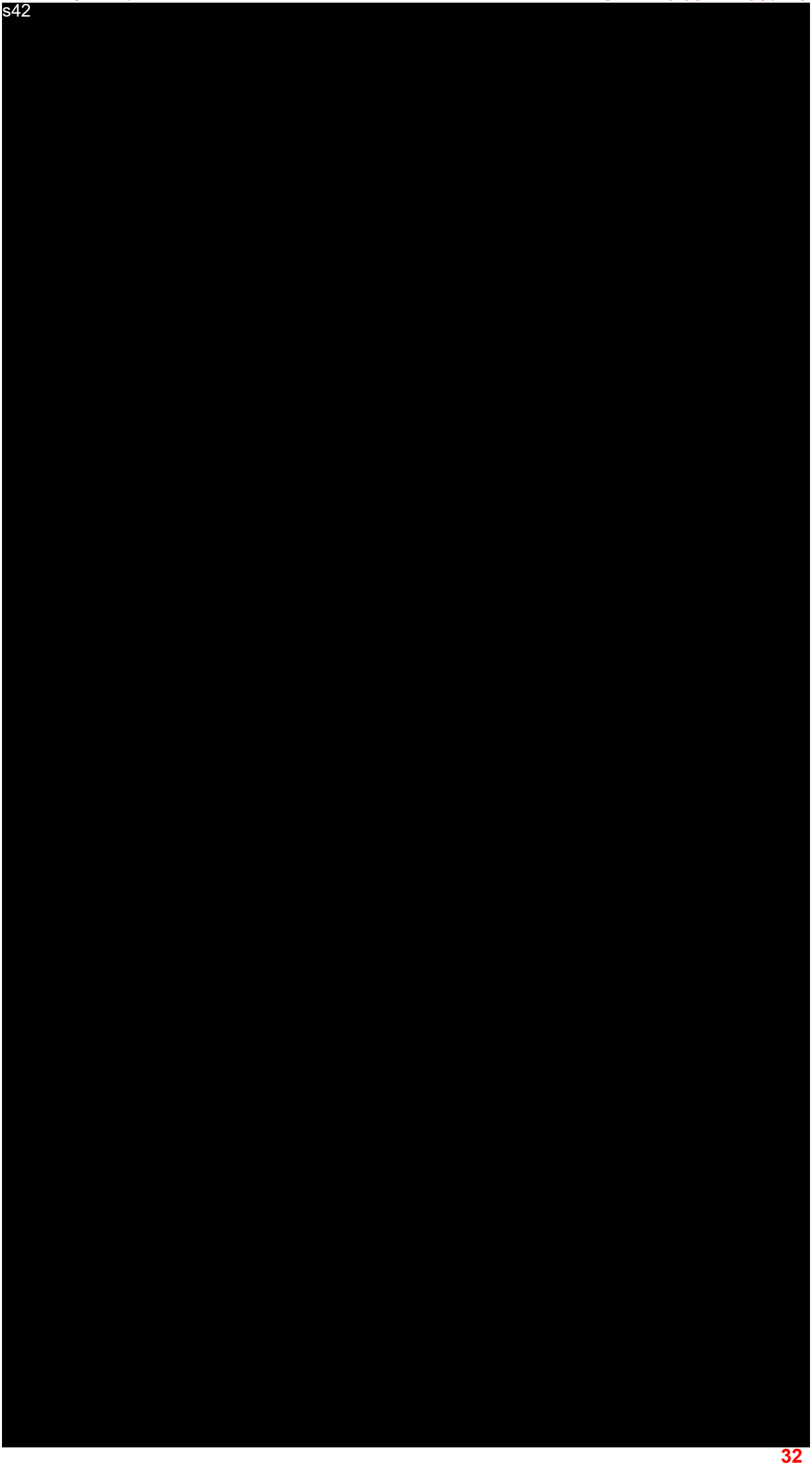

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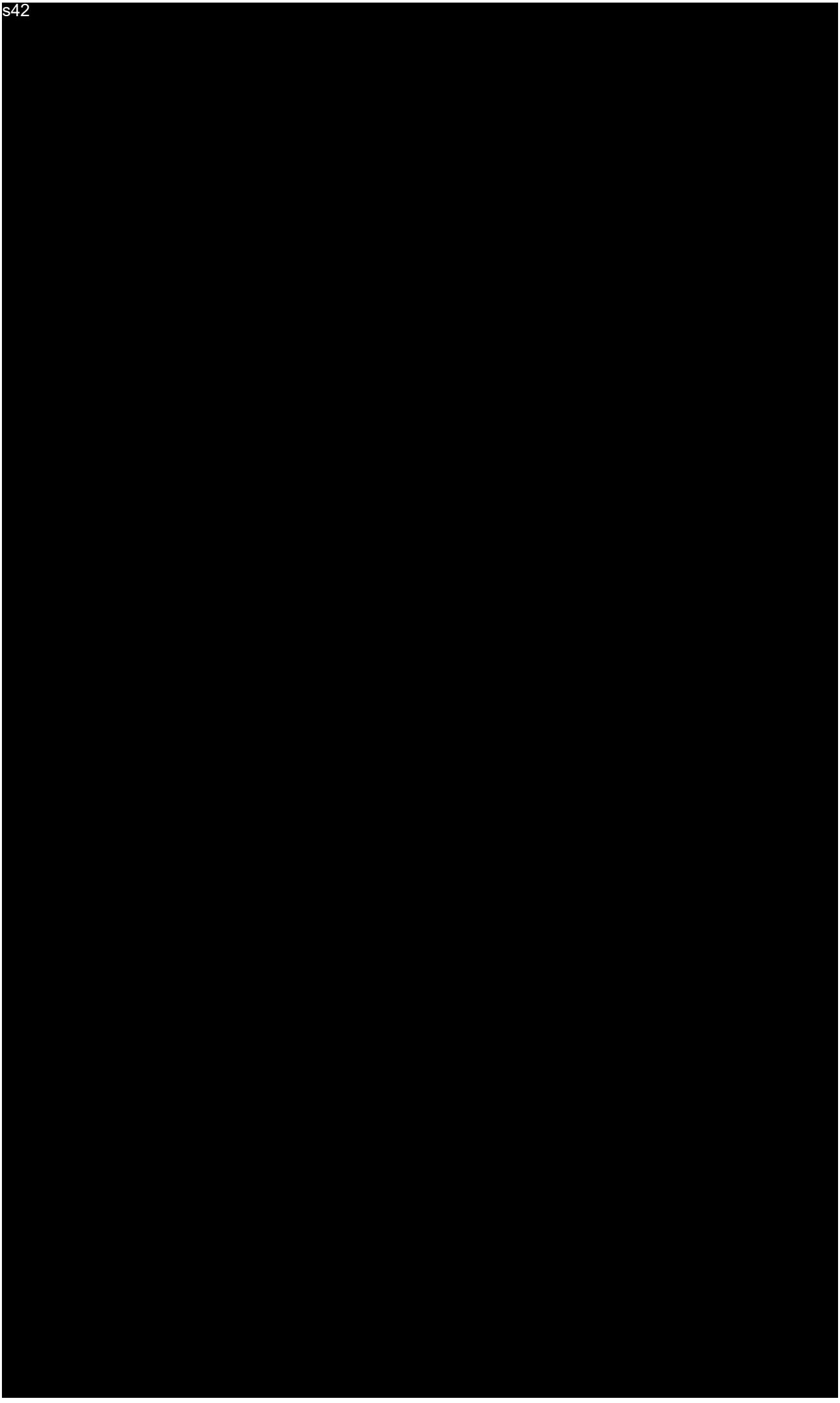

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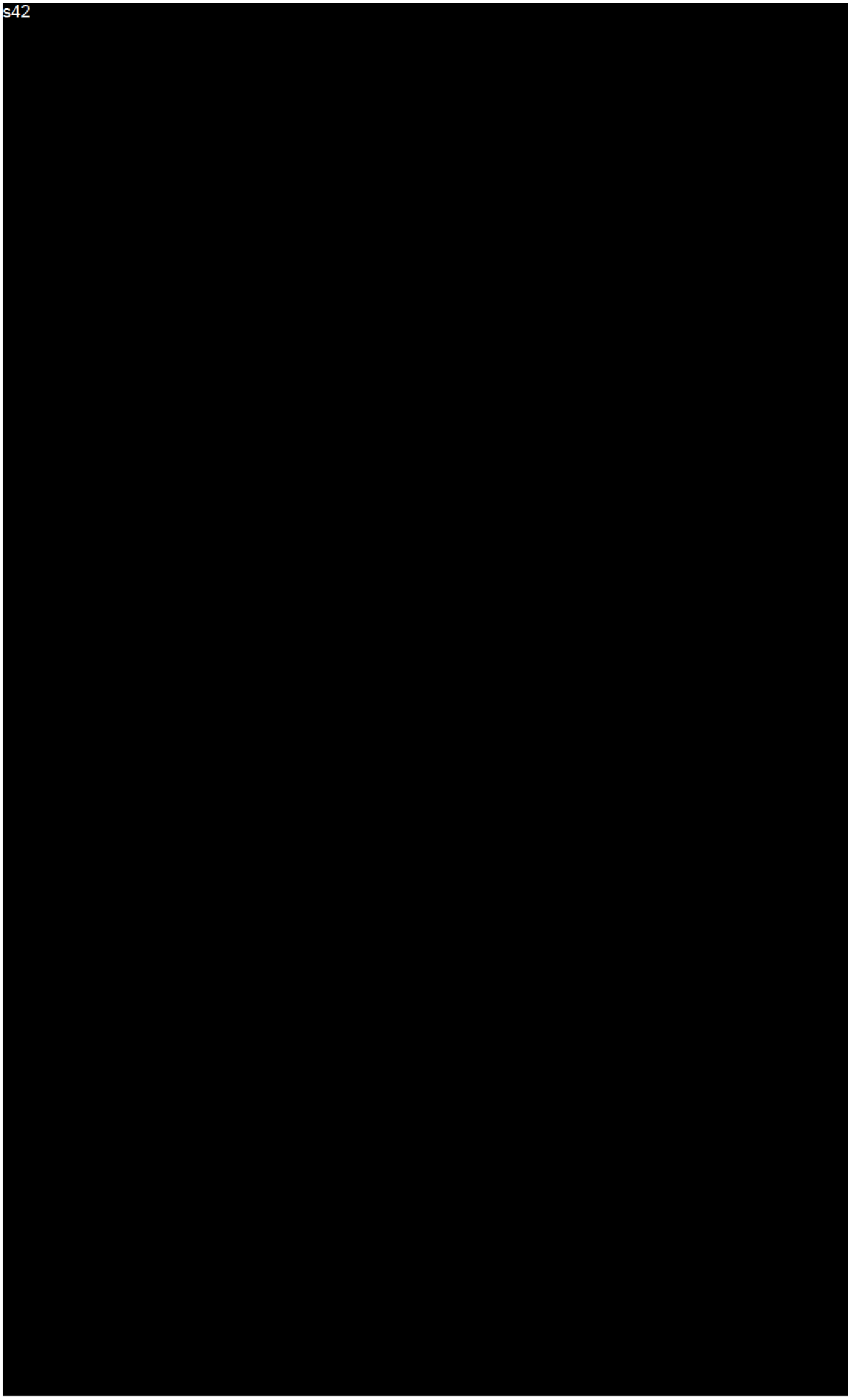

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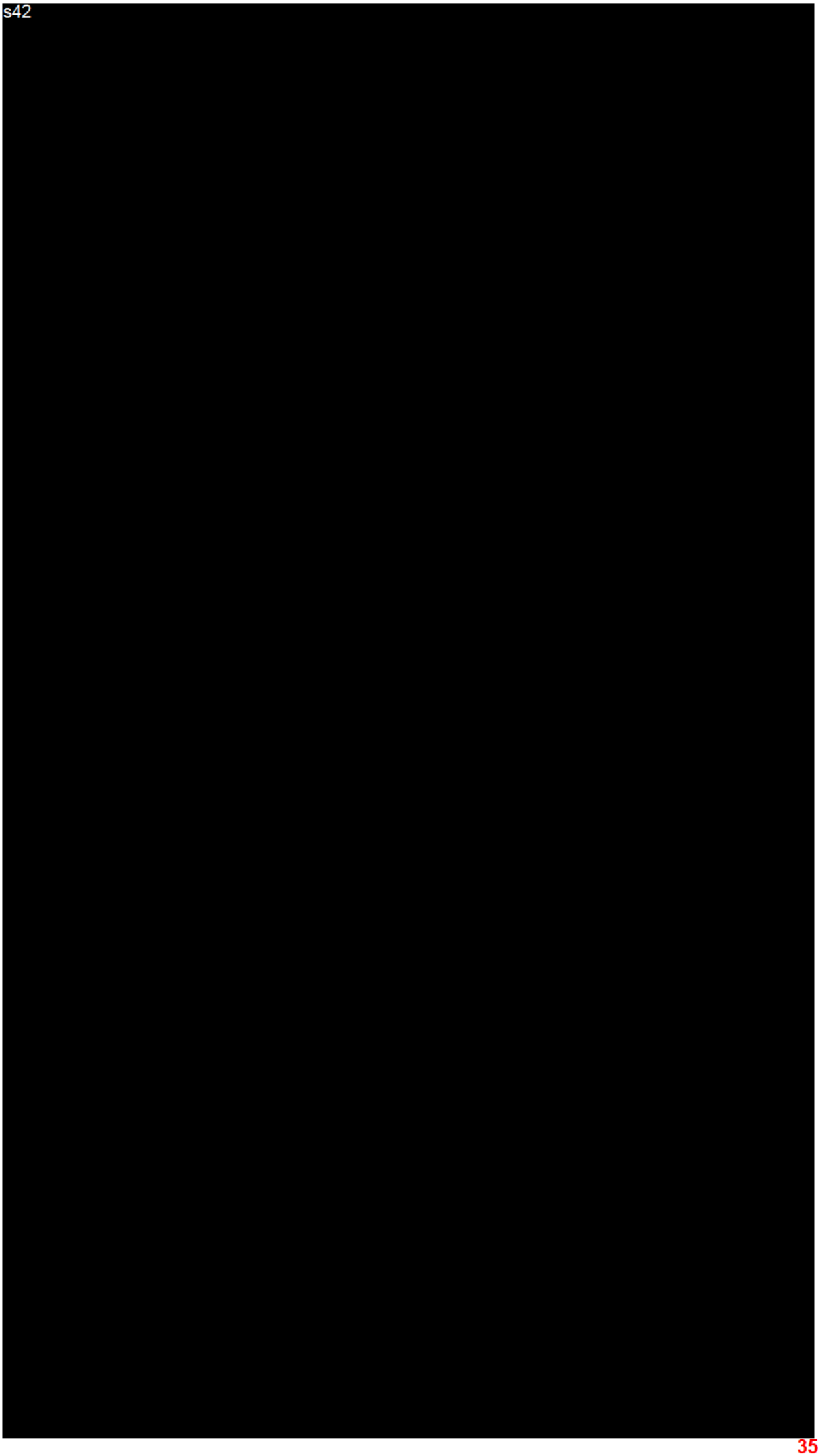

From: Financial Framework (Supplementary Powers) Regulations
To: s22
Subject: FW: Incoming Corro - Butler to Gallagher - Seeking agreement to amend Schedule 1AB of the Financial Framework (Supplementary Powers) Regulation 1997 - Messenger Ribonucleic Acid (mRNA) [SEC=PROTECTED, CAVEAT=SH:CABINET]
Date: 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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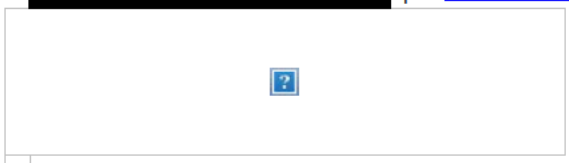
Ministerial correspondence form

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
T: s22 | E: DLO-finance@finance.gov.au



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.

Current status of negotiations

s47C [redacted]

s47C, 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

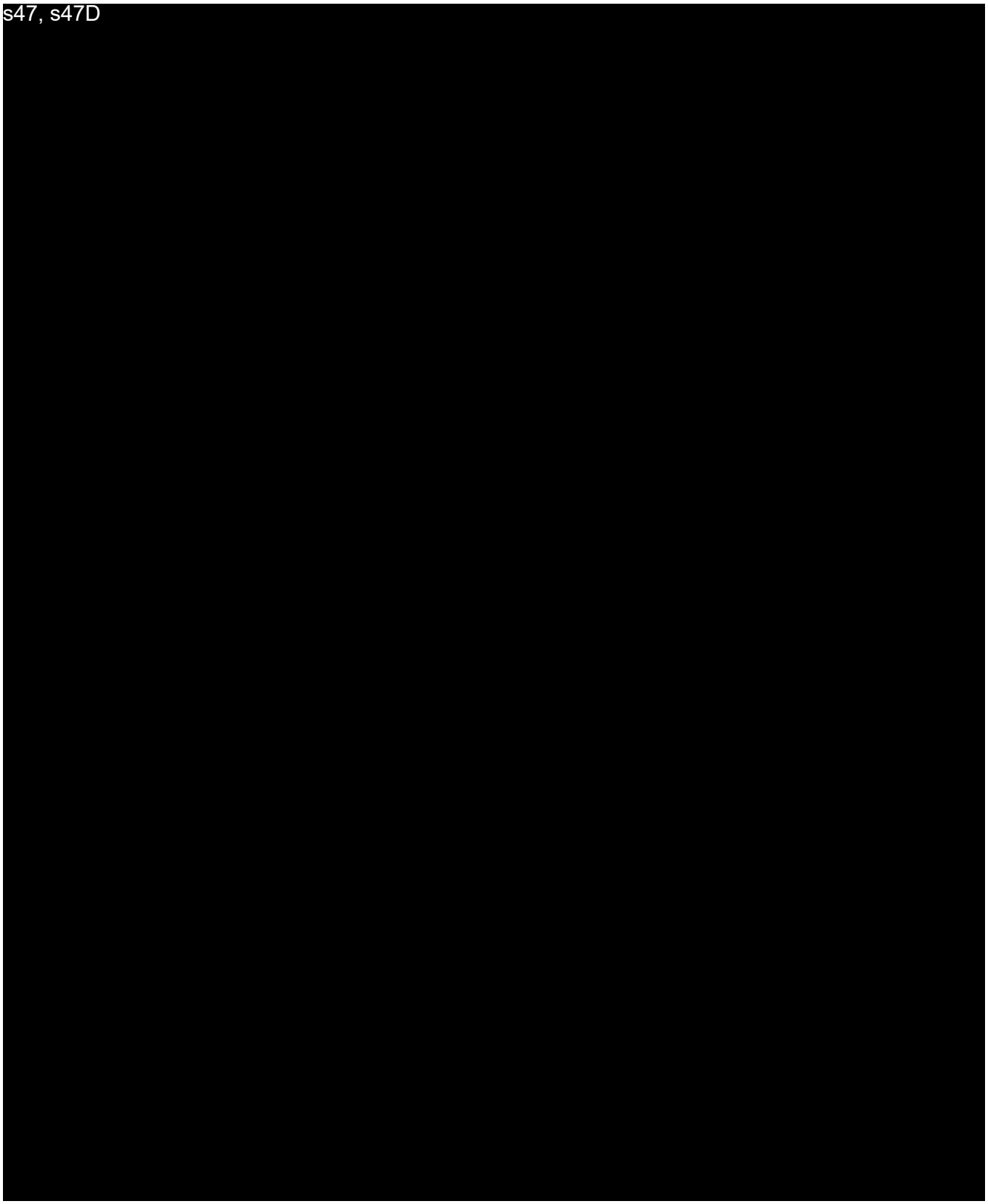
The express incidental power in section 51(xxxix) of the Constitution empowers the Parliament to make laws with respect to matters incidental to the execution of any power vested in the Parliament, the executive or the courts by the Constitution. Section 61 of the Constitution supports activities that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

s47, s47D



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: REVISED: For AS clearance: draft Regulations and Explanatory Statement (Health Measures No. 4) - 24 Oct Exco [SEC=OFFICIAL]
Date: Friday, 13 September 2024 11:43:56 AM
Attachments: image001.png
ES - Health No. 4 - 13 Sept 24.docx

From: s22 @Protected.Health.gov.au>
Sent: Friday, September 13, 2024 11:40:05 AM (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: REVISED: For AS clearance: draft Regulations and Explanatory Statement (Health Measures No. 4) - 24 Oct Exco [SEC=OFFICIAL]

Hi s22

Please find **attached** the department's ES cleared at AS level. s22

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
Sent: Thursday, 12 September 2024 5:34 PM
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: REVISED: For AS clearance: draft Regulations and Explanatory Statement (Health

Measures No. 4) - 24 Oct Exco [SEC=OFFICIAL]

Hi s22

s22

I am still waiting for clearance of the ES from one program area. I am hoping to get the ES to you tomorrow morning.

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

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Duplicate content from Document 36

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 (DLP) and Pacific (PLP) 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

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, which is administered by the Department of Health and Aged Care (the department).

Item 1 amends table item 306 by omitting "to NPS Medicine Wise" in the column headed "Objective(s)". The amendment reflects 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 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 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 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) – aimed 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.

- former NPS MedicinWise 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 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 aimed 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, comprised of 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. For the QUDTP Program is 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 re-making 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, the Pharmaceutical Society of Australia, Consumers Health Forum, the National Aboriginal Community Controlled Health Organisation and the ACSQHC. NPS MedicineWise and ACSQHC were heavily involved as part of the independent review process which was completed in August 2022.

NPS MedicineWise were dissatisfied with the decision, and subsequently decided to cease operating (effective 23 December 2022). Other stakeholders such RACGP raised concern over the loss of NPS MedicineWise but welcomed the opportunity to compete for the grants and other activities. NACCHO have 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 realization 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), which is administered by the department.

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 "(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 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.

Funding under the Program supports activities across three streams:

- major international sporting events, which aim 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, which aim 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, which aim 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 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 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 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 our international reputation.

Funding amount and arrangements, merits review and consultation

Funding of $30.0 million ($15m for Domestic Legacy and $15m for Pacific Legacy) over six years from 2024-25 for the amended item 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 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), 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).

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 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 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 Pacific Legacy Program and 2029 Women's Rugby World Cup Pacific Legacy Program (both referred to 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 $30.0 million ($15m to Domestic Legacy and $15m to Pacific Legacy) over six years from 2024-25 to 2029-2030 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.

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