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

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

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

Error! Not a valid filename.

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

SEC=PROTECTED, ACCESS=Legal-Privilege

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

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

SEC=PROTECTED, ACCESS=Legal-Privilege

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

Privilege]

SEC=PROTECTED, ACCESS=Legal-Privilege

Thanks Cameron and s22
Kind regards
s22

SEC=PROTECTED, ACCESS=Legal-Privilege

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

SEC=PROTECTED, ACCESS=Legal-Privilege

Ok, great thanks.
Regards,
Cameron.

SEC=PROTECTED, ACCESS=Legal-Privilege

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

SEC=PROTECTED, ACCESS=Legal-Privilege

Thanks Cameron.
s47C

s22

SEC=PROTECTED, ACCESS=Legal-Privilege

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

SEC=PROTECTED, ACCESS=Legal-Privilege

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

SEC=PROTECTED, ACCESS=Legal-Privilege

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

SEC=PROTECTED, ACCESS=Legal-Privilege

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

SEC=PROTECTED, ACCESS=Legal-Privilege

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

SEC=PROTECTED, ACCESS=Legal-Privilege

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

SEC=PROTECTED, ACCESS=Legal-Privilege

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

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

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

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

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

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

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

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

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

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

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

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Finance

Financial Framework (Supplementary Powers) Act 1997

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

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

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

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

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

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

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

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

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

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

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

Consultation

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

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

Attachment A

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

Section 1 – Name

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

Section 2 – Commencement

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

Section 3 – Authority

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

Section 4 – Schedules

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

Schedule 1 – Amendments

Financial Framework (Supplementary Powers) Regulations 1997

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

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

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

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

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

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

Under final agreements, the Commonwealth is expected to:

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

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

Building on the success of breakthrough COVID-19 mRNA vaccines, the Government recognises that mRNA technology is part of the next generation in advanced health care. Onshore production of mRNA vaccines will strengthen Australia's capacity against COVID-19 and its variants, as well as future pandemics and other diseases. Once established, an onshore manufacturing facility for mRNA vaccines would provide Australia with priority access to existing and pipeline mRNA products, rather than relying on delivery from offshore.

The COVID-19 Vaccines and Treatments for Australia – Science and Industry Technical Advisory Group (SITAG) has also maintained support for onshore manufacturing, emphasising the importance of investing in onshore mRNA manufacturing capabilities to ensure Australia has ongoing access to a diverse vaccine portfolio and at a magnitude that provides above population coverage. The SITAG provides advice to the Government on the purchasing and manufacturing of COVID-19 vaccines and treatments.

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

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

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

The overarching requirements in the development and maintenance of a sovereign mRNA manufacturing capability include:

- an end-to-end onshore manufacturing solution for the production and supply of mRNA pandemic and non-pandemic vaccines for the Australian population; and
- participation in the broader mRNA ecosystem, including contribution to research and development.

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

It is proposed that the department would provide ongoing funding to deliver the mRNA manufacturing capability in accordance with applicable legislative requirements and the Commonwealth resource management framework, including the *Public Governance, Performance and Accountability Act 2013* (PGPA Act), the *Commonwealth Procurement Rules* (CPRs) and the department's Accountable Authority Instructions.

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

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

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

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

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

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

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

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

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

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

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

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

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

External affairs power

Section 51(xxix) of the Constitution empowers the Parliament to make laws with respect to 'external affairs'. The external affairs power supports legislation implementing Australia's international obligations under treaties to which it is a party.

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

Article 12(1) of the ICESCR recognises the 'right of everyone to the enjoyment of the highest attainable standard of physical and mental health'. Article 12(2)(c) relevantly requires Australia to take steps necessary for 'the prevention, treatment and control of epidemic, endemic, occupational and other diseases', and Article 12(2)(d) requires Australia to take steps necessary for 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness'.

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

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

Social welfare power

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

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

Executive power and express incidental power, including the nationhood aspect

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

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

Attachment B

Statement of Compatibility with Human Rights

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

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

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

Overview of the legislative instrument

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

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

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

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

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

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

The overarching requirements in the development and maintenance of a sovereign mRNA manufacturing capability include:

- an end-to-end onshore manufacturing solution for the production and supply of mRNA pandemic and non-pandemic vaccines for the Australian population; and
- participation in the broader mRNA ecosystem, including contribution to research and development.

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

Human rights implications

This disallowable legislative instrument engages the following right:

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

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

Article 12(1) of the ICESCR recognises the 'right of everyone to the enjoyment of the highest attainable standard of physical and mental health'. Article 12(2)(c) requires Australia to take steps necessary for 'the prevention, treatment and control of epidemic, endemic, occupational and other diseases', and Article 12(2)(d) requires Australia to take steps necessary for 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness'.

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

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

Overall, this measure would support the right of individuals to the enjoyment of the highest standard of health and further contribute to overall community health through the prevention, treatment and control of epidemic, endemic, occupational and other diseases.

Conclusion

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

Senator the Hon Simon Birmingham
Minister for Finance

From:	Financial Framework (Supplementary Powers) Regulations
To:	s22
Subject:	FW: Draft papers for late FFSP item for 16 Dec Exco [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]
Date:	Friday, 10 December 2021 11:13:29 AM
Attachments:	I21PL119.PDF Draft Exco minute - Health No. 9.docx Draft EM - Health No. 9.docx
Importance:	High

From: Financial Framework (Supplementary Powers) Regulations
Sent: Friday, 10 December 2021 11:13:26 AM (UTC+10:00) Canberra, Melbourne, Sydney
To: Exco
Cc: Financial Framework (Supplementary Powers) Regulations; s22
Subject: Draft papers for late FFSP item for 16 Dec Exco [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

Hi Exco Secretariat team

Please find attached draft papers for the late FFSP item for the 16 December Exco. Grateful for your urgent clearance **by 2pm if at all possible**.

Many thanks

s22

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

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

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

Dated 2021

David Hurley
Governor-General

By His Excellency's Command

Simon Birmingham
Minister for Finance

Contents

1 Name

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

2 Commencement

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

Commencement information

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

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

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

3 Authority

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

4 Schedules

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

Schedule 1—Amendments

Financial Framework (Supplementary Powers) Regulations 1997

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

Insert:

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

MINISTER FOR FINANCE

Departmental No. 2021/72

Executive Council
Meeting No. .....

Approved in Council

.....

David Hurley
Governor-General

.....

Filed in the Records
of the Council

.....
Secretary to the Executive Council

Minute Paper for the Executive Council

Subject

Financial Framework (Supplementary Powers) Act 1997

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

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

Simon Birmingham
Minister for Finance

EXPLANATORY MEMORANDUM

Minute No. 72 of 2021 – Minister for Finance

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

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

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

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

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

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

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

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

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

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

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

Under final agreements, the Commonwealth would be expected to:

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

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

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

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

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

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

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

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

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

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

OFFICIAL

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

SEC=UNOFFICIAL

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

SEC=UNOFFICIAL

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

Error! Not a valid filename. Hi Amy

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

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

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

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

Thank you one more time
s22

Error! Not a valid filename.

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

SEC=UNOFFICIAL

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

SEC=UNOFFICIAL

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

SEC=UNOFFICIAL

PDR Number:
MS21-001343

Australian Government
Department of Finance

MINISTERIAL SUBMISSION

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

Minister for Finance 10 December 2021

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

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

Recommendations:

That you:

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

AGREED / NOT AGREED / PLEASE DISCUSS

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

SIGNED / PLEASE DISCUSS

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

SIGNED / PLEASE DISCUSS

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

INITIALLED / PLEASE DISCUSS

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

APPROVED / NOT APPROVED / PLEASE DISCUSS

Key Issues:

s34(3)

[redacted]

s42 [redacted]

s47C [redacted]

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

Financial Implications:

s34(3) [redacted]

Consultation:

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

Approved for electronic transmission

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

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

/ /

Simon Birmingham

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

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

Dated 2021

David Hurley
Governor-General

By His Excellency's Command

Simon Birmingham
Minister for Finance

Contents

1 Name

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

2 Commencement

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

Commencement information

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

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

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

3 Authority

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

4 Schedules

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

Schedule 1—Amendments

Financial Framework (Supplementary Powers) Regulations 1997

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

Insert:

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

MINISTER FOR FINANCE

Departmental No. 2021/72

Executive Council
Meeting No. .....

Approved in Council

.....

David Hurley
Governor-General

.....

Filed in the Records
of the Council

.....
Secretary to the Executive Council

Minute Paper for the Executive Council

Subject

Financial Framework (Supplementary Powers) Act 1997

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

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

Simon Birmingham
Minister for Finance

EXPLANATORY MEMORANDUM

Minute No. 72 of 2021 – Minister for Finance

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

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

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

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

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

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

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

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

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

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

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

Under final agreements, the Commonwealth would be expected to:

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

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

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

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

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

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

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

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

EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Finance

Financial Framework (Supplementary Powers) Act 1997

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

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

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

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

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

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

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

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

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

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

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

Consultation

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

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

Attachment A

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

Section 1 – Name

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

Section 2 – Commencement

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

Section 3 – Authority

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

Section 4 – Schedules

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

Schedule 1 – Amendments

Financial Framework (Supplementary Powers) Regulations 1997

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

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

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

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

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

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

Under final agreements, the Commonwealth is expected to:

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

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

Building on the success of breakthrough COVID-19 mRNA vaccines, the Government recognises that mRNA technology is part of the next generation in advanced health care. Onshore production of mRNA vaccines will strengthen Australia's capacity against COVID-19 and its variants, as well as future pandemics and other diseases. Once established, an onshore manufacturing facility for mRNA vaccines would provide Australia with priority access to existing and pipeline mRNA products, rather than relying on delivery from offshore.

The COVID-19 Vaccines and Treatments for Australia – Science and Industry Technical Advisory Group (SITAG) has also maintained support for onshore manufacturing, emphasising the importance of investing in onshore mRNA manufacturing capabilities to ensure Australia has ongoing access to a diverse vaccine portfolio and at a magnitude that provides above population coverage. The SITAG provides advice to the Government on the purchasing and manufacturing of COVID-19 vaccines and treatments.

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

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

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

The overarching requirements in the development and maintenance of a sovereign mRNA manufacturing capability include:

- an end-to-end onshore manufacturing solution for the production and supply of mRNA pandemic and non-pandemic vaccines for the Australian population; and
- participation in the broader mRNA ecosystem, including contribution to research and development.

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

It is proposed that the department would provide ongoing funding to deliver the mRNA manufacturing capability in accordance with applicable legislative requirements and the Commonwealth resource management framework, including the *Public Governance, Performance and Accountability Act 2013* (PGPA Act), the *Commonwealth Procurement Rules* (CPRs) and the department's Accountable Authority Instructions.

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

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

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

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

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

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

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

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

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

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

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

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

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

External affairs power

Section 51(xxix) of the Constitution empowers the Parliament to make laws with respect to 'external affairs'. The external affairs power supports legislation implementing Australia's international obligations under treaties to which it is a party.

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

Article 12(1) of the ICESCR recognises the 'right of everyone to the enjoyment of the highest attainable standard of physical and mental health'. Article 12(2)(c) relevantly requires Australia to take steps necessary for 'the prevention, treatment and control of epidemic, endemic, occupational and other diseases', and Article 12(2)(d) requires Australia to take steps necessary for 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness'.

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

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

Social welfare power

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

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

Executive power and express incidental power, including the nationhood aspect

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

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

Attachment B

Statement of Compatibility with Human Rights

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

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

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

Overview of the legislative instrument

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

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

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

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

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

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

The overarching requirements in the development and maintenance of a sovereign mRNA manufacturing capability include:

- an end-to-end onshore manufacturing solution for the production and supply of mRNA pandemic and non-pandemic vaccines for the Australian population; and
- participation in the broader mRNA ecosystem, including contribution to research and development.

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

Human rights implications

This disallowable legislative instrument engages the following right:

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

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

Article 12(1) of the ICESCR recognises the 'right of everyone to the enjoyment of the highest attainable standard of physical and mental health'. Article 12(2)(c) requires Australia to take steps necessary for 'the prevention, treatment and control of epidemic, endemic, occupational and other diseases', and Article 12(2)(d) requires Australia to take steps necessary for 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness'.

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

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

Overall, this measure would support the right of individuals to the enjoyment of the highest standard of health and further contribute to overall community health through the prevention, treatment and control of epidemic, endemic, occupational and other diseases.

Conclusion

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

Senator the Hon Simon Birmingham
Minister for Finance

Subject: FW: APPROVED ES HEALTH to FINANCE - mRNA exco item - Schedule 1AB: draft ES for mRNA [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]
Attachments: DRAFT ES cleared by program area - mRNA vaccines - at F 10 Dec 21.docx

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From: Financial Framework (Supplementary Powers) Regulations
Sent: Monday, 13 December 2021 4:23:16 PM (UTC+10:00) Canberra, Melbourne, Sydney
To: s22 [redacted]; Financial Framework (Supplementary Powers) Regulations
Cc: Constitutional Risk
Subject: RE: APPROVED ES HEALTH to FINANCE - mRNA exco item - RE: Schedule 1AB: draft ES for mRNA [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

Hi s22 [redacted] – apologies for not responding to your previous emails. s22 [redacted]

I will try and check with the secretariat what happens with our papers if the Prime Minister still hasn't signed the late letter. They can be pretty strict about it.

And thank you for your kind words ☺ Hope this item gets through!

s22 [redacted]

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

From: s22 [redacted]@health.gov.au>
Sent: Monday, 13 December 2021 2:33 PM
To: Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>
Cc: Constitutional Risk <Constitutional.Risk@protected.health.gov.au>
Subject: RE: APPROVED ES HEALTH to FINANCE - mRNA exco item - RE: Schedule 1AB: draft ES for mRNA [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

Ahhh I sent my email too soon – I have just been informed that "PM&C have confirmed the letter is with the PM for signing".

s22 [redacted]
Principal Lawyer
Constitutional Risk Team

Legal Advice and Legislation Branch | Legal & Assurance Division
Corporate Operations Group
Australian Government Department of Health
T: s22 [redacted]@health.gov.au
Location: s22 [redacted]

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: s22
Sent: Monday, 13 December 2021 2:29 PM
To: 'Financial Framework (Supplementary Powers) Regulations' <FFSPRegs@finance.gov.au>
Cc: 'Constitutional Risk' <Constitutional.Risk@protected.health.gov.au>
Subject: RE: APPROVED ES HEALTH to FINANCE - mRNA exco item - RE: Schedule 1AB: draft ES for mRNA [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

Hi again s22

We don't have any information on whether or not the letter has been signed…..I am thinking that even if it is not it will still go ahead??

Thank you for all your assistance with this matter. Both s22 and I (and our department) really appreciate your support and assistance. You make the impossible – possible!

Kind regards
s22

s22
Principal Lawyer
Constitutional Risk Team

Legal Advice and Legislation Branch | Legal & Assurance Division
Corporate Operations Group
Australian Government Department of Health
T: s22 @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: s22
Sent: Monday, 13 December 2021 2:02 PM
To: 'Financial Framework (Supplementary Powers) Regulations' <FFSPRegs@finance.gov.au>
Cc: s22 @health.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>
Subject: RE: APPROVED ES HEALTH to FINANCE - mRNA exco item - RE: Schedule 1AB: draft ES for mRNA [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

Thanks s22

Kind regards
s22

s22
Principal Lawyer
Constitutional Risk Team

Legal Advice and Legislation Branch | Legal & Assurance Division

Corporate Operations Group
Australian Government Department of Health
T: s22 @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: Monday, 13 December 2021 1:03 PM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>; Financial Framework (Supplementary Powers) Regulations <FFSPRegs@finance.gov.au>; Constitutional Risk <Constitutional.Risk@protected.health.gov.au>
Subject: RE: APPROVED ES HEALTH to FINANCE - mRNA exco item - RE: Schedule 1AB: draft ES for mRNA [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

Hi s22

Finance Minister has signed Exco papers for this item and they have been submitted to the secretariat. The Commercial Policy and Advice team in our department has advised this to your program area.

We haven't had updates on whether the PM has signed the late letter (PM&C has sought his signature by last Friday, 10 December).

This instrument will be lodged for routine registration now as advised by s22

Kind regards
s22

From: s22
Sent: Friday, 10 December 2021 10:17:20 AM (UTC+10:00) Canberra, Melbourne, Sydney
To: Financial Framework (Supplementary Powers) Regulations
Cc: Constitutional Risk; s22
Subject: RE: APPROVED ES HEALTH to FINANCE - mRNA exco item - RE: Schedule 1AB: draft ES for mRNA [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

Dear s22

One final email. I hope this is the last you hear from me about this.

The program area AS has requested that we "proceed with routine registration (within two working days) rather than urgent registration or specifying a precise commencement date."

If anything further is decided, we will let you know asap.

Kind regards, s22
Constitutional Risk Assessment Section

s22
@health.gov.au
constitutional.risk@protected.health.gov.au

From: s22
Sent: Friday, 10 December 2021 10:11 AM
To: 'Financial Framework (Supplementary Powers) Regulations' <FFSPRegs@finance.gov.au>
Cc: 'Constitutional Risk' <Constitutional.Risk@protected.health.gov.au>; s22
@health.gov.au>
Subject: RE: APPROVED ES HEALTH to FINANCE - mRNA exco item - RE: Schedule 1AB: draft ES for mRNA [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

Apologies, s22

Our Covid legal area has made one minor edit to the document – fortunately this is tracked. Please use this version now.

I am really sorry for all of the hassle.

Kind regards,
Constitutional Risk Assessment Section
@health.gov.au
constitutional.risk@protected.health.gov.au

From: s22
Sent: Friday, 10 December 2021 10:04 AM
To: 'Financial Framework (Supplementary Powers) Regulations' <FFSPRegs@finance.gov.au>
Cc: 'Constitutional Risk' <Constitutional.Risk@protected.health.gov.au>; s22
@health.gov.au>
Subject: APPROVED ES HEALTH to FINANCE - mRNA exco item - RE: Schedule 1AB: draft ES for mRNA [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

Good morning, s22

Thank you again for your assistance and patience. I now **attach** the final, approved ES that I received from the program area. Unfortunately, I have been provided with a clean version so cannot see any changes in tracking.

In terms of registration, I have now been advised that the program area AS does ***not*** consider that urgent registration is needed anymore, given that the announcement has been pushed back and there is no need for binding agreement with Moderna prior to Christmas. I have asked whether they require registration on a specific date, e.g. 1 January or whether it is okay if registration occurs before then.

I will provide you with any further updates as soon as I have them. I just wanted to get this to you as soon as I could.

I sincerely apologise for any confusion or difficulties from our end, and apologies for the delay – our program area was having some IT difficulties this morning.

Kind regards, s22
Constitutional Risk Assessment Section
s22
@health.gov.au
constitutional.risk@protected.health.gov.au

Duplicate of Document 16

Duplicate of Document 16

EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Finance

Financial Framework (Supplementary Powers) Act 1997

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

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

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

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

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

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

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

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

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

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

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

Consultation

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

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

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

Section 1 – Name

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

Section 2 – Commencement

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

Section 3 – Authority

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

Section 4 – Schedules

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

Schedule 1 – Amendments

Financial Framework (Supplementary Powers) Regulations 1997

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

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

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

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

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

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

Under final agreements, the Commonwealth is expected to:

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

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

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

Once established, an onshore manufacturing facility for mRNA vaccines would provide Australia with priority access to existing and pipeline mRNA products, rather than relying on delivery from offshore.

The COVID-19 Vaccines and Treatments for Australia – Science and Industry Technical Advisory Group (SITAG) has also maintained support for onshore manufacturing, emphasising the importance of investing in onshore mRNA manufacturing capabilities to ensure Australia has ongoing access to a diverse vaccine portfolio and at a magnitude that provides above population coverage. The SITAG provides advice to the Government on the purchasing and manufacturing of COVID-19 vaccines and treatments.

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

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

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

The overarching requirements in the development and maintenance of a sovereign mRNA manufacturing capability include:

- an end-to-end onshore manufacturing solution for the production and supply of mRNA pandemic and non-pandemic vaccines for the Australian population; and
- participation in the broader mRNA ecosystem, including contribution to research and development.

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

It is proposed that the Department of Health would provide ongoing funding to deliver the mRNA manufacturing capability in accordance with applicable legislative requirements and the Commonwealth resource management framework, including the *Public Governance, Performance and Accountability Act 2013* (PGPA Act), the *Commonwealth Procurement Rules* (CPRs) and the department's Accountable Authority Instructions.

The expenditure is expected to be provided through an approved process, including but not limited to a procurement process.

In this regard, the Secretary of the Department of Health (as the relevant Accountable Authority) has made a determination under paragraph 2.6 of the CPRs to disapply Divisions 1 and 2 of the CPRs to the proposed procurement of onshore mRNA manufacturing capability and supply of mRNA vaccines and treatments for both pandemic and non-pandemic purposes and all incidental or related matters (the procurement) on the basis that it is necessary to protect human health.

Accordingly, the requirement to publish the details of the proposed procurement on AusTender as set out in the CPRs will not apply. However, the Department will be required to table details relating to the proposed procurement, in accordance with the *Senate Procedural Orders of Continuing Effect No. 12* (Production of Indexed Lists of Departmental and Agency Files).

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

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

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

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

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

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

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

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

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

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

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

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

External affairs power

Section 51(xxix) of the Constitution empowers the Parliament to make laws with respect to 'external affairs'. The external affairs power supports legislation implementing Australia's international obligations under treaties to which it is a party.

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

Article 12(1) of the ICESCR recognises the 'right of everyone to the enjoyment of the highest attainable standard of physical and mental health'. Article 12(2)(c) relevantly requires Australia to take steps necessary for 'the prevention, treatment and control of epidemic, endemic, occupational and other diseases', and Article 12(2)(d) requires Australia to take steps necessary for 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness'.

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

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

Social welfare power

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

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

Executive power and express incidental power, including the nationhood aspect

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

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

Statement of Compatibility with Human Rights

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

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

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

Overview of the legislative instrument

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

The *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021* amend Schedule 1AB to the FF(SP) Regulations to establish legislative authority for government spending on the development and maintenance of Australia's onshore capability to manufacture mRNA (Messenger Ribonucleic Acid) products. The capability will be initially founded through a partnership with one or more suppliers. The partnership is expected to be underpinned by a ten-year agreement commencing in 2021-22 that would establish a population-scale mRNA manufacturing capability and guarantee the supply of locally manufactured mRNA vaccines and therapeutics, including COVID-19 vaccines.

mRNA has been identified as a key growth opportunity in the Medical Products National Manufacturing Priority road map under the Government's *Modern Manufacturing Strategy*. The mRNA technology underpins the highly effective Pfizer and Moderna COVID-19 vaccines which have been embraced by Australians, accelerating the country's recovery from the pandemic.

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

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

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

- an end-to-end onshore manufacturing solution for the production and supply of mRNA pandemic and non-pandemic vaccines for the Australian population; and
- participation in the broader mRNA ecosystem, including contribution to research and development.

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

Human rights implications

This disallowable legislative instrument engages the following right:

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

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

Article 12(1) of the ICESCR recognises the 'right of everyone to the enjoyment of the highest attainable standard of physical and mental health'. Article 12(2)(c) requires Australia to take steps necessary for 'the prevention, treatment and control of epidemic, endemic, occupational and other diseases', and Article 12(2)(d) requires Australia to take steps necessary for 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness'.

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

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

Overall, this measure would support the right of individuals to the enjoyment of the highest standard of health and further contribute to overall community health through the prevention, treatment and control of epidemic, endemic, occupational and other diseases.

Conclusion

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

Senator the Hon Simon Birmingham
Minister for Finance

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

SEC=PROTECTED

Hi s22

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

SEC=PROTECTED

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

Error! Not a valid filename. Hi s22

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

Error! Not a valid filename.

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

SEC=PROTECTED

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

s34(3)

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

Kind regards

s22

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

SEC=PROTECTED

PDR Number:
MS21-001343

Australian Government
Department of Finance

MINISTERIAL SUBMISSION

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

Minister for Finance 10 December 2021

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

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

Recommendations:

That you:

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

AGREED / NOT AGREED / PLEASE DISCUSS

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

SIGNED / PLEASE DISCUSS

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

SIGNED / PLEASE DISCUSS

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

INITIALLED / PLEASE DISCUSS

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

APPROVED / NOT APPROVED / PLEASE DISCUSS

Key Issues:

s34(3)
[redacted]

s42 [redacted]

s47C [redacted]

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

Financial Implications:

s34(3) [redacted]

Consultation:

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

Approved for electronic transmission

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

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

13/12/21.

Simon Birmingham

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

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

Dated 2021

David Hurley
Governor-General

By His Excellency's Command

Simon Birmingham
Minister for Finance

OPC65631 - A

Contents

1 Name

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

2 Commencement

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

Commencement information

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

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

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

3 Authority

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

4 Schedules

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

Schedule 1—Amendments

Financial Framework (Supplementary Powers) Regulations 1997

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

Insert:

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

MINISTER FOR FINANCE

Departmental No. 2021/72

Executive Council
Meeting No. .....

Approved in Council

.....

David Hurley
Governor-General

.....

Filed in the Records
of the Council

.....
Secretary to the Executive Council

Minute Paper for the Executive Council

Subject

Financial Framework (Supplementary Powers) Act 1997

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

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

Simon Birmingham
Minister for Finance

EXPLANATORY MEMORANDUM

Minute No. 72 of 2021 – Minister for Finance

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

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

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

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

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

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

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

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

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

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

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

Under final agreements, the Commonwealth would be expected to:

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

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

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

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

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

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

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

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

12

EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Finance

Financial Framework (Supplementary Powers) Act 1997

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

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

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

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

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

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

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

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

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

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

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

Consultation

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

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

Attachment A

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

Section 1 – Name

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

Section 2 – Commencement

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

Section 3 – Authority

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

Section 4 – Schedules

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

Schedule 1 – Amendments

Financial Framework (Supplementary Powers) Regulations 1997

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

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

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

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

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

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

Under final agreements, the Commonwealth is expected to:

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

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

Building on the success of breakthrough COVID-19 mRNA vaccines, the Government recognises that mRNA technology is part of the next generation in advanced health care. Onshore production of mRNA vaccines will strengthen Australia's capacity against COVID-19 and its variants, as well as future pandemics and other diseases. Once established, an onshore manufacturing facility for mRNA vaccines would provide Australia with priority access to existing and pipeline mRNA products, rather than relying on delivery from offshore.

The COVID-19 Vaccines and Treatments for Australia – Science and Industry Technical Advisory Group (SITAG) has also maintained support for onshore manufacturing, emphasising the importance of investing in onshore mRNA manufacturing capabilities to ensure Australia has ongoing access to a diverse vaccine portfolio and at a magnitude that provides above population coverage. The SITAG provides advice to the Government on the purchasing and manufacturing of COVID-19 vaccines and treatments.

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

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

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

The overarching requirements in the development and maintenance of a sovereign mRNA manufacturing capability include:

- an end-to-end onshore manufacturing solution for the production and supply of mRNA pandemic and non-pandemic vaccines for the Australian population; and
- participation in the broader mRNA ecosystem, including contribution to research and development.

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

It is proposed that the department would provide ongoing funding to deliver the mRNA manufacturing capability in accordance with applicable legislative requirements and the Commonwealth resource management framework, including the *Public Governance, Performance and Accountability Act 2013* (PGPA Act), the *Commonwealth Procurement Rules* (CPRs) and the department's Accountable Authority Instructions.

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

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

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

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

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

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

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

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

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

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

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

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

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

External affairs power

Section 51(xxix) of the Constitution empowers the Parliament to make laws with respect to 'external affairs'. The external affairs power supports legislation implementing Australia's international obligations under treaties to which it is a party.

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

Article 12(1) of the ICESCR recognises the 'right of everyone to the enjoyment of the highest attainable standard of physical and mental health'. Article 12(2)(c) relevantly requires Australia to take steps necessary for 'the prevention, treatment and control of epidemic, endemic, occupational and other diseases', and Article 12(2)(d) requires Australia to take steps necessary for 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness'.

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

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

Social welfare power

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

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

Executive power and express incidental power, including the nationhood aspect

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

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

Attachment B

Statement of Compatibility with Human Rights

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

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

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

Overview of the legislative instrument

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

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

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

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

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

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

The overarching requirements in the development and maintenance of a sovereign mRNA manufacturing capability include:

- an end-to-end onshore manufacturing solution for the production and supply of mRNA pandemic and non-pandemic vaccines for the Australian population; and
- participation in the broader mRNA ecosystem, including contribution to research and development.

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

Human rights implications

This disallowable legislative instrument engages the following right:

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

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

Article 12(1) of the ICESCR recognises the 'right of everyone to the enjoyment of the highest attainable standard of physical and mental health'. Article 12(2)(c) requires Australia to take steps necessary for 'the prevention, treatment and control of epidemic, endemic, occupational and other diseases', and Article 12(2)(d) requires Australia to take steps necessary for 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness'.

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

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

Overall, this measure would support the right of individuals to the enjoyment of the highest standard of health and further contribute to overall community health through the prevention, treatment and control of epidemic, endemic, occupational and other diseases.

Conclusion

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

Senator the Hon Simon Birmingham
Minister for Finance

From: Financial Framework (Supplementary Powers) Regulations
To: s22
Subject: FW: Late FFSP item for 16 December Exco - final papers [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]
Date: Monday, 13 December 2021 12:49:31 PM
Attachments: Duplicate attachments from Document 21

From: Financial Framework (Supplementary Powers) Regulations
Sent: Monday, 13 December 2021 12:49:29 PM (UTC+10:00) Canberra, Melbourne, Sydney
To: Exco
Cc: Financial Framework (Supplementary Powers) Regulations
Subject: Late FFSP item for 16 December Exco - final papers [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

Hi Exco Secretariat team

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

Please find attached signed papers for the above late item proposed for consideration at the 16 December 2021 Exco meeting.

s22 has advised that the late letter for the Prime Minister to send to the Governor-General is with the PMO, seeking the Prime Minister's signature by Friday, 10 December (MS21-001956 refers). We have not had updates on whether this letter has been signed.

Kind regards

s22

SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege

Senator the Hon Katy Gallagher
Minister for Finance
Minister for Women
Minister for the Public Service
Senator for the Australian Capital Territory

REF: MS22-000544

The Hon Mark Butler MP
Minister for Health and Aged Care
Parliament House
CANBERRA ACT 2600

Dear ~~Minister~~ Mark

I am writing regarding the letter of 10 March 2022 from the Senate Standing Committee for the Scrutiny of Delegated Legislation (the Committee) to my predecessor, Senator the Hon Simon Birmingham, the then Minister for Finance.

The letter seeks information regarding the mRNA vaccines and treatments program (the program) prescribed in the *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 9) Regulations 2021* (the Health Regulations). Details of the Committee's request are set out at Attachment A.

Due to the Governor-General issuing a Proclamation proroguing the Parliament and dissolving the House of Representatives on 11 April 2022, a response to the Committee's request has been suspended until Parliament resumes its operation.

As the Minister for Finance, I am responsible for the *Financial Framework (Supplementary Powers) Act 1997*. The Act provides a mechanism for authorising Commonwealth expenditure on arrangements, grants and programs specified in Schedule 1AA and Schedule 1AB to the *Financial Framework (Supplementary Powers) Regulations 1997*, including the Health Regulations. Details of the program prescribed in the Health Regulations are provided at Attachment B.

As the program is within your policy responsibility, your advice on the matters raised by the Committee would be appreciated by 12 August 2022. I will include your advice in my response to the Committee by 18 August 2022 to enable the Committee to consider it at its meeting on 7 Septebmer 2022. The Committee's correspondence and my response will be published on the Committee's website.

The disallowance period for the Health Regulations will end on 7 September 2022. The Committee may give notice of a disallowance motion for the Health Regulations as a precautionary measure to allow it sufficient time to consider the matters raised.

Yours sincerely

Katy Gallagher

Katy Gallagher

1 August 2022

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

s42

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

s42

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

Dear Schedule 1AB team

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

s42

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

Please let me know if there are any questions.

Kind regards,

s22
Senior Lawyer – Constitutional Risk Team

Legal Advice and Legislation Branch

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

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

Attachment A1

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

Description of the proposed new or materially changed Commonwealth expenditure

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

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

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

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

- Secure onshore population-scale mRNA vaccine manufacturing capability, supply and resilience to respond to future pandemics and other health emergencies;
- Provide priority access to mRNA COVID-19 vaccines and other respiratory vaccines should those vaccines obtain regulatory approval from the TGA;
- Place Australia at the forefront of the development of transformative mRNA technology, which could have potential widespread applications for cancer, respiratory illnesses and other medical conditions; and
- Bolster industry growth and job creation, by strengthening Australia's biopharmaceuticals sector, including through enabling potential translation and commercialisation paths for Australian-based research and development.

The overarching requirements in establishing a sovereign mRNA manufacturing capability include:

- An end-to-end onshore manufacturing solution for the production and supply of mRNA pandemic and non-pandemic vaccines, for the Australian population;

- Participation in the broader mRNA ecosystem including contribution to research and development;
- Non-pandemic vaccine supply agreements to procure Australia's requirement for COVID-19 vaccines, respiratory syncytial virus (RSV), influenza and other mRNA vaccines should those vaccines be developed and approved;
- Ongoing pandemic preparedness fees to secure priority access to mRNA pandemic vaccines; and
- Pandemic vaccine advance purchase agreements if Moderna identifies and/or develops vaccine candidates for future pandemics.

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

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

Background

- The process to establish an mRNA manufacturing capability started at the beginning of the COVID-19 pandemic in 2020, when the Commonwealth was squarely focused on pandemic preparedness. Local mRNA vaccine production capacity was identified as a priority growth opportunity in the *Medical Products National Manufacturing Priority road map*, published by the DISER in February 2021, refer to Medical Products National Manufacturing Priority road map (https://www.mtaa.org.au/news/medical-products-national-manufacturing-priority-road-map).
- During the COVID-19 pandemic, there were some challenges to the procurement and delivery of offshore manufactured COVID-19 vaccines, presenting risks to the security of Australia's vaccine supply. Enduring and streamlined manufacturing and supply arrangements for mRNA vaccines would enable a secure and diverse supply of vaccines and equip Australia to deal with any new challenges for any future pandemics. Once established, an onshore manufacturing facility for mRNA vaccines would provide Australia with priority access to existing and pipeline mRNA products, rather than relying on delivery from other countries.
- The 2020 audit of Australia's vaccine manufacturing capability, followed by a March 2021 business case, identified a need for Australia to undertake onshore mRNA manufacturing. Then in the 2021-22 Budget, the Australian Government announced a measure that included funding to DISER to work with the Department to develop an onshore mRNA vaccine manufacturing capability in Australia, refer to Budget Paper No. 2, page 134.

s42

[redacted]

Statement of the relevance and operation of constitutional heads of power

External affairs power (s 51(xxix))
Section 51(xxix) of the Constitution empowers the Parliament to make laws with respect to 'external affairs'. The external affairs power supports legislation implementing Australia's international obligations under treaties to which it is a party.

Australia has international obligations under the International Covenant on Economic, Social and Cultural Rights (ICESCR). Article 12(1) of the ICESCR recognises the 'right of everyone to the enjoyment of the highest attainable standard of physical and mental health'. Article 2 requires each State Party to 'take steps…to the maximum of its available resources, with a view to achieving progressively the full realisation' of this right 'by all appropriate means, including particularly the adoption of legislative measures'.

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

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

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

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

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

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

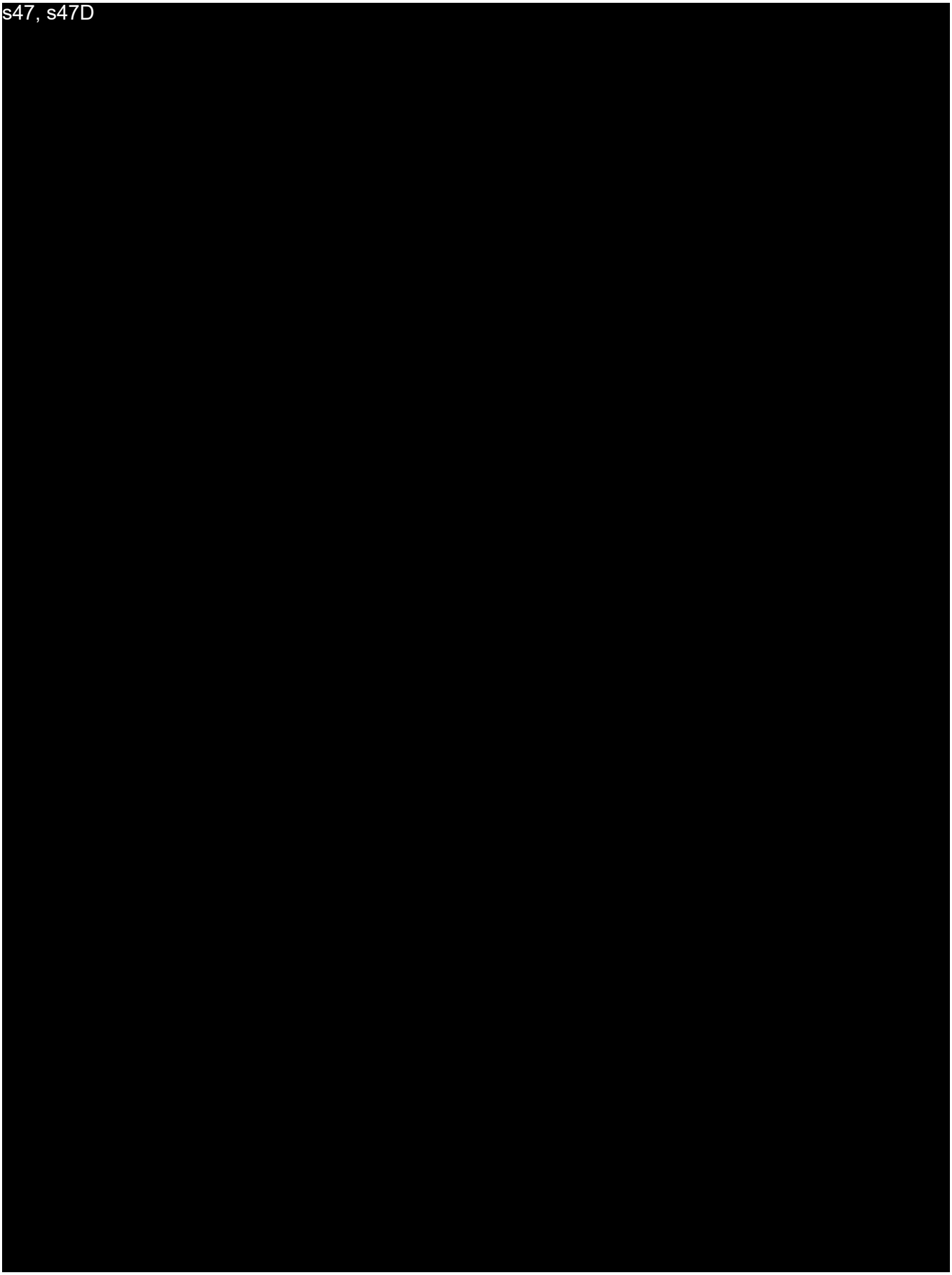
The proposed measure relates to the provision of pharmaceutical benefits and the manufacturing of vaccines and treatments in order to prevent and treat diseases and medical conditions using mRNA technology.

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

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

s47, s47D

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

The Department would propose to:

- Execute and manage all contracts for the above services for the term of the agreements;
- Work collaboratively with DISER and the supplier to meaningfully engage in ecosystem requirements to strengthen mRNA capability in Australia; and
- Report on the performance and progress of the mRNA capability, and monitor expenditure on the mRNA capability.

Availability of independent merits review

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

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

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

Consultation

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

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

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

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

Input to the statement of compatibility with human rights

Human rights implications

The amended table item engages the following human rights:

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

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

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

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

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

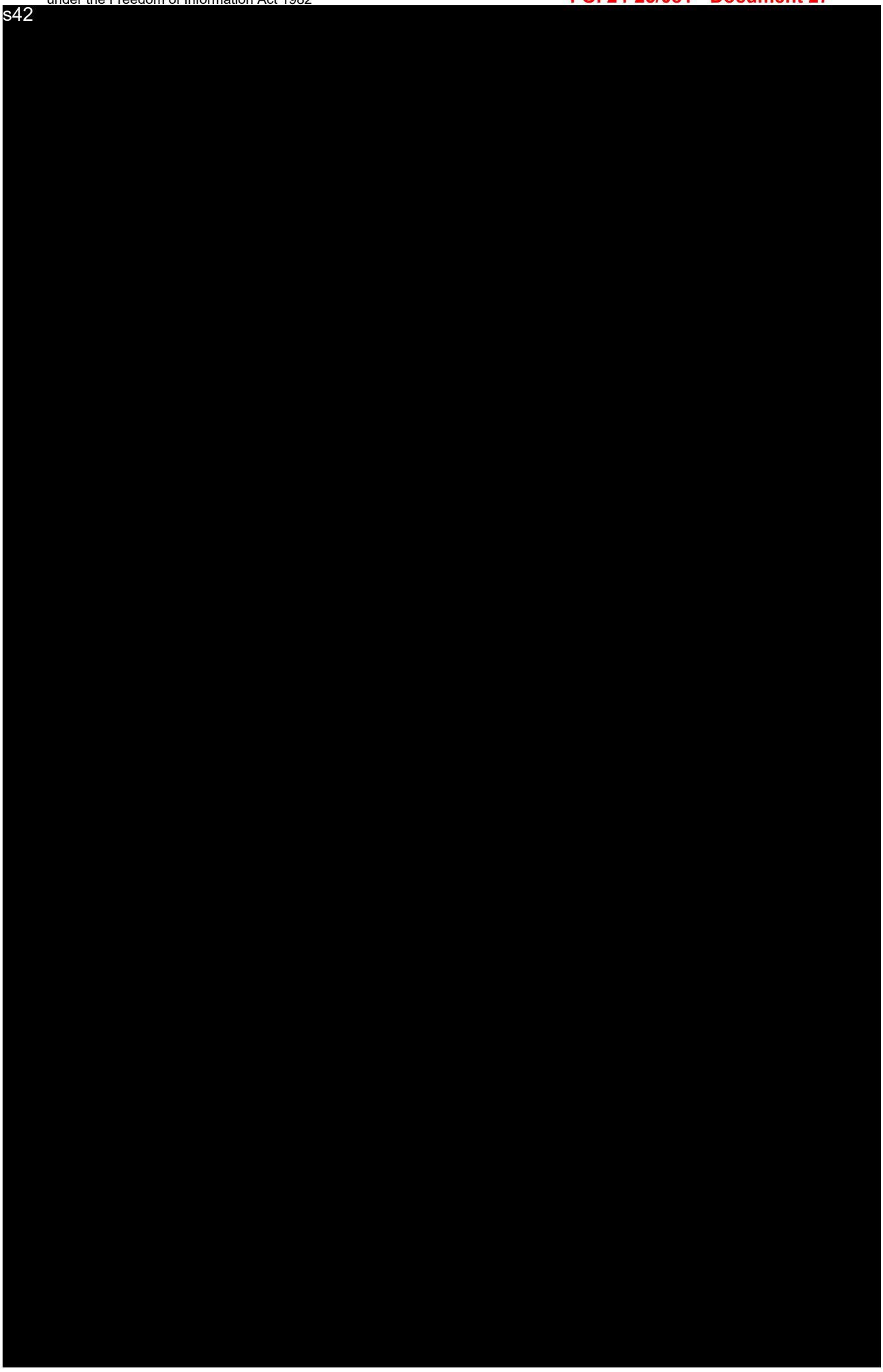
The proposed measure would promote the right to health by ensuring that Australia is well prepared to prevent, treat and control diseases and other medical conditions using mRNA technology. Having mRNA manufacturing capability onshore would also ensure that Australia is not subject to potential supply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

Overall, this measure would support the right of individuals to the enjoyment of the highest standard of health and further contribute to overall community health through the prevention, treatment and control of epidemic, endemic, occupational and other diseases.

Conclusion

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

s42



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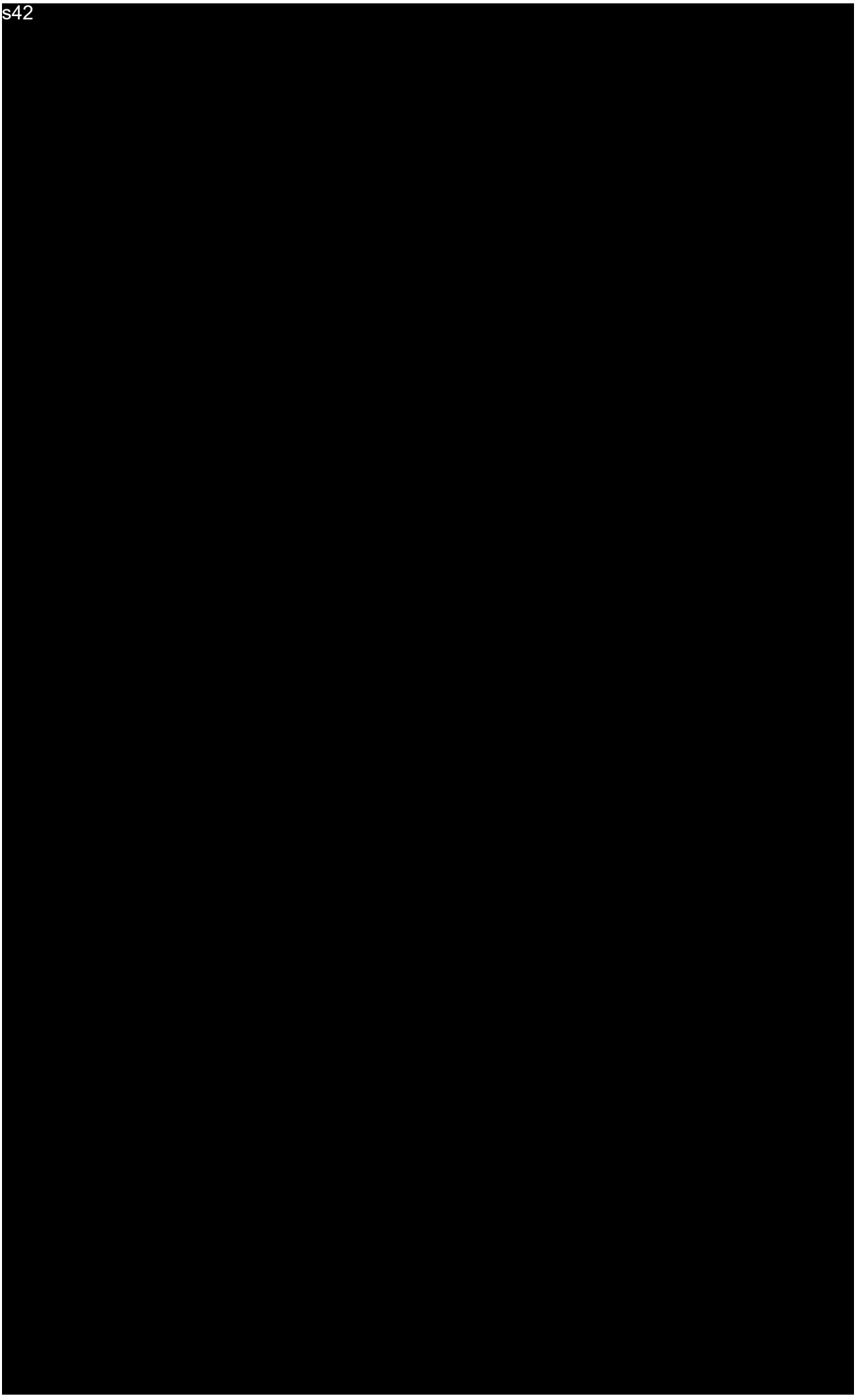

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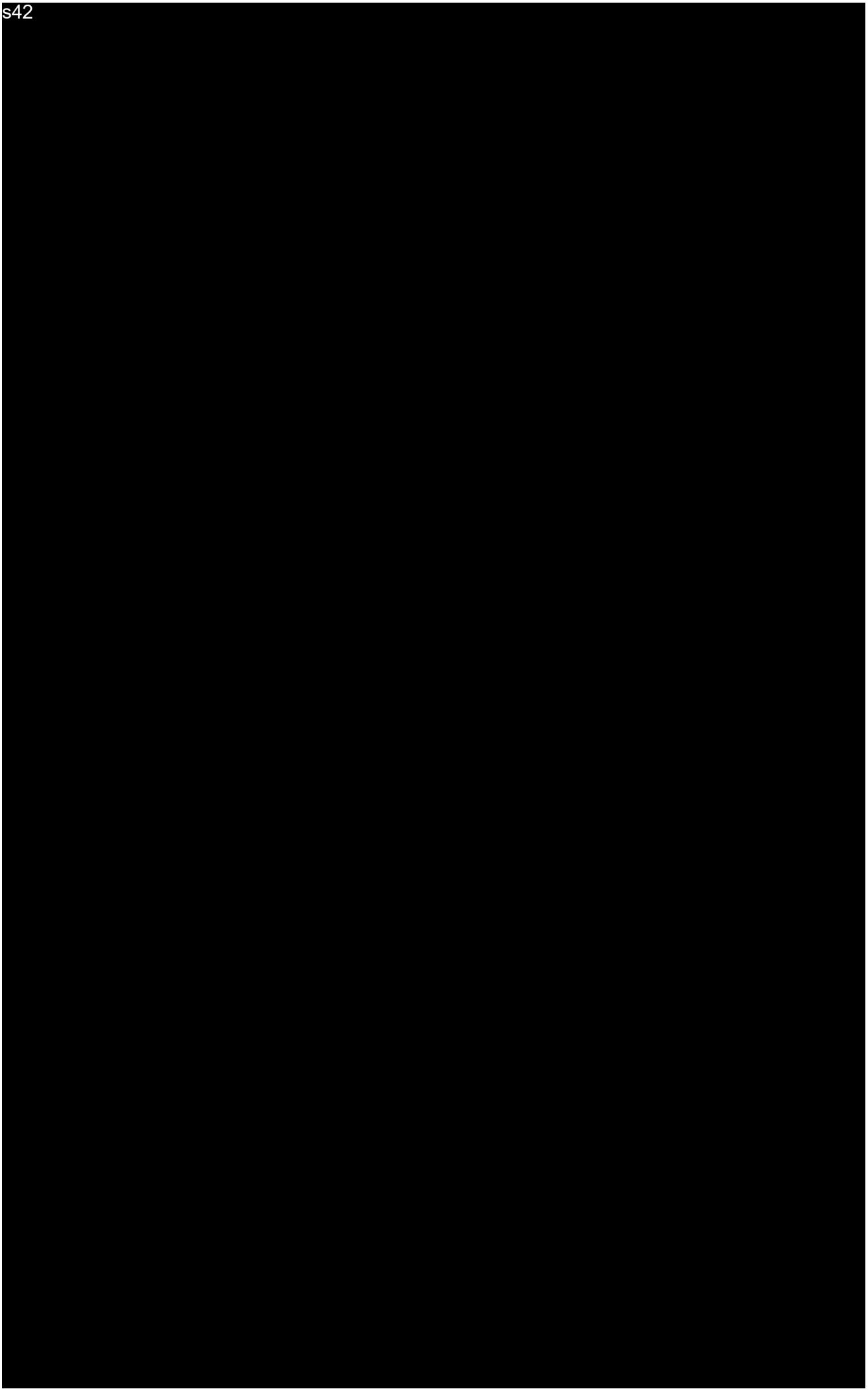

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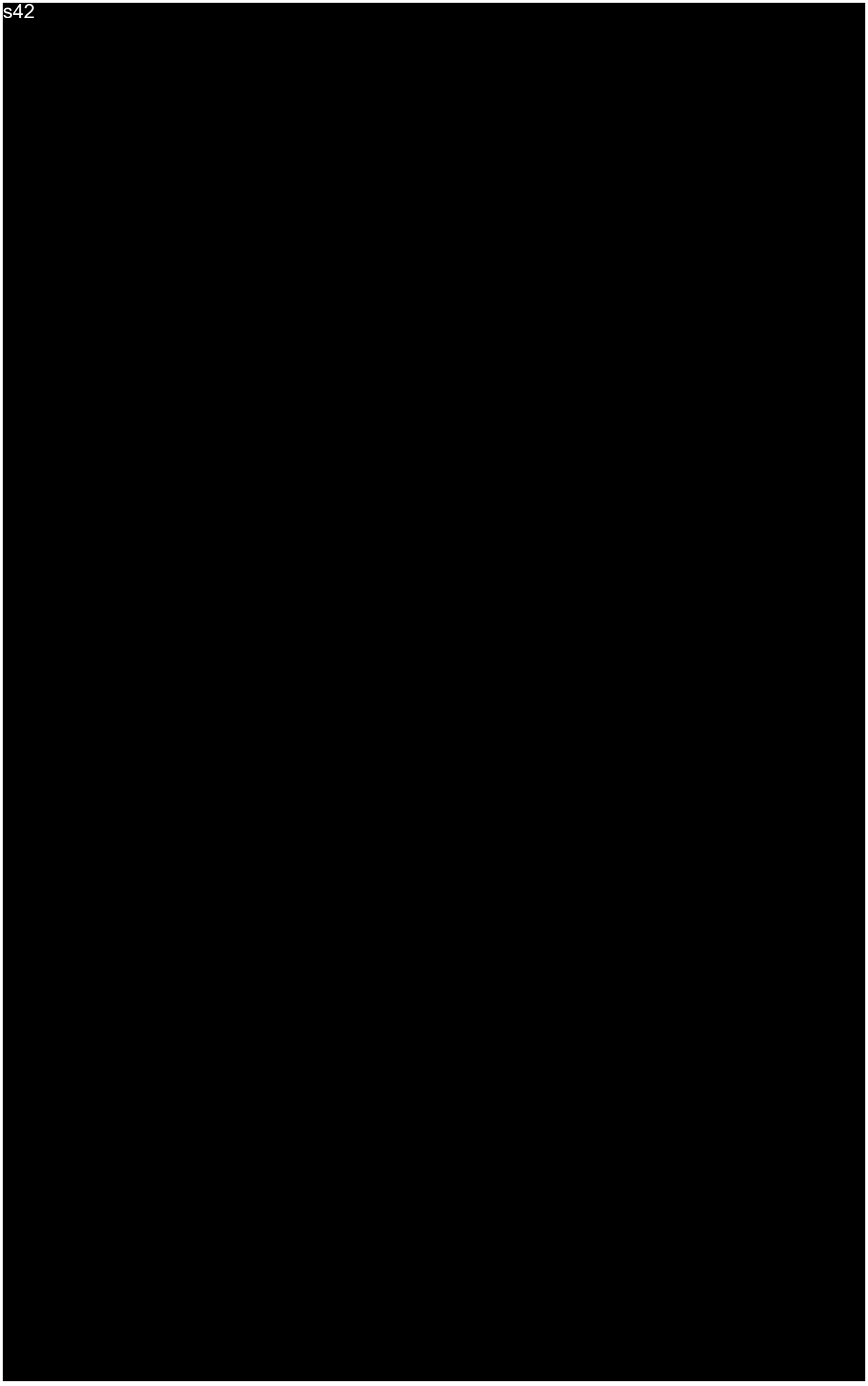

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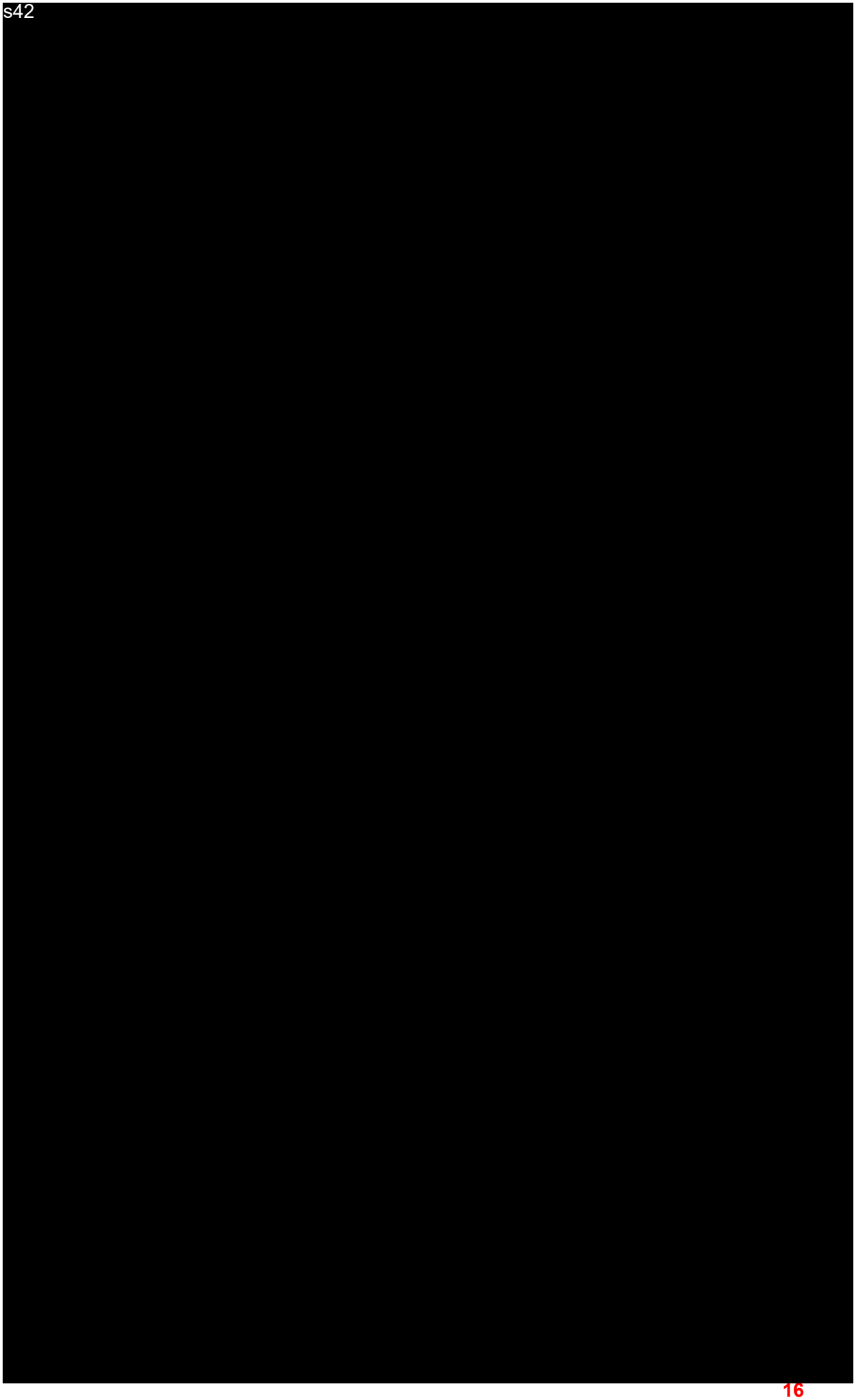

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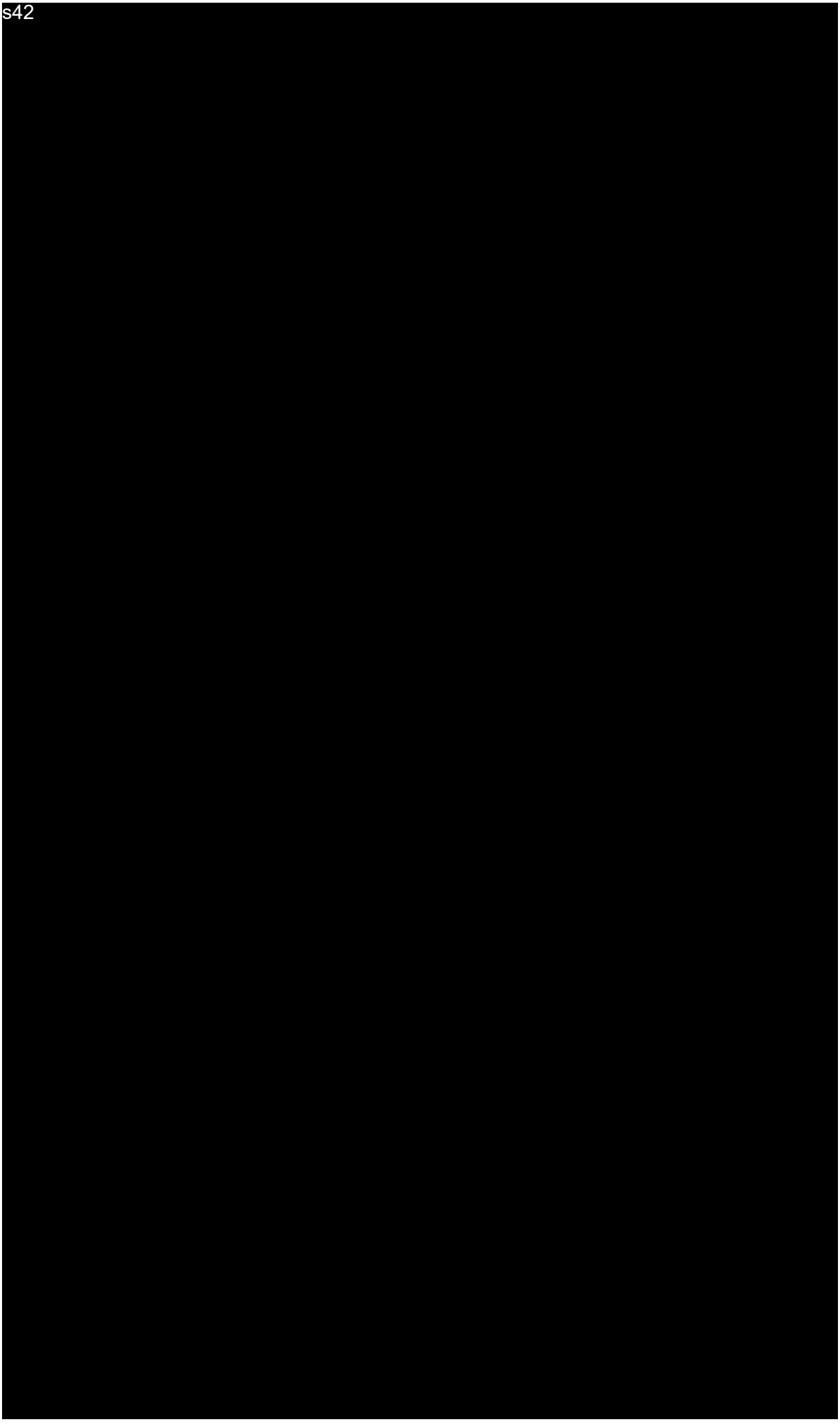

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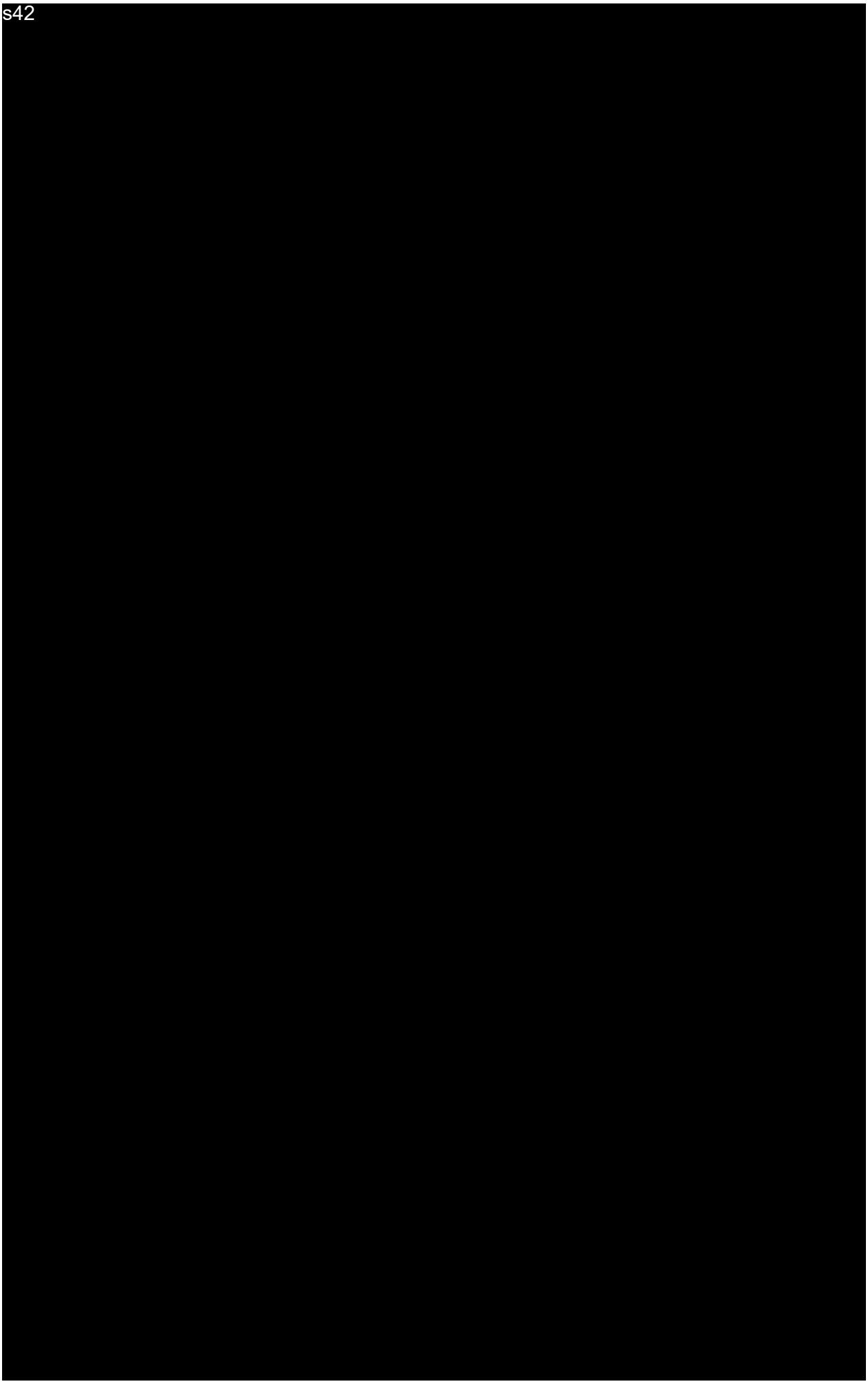

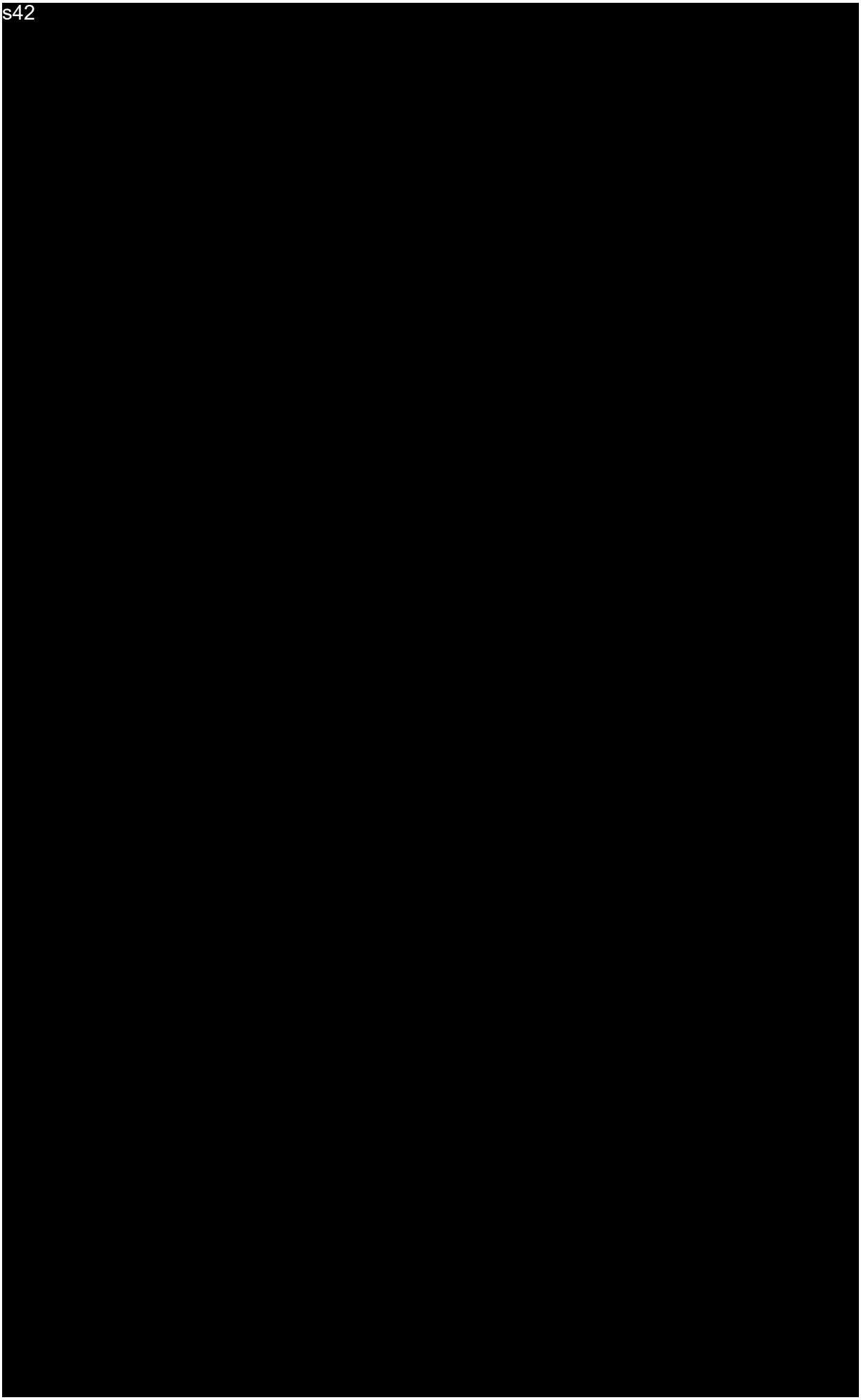

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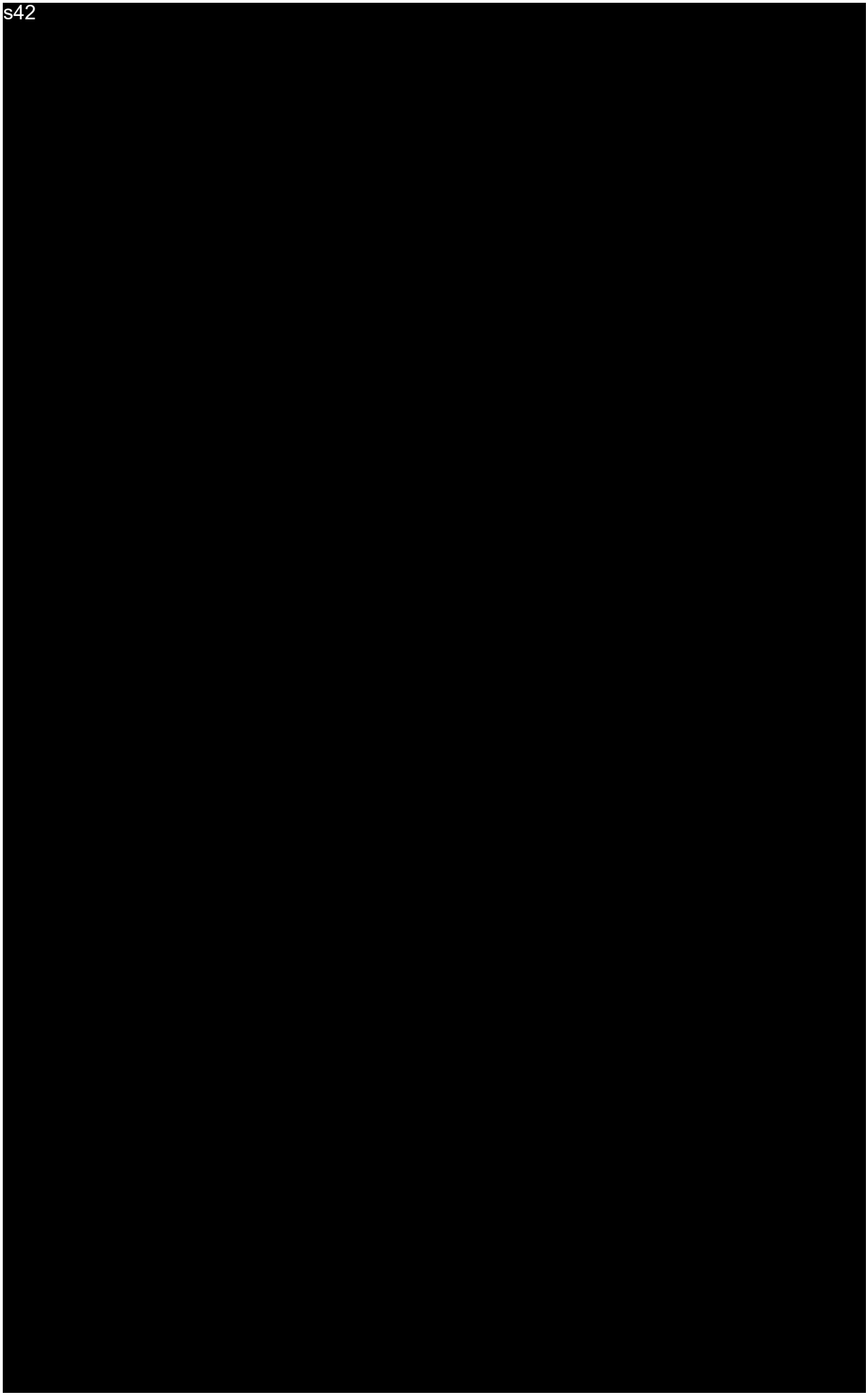

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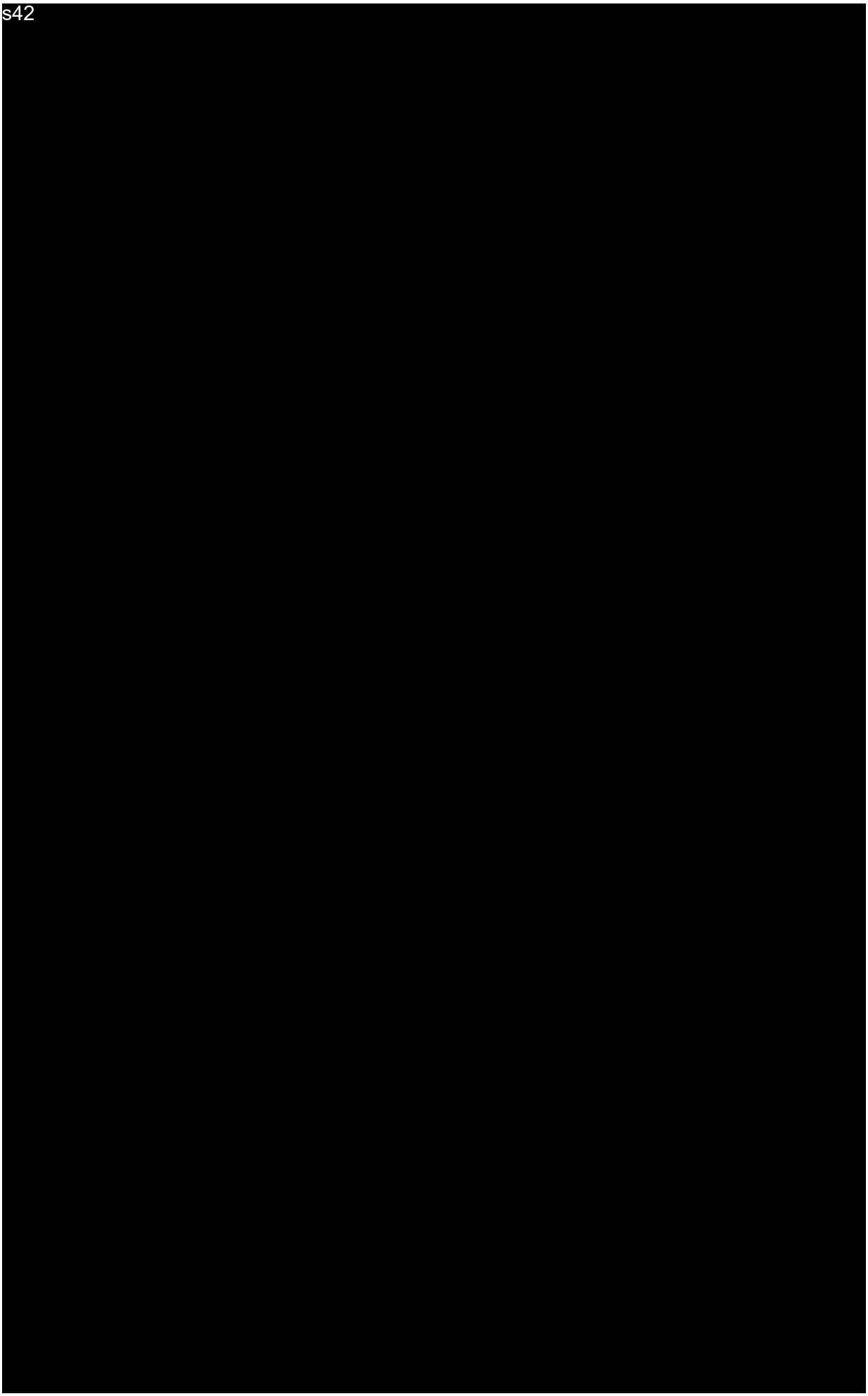

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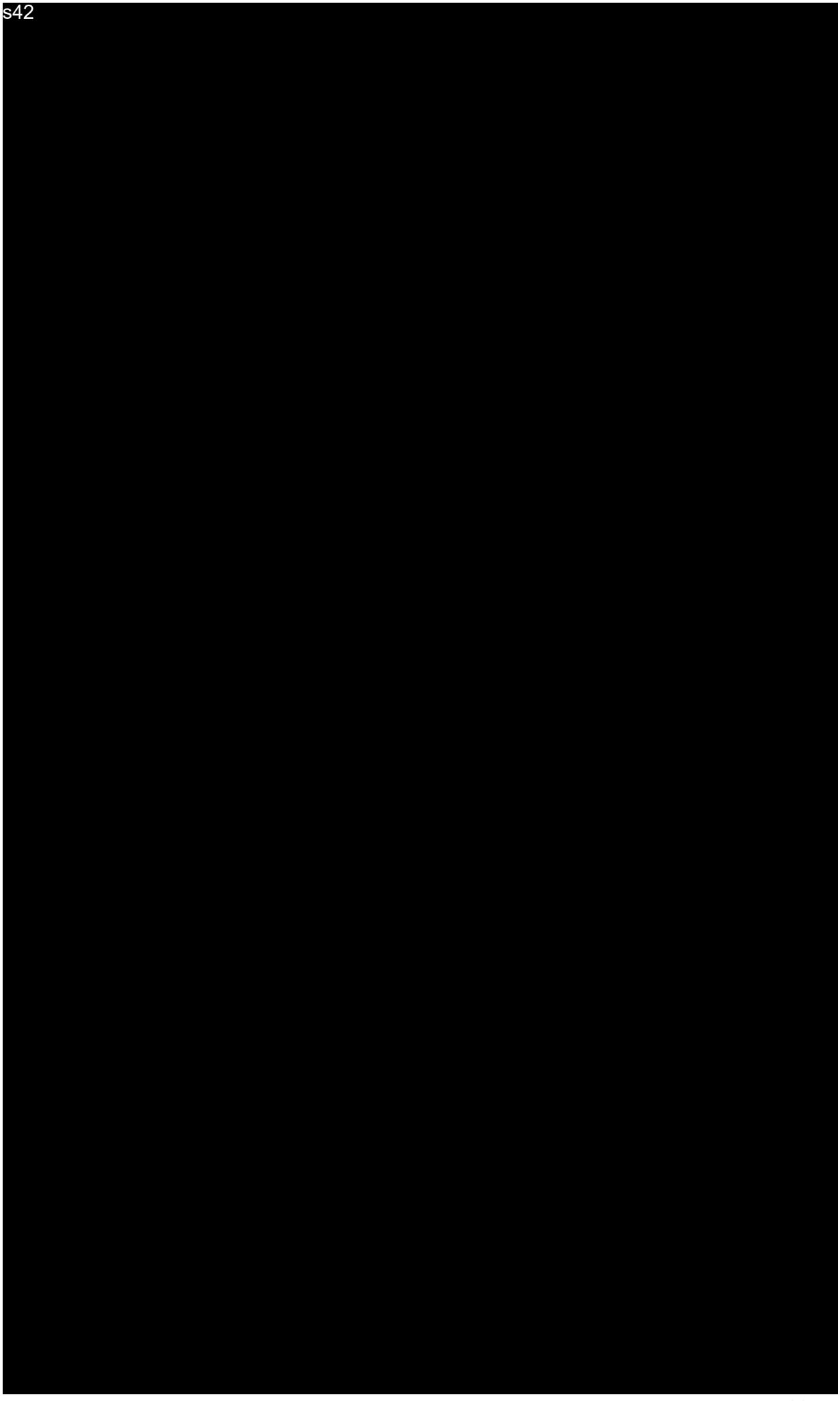

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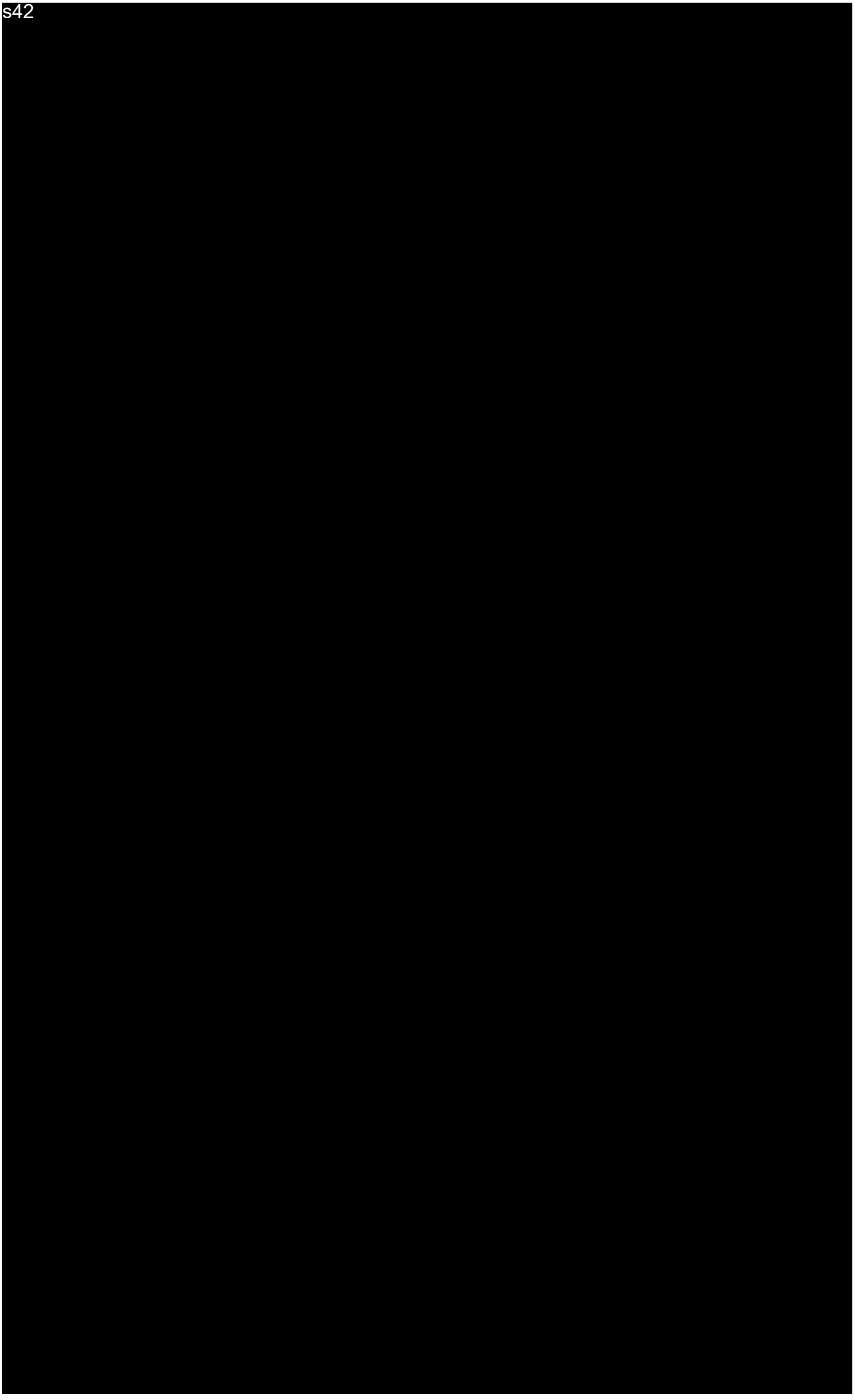

PROTECTED: CABINET

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 Agreement with Moderna.

Policy authority

s34(3) [redacted]

Funding information

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

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

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

s42 [redacted]

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

Yours sincerely

Mark Butler

……/……/2024
Encl (Attachment A1)