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Subject: 371 - Final Papers FFSP Health and Aged Care No. 4 Regulations 2024 - ExCo 24 October 2024 [SEC=OFFICIAL:Sensitive]

OFFICIAL:Sensitive

Dear ExCo team,

Please find attached Final Papers for FFSP Health and Aged Care No. 4 Regulations 2024 for the ExCo meeting of 24 October 2024.

Please let us know if you have any questions.

Kind regards,

s22

s22 | Policy Officer

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MINISTER FOR FINANCE

Departmental No. 371 of 2024

Meeting No.

Executive Council

Minute Paper for the Executive Council

Subject

Financial Framework (Supplementary Powers) Act 1997

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

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

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Approved in Council

Sam Mostyn AC Governor-General

.....

Filed in the Records of the Council

Secretary to the Executive Council

aty ballagher

Katy Gallagher Minister for Finance



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

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

Dated

2024

Sam Mostyn AC Governor-General

By Her Excellency's Command

Laty barregher

Katy Gallagher Minister for Finance

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1 Name

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

2 Commencement

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

Column 1	Column 2 Commencement	Column 3 Date/Details
Provisions		
1. The whole of this instrument	The day after this instrument is registered.	
Note:	This table relates only to the provisions of this instrumen not be amended to deal with any later amendments of thi	

(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.

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Schedule 1 Amendments

Schedule 1—Amendments

Financial Framework (Supplementary Powers) Regulations 1997

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

Omit "to NPS MedicineWise".

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

Insert:

- ; and (e) to provide education and awareness activities, events, conferences and symposiums on the safe and appropriate use of medicines.
- 3 Part 4 of Schedule 1AB (table item 306, column headed "Objective(s)") Omit "also".

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

Repeal the paragraph, substitute:

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

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

Add:

- ; or (c) with respect to postal, telegraphic, telephonic, and other like services (within the meaning of paragraph 51(v) of the Constitution).
- 6 Part 4 of Schedule 1AB (table item 429, column headed "Objective(s)", paragraph (b) (first occurring))

Omit "by members of the community".

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

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

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

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

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

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

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

Insert:

or (iv) in Pacific Island countries;

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

Insert:

- (ea) with respect to places, persons, matters or things external to Australia; or
- (eb) with respect to the relations of the Commonwealth with the islands of the Pacific; or

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

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

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EXPLANATORY MEMORANDUM

Minute No. 371 of 2024 - Minister for Finance

Subject - Financial Framework (Supplementary Powers) Act 1997

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

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

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

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

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

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

Existing funding is allocated for the:

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

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

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

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

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

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

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

<u>Authority</u>: Section 65 of the Financial Framework (Supplementary Powers) Act 1997



ATTACHMENT

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

Section 1 - Name

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

Section 2 - Commencement

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

Section 3 – Authority

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

Section 4 – Schedules

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

Schedule 1 – Amendments

Financial Framework (Supplementary Powers) Regulations 1997

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The objectives of the QUDTP Program are to:

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

• support the effectiveness and efficiency of the health system.

The intended outcomes of the QUDTP Program are for:

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

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

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

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

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

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

Amended Table item 429 – Sport and Recreation Program

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Amended Table item 531 - mRNA vaccines and treatments

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

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

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

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

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

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

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

The Australian Government funding commitments under the FEA include:

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

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

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

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

- an end-to-end onshore manufacturing solution for the production and supply of mRNA pandemic and non-pandemic vaccines, for the Australian population;
- participation in the broader mRNA ecosystem including contribution to research and development;
- non-pandemic vaccine supply agreements to procure Australia's requirement for COVID-19 vaccines, RSV, influenza and other mRNA vaccines should those vaccines be developed and approved;
- ongoing pandemic preparedness fees to secure priority access to mRNA pandemic vaccines; and
- pandemic vaccine advance purchase agreements if Moderna identifies and/or develops vaccine candidates for future pandemics.

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

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

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

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