



Approach to Market

Proposals to establish an end-to-end onshore mRNA manufacturing

Questions and Answers from potential respondents

30 June 2021

1. Question: Skills

- How are skill shortages to be addressed?

Answer:

- It is up to respondents to demonstrate how they propose to establish the mRNA capability, including by identifying any constraints (such as any shortage in the necessary skills and expertise) that they may face and demonstrate how they propose to deal with those constraints.

2. Question: Sovereign Real Estate

- Could sovereign real estate be considered as part of the solution for facilities?

Answer:

- Yes. It is up to respondents to demonstrate their ability to establish the mRNA capability. The Statement of Requirements in the Approach to Market does not impose any constraints on site ownership for facilities.

3. Question: Ownership

- How are capabilities that may be funded by the Australian Government to be treated from an ownership perspective?

Answer:

- The Australian Government is looking for respondents to propose arrangements that will best meet the Australian Government's requirements. A common approach or position on ownership is not able to be specified at this stage. Each proposal (including the respondent's approach to ownership of any capabilities to be funded by the Australian Government) will be considered on a case-by-case basis.
- Respondents should clearly demonstrate the features of their proposal and the rationale for their proposed approach. Respondents may wish to identify how their proposals would be affected if their preferred ownership model is not adopted (e.g. by explaining any impact on the proposed fully costed position or by identifying any relevant alternative positions in their proposals based on different ownership models).

4. Question: Technology Transfer

- How would any technology transfer be handled between current providers of COVID-19 vaccines, the Australian Government, and the manufacturer?

Answer:

- The Australian Government is seeking proposals to establish an onshore, population-scale mRNA manufacturing capability. It is up to respondents to demonstrate how they propose to establish the mRNA capability, including any technology transfer that may be required and how it would be managed (e.g. this may include sourcing a fully costed technology transfer from an mRNA intellectual property owner or by entering into a consortium arrangement to provide an end-to-end capability).
- The Approach to Market does not require technology to be sourced from a specific provider. Furthermore, the requirement is not limited to producing COVID-19 vaccines, and includes the ability to access or develop mRNA vaccines for seasonal influenza and other mRNA products.
- Each respondent should demonstrate any proposed intellectual property arrangements, as relevant to their proposal, to establish the required facility. Respondents should demonstrate how they will source any required intellectual property. If respondents need to secure intellectual property from another organisation, respondents should clearly demonstrate how they will secure all necessary intellectual property rights.
- Respondents should note that the Australian Government does not intend to facilitate any arrangements between the respondent and any third party which may be required to establish the facility.

5. Question: Cost of Technology Transfer

- Who will be absorbing the cost of the licence from current providers of COVID-19 vaccines?

Answer:

- Please refer to the answer to Question 4.
- Respondents should ensure that all proposed financial arrangements as are clearly specified in their proposal.
- The Approach to Market also asks respondents to provide full details on any required investment, support or assistance from the Australian Government that may be necessary to establish the capability. This may include support regarding the costs of any technology transfer (if applicable).

6. Question: Reimbursement

- Assuming the Government agrees to pay the cost of the licence, would it be stipulating the price it will be reimbursing the manufacturer per dose?

Answer:

- Please refer to the answer to Question 5. Respondents should demonstrate how they propose to establish the mRNA capability, including its proposed financial arrangements.
- Respondents should specify all associated costs in its proposal, this includes any investment, support or assistance required from the Australian Government is to establish the capability.

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Respondents should also provide details on any costs which cannot be quantified at this time.

7. Question: Number of Government support Recipients

- How many companies will be able to get any amount of government support (e.g. grant)?

Answer:

- The Australian Government has not yet determined how many organisations (if any) will be approached to establish any mRNA facility.
- This Approach to Market is intended to inform and elicit the development of fully costed proposals with sufficient detail to support the Australian Government to make decisions about the establishment of an onshore mRNA manufacturing capability and any potential investment, as detailed in the Approach to Market.
- Any decision(s) by the Australian Government may result in a procurement, grant or other form of involvement, support or assistance or a combination of arrangements to establish suitable manufacturing capability.
- However, as set out in the Approach to Market, there is no guarantee that this Approach to Market process will result in the Australian Government undertaking any grant or procurement activity, or providing other financial support in relation to any proposal received in response to the Approach to Market.
- The Australian Government may not undertake any open procurement or grant process following this Approach to Market. The Australian Government 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 holders).

8. Question: Government assistance amounts

- What are the price ranges of government assistance (e.g. grants)?

Answer:

- It is up to respondents to demonstrate the level of support they require to establish the mRNA capability. There are no set price ranges for any investment, support or assistance required to establish this capability which may be provided by the Australian Government.
- This Approach to Market is designed to understand the full costs of support that industry requires in order to establish this capability.
- Respondents should demonstrate in their proposals all costs required to establish the capability, including fully costed details of investment, support or assistance from the Australian Government that may be necessary to establish the capability, as set out in the Approach to Market.

9. Question: TGA Certification

- Does the manufacturing facility need to be TGA or USFDA certified?

Answer:

- Yes, the manufacturing capability will need to have all required certifications for relevant markets.
- One of the requirements specified in the Approach to Market, is the ability to engage relevant regulatory bodies to acquire all necessary site (current Good Manufacturing

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Practice (cGMP) licensing) and product (Australian Register of Therapeutic Goods (ARTG) product registration) regulatory approvals to support mRNA manufacturing.

10. Question: Expected Timeline

- By which date do you expect the site to be fully operational?

Answer:

- The Australian Government is seeking proposals to establish onshore population-scale mRNA manufacturing, to –be fully operational with requisite regulatory approvals/licences within a timeframe of between 12 months (or earlier, if possible) and no later than three years from finalisation of any agreement with the Australian Government.
- If a respondent is not able to meet this timeframe, the respondent should provide details of the expected timeframes required to provide a fully operational facility that meets the Australian Government’s requirements.

11. Question: Next Steps

- After receiving proposals from the Approach to Market, what will be the next steps (e.g. review process, selection of the proposal) and foreseeable timeframes?

Answer:

- The next steps are set out in the Approach to Market document and include review by an Expert Advisory Group prior to the Department of Industry, Science, Energy and Resources and the Department of Health jointly providing advice to Government.

12. Question: How are proposals to be used

- Is it possible that multiple proposals will be approved and/or will different components of proposals be combined or used in other ways?

Answer:

- It is not yet known how the Australian Government will proceed. 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. Any future processes may be based on the information received in response to this Approach to Market process (including any proposal or component of any proposal).

13. Question: manufacturing elements onshore

- Can you confirm that fill and finish and other manufacturing elements must be onshore?

Answer:

- As per the Approach to Market document, even though the Australian Government recognises the complex global supply chain involved in mRNA vaccine manufacture proposals should assume that key mRNA manufacturing steps for onshore manufacturing such as fill and finish services are undertaken onshore.

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14. Question: partnership options

- What are the options for partnerships with the approach to market?

Answer:

- The Australian Government is looking for respondents to propose arrangements that will best meet the Australian Government's requirements. There are no restrictions on partnerships in the Approach to Market.
- Respondents should clearly specify any proposed partnerships and demonstrate the features of their proposal and the rationale for their proposed approach.

15. Question: Research and Development

- How will the Approach to Market optimally support the local research and development (R&D) ecosystem (including addressing intellectual property, translation and pilot scale development)?

Answer:

- The Approach to Market seeks proposals for establishing onshore manufacturing capability that could satisfy population-scale, commercial supply and regulation demands.
- The objectives of the Approach to Market include strengthening Australia's biopharmaceuticals sector, including through enabling potential translation and commercialisation paths for Australian-based research and development.
- Respondents should demonstrate how their proposal would support the local research and development ecosystem.

16. Question: Demonstrate support of the local research and development ecosystem

- How should the proposals demonstrate support of the local research and development ecosystem?

Answer:

- Respondents are required to make their own judgements about how to demonstrate their capability and proposed support of the local research and development ecosystem.

17. Question: Scope of approach to market?

- Does this Approach to Market enable a sustainable ecosystem that includes small molecule and other medical drug candidates enabling local scalable manufacturing for pre-clinical and clinical trials?

Answer:

- 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).

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- However, one of the objectives of this Approach to Market is to strengthen Australia's biopharmaceuticals sector, including through enabling potential translation and commercialisation paths for Australian-based research and development.
- Respondents should demonstrate how their proposal would support the local research and development ecosystem.

18. Question: Approvals/licences

- There is a requirement for the facility to have 'requisite approvals/licences', in no later than 3 years. Can you clarify if this is a facility GMP licence, or a registered product approval?

Answer:

- The Australian Government is seeking proposals to establish onshore population-scale mRNA manufacturing, to –be fully operational with requisite regulatory approvals/licences within a timeframe of between 12 months (or earlier, if possible) and no later than three years from finalisation of any agreement with the Australian Government.
- One of the requirements specified in the Approach to Market, is the ability to engage relevant regulatory bodies to acquire all necessary site (current Good Manufacturing Practice (cGMP) licensing) and product (Australian Register of Therapeutic Goods (ARTG) product registration) regulatory approvals to support mRNA manufacturing.
- Additional information is specified in the Approach to Market in the Statement of Requirements (see pages 17 and 18).

19. Question: Progression of discussions

- How progressed are the discussions between the Australian Government and any other companies?

Answer:

- In parallel to this Approach to Market, the Australian Government continues to consult with companies' involved in mRNA manufacturing and mRNA vaccine production to inform the Australian Government's planning and decision making. However, information relating to these discussions is confidential in nature and not appropriate to disclose.

20. Question: can the Industry Briefing be accessed from overseas?

Answer:

- A recording of the Industry Briefing can be accessed at industry.gov.au/mrna.

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21. Question: What is the relationship between Schedules 1 and 2 in the Approach to Market?

Answer:

- Schedule 1 provides a description of the Australian Government's statement of requirements while Schedule 2 provides a form to be used for responses. It is expected that respondents completing Schedule 2 address all the requirements in Schedule 1 and the specific questions which are set out in the Proposal Requirements of Schedule 2. Respondents should also address in their response any additional information set out in the Proposal Requirements which is requested by the Australian Government (e.g. the information set out in question 15, noting respondents may wish to cross reference to other components of their proposal). This reflects the relationship between Schedules 1 and 2.
- Please note, as set out in clause 13 of the Approach to Market, the Commonwealth, based on its discretion, may elect not to consider a response. That includes the discretion for the Australian Government to disregard a response that does not respond to the Approach to Market, either because it does not contain responses to the questions in Schedule 2, or because those responses do not address the requirements set out in Schedule 1. However, there are no prescribed minimum requirements and respondents should set out their proposal against the requirements to the best of their ability.
- The Australian Government is seeking information as set out in the approach to market. To the extent that respondents are not able to meet a requirement, respondents should clearly demonstrate why they cannot meet that requirement and demonstrate any potential alternative arrangements or mitigation options for the Australian Government's consideration.