MINISTRY OF HEALTH
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Wendy McGuinness

By email: wmcg@mcguinnessinstitute.org
Ref: H202002651

Dear Wendy McGuinness

Response to your request for official information

Thank you for your request of 28 April 2020 under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) for information regarding vaccine manufacturing and vaccination strategy within New Zealand.

On 25 May 2020, the due date for responding to you request was extended in accordance with section 15A of the Act, as further research, collation and consultation was required.

The Ministry's response to each part of your request is as follows.

"PART A: Vaccine manufacturing
1. Is there a vaccine manufacturing facility in New Zealand (i.e. assuming a license can be obtained to mass produce a vaccine here)?"

Sites with a licence to manufacture medicines in New Zealand can be found on the Medsafe website: https://www.medsafe.govt.nz/regulatory/licensed.asp

Please note that the 'Malaghan Institute of Medical Research' is the one site listed to manufacture medicines in New Zealand that includes 'vaccine and sera' within the licence scope.

Please also note that a licence to manufacture medicines is often restrictive in its scope. For example, it may specify products that are covered by the licence.

"2. If there is a vaccine manufacturing facility in New Zealand, can you advise: a. Who owns the manufacturing facility? Note: We understand Otago University has the ability to contribute to making vaccines but we would like official confirmation that this is the case and that manufacturing at scale is possible."

The licence to manufacture is issued to the Malaghan Institute of Medical Research, which is a registered charity. The Ministry can also confirm that Otago University does not have a licence to manufacture medicines however the Ministry does not hold any further information relating to Otago University and vaccine manufacturing.

"b. How long would it take to manufacture 5 million or 10 million (in case we need to vaccinate people twice) vaccines? Note: We are only looking for rough estimates; for

example if New Zealand does have a manufacturing facility, how many months it would take to manufacture 5 and 10 million respectively."

This part of your request is refused under section 18(g) of the Act as the Ministry does not hold this information and I have no reason to believe that it is held by another agency subject to the Act.

"c. Does the manufacturing facility have the necessary components to make a vaccine in stock (see list of vaccine components here)? If yes, what expiry date do they have on current stock levels? A copy of a recent stock take would be sufficient. If it does not, are they able to purchase the remaining stock from overseas? Are any essential components in short supply?"

Your request is refused under section 18(g) of the Act as the Ministry does not hold this information and I have no reason to believe that it is held by another agency subject to the Act.

"d. Has the facility manufactured any human vaccines over the last 20 years (since 2000)? If yes, what vaccines were produced and how much did the licenses cost? Were there resulting logistical or safety issues?"

The Malaghan Institute has held a manufacturing licence including the following products within its scope:

Genetically modified T Cells; including:

- *(i) Human Cell Line for Lentiviral Vector Manufacture*
- *(ii) Lentiviral Vector for in vitro gene transduction*
- *(iii) Genetically modified T-cells (WZTL-002)*
- *(iv) Dendritic cells*

The Ministry does not hold information relating to the total cost of licences, quantities of vaccines produced, logistical or safety issues. You can however find fees listed publicly on the Medsafe website: https://www.medsafe.govt.nz/regulatory/fees.asp

"3. Does Australia have a vaccine manufacturing facility?
a. If yes, what is the size of its production facility? Is it large enough to supply the New Zealand market?
b. If yes, do New Zealand and Australia have a mutual arrangement where New Zealand would get priority over other countries? If yes, please explain. If no, is this being considered?"

The Ministry does not hold any information pertaining to this part of your request. As such this part of your request is refused under section 18(g) of the Act, as the Ministry does not hold this information and I have no reason to believe that it is held by another agency subject to the Act.

However, we do note that if New Zealand and Australia work together on this matter, we collectively have a better chance of securing vaccine supplies.

"4. Does New Zealand have any specific agreements or loose relationships with vaccine suppliers around the world that the country can rely upon or leverage?"

Please be advised that PHARMAC has existing supply agreements and relationships with providers who supply vaccines listed on the National Immunisation Schedule, as well as other providers who may supply vaccines on other markets outside of New Zealand. The

Ministry has also maintained an advance purchase agreement with vaccine manufacturers for the supply of influenza pandemic vaccine.

"a. If yes, please name the vaccine supplier and the type of agreement (if this is confidential information, a simple 'yes' is sufficient)."

PHARMAC has specific vaccine agreements with the following companies listed below. Please note that PHARMAC also has pharmaceutical supply agreements with a wide range of pharmaceutical suppliers who may supply vaccines in other markets but not currently in New Zealand:

GlaxoSmithKline NZ Limited – vaccine purchase
Merck Sharp and Dohme (New Zealand) Limited - vaccine purchase
Seqirus (NZ) Limited - vaccine supply and purchase
Sanofi-Aventis New Zealand Limited - vaccine purchase
Mylan New Zealand Limited – stock guarantee

"b. If no, do we have any country agreements? If we do not, can you clarify whether New Zealand is simply reliant on aggressively going to the market?"

Please refer to the response provided in question 4.

"PART B: A New Zealand vaccination strategy
5. Has an inoculation strategy been developed or in development, in preparation for a mass vaccination program against SARS-CoV-2? a. Yes, if it has been developed, can you advise name and link to the document?"
b. Yes, if it is in development, can you advise name and timeframe when the document is expected to be released?"
c. If no, is there a previous inoculation strategy document that you will use or might update? Can you provide the link or name of the previous inoculation strategy document?"

The documents you have requested do not currently exist as work on a COVID-19 immunisation programme is only in its very early stages. As such this part of your request is refused under section 18(e) of the Act, as the information does not exist.

You may be interested to know that the Ministry of Business, Innovation and Employment have recently published initial details regarding the COVID-19 vaccine strategy on their website: https://www.mbie.govt.nz/science-and-technology/science-and-innovation/international-opportunities/covid-19-vaccine-strategy/

"6. We understand special fridges are required to hold vaccines. How many fridges does New Zealand have available? Has there been any consideration of taking a stock take and purchasing any additional fridges now globally (before they are in short supply)?"

The 'National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd edition)' outline the requirements for all immunisation providers in New Zealand. The standards require that all immunisation providers must use a pharmaceutical refrigerator for vaccine storage. Vaccine storage capacity would be considered as part of the delivery of any immunisation programme.

"7. Have the syringes (listed on the national reserve supply composition here) been checked for quality (we note they expire in 2022)? As the vaccine may take over 18 months to develop, there is a risk the syringes may expire. Has the MoH considered purchasing another 10 million?"

The National Reserve Supply's current syringe stock expires in 2022. As with any item in the Ministry's National Reserve Supply there is an ongoing need to review stock, including volumes before purchase of new stock. Many vaccines are supplied with needles attached, so any requirement for separate needles will not be known until a suitable vaccine is identified.

"8. Has there been consideration of the anti-vaccine lobby in New Zealand?"

The Ministry is aware of some groups and individuals who oppose vaccination. The COVID-19 immunisation strategy will include the development of communications that will address issues that the anti-vaccine lobby may raise.

"9. To what extent will vaccination be compulsory, or will it be voluntary? Note: We expect that the benefits of being vaccinated will be measured against the perceived risk of acquiring the disease."

As per the response provided for question 5 of your request, an immunisation strategy has not been developed therefore this part of your request is refused under section 18(e) of the Act, as the information does not exist.

"10. Can inoculation of a vaccine be made mandatory under current New Zealand law?"

Currently New Zealand law would not enable compulsory vaccination.

"11. What lessons can be learned from the flu vaccine? Given concerns about the quantity ordered and the public release to GPs not being adequate, has a review been undertaken? If yes, can we please have a link to or soft copy of the written review?"

The Ministry is currently undertaking a project to investigate all aspects of supply and distribution of influenza vaccines. This work involves discussions with a wide range of sector stakeholders. A summary of findings is expected by the end of June 2020, this will allow any key changes to be made ahead of the 2021 programme.

"12. In recent years, the government has rolled out the meningococcal vaccine and the HPV vaccine? Was a review undertaken for each of these? If yes, can we please have a link to or soft copy of the written review/s?"

Information pertaining to this part of your request is publicly available on the Ministry website:

- HPV Immunization Programme Implementation Evaluation - https://www.health.govt.nz/publication/hpv-immunisation-programme-implementation-evaluation

- Evaluation of Meningococcal B Immunisation National Roll-out - https://www.health.govt.nz/system/files/documents/publications/menzb-implementation-evaluation-nov06.pdf

"13. We expect GPs will be paid for giving the vaccine to eligible patients and pharmacists to customers; however, can you confirm this?

Health professionals providing a funded COVID-19 vaccine will be reimbursed according to the immunisation benefit in place at the time.

“14. Who is undertaking viral surveillance for SARS-CoV-2 in New Zealand? (e.g. is it ESR or MoH)?””

The COVID-19 response developed a comprehensive testing strategy that is key to New Zealand’s COVID surveillance. The implementation of this strategy is a coordinated effort among the Ministry, the Institute of Environmental Science and Research (ESR) and DHBs, but the actual testing for SARS-CoV-2 is currently conducted by DHBs, with ESR as a reference laboratory. In order to overcome some of the challenges created by COVID-19 to our National Flu Surveillance programme this year, some General Practitioner sentinel practices will be sending samples for both SARS-CoV-2 and influenza testing directly to ESR.

15. What mutations (or strains) of SARS-CoV-2 has New Zealand found to date?
a. Does New Zealand have the ‘L-type’ or ‘S-type’ strains? If yes, what is the numbers of percentages?
b. Are there any other strains in New Zealand?”

The Ministry is expecting to receive a report on the first 100 cases in the coming weeks. This report will be prepared by ESR who are undertaking the genomic analysis. As such your request for this information is refused under section 18(d) of the Act as the information requested will soon be made publicly available.

“c. From your experience, do you consider one of the strains is more deadly than another?”

The Ministry does not hold information pertaining to this part of your request and as such, this part of your request is refused under section 18(g) of the Act.

d. What is the MoH advice to officials (e.g. to ministers, Treasury, and the Reserve Bank) as to when a vaccine might be available for sale to the New Zealand Government (e.g. a 5% chance in less than six months, an 80% chance in six to 18 months, a 10% chance in 18–36 months, and 5% beyond 36 months)? We are interested in how this has been positioned with officials.

The Ministry has not provided formal advice on this topic as it would be speculative. The Ministry and other government agencies are however monitoring developments closely. This part of your request is refused under section 18(e) of the Act.

“16. Given the vaccine is being fast-tracked, there is a risk countries might agree to indemnify vaccine makers from legal liability in the event of manufacturing defects?
a. Has the New Zealand Government ever accepted legal liability for a past vaccine in the last 20 years? Note: The US underwrote the risks of H1N1 in 1976/77, which added to the fear of the vaccine itself (see Nate Silver’s The Signal and the Noise, pp. 209–210). Shortly after the programme started it was halted largely due to an unusually high number of Guillain-Barre syndrome cases occurring in vaccinated people.”

The Ministry does not hold information pertaining to this part of your request and as such, this part of your request is refused under section 18(g) of the Act. A ‘no-fault’ compensation exists for vaccine treatment injuries available through Accident Compensation Corporation (ACC). Any further information on this topic would be best sought directly from ACC.

“b. Would the New Zealand Government ever accept legal liability for a fast-tracked vaccine? If no, is this because it would be covered by ACC?”

Please be advised that a response to this question would be speculative. Thus, in line with section 2 of the Act, this part of your request does not constitute a request under the Act as it is not a request for official information.

"17. Have any New Zealand patients been tested to see if they have developed antibodies?
a. If yes, what number have been tested?"

There are no validated antibody tests being used in New Zealand at this time. Once a validated test has been developed or approved antibody testing will be possible.

"b. Of those tested, what number of people showed 'very low levels of neutralizing antibodies in their blood'? [See background below, WHO 24 April]
c. If yes, what was the level of antibodies and the median found?
d. If yes, has their immunity been tested more than once to indicate over time whether their immunity has stayed the same, increased or waned?"

Please refer to the response provided in question 17a.

"18. Is the MoH considering an immunity passport system?"

The Ministry notes there has been some speculation about this regarding border controls, but an immunity passport system is not being actively considered at this time.

"19. Does New Zealand have the necessary skills and equipment to create in vats antibodies for COVID-19 patients?"

Your request is refused under section 18(g) of the Act as the Ministry does not hold the information requested and I have no reason to believe that it is held by another agency subject to the Act.

I trust this fulfils your request. Under section 28 of the Act, you have the right to ask the Ombudsman to review any decisions made under this request.

Please note that this response, with your personal details removed, may be published on the Ministry website.

Yours sincerely

Deborah Woodley
Deputy Director-General
Population Health and Prevention