PHARMAC

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13 July 2020

Dear Suppliers

REQUEST FOR INFORMATION – COVID-19 VACCINE RESEARCH, MANUFACTURE AND SUPPLY

In May 2020, the New Zealand Government announced a <u>COVID-19 vaccine strategy</u> that sets out the Government's mission to ensure that New Zealand has access to a safe and effective COVID-19 vaccine as early as possible.

The COVID-19 vaccine strategy is based around five pillars:

- Connecting globally to contribute to all aspects of vaccine development, distribution and use
- Investing in research that contributes to global efforts, builds relationships and supports early access to a vaccine
- Developing the ability to manufacture in case it is needed to secure supply
- Optimising regulatory approaches to ensure safety, support research and enable manufacturing
- Using purchasing arrangements to secure supply where possible and to enhance resilience

A task force has been set up to oversee the implementation of this strategy. It consists of the Ministry of Business, Innovation and Employment, the Ministry of Health, Medsafe, PHARMAC and the Ministry of Foreign Affairs and Trade.

PHARMAC, on behalf of the task force, is seeking information regarding COVID-19 vaccine research, manufacture and supply, including supplier willingness to consider a range of different commercial scenarios for supply to New Zealand.

This Request for Information (**RFI**) will inform and assist the task force in developing its approach to securing supply of a COVID-19 vaccine through possible future procurement processes to support the purchasing pillar of the COVID-19 vaccine strategy.

This **RFI** incorporates the following schedules:

• Schedule 1 specifies the vaccines for which PHARMAC is requesting information and sets out the background to the RFI and the types of information sought;

 Schedule 2 contains the RFI response form in which you are to provide the details requested.

How to respond

We appreciate the time and effort it takes to compile responses to an RFI. Not all questions will be relevant or of interest for all suppliers, so your responses can be limited to just some of the questions asked or can cover the full range questions.

Please provide the information requested in this RFI, and any additional information you consider may be of assistance to PHARMAC via email to procurement@pharmac.govt.nz, by 5pm (New Zealand time) 31 July 2020.

Suppliers are encouraged to raise any queries via the GETS Question and Answer function. Where PHARMAC identifies that a question may be of value to other suppliers, PHARMAC reserves the right publish both the question and answer so they are visible to all interested parties. Alternatively, suppliers may use the GETS Question and Answer function to request a confidential teleconference with PHARMAC.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like withheld. PHARMAC will give due consideration to any such request.

We wish to emphasise that this is not a Request for Proposals and at this time PHARMAC is not seeking commercial proposals for the supply of COVID-19 vaccines. PHARMAC does not intend to convert information provided in response to this RFI into a contract for supply. Any information you provide in response to this RFI will be considered non-binding in relation to any competitive process or other procurement process that PHARMAC may, at its sole discretion, undertake in the future.

We look forward to receiving your proposal.

Yours sincerely

Lisa Williams Director of Operations

Schedule 1: Vaccines, type of information sought and desired outcome

1. COVID-19 Vaccine

PHARMAC is seeking information regarding your organisation's plans for COVID-19 vaccine development, manufacture and supply for the New Zealand market.

COVID-19 vaccines of interest may include, but are not restricted to the following technology platforms:

- Inactivated virus
- Live attenuated virus
- DNA-based vaccine
- RNA-based vaccine
- Non-replicating viral vector
- Replicating viral vector
- Protein subunit
- Virus-like particle

2. Desired Outcome

PHARMAC aims to gain further information from potential COVID-19 vaccine suppliers with respect to their plans for the research, manufacture and supply of vaccines to New Zealand.

The information provided will help inform the task force's approach to securing a safe and effective COVID-19 vaccine, in sufficient quantities at the earliest possible time.

The specific information requested is set out in Schedule 2 of this RFI.

Schedule 2: Information Requested – Response form

[Insert Date]

Andrew Oliver (Senior Therapeutic Group Manager) Craig Butler (Manager Procurement and Contracts) PHARMAC PO Box 10-254 Wellington 6143 New Zealand

Via email to procurement@pharmac.govt.nz

Dear Sirs

Information regarding research, manufacturing and supply of COVID-19 vaccines.

In response to PHARMAC's request for information (**RFI**) dated 13 July 2020, we put forward the following information in respect of **COVID-19 vaccines**:

Our contact details:

| Name of organisation | |
|----------------------|--|
| Contact person | |
| Address | |
| Phone | |
| Facsimile | |
| Email address | |

1. Are you willing to be contacted for any follow up questions relating to your responses to this RFI?

Yes / No (delete as appropriate)

a. If you responded 'No' to question 1 above, please tell us why

Interest

2. Does your organisation have an interest in COVID-19 vaccine development, manufacture or supply? Please describe.

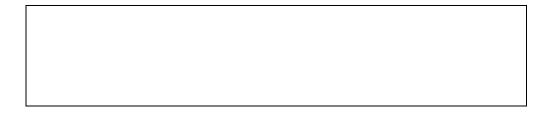
Covid-19 vaccine candidates

3. Do you have, or are you planning to have a COVID-19 vaccine development programme?

4. What technology platform is(are) your vaccine candidate(s) based on?

5. Is your development in-house or in a partnership with other parties? Please describe.

6. Have you previously commercialised a vaccine based on the same technology platform? Please describe.



Intellectual Property

7. Please describe the ownership of intellectual property related to your vaccine candidates.

8. Is your organisation considering opportunities to expand manufacturing capacity by allowing licenced manufacture in third party manufacturing facilities? Please provide details.

Manufacturing capability/capacity

9. Please describe your anticipated COVID-19 vaccine manufacturing capacity, by year, for the next five years.

10. What proportion of your existing or potential capacity for a COVID-19 vaccine, if any, has already been allocated to pre-commitments to purchasing arrangements?



11. Is your organisation open to licencing manufacture in approved third party vaccine manufacturing facilities as part of your capacity planning?

Global vaccine allocation plan

12. Does your organisation have, or is it intending to develop, a global COVID-19 vaccine allocation policy or plan?

13. What are the guiding principles of any allocation plan? Please include any information relating to your plans to provide equitable supply to countries, including where you see New Zealand and Pacific countries sitting in this framework.

- 14. What plans does your organisation have for allocating vaccine supply to New Zealand and Pacific countries? Please include information about possible timing and quantity of any allocations to New Zealand and Pacific countries.
- 15. Has your organisation made, or is it intending to make any commitments to pooled global procurement initiatives such as the Gavi COVAX Facility or COVAX AMC?

16. Has your organisation made, or is it intending to make any commitments to collaborative purchasing alliances such as the European Commission initiative, International Vaccine Alliance, International Buyers Club or other groupings of countries?

17. What plans does your organisation have in relation to direct agreements with individual countries, including Advanced Purchase Agreements?

Regulatory plans

18. Please describe your approach to securing regulatory approval around the world. Please describe the type of approach you would use for New Zealand and the sequencing of this relative to other countries.

19. Would you consider New Zealand regulatory approval in parallel with other countries?

Commercial interests

20. Please describe your organisation's approach to the commercialisation of COVID-19 vaccines. To what extent do you consider the supply of COVID-19 vaccines to be a public good priority vs a commercial opportunity?

Other relevant information

21. Please provide any other relevant information about your COVID-19 vaccine plans or capability that has not already been provided above.