Commonwealth of Australia as represented by the Department of Industry, Science, Energy and Resources and the Department of Health

Approach to Market: proposals to establish an onshore mRNA manufacturing capability

Version 1.1: Correct as at 24 May 2021

Any questions regarding this Approach to Market should be addressed to: onshoremrna@industry.gov.au

Lodgement of proposals

Closing time and date: 2.00pm, Canberra time, on Friday, 16 July 2021.

Proposals must be lodged electronically to onshoremrna@industry.gov.au.

A DISER approved file upload service is available to accept proposals that exceed 20 megabytes. Requests for this service is required at least 48 hours prior to the closing time above. Requests must be made in writing via onshoremrna@industry.gov.au

Approach to Market

General Information

1. Overview

The Commonwealth of Australia (the Australian Government), represented by the Department of Industry, Science, Energy and Resources (DISER) and the Department of Health (collectively the Departments), is seeking information in the form of fully costed proposals to establish an onshore, population-scale mRNA manufacturing capability, to be fully operational with requisite regulatory approvals/licences within a timeframe of between 12 months (or earlier, if possible) and no later than 3 years from finalisation of an agreement with the Australian Government. In doing so, the Australian Government seeks to meet the following objectives:

- 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;
- To provide security of vaccine supply to address pandemics and other health emergencies into the future; and
- To strengthen Australia's biopharmaceuticals sector, including through enabling potential translation and commercialisation paths for Australian-based research and development.

This Approach to Market is complementary to any current discussions in which the Australian Government is engaging directly with relevant mRNA vaccine IP owners to establish mRNA manufacturing facilities in Australia. It provides an additional competitive process, an opportunity for industry to provide solutions, and will ultimately help us secure the best mRNA capability for Australians. The Australian Government will consider proposals from this Approach to Market alongside the outcomes of the discussions with mRNA vaccine IP owners.

The fully costed proposals from this Approach to Market should provide a sufficient level of detail to support Australian Government decisions regarding options for the establishment of any such mRNA capability with a minimum timeframe for supply of mRNA vaccines and treatments of 10 years from commencement of operation of the capability, including details of investment, support or assistance from the Australian Government that may be necessary to establish the capability. The detailed information will be used to support Australian Government decisions about the establishment of an onshore capability with a minimum timeframe for supply of mRNA vaccines and any mRNA therapeutics of 10 years from commencement of operation of the capability.

Respondents are requested to:

- submit a fully costed proposal to establish an end-to-end onshore population-scale mRNA capability which specifies how and when the requirements set out below will be met;
- demonstrate how the proposed capability will deliver secure supply of population-scale mRNA vaccines and any mRNA therapeutics for a minimum timeframe of 10 years from commencement of operation of the capability;
- if the Australian Government wishes to proceed with any future procurement or grant process that involves the respondent, it is anticipated that, subject to the process required to be undertaken (see below), the Australian Government would enter into a contract with the respondent that requires the respondent to:
    - establish and maintain the capability as set out in the fully costed proposal in accordance with the contract and subject to any modifications required or conditions imposed by the Commonwealth; and

- make products available to the Australian Government as required and on a 'first priority' basis, ahead of any other purchaser and notwithstanding any advance purchase agreement or other arrangement with any other purchaser on terms set out in the contract.

2. Background

The Australian Government has made substantial investments to support early access to safe and effective vaccines for all Australians.

This Approach to Market builds on a previous audit of Australia's vaccine manufacturing capability, and a business case for Australia to undertake onshore mRNA manufacturing.

Proposals from this process, along with existing information, will be used to inform the Australian Government of opportunities to establish an onshore mRNA manufacturing capability. Proposals will also be used to quantify any associated Australian Government involvement, support or assistance to enable them to establish an onshore population-scale mRNA facility.

It is expected that applicants may engage with state and/or territory governments, in order to develop their proposals to provide maximum value to Australia. In the event that applicants anticipate a role of state/territory governments in their proposal for onshoring mRNA manufacturing capability, the Australian Government's preference is for such engagement to occur prior to proposal submission (and for any state/territory government support to be reflected in the proposals). Notwithstanding this, the Departments reserve the right to engage with states and territories as outlined in Clause 12.1(c) of this Approach to Market.

The detailed proposals are for a flexible onshore capability for a minimum timeframe of 10 years from commencement of operation of the capability. This Approach to Market does not seek proposals for establishing onshore manufacturing capability that could not satisfy population-scale, commercial supply and regulation demands (e.g., proposals for facilities that primarily serve research and development/clinical trial-scale production needs). This Approach to Market is seeking proposals from organisations already regulatory compliant or capable of seeking regulatory approval through the Therapeutic Goods Administration.

This Approach to Market is intended to inform and elicit the development of fully costed proposals with sufficient detail to allow for consideration by the Commonwealth Government to involve, support or assist decision-making and potential investment. The result of decisions by the Commonwealth Government may result in a procurement, grant or other form of involvement, support or assistance or a combination of arrangements, in all cases with a binding commitment to maintain the capability and make products available to the Australian Government. However, there is no guarantee that this process will result in the Commonwealth undertaking any grant, procurement activity or other financial support from the Commonwealth for any proposal or that involves any respondent to this Approach to Market.

Without prejudice to Clause 19 of this document, proposals received through this Approach to Market will be used to inform the Australian Government. Information obtained through this process may be shared with other Commonwealth bodies or with state and territory bodies, and with expert advisory bodies established to support the Australian Government on its vaccine and treatment activities and related purposes. One or more proposals from this process may be put to Cabinet to determine whether they will be supported by the Australian Government, and if so, how. Cabinet may also consider one or more proposals from existing mRNA vaccine IP holders, in competition with any proposal submitted through this Approach to Market. The Australian Government may decide to support one or more proposals obtained through this process, to support one or more proposals with conditions or modifications, or not to support any proposals.

Respondents should note that the Australian Government will determine the best method of supporting the establishment of the onshore mRNA manufacturing capability.

The Australian Government may not undertake any open procurement or grant process following this Approach to Market and may seek to enter into arrangements directly with one or more respondents to this Approach to Market or with any other entity (including any existing mRNA vaccine IP holder).

Pursuant to paragraph 2.6 of the Commonwealth Procurement Rules (CPRs), the Accountable Authorities of the Departments have determined that parts of the CPRs do not apply to any procurement activity arising in relation to or from this process as this process to establish onshore mRNA manufacturing capability is considered to be necessary to protect public health. The exemption under paragraph 2.6 of the CPRs includes that the Departments are not required to comply with the rules for open tender or restrictions on the use of a limited tender, should a procurement process be undertaken.

This Approach to Market has been issued publicly, and proposals are sought from both Australian and overseas businesses, institutions and consortia, and may include the involvement of state and territory governments. If a state or territory is proposing to provide support to the bid, details of that support should be included in the proposal but it is not a requirement that the state or territory be a member of the consortium or a subcontractor.

All proposals should be completed in the template provided (see Approach to Market Proposal Template). Respondents must limit proposals to 120 pages including attachments and in-line with clause 11 'How to lodge the Approach to Market proposal'.

For clarity, respondents should note that this Approach to Market may not be or result in a procurement or a grant process but may lead to a procurement activity or grant without a further Approach to Market. As explained above, the Australian Government will use the information provided in this Approach to Market to determine whether any subsequent procurement or grant process will be utilised to engage any entity, and the features of any such process. If the Australian Government proceeds with any subsequent procurement or grant process, any entity invited to participate in such process will be required to comply with the requirements that apply to that process as notified at the time.

A respondent who receives or accesses this Approach to Market is under no obligation to respond and any proposal that is provided is submitted on a voluntary basis in accordance with the terms of this Approach to Market.

The Commonwealth may, in its sole discretion, consider proposals received outside of this Approach to Market process in any future procurement or grant processes. However, respondents are encouraged to respond to this Approach to Market, including to ensure that the Australian Government is able to make an informed decision about future processes and the entities that may be invited to participate in those processes.

Respondents should nevertheless be aware that the Australian Government may use proposals to this Approach to Market for its planning and decision making purposes, including to assist the Australian Government to identify and cost capability options and to inform the preparation of any future capability development and procurements or grants processes.

3. About this document

a) This Approach to Market is made up of:

(i) the clauses, which set out the conditions applying to the Approach to Market process;

(ii) Schedule 1, which sets out the Statement of Requirements; and

(iii) Schedule 2, which sets out the information respondents need to include in their proposal.

4. Further information about this Approach to Market

Respondents should direct in writing any questions arising from preparing a proposal for this Approach to Market or any requests for clarification to onshoremrna@industry.gov.au

a) The Departments may refuse to answer any question received less than five business days before the Closing Time.

b) Where appropriate, the Departments will publish questions and answers in accordance with clause 5 below without disclosing commercially sensitive information.

c) If a respondent finds any discrepancy, error or omission in this Approach to Market, it should notify the Departments in writing before the Closing Time.

5. Respondents and Notices

a) In the event that the Departments elect to vary or supplement this Approach to Market or change the conditions of the Approach to Market, it will make reasonable efforts to inform respondents in accordance with this clause.

b) Respondents may be informed by notices and other information issued as addenda posted on industry.gov.au/mrna.

c) It is in the interests of respondents to ensure they check industry.gov.au/mrna prior to downloading Approach to Market documentation, regularly before the Closing Time, and prior to submission of proposals to ensure they are aware of any addendum.

d) The Departments will accept no responsibility if a respondent fails to become aware of any addendum notice which would have been apparent from a visit to industry.gov.au/mrna for this Approach to Market.

e) If a respondent has obtained Approach to Market documentation other than from industry.gov.au/mrna, they should download the documentation for this Approach to Market from the industry.gov.au/mrna.

f) The Departments will accept no responsibility if the information contained in Approach to Market documentation obtained from a source other than industry.gov.au/mrna differs from that listed on the industry.gov.au/mrna.

What Respondents need to do

6. Respondent behaviour

a) Respondents must not, and must ensure that their officers, employees, agents and advisors do not, in relation to the preparation, lodgement or assessment of the Approach to Market:

(i) make false or misleading claims or statements;

(ii) improperly obtain confidential information;

(iii) receive improper assistance;

(iv) engage in collusive tendering, anti-competitive conduct or other similar conduct with any other respondent or other person; or

(v) attempt to improperly influence an officer of the Australian Government, an expert consultant or member of any expert advisory bodies engaged by the Australian Government to provide advice on this Approach to Market process; or attempt to approach any Commonwealth officer other than in the manner set out in clause 4.

b) Note that the Department may, in its sole discretion, exclude a respondent from consideration if the respondent fails to comply with these requirements.

7. Seek own advice

This Approach to Market is not business, investment, legal or tax advice. Respondents should seek their own independent professional advice in respect of all matters in connection with this Approach to Market.

8. Bear own costs

a) All expenses and costs incurred by a respondent in connection with this Approach to Market, including preparing and lodging a proposal, providing the Departments with further information, giving presentations, attending interviews and participating in any discussions, are the sole responsibility of the respondent.

b) The Departments are not liable for any costs or other compensation in relation to the consideration of this Approach to Market, lodgement of any proposal or participation in the Approach to Market process by any respondents where the Departments take any action permitted under this Approach to Market, including (without limitation) any exercise of the Departments' rights under clause 6 or 19.

9. What the respondent needs to include

Respondents should include the following documents in their proposal for this Approach to Market:

(i) Completion of Schedule 2 - Proposal Form.

If a respondent does not complete Schedule 2 – Proposal Form, the proposal may not be considered.

9.1 Consortium proposals

A consortium should submit a single proposal to this Approach to Market on the basis that one legal entity will take full responsibility as it is the Commonwealth's intention that it enters into an arrangement with a single legal entity to establish the capability. The proposal should provide full details of that legal entity, the consortium members and any proposed subcontractors.

Individual entities/companies may be part of multiple proposals/consortia.

10. Approach to Market Closing Time and Date

a) Approach to Market proposals must be lodged before the Closing Time.

b) The Closing Time is 2.00pm, local time in Canberra, Australia on Friday, 16 July 2021.

c) The Departments may refuse to consider a proposal responding to this Approach to Market that is not lodged by email to onshoremrna@industry.gov.au or the Electronic Submission Method outlined in Clause 11.2 (c) by the Closing Time.

d) The Departments will accept a late proposal if the delay in the proposal being submitted is solely because of the Departments' own mishandling.

e) The Departments will treat a proposal as being made within time if it is dispatched by email prior to the Closing Time or an upload commenced prior to the Closing Time, even though such a proposal might not be received until after the Closing Time.

11. How to lodge the Approach to Market proposal

11.1 Electronic lodgement

Approach to Market proposals must be lodged electronically via onshoremrna@industry.gov.au before the Closing Time and in accordance with the Approach to Market lodgement procedures set out in this Approach to Market documentation. Physical submissions will not be accepted.

11.2 File format, name and submission

a) **File format:** Proposals should not be more than 120 pages and should be lodged in both PDF and editable (pptx or docx) formats. The Departments may disregard a proposal that exceeds 120 pages or not is not lodged in the required formats, or require that such a proposal be relodged.

b) **File names:** The proposal file name/s:

   (i) should incorporate the respondent's company name; and

   (ii) should reflect the requirements stated in Schedule 2.

c) **Electronic Submission**: Approach to Market proposal documents can be submitted by email at onshoremrna@industry.gov.au; or by DISER's file upload service. DISER notes it has a 20 megabyte limit per email for incoming emails. If required, instructions on managing this limitation are below.

   (i) Multiple emails regarding a single proposal must be highlighted within the Subject field of submission emails and include the total number of emails being submitted as part of a single submission (e.g. [1/10]).

   (ii) A DISER approved and secure file upload service is available to accept proposals that exceed 20 megabytes, upon request, at least 48 hours prior to the closing time above.

Requests for a file upload service must be made in writing via onshoremrna@industry.gov.au

12. After lodging the Approach to Market proposal

12.1 Ownership of Approach to Market proposals documents

(a) All proposals become the property of the Australian Government on lodgement. However, subject to clause 16, ownership of the intellectual property in the Approach to Market proposal documents will remain unchanged.

(b) The Australian Government may use, copy, retain, and adapt any proposal to this Approach to Market it receives from respondents, as required for purposes relating to the establishment of the onshore mRNA capability, including for the purposes of:

(i) this Approach to Market process;

(ii) undertaking any subsequent process including as a result of or related to this Approach to Market;

(iii) identifying, refining and costing options and developing any strategies;

(iv) preparing any future requirements and procurement and grant documentation (including developing a statement of requirements for any future process);

(v) considering proposals received in response to this Approach to Market or any subsequent approach undertaken by the Australian Government;

(vi) negotiating and preparing any agreements with the respondent following this Approach to Market or any future processes undertaken by the Australian Government; and

(vii) complying with any audit requirements and complying with governmental and parliamentary reporting requirements including requests for information by Parliament or Parliamentary Committees.

(c) The Department reserves the right to share, discuss and negotiate with state and territory governments at any stage of the Approach to Market process or any subsequent process (including for the purposes of considering proposals and making any decisions related to them as well as to clarify, quantify and finalise possible support measures in relation to a proposal).

Consideration Process

13. Screening

(a) The Departments may not consider a proposal for any reason, including if:

(i) the proposal is lodged after the Closing Time;

(ii) the respondent does not complete Schedule 2 – Proposal Form;

(iii) the proposal includes electronic files that cannot be read or decrypted or that exceeds the combined file size;

(iv) the respondent does not comply with this Approach to Market;

(v) prices are not clearly and legibly stated in the Approach to Market proposal; or

(vi) the proposal is lodged electronically and is found to contain or believed to potentially contain a virus, worm or other disabling feature that might compromise the integrity or security of DISER's computing environments.

14. Considering Proposals

(a) Proposals will be considered by the Australian Government to assist the Australian Government to make decisions in relation to establishing an onshore mRNA capability. In doing so, the Australian Government may consider the information provided by the respondent in response to this Approach to Market and any other information considered appropriate by the Australian Government.

(b) Respondents should provide sufficient information in this Approach to Market to enable to the Australian Government to understand the respondent's:

(i) capability;

(ii) capacity;

(iii) costs; and

(iv) risk management practices,

including by providing the information requested in this Approach to Market.

(c) The Departments may, but are under no obligation to, provide feedback on proposals to this Approach to Market on a case by case basis.

15. Additional steps

15.1 Clarification, additional information and corrections

(a) After the Closing Time, the Departments may engage in any discussions with, or seek clarification on any matter from, any respondent.

(b) The Departments may require a respondent to submit additional information to allow further consideration of its proposal.

(c) If the Departments consider that there is an unintentional error of form in a proposal, the Departments may give the respondent an opportunity to correct the error. If the Departments give a respondent an opportunity to correct an unintentional error of form, it will give the same opportunity to all respondents in the same position.

15.2 Independent inquiries

(a) The Departments may make independent inquiries about any of the matters that may be relevant to the evaluation of any proposal.

(b) The Departments reserve the right to contact respondents, or any other person associated with a proposal, directly and without notifying the respondents.

15.3 Security, probity and financial checks

(a) The Departments may conduct such security, probity and financial (including credit) checks as it deems necessary on respondents, their partners, associates or related entities (including consortium members) or their officers or employees, for the purpose of evaluating proposals to this Approach to Market. These checks may require individuals to

sign forms verifying information relating to that individual and authorising the provision of confidential or personal information.

(b) Respondents must provide, at their own cost, all reasonable assistance required by the Departments in undertaking and conducting the security, probity and financial checks.

(c) The Departments reserve the right to request financial statements and other information relevant to determining the financial viability of respondents, their partners, associates, or related entities including consortium members.

16. Ownership of Approach to Market documents

(a) All documents comprising this Approach to Market remain the property of the Australian Government. Each respondent is permitted to use them only for the purpose of compiling a proposal for this Approach to Market.

(b) All copyright and other intellectual property rights contained in this Approach to Market are and remain vested in the Australian Government and any third party who has given the Australian Government permission to incorporate them in this Approach to Market.

17. Important notices about this Approach to Market

(a) Proposals are made on the basis that each respondent acknowledges that:

(i) the Australian Government may approach other entities (including suppliers that have not responded to this Approach to Market) to provide information relevant to the onshore mRNA capability, including information the same or similar to that requested by this Approach to Market;

(ii) the Australian Government may conduct other industry engagement activities and future procurement and grant processes in relation to the onshore mRNA capability in which the respondent may or may not be invited to participate;

(iii) providing a proposal to this Approach to Market does not of itself entitle, qualify or disqualify the respondent to be invited to participate in any future industry engagement activity or procurement or grant process;

(iv) it has examined the Approach to Market, any documents referred to in it, and any other information made available in writing by the Departments to respondents for the purpose of participating in the Approach to Market process;

(v) this Approach to Market is designed to summarise information concerning The Departments' requirement only and is not necessarily a comprehensive description of it;

(vi) to the maximum extent permitted by law, neither the Departments, nor their employees, advisers or agents will in any way be liable to any person or body for any cost, expense, loss, claim or damage of any nature arising in any way out of or in connection with the statements, opinions, projections, forecasts or other representations, actual or implied, contained in or omitted from this Approach to Market or by reason of any reliance on them by any person or body;

(vii) it has sought and examined all necessary information which is obtainable by making reasonable enquiries relevant to the Departments' requirement including the risks and other circumstances which may affect a proposal;

(viii) in lodging its proposal, it did not rely on any express or implied statement, warranty or representation, whether oral, written, or otherwise made by or on behalf of the Departments other than as expressly contained in this Approach to Market or an addendum to this Approach to Market issued by the Departments;

(ix) it did not use the improper assistance of Australian Government employees;

(x) it has satisfied itself as to the correctness and sufficiency of its proposal; and

(xi) it will comply with the terms and conditions set out in this Approach to Market.

(b) The Departments believe the contents of this Approach to Market to be accurate at the date of this Approach to Market. The accuracy of any statements, opinions, projections, forecasts, representations or other information (Statements) contained in this Approach to Market may change. Where any Statement relates to future matters, no steps have been taken to verify that the Statement is based on reasonable grounds, and, to the maximum extent permitted by law, no representation or warranty, expressed or implied, is made by the Departments, or any of their officers, employees, advisers or agents that the Statement is accurate.

(c) Nothing in this Approach to Market, or the submission of any proposal for this Approach to Market constitutes a contract, express or implied, with the Australian Government. The Australian Government intends that no contract will be formed unless and until the Australian Government signs a formal contract with a preferred respondent.

18. Disclosure of Approach to Market information

18.1 Freedom of information

Respondents should be aware that the Australian Government is subject to the operation of the *Freedom of Information Act 1982* (Cth), which allows public access to Government documents. Where a freedom of information application is made, the *Freedom of Information Act 1982* (Cth) provides avenues for submissions to be made that particular information about the business, commercial or financial affairs of an entity or undertaking should not be disclosed.

18.2 Sub-contractors

The Departments may be required under the *Commonwealth Procurement Rules 2012* to make available on request by any person the details of any subcontractors engaged by a contractor in the performance of a Commonwealth contract for procurement.

In submitting a proposal to this Approach to Market, a respondent will be confirming that it consents to the public disclosure of the name, ABN and address of, and work to be performed by, a subcontractor, and that all proposed subcontractors have consented to the disclosure of this information, if the respondent is selected to enter into any resulting contract following this Approach to Market or any subsequent process.

18.3 Confidentiality

(a) Respondents may specify information contained in their proposal that they consider to be confidential information, and subject to this clause 18.3, the Australian Government will treat such information as confidential, and will only use that information for the purposes of the Approach to Market process.

(b) The Departments may, without the need to notify any respondent, disclose or allow the disclosure of, at any time, any information provided by respondents, including their tenders:

(i) to the Departments' advisers or employees solely in order to evaluate or otherwise assess the proposal;

(ii) to the Departments' internal management personnel for purposes related to the Approach to Market process;

(iii) to the responsible Ministers;

(iv) in response to a request by a House or a Committee of the Parliament of the Commonwealth of Australia, if the circumstances provide for such a response and in

consideration of commercial-in-confidence requirements the Australian Government considers it warranted;

(v) within the Departments, or with another department or agency, or an agency of a state or territory government, where this serves the Commonwealth's legitimate interests;

(vi) where information is authorised or required by law to be disclosed; or

(vii) where the information is in the public domain otherwise than by a Commonwealth disclosure.

18.4 Australian National Audit Office

(a) The attention of respondents is drawn to the Auditor-General Act 1997 (Cth), which provides the Auditor-General or an authorised person with a right to have, at all reasonable times, access to information, documents and records.

(b) Respondents should obtain, and will be deemed to have obtained, their own advice on the impact of the Auditor-General Act 1997 (Cth) on their participation in the Approach to Market process.

19. Australian Government's rights

Without limiting its rights at law or otherwise, the Departments may:

(a) amend this Approach to Market or any future processes undertaken in relation to the mRNA capability (including the requirements for that capability);

(b) suspend, discontinue, or terminate the Approach to Market process or any subsequent process resulting from this Approach to Market at any time, including where the Departments consider that it is in the public interest to do so;

(c) approach other entities (including suppliers that have not responded to this Approach to Market) to provide information relevant to the onshore mRNA capability, including information the same or similar to that requested by this Approach to Market;

(d) conduct other industry engagement activities and future procurement and grant processes in relation to the onshore mRNA capability in which the respondent may or may not be invited to participate;

(e) require additional information or clarification from any respondent or anyone else;

(f) provide additional information or clarification;

(g) change the structure and timing of the Approach to Market process; and

(h) vary or extend any time or date in this Approach to Market at any time and for such period as the Departments in their absolute discretion considers appropriate. The Departments will issue an addendum notifying any decision to extend.

20. Relevant laws

(a) The law applying in the Australian Capital Territory applies to this Approach to Market and to the Approach to Market process.

(b) Each respondent must comply with all relevant laws and Commonwealth policy in preparing and lodging its proposal and taking part in the Approach to Market process.

21. Workplace Gender Equality Act 2012 (Cth)

(a) Commonwealth policy prevents the Commonwealth from entering into contracts with suppliers who are non-compliant under the Workplace Gender Equality Act 2012 (Cth) (the WGE Act).

22. Dictionary

In this Approach to Market, unless the contrary intention appears:

Closing Time	means the Closing Time specified on the front page of this Approach to Market, as amended by any addendum in accordance with clause 5 of the Approach to Market.
Approach to Market	means this request seeking proposals.

Schedule 1 – Statement of Requirements

Overview

The Commonwealth of Australia (the Australian Government), represented by the Department of Industry, Science, Energy and Resources (DISER) and the Department of Health (collectively the Departments), is seeking information in the form of fully costed proposals to establish an onshore, population-scale mRNA manufacturing capability, to be fully operational with requisite regulatory approvals/licences within a timeframe of between 12 months (or earlier, if possible) and no later than 3 years from finalisation of an agreement with the Australian Government. In doing so, the Australian Government seeks to meet the following objectives:

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

This Approach to Market is complementary to any current discussions in which the Australian Government is engaging directly with relevant mRNA vaccine IP owners to establish mRNA manufacturing facilities in Australia. It provides an additional competitive process, an opportunity for industry to provide solutions, and will ultimately help us secure the best mRNA capability for Australians. The Australian Government will consider proposals from this Approach to Market alongside the outcomes of the discussions with mRNA vaccine IP owners.

The fully costed proposals from this Approach to Market should provide a sufficient level of detail to support Australian Government decisions regarding options for the establishment of any such mRNA capability with a minimum timeframe for supply of mRNA vaccines and treatments of 10 years from commencement of operation of the capability, including details of investment, support or assistance from the Australian Government that may be necessary to establish the capability. The detailed information will be used to support Australian Government decisions about the establishment of an onshore capability with a minimum timeframe for supply of mRNA vaccines and any mRNA therapeutics of 10 years from commencement of operation of the capability.

Respondents are requested to:

- submit a fully costed proposal to establish an end-to-end onshore population-scale mRNA capability which specifies how and when the requirements set out below will be met;
- demonstrate how the proposed capability will deliver secure supply of population-scale mRNA vaccines and any mRNA therapeutics for a minimum timeframe of 10 years from commencement of operation of the capability; and
- if the Australian Government wishes to proceed with any future procurement or grant process that involves the respondent, it is anticipated that, subject to the process required to be undertaken (see below), the Australian Government would enter into a contract with the respondent that requires the respondent to:
    - establish and maintain the capability as set out in the fully costed proposal in accordance with the contract and subject to any modifications required or conditions imposed by the Commonwealth; and

- make products available to the Australian Government as required and on a 'first priority' basis, ahead of any other purchaser and notwithstanding any advance purchase agreement or other arrangement with any other purchaser on terms set out in the contract.

Requirements for an onshore mRNA manufacturing capability

The Australian Government is seeking fully costed proposals from respondents with evidenced capability to establish and operate an end-to-end onshore population-scale mRNA capability which specifies how and when the requirements below will be met.

This is to ensure priority access to, and reliable delivery of, safe and effective mRNA vaccines and any mRNA therapeutics to Australians as soon as they are available on an ongoing basis, and to address pandemics and other health emergencies into the future.

The requirements are for an end-to-end, onshore, population-scale mRNA capability, to be fully operational with requisite regulatory approvals/licences within a timeframe of between 12 months (or earlier, if possible) and no later than 3 years from finalisation of an agreement with the Australian Government. Detailed requirements are as follows:

Category	Requirement	Description of requirement
Suitable product portfolio / pipeline and intellectual property (IP) arrangements	COVID-19 vaccines	Access or ability to develop IP required to manufacture mRNA vaccines for COVID-19 revaccination (e.g., boosters, multivariant / multivalent vaccines).
	Seasonal influenza vaccines	Access or ability to develop IP required to manufacture mRNA seasonal influenza vaccines for Australian seasonal flu program.
	Other mRNA products	Access or ability to develop IP required to manufacture other mRNA products (e.g., oncology, infectious diseases).
Manufacturing capabilities and capacity	Manufacturing site(s) / facilities	Establishment of current Good Manufacturing Practice (cGMP) brownfield and/or greenfield site(s) required to support mRNA vaccine manufacturing within a timeframe of between 12 months (or earlier, if possible) and no later than a 3 years from finalisation of an agreement with the Australian Government.
	Input materials and equipment	Ability to procure required input materials and equipment to stand-up and achieve population-scale manufacturing.
	Process establishment	Ability to stand-up mRNA vaccine manufacturing processes (e.g. via technology transfer) in an end-to-end or modular manner.
	Scale	Ability to achieve population-scale manufacturing of mRNA vaccines.
	Workforce	Ability to hire and train sufficient workforce (either local or overseas) to operate population-scale mRNA vaccine manufacturing site(s).

Category	Requirement	Description of requirement
	Regulatory compliance	Ability to engage relevant regulatory bodies to acquire necessary site (cGMP licensing) and product (Australian Register of Therapeutic Goods (ARTG) product registration) regulatory approvals to support mRNA vaccine manufacturing.
Sustainability, security, flexibility and synergy	Sustainable and secure vaccine supply	Ability to maintain uninterrupted mRNA vaccine supply to Australian population in the context of potential supply risks (i.e., supply chain shocks, geopolitical instability, additional demands etc.). A commercially sustainable facility over 10 years once it is operational; with an undertaking to maintain the capability onshore.
	Flexibility of mRNA technology platform and pandemic preparedness	Ability for mRNA vaccine manufacturing site to produce multiple mRNA product types in parallel. Flexibility of manufacturing site and technological platform to respond to shifting vaccine demands in context of future pandemics or health emergencies (including the ability to rapidly switch and scale-up production of new products, as required). Potential for technological advancement/innovation in the mRNA technology platform.
	Support of local R&D ecosystem	Ability to support commercialisation of Australian mRNA related R&D, including relationships and opportunities for collaboration with the Australian research community.

Respondents should assume that:

- *end-to-end* capability means for the purposes of this Approach to Market all the elements needed to establish and deliver an onshore population-scale mRNA manufacturing capability. The steps can be broadly described as acquisition or ownership of sufficient IP and know-how, establishing appropriate plant and equipment, undertaking technology transfer, having sufficient labour and expertise, quality management systems, resultantly undertaking key mRNA manufacturing steps, and successfully acquiring the relevant regulatory approvals/GMP licencing to supply the Australian market (and potentially export markets).

  The Australian Government recognises the complex global supply chain involved in mRNA vaccines manufacture. While it may not be feasible to manufacture onshore all raw materials/inputs and equipment required in the mRNA vaccine manufacturing process, proposals should assume that key mRNA manufacturing steps to onshore include:

  - mRNA drug substance production (e.g., through in-vitro transcription from a DNA template, purification, etc.);
  - formulation of the drug product (e.g., including formation of lipid nanoparticles or alternative delivery vehicle);
  - fill and finish of the drug product; and

- supporting manufacturing activities required for the above three steps (such as quality control testing and quality release).

In addition, proposals may consider production of the starting material onshore (e.g., plasmid DNA templates, through pDNA bacterial transformation and propagation processes). The Australian Government requires sufficient and secure supply of any materials (including plasmid DNA templates) necessary to mRNA manufacturing that are not produced onshore.

- *Population-scale* means sufficient production capacity to:
    - provide timely supply of vaccines in a pandemic/health emergency context to fully vaccinate the entire Australian population (e.g., using a 2-dose regimen, within a 9 month period), and
    - provide a buffer to account for both population growth (i.e., over the next 10 years), allow for parallel production of, e.g., vaccines for new variants, and allow for the ongoing production of any other mRNA products that may continue to be required during a pandemic (e.g., therapeutics).

  The annualised production capacity necessary to meet the above requirements may depend on the technological characteristics of the platform, and the anticipated products that will be produced using the onshore facility and the possible export market demands expected for products. The Australian Government welcomes the advice of the respondents on the appropriate annualised dose production capacity considering the points above. By way of illustrative example, this may require a dose production capacity of >100M on an annualised basis.
- *mRNA capability* includes the capability to produce vaccines and any mRNA therapeutics using the mRNA technology platform, such as COVID-19 vaccines, mRNA vaccines for other infectious diseases, and potential mRNA products such as for cancer, cardiovascular and metabolic diseases.
- *Timeframe to be fully operational* refers to the time to first batch release under GMP license and other relevant regulatory approvals from the date of finalisation of an agreement with the Australian Government.

In addition the proposals should confirm:

- that the respondent is compliant with the Workplace Gender Equality Act 2012 (Cth);
- that in dealing with its employees and independent contractors, the respondent has due regard to Commonwealth policies on the engagement of workers, will comply with Commonwealth policies on the engagement of workers, including the Fair Work Act 2009 (Cth) and obligations under the Work Health and Safety Act 2011 (Cth) and relevant work health and safety laws; and
- the respondent and any subcontractors proposed in the proposal are not insolvent, bankrupt, in liquidation, or under administration or receivership.

All proposals should be completed according to the instructions in Schedule 2 – Proposal Requirements.

Responding to this Approach to Market

Interested parties are invited to respond to this Approach to Market by the closing date on the coversheet. The supplier's proposal should indicate their capability, capacity, cost (including estimated future costs where actual costs cannot be provided, and a mechanism for determining

those future costs) and proposals to manage any risks associated with the purchase or production of mRNA vaccine/or therapeutics arising from the capability.

Proposal requirements

4.1 Capability

The respondent should provide information about its capability to undertake functions for an end-to-end onshore population-scale mRNA capability. This includes:

- the respondent's ability to provide end-to-end onshore population-scale mRNA capability (including in a manner that is consistent with the assumptions set out above, or if the respondent cannot provide the capability based on those assumptions, the degree of the respondent's departure from those assumptions);
- the range of products that the respondent reasonably expects to be able to produce;
- how the respondent would have or would obtain access to the rights to intellectual property required to produce these mRNA products;
- the ability of the respondent to provide certain products in the volumes required by the Commonwealth, including the ability to quickly vary the number of doses required to meet the Commonwealth's requirement for particular products, as they may be determined from time to time; and
- the respondent's plan for, and assumptions relating to, obtaining regulatory approvals (both for manufacture, such GMP licensing, and for supply, i.e., product registration), including whether products made by the respondent have or have not been approved for use in the past ten years.

4.2 Capacity

The respondent should provide information about its capacity to deliver the desired capability, including their capacity to:

- incorporate redundancies relating to communications, staffing, equipment and the delivery of products;
- flexibly meet changing workloads and priorities for various categories of product that may be foreseeably demanded by the Commonwealth or the Australian public;
- use suitably skilled staff to establish and deliver the capability; and
- ensure that their staff, if required by the Commonwealth, have and maintain a Baseline security clearance undertaken by the Australian Government Security Vetting Agency if engaged. Such clearance may be required to receive certain materials from Government, in order to facilitate planning and ongoing operations of the onshore facility and its use. The cost of obtaining and maintaining security clearances for staff is the responsibility of the respondent.

4.3 Costs

The respondent should provide information about the costs (in Australian dollars) involved in the proposal, including in relation to:

- full costs estimates, as described and sought under Schedule 1 and Schedule 2, and components of the total cost;

- the proposed commercial model and overall cost of the involvement, support or assistance sought from the Commonwealth to establish an onshore population-scale mRNA manufacturing capability;
- the timing of payments relative to the production of pharmaceuticals;
- the overall cost to the Commonwealth of establishing the capability and providing products as directed;
- proposed state or territory contributions or support, if applicable; and
- details of any pricing model proposed in the event of a new product being identified, and any price review process.
- NB: Please note that the Commonwealth will require full transparency and audit access under any contract to enable proper management of the pricing model.

4.4 Risk Management

The respondent should provide information about its approach to managing risk involved in the proposal, including in relation to:

- the timing of payments and delivery of the capability;
- the steps that the respondent will take to manage risks associated with supply chain disruptions and continuity of supply;
- the likelihood that the respondent will, as applicable, retain, develop, or otherwise have the capacity and capability to provide the capability;
- identifying real or perceived conflicts of interest that may arise from establishing and delivering the capability;
- how the respondent proposes to manage any conflicts of interests;
- how the respondent will secure and manage confidential information; and
- the likelihood that the respondent will be able to obtain the necessary approvals for the products.

4.5 Benefit to the Australian economy

The respondent should provide information about the broader benefit to the Australian economy, including how the proposed capability will support Australia's biopharmaceutical ecosystem, broader economy, and benefits of the proposal for job creation and other spillover benefits.

Schedule 2 – Proposal Requirements

Respondents should complete and submit a proposal in the format set out in the Schedule 2. The Respondent is requested to submit a proposal document in both PDF and editable (pptx or docx) format.

Proposals should include a completed proposal coversheet (template below); as well as a respondent profile, response to the statement of requirement, and costing information per the proposal requirements detailed below. The total proposal should be limited to not more than 120 pages. NB: proposals should include any assumptions made, and be sufficiently detailed and outline the full costs of the respondent's proposals to enable government decision-making.

Proposal coversheet

1. Respondent name

If a company	Company name	
	ACN or equivalent	
If a partnership	Trading name (if any)	
	Full name of partners	
If a sole trader	Trading name	
	Full name of sole trader	
If any other type of organisation	Name of organisation	
	Type of organisation	

2. ABN or equivalent

3. Contact for liaison and notices

Name	
Postal Address	
Telephone	
Facsimile	
Email	

4. Small to medium enterprise

Is the Respondent a small to medium enterprise (i.e. an entity employing fewer than 200 full time equivalents)?	Y/N
Is the Respondent a small business (i.e. an entity employing fewer than 20 full time equivalents)? Note: If the enterprise is associated with one or more other entities, this test is applied to the group of associated entities as a whole.	Y/N

5. Conflicts of interest

The Respondent confirms that there are no circumstances or relationships which constitute or may constitute a conflict or potential conflict of interest in relation to this Approach to Market or the Respondent's obligations under any contract resulting from this Approach to Market other than:

The Respondent undertakes to advise the Departments in writing of any additional actual or potential conflicts of interest immediately after becoming aware of it.

6. If the respondent is lodging a proposal for a consortium, details of the consortium arrangement, and all members of the consortium.

7. Details of any proposed subcontractors, including the work to be performed by subcontractors.

NB: details of subcontractors are required, regardless of whether the proposal under this Approach to Market is submitted by a consortium or by another individual entity.

8. Details of its enterprise profile, including the size, location of sites and principal locations (including where it would establish the proposed onshore mRNA capability).

9. Details of any specified personnel who may be responsible for the delivery of the proposed onshore mRNA manufacturing capability.

10. Executive Summary

Please provide an Executive Summary of your proposal (no more than 1000 words).

11. Responses to Requirements

Please indicate how your proposal answers or responds to each of the Response Requirements set out in Schedule 1. Please note that there is further detail below outlining matters that are expected in your response.

11.1 Capability

11.1.2 The respondent's ability to provide end-to-end onshore population-scale mRNA capability on the assumptions set out above, or if the respondent cannot provide the capability based on those assumptions, the degree of the respondent's departure from those assumptions.

11.1.3 The range of products that the respondent reasonably expects to be able to produce.

11.1.4 How the respondent would have or has access to the rights to intellectual property required to produce these mRNA products.

11.1.5 The ability of the respondent to provide certain products in the volumes required by the Commonwealth, including the ability to quickly vary the number of doses required to meet the Commonwealth's requirement for particular products, as they may be determined from time to time.

11.1.6 The respondent's plan for, and assumptions relating to, obtaining regulatory approvals (both for manufacture, such GMP licensing, and for supply, i.e., product registration), including whether products made by the respondent have or have not been approved for use in the past ten years.

11.2 Capacity

11.2.1 Incorporated redundancies relating to communications, staffing, equipment and the delivery of products.

11.2.2 Flexibly to meet changing workloads and priorities for various categories of product that may be foreseeably demanded by the Commonwealth or the Australian public.

11.2.3 Suitably skilled staff to establish and deliver the capability.

11.2.4 Ensure that their staff, if required by the Commonwealth, have and maintain a Baseline security clearance undertaken by the Australian Government Security Vetting Agency if engaged.

11.3 Cost

Please provide information about the costs of your proposal in the tables at the end of this Schedule 2, and provide any further information here relevant to the costs of your proposals against the Proposal Requirements in Schedule 1.

11.4 Risk Management

Please provide information about your approach to managing risk involved in the proposal, including in relation to:

11.4.1 The timing of payments and delivery of the capability.

11.4.2 The steps that the respondent will take to manage risks associated with supply chain disruptions and continuity of supply.

11.4.3 The likelihood that the respondent will, as applicable, retain, develop, or otherwise have the capacity and capability to provide the capability.

11.4.4 Identifying real or perceived conflicts of interest that may arise from establishing and delivering the capability.

11.4.5 How the respondent proposes to manage any conflicts of interests.

11.4.6 How the respondents will secure and manage confidential information.

11.4.7 The likelihood that the respondent will be able to obtain the necessary approvals for the products.

11.5 Benefit to the Australian economy

Please provide information about the broader benefit to the Australian economy, including how the proposed capability will support Australia's biopharmaceutical ecosystem, broader economy, and benefits of the proposal for job creation and other spillover benefits.

12. Confirmation

12.1 The Respondent:

(a) confirms that it and any proposed subcontractors are not currently named as non-compliant with the Workplace Gender Equality Act 2012 (Cth);

(b) confirms that in dealing with its employees and independent contractors, the Respondent has due regard to Commonwealth policies on the engagement of workers and that the Respondent complies with Commonwealth policies on the engagement of workers, including obligations under the Work Health and Safety Act 2011 (Cth) and relevant work health and safety laws;

(c) confirms that in dealing with its employees and independent contractors, the Respondent has due regard to Commonwealth policies on the engagement of workers, will comply with Commonwealth policies on the engagement of workers, including the *Fair Work Act 2009* (Cth) and obligations under the *Work Health and Safety Act 2011* (Cth) and relevant work health and safety laws;

(d) confirms that it and any proposed subcontractors are not insolvent, bankrupt, in liquidation, or under administration or receivership;

(e) confirms that it and any proposed subcontractors may be required to consent to the public disclosure of the name, ABN and address of, and work to be performed by, a subcontractor if the Respondent is selected to enter into any subsequent contract;

(f) confirms that it and any proposed subcontractors do not have any judicial decision against them (not including decisions under appeal) relating to employee entitlements in respect of which they have not paid the claim; and

(g) consents to the Departments undertaking checks in accordance with this Approach to Market.

12.2 The Respondent warrants that neither the Respondent nor any of its officers, employees, agents, and subcontractors has, in relation to the preparation, lodgement or assessment of the proposal:

(a) improperly obtained confidential information;

(b) received improper assistance;

(c) engaged in collusive tendering, anti-competitive conduct or other similar conduct with any other respondent or other person; or

(d) attempted to improperly influence an officer of the Australian Government, an expert consultant or member of any expert advisory bodies engaged by the Australian Government to provide advice on this Approach to Market process; or attempt to approach any Commonwealth officer other than in the manner set out in clause 4.

12.3 The Respondent notes that giving false or misleading information is a serious offence, and confirms that all information in its proposal is true and correct in every material respect.

12.4 **Compliance with the *Workplace Gender Equality Act 2012* (Cth)**

Under Australian Government procurement policy, respondents are obliged to indicate whether or not their organisation is covered by the *Workplace Gender Equality Act 2012* (Cth) (the WGE Act). An organisation is covered by the WGE Act if it is a 'relevant employer', defined as being a non-public sector employer (including higher education institutions, trade unions and not-for-profit organisations) of 100 or more employees in Australia. For information about the coverage of the WGE Act, contact the Workplace Gender Equality Agency on (02) 9432 7000.

Please mark one of the following:

(a) Yes, I am a relevant employer. ☐

(b) No, I am not a relevant employer. ☐

13. Signature on behalf of Respondent

[Note: To be signed by the Respondent personally, or if the Respondent is not an individual, by someone authorised to sign on behalf of the Respondent, e.g. managing director. If the proposal is being provided on behalf of a consortium, the respondent warrants that it has made relevant inquiries of the consortium members in providing the proposal.]

By signing this document, the Respondent declares that it agrees to the terms and conditions of this Approach to Market, including the rights of the Departments and Australian Government set out in the Approach to Market and that it has complied with the matters set out at clause 12 of this Schedule 2.

Signature _____

Name _____

Position _____

14. Respondent profile

Profile category	Details of expected proposal
Financial performance	5-year historical financial performance of respondent to assess financial viability and capability to support onshore manufacturing.
Manufacturing footprint	Detailed view of respondent's current and expected vaccines and biologics manufacturing footprint. Site details across footprint should include: location, capabilities, length of site operation by respondent, scope of regulatory licenses, presence of infringement notices at site, type of site (i.e., Brownfield/greenfield). Details of experience in the development of brownfield and greenfield site development should be highlighted, noting the: • Size of plant(s) built / redeveloped • Type of plant(s) built / redeveloped • Cost of plant(s) built / redeveloped • CMO/CDMO partners (if applicable)
Workforce	Size, geographic distribution and skillset of current workforce able to support mRNA vaccine manufacturing.
Research & development (R&D) investment	Volume and duration of previous (10-year horizon) and committed R&D investment relating to mRNA products and other biologics / vaccines; and information on any products successfully brought to market after development, by the respondent.
IP arrangements	Duration and application of all current IP arrangements relating to mRNA products and manufacturing processes.
Partnerships	Duration and scope of current mRNA related commercial partnerships with focus on Governments, CDMO/CMOs, research and academic institutions etc.

15. Response to statement of requirement

Category	Onshoring requirement (per statement of requirement)	Details of expected response in proposal
Product pipeline and IP arrangements	COVID-19 vaccines	Characteristics (e.g., efficacy, thermostability etc.) of mRNA COVID-19-related vaccines including those in development / testing.
	Seasonal influenza vaccines	Characteristics of mRNA seasonal influenza vaccine candidates in development / testing.
	Other mRNA pipeline products	Characteristics of broader mRNA product pipeline (i.e., application, stage of development, etc.). 10-year breakdown of respondent's track record in development of mRNA related (i.e., biologics, vaccines) products.
Manufacturing capabilities and capacity	Manufacturing site(s) / facilities	Outline of greenfield/brownfield manufacturing site(s) and partners to be used in end-to-end or consortium approach.
	Input materials and equipment	Outline of approach and supply partners to procure required input materials and equipment to support population-scale mRNA vaccine manufacturing.

		Must include approach to ensure uninterrupted supply to support resilient and secure vaccine supply.
	Process establishment	5-year track record of ability to perform internal / external technology transfer for vaccines and biologics products.
	Scale	Expected annual volume (in doses per year) of vaccine manufacturing at proposed site(s).
	Workforce	Outline of plan to hire and train sufficient workforce (specify local vs. overseas) to support manufacturing.
	Regulatory compliance	Track record and engagement plan for relevant regulatory bodies to achieve product and site regulatory approvals.
Cross-cutting	Government supports	Outline scope (i.e., type and duration) of required Govt. engagement to support mRNA vaccine manufacturing, namely details of investment, support or assistance from the Australian Government. pondents should describe how their proposed mechanisms for preparing for and delivering mRNA vaccines and any mRNA therapeutics, including for pandemic and health emergencies, will deliver value for money to the Australian Government.
	Sustainable and secure vaccine supply	In addition to describing the approach to supply chain resilience (as above), outline any further plans to ensure sustainability and security of the onshore vaccine supply. In particular, note the approach and assumptions to maintaining commercial sustainability of the onshore facility, beyond that outlined in relation to government supports.
	Flexibility of mRNA tech. platform and pandemic preparedness	Outline of plan (e.g. minimum site activity, degree of flexibility to support other vaccines etc.) to ensure pandemic preparedness, including expected time to scale the facility to full production from non-pandemic period baseline operations. Describe the mechanism proposed for pandemic and health emergency preparedness and for the Commonwealth Government to specify priority products required for pandemics and health emergencies. Respondents should also provide a mechanism for determining the price of certain goods reasonably expected to be demanded by the Australian population, and to be provided to the Commonwealth using the capability (whether or not it forms part of the assistance sought in response to this Approach to Market).

	Risks and uncertainties	Outline of key assumptions to support timeline and feasibility of respondent onshoring mRNA manufacturing.
	Timeline	Detailed milestone plan for respondent to meet expected manufacturing deliverables across following landmarks: • **Site selection:** Selection of brownfield / greenfield site(s) to support mRNA vaccine manufacturing • **Procurement**: Procurement of necessary raw materials and equipment to enable manufacturing commencement • **Workforce**: Hiring / training of necessary scale of workforce to support ramp-up of manufacturing • **Process validation:** Establishment of cGMP license / variation to license to support mRNA vaccine manufacturing • **Batch release:** Release of population-scale batch of mRNA vaccines for distribution

If you are able to provide capability in addition to these specifications, please set it out in your proposal.

If you are not able to provide the capability as set out in the specifications above, please set out in your proposal how your proposal would differ from these assumptions.

16. Costing information

Respondents should provide detailed information about their proposed costing arrangements. The costing information required to be provided by Respondents consists of four tables:

- **Establishment costs:** This should include the total costs expected (and timings) to develop a facility with end-to-end mRNA vaccine and any mRNA therapeutic production capabilities of at least the minimum required scale called out in the RFI (e.g. site acquisition costs)
- **Operational costs:** This should include the total costs expected to operate the facility under a variety of operational scenarios with the costs expressed as annualised costs, or expected costs per dose as appropriate (e.g. raw materials and consumables costs)
- **Additional ad-hoc costs:** This should include predictable costs that are required for generation of future pandemic mRNA therapeutics (e.g. licencing for future pandemic vaccine production)
- **Government support requirements:** In this table, the government investment, support or assistance requirement is broken down into 3 types;

- Upfront - investment, support or assistance that is required for initiation of the project, and the expected timeline for this support
- Ongoing - investment, support or assistance that is required over time, annualised where possible
- Ad hoc - investment, support or assistance that may be required in the case of uncertain future events (e.g. future pandemic)

Respondents should set out how they would propose that the ultimate price of the different products be determined, the model that underpins this and the level of financial transparency and audit access they propose to provide to the Commonwealth.

Details should be provided of the Australian Government involvement, support or assistance sought (including the timing, options and mechanisms of support sought). Examples of the support sought could include Advance Purchase Agreements, upfront payments, loans etc.

Details should also be provided of any support to be provided by a state or territory government, if applicable.

Where possible, please use the provided template to limit the need for clarifying questions. If there are additional costs that cannot be mapped to these tabs, an extra tab may be included to document the expected costs. Costs should be provided as best estimate, with a range included as required.

The costings should include the total expected costs for the organisation or consortia. There is no need for a breakdown of how the costs will be distributed across individual entities working within a consortia.

Respondents may provide further information as they see fit.

Development costs

Type of cost	**Year 1** (A$m)	**Year 2** (A$m)	**Year 3** (A$m)	**…** (Add years if required)	**Total cost**	**Key assumptions**	**Additional commentary**
Site(s) acquisition costs							
Facility planning and design costs							
Construction costs (incl. fees)							
Fit-out costs (not incl. equipment)							
Equipment and installation costs							
Other modification costs to prepare the facility							
Tech transfer costs (please provide breakdown as appropriate, e.g., for licenses)							
GMP certification and other certification costs (including necessary testing)							
Human capital (including, testing and approvals) to deliver an operational facility							
Other regulatory costs (please specify)							
Project management costs							
Other costs… (add rows and explanations as required)							
Total cost							

Operational costs

	Type of cost	Minimum costs for retention of operational capabilities (i.e. facility in hibernation)	Non-pandemic expected base operations	Pandemic scale operations	(Add additional scenarios if required)	Key Assumptions	Explanatory commentary
Variable (express as A$ per dose)	Raw Materials / Consumables						
	Labour costs						
	Logistics and distribution costs						
	Storage costs						
	Other costs - please specify						
Fixed (express as A$m, annualised)	Facility, utility and maintenance						
	Training and uplift costs						
	Other costs - please specify						

Additional ad hoc costs

Type of cost	Estimate (A$m)	Key assumptions	Description / Rationale and timing

Government investment, support or assistance requirements

Type	Estimated value	Low-end estimate	High-end estimate	Expected timing/distribution	Assumptions and drivers used to calculate	Explanatory notes
Upfront						
Ongoing						
One off						