REFERENCE NUMBER: 0001

REQUEST FOR QUOTATION (RFQ) FOR COVID 19 Vaccine Onshore Manufacturing Business Case

STATEMENT OF REQUIREMENT

This Statement of Requirement is made pursuant to the Business Advisory Panel Standing Offer Notice – SON3305648.

Background:

The Australian Government is making substantial investments to support early access to safe and effective COVID-19 vaccines for all Australians. These efforts are guided by the COVID-19 Vaccine and Treatment Strategy (the Strategy) with expert advice provided by the COVID-19 Vaccines and Treatments for Australia – Science and Industry Technical Advisory Group (SITAG).

The Strategy is focusing on five key areas including opportunities to use and strengthen local manufacturing as part of investment decisions.

Investments by the Government to date include securing access to several promising vaccine candidates, subject to completion of clinical trials and approval by the Therapeutic Goods Administration. The Government is also investing in the manufacturing by CSL of some vaccine candidates.

However, there is no guarantee that any given vaccine candidate will prove safe and effective which is why the Government is building a diverse global portfolio of investments to secure early access to promising vaccines and treatments as part of its Strategy.

Earlier this year, the Department of Industry, Science, Energy and Resources and the Department of Health undertook an audit of Australian vaccine and therapeutics manufacturing capability and capacity. This audit found that onshore manufacturing capability is limited, particularly regarding onshore capability for promising mRNA platform COVID-19 vaccines.

The audit did however identify a potential consortia of Australian entities in which investments could be made to establish an mRNA platform manufacturing facility with population scale vaccine production capacity.

mRNA vaccine technology is novel and prior to COVID-19 a vaccine on this platform had not been approved for use in humans. There are two very strong COVID-19 vaccine candidates from Pfizer and Moderna, with initial doses of the Pfizer vaccine already being administered in the United Kingdom and the United States. mRNA technology is also considered to have significant future potential for the prevention and treatment of a range of health conditions.

Requirement:

The Government is now seeking a detailed business case on opportunities for investment in a new onshore mRNA vaccine manufacturing capability.

This procurement seeks to engage a suitably qualified and experienced organisation to develop a business case for investment in onshore manufacturing capability and capacity for the local production of an mRNA-based COVID-19 vaccine (Business Case), including costs and requirements to build on the capability of existing pharmaceutical organisations identified through the earlier manufacturing audit.

The successful organisation will be required to prepare and provide a Business Case as a PDF document (with a Word version to be made available on request by the Commonwealth) which includes (but is not limited to) advice on:

Mandatory requirements:

- Key manufacturing supplies and inputs including technology transfer and knowhow for production at scale;
- Access to necessary intellectual property (IP) including IP for manufacturing processes;
- Supply chain gaps in onshore vaccine manufacturing capability for the mRNA vaccine platform;
- Approach to market to consider broader international commercial partnerships:
- The Commonwealth Government's short and long-term roles in supporting manufacturing capabilities;
- Timeframes for developing capability;
- Alignment with other manufacturing projects and opportunities including research collaboration;
- Approximate cost of the options for Commonwealth investment in onshore capability to manufacture vaccines consistent with the Commonwealth Investment Framework;
- Negotiation of collaborative arrangements between likely partners and/or multiple companies across the manufacturing supply chain where required;
- Whether international vaccine developers would be amenable to establishing an Australian mRNA manufacturing capability without partnering with a local company;
- Identify regulatory evaluation and approval requirements;
- Detailed risk assessment and management plans: and
- Financial, governance and performance assessment of organisations identified through the audit of Australian capability and capacity in manufacturing of vaccines and treatments.

Skills and experience required:

The services sought for this procurement will require performance of the services by personnel with extensive knowledge of the medical and pharmaceutical industry, its stakeholders, domestic and international supply chains, Commonwealth, State and Territory government health systems and services, and regulatory processes and approval requirements.

Details of key personnel are to be provided in the Response to this RFQ including CVs, proposed role and time commitment including any intended gaps during the duration of the contract.

Work program:

The Response to this RFQ should include a proposed weekly work program against which the successful Respondent will be required to report.

Conflict of interest:

The Response to the RFQ is to include all actual, perceived and potential conflicts of interest of the Respondent organisation and all personnel with respect to the proposed delivery of the services.

Industry briefings:

RFQ Respondents may request an industry briefing from the Department which can be held on 21 December 2020. A request for an industry briefing must be made in writing to the Commonwealth Point of Contact (identified below).

An industry briefing can:

- provide clarification of the RFT including background, scope and timing
- outline the expectations of the Commonwealth for the submission
- advise the requirements for submissions
- provide guidance on the evaluation criteria

When an industry briefing takes place, a record of the briefing will be prepared and made available to all potential Respondents (excluding identifying information of the Respondent with which the briefing has been held).

Deliverables:

It is expected the services will commence on 4 January 2021.

Number	Deliverable	Delivery Date
1	Weekly reporting to the Department	From 4 January 2021
2	Draft interim Business Case	19 February 2021
3	Interim Business Case	26 February 2021
4	Final Business Case	12 March 2021

Reporting requirements:

Weekly reporting to the Department will be in the form of a written report against the agreed work program.

The successful organisation is to provide to the Department all relevant working documents associated with the weekly reporting and Business Case at all stages of its development.

The successful organisation will be required to meet with the Department as required as part of the reporting requirements. Key personnel are to be made available for these meetings.

Expert Advisory Group:

The Department may engage an Expert Advisory Group (EAG) comprising Commonwealth and non-Commonwealth individuals. All reporting and the Business Case at all stages of its development will be provided to members of the EAG. All members of the EAG will be required to sign, where required, conflict of interest and confidentiality agreements.

Duration:

The proposed term of the contract is eleven weeks. The term of the contract may be extended by mutual agreement.

Standards:

Costing:

A fixed price quote is to be provided in the Response to this RFQ. Please include both GST exclusive and GST inclusive figures.

Rates for all key personnel are to be included in the Response to this RFQ. A summary of other costs is also to be included in the Response.

Response requirements:

The Response to this RFQ should not exceed 15 pages, excluding CVs of key personnel and costings.

Security Requirements:

All personnel are required to have a baseline security clearance required for the term of the contract.

QUOTATION RESPONSE

Closing Date:

Responses to this RFQ are to be provided to the Commonwealth Point of Contact via email by 11:59pm Australian Eastern Daylight Savings Time on 22 December 2020. Responses received after this time will not be accepted.

Commonwealth Point of Contact:

All communications should be in writing to the Commonwealth representatives for this procurement process (Kris Browne and Peter Lunn, Executive Project Officers) at the below email address:

<u>SciencePolicyProcurements@industry.gov.au</u>

Evaluation Criteria:

Responses will be assessed on the basis of value for money through the application of the Evaluation Criteria as detailed in the Commonwealth Procurement Rules (CPRs). Value for money is a comprehensive assessment that takes into account both price and the value represented by the assessment of capability and capacity, in the context of the risk profile represented by each Response.

The Evaluation Criteria to be used and comparative weightings are summarised in the table below:

No.	Evaluation Criteria	
1.	 Capability (50%) The capability of the Respondent to provide the goods or services in accordance with the Statement of Requirement. For example: Respondent's skills, experience and past performance 	
	 skills, experience and past performance of the Respondent's personnel 	
2.	Capacity (50%)	
	The capacity of the Respondent to provide the goods or services in accordance with the Statement of Requirement. For example:	
	 availability of Respondent's personnel and time allocation to the task 	
	ability to meet project deadlines	
	 capacity to provide the goods or services over the required period 	
3.	Price (not weighted)	
	All costs, fees, allowances and charges associated with the implementation and completion of contract obligations	

No.	Evaluation Criteria	
4.	Risk (not weighted)	
	Any risks inherent in the Response. For example:	
	any actual or perceived conflict of interest	
	level of compliance with this RFQ	

Responses will be evaluated using the following approach:

- Assessment of the technical worth of Responses using Evaluation Criteria 1 and 2 (Capability and Capacity);
- Financial assessment of Respondents prices;
- Assessment of best value for money by a comparison of technical worth as against Respondent prices and risks associated with Respondents, to determine best value for money.

The Department is not obliged to accept the lowest priced Response. Value for money involves assessing various factors over the entire procurement cycle.

Work order:

The Department will negotiate a Work Order with the successful Respondent in accordance with the Deed of Standing Offer in Relation to Business Advisory Services.

Contact:

Any written questions regarding this RFQ are to be emailed to the Commonwealth Point of Contact by 10:00am Australian Eastern Daylight Savings Time on 21 December 2020.

Attachments:

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