Covid-19 Vaccine Strategy
Science and Technical Advisory Group

Minutes – Wednesday 7 October (Confidential)

Date & time	10:00 to 11:00AM, Wednesday 7 October	
Attendees	Ian Town (Chair) David Murdoch (Deputy Chair) Sue Crengle Ian Frazer Graeme Jarvis Peter McIntyre Nikki Moreland Helen Petousis-Harris John Taylor Nikki Turner	Justine Daw Jonathan Lane Zachary Clarke Emily Robinson
Apologies	Matire Harwood James Ussher	

Item for discussion	Led by
Administration	
1. Apologies Matire Harwood James Ussher	Ian Town
2. STAG Conflicts of Interest The updated COI register was noted, with any COIs not listed to be declared	Ian Town
3. Review of minutes from last STAG meeting The minutes from the meeting on 23 September 2020 were approved	Ian Town
4. Review of rolling monthly planner There are now seven target vaccine candidates under consideration through the APA process. With COVAX membership now confirmed, relevant candidates will also need to be assessed by the STAG's Science Review Panel. We do not have a clear line of sight of timing for this or the specific candidates, or if they will be offered to us via COVAX individually or in groups. However, it is possible that potential candidates may be presented to New Zealand from 12 October. **Action:** MBIE will provide updates on COVAX as soon as they become available.	Ian Town

Updates	
5. Medsafe regulatory approvals process Chris James (Group Manager, Medsafe) presented on the role of Medsafe as the authority responsible for the approval and regulation of potential COVID-19 vaccines, and the global regulatory context in which Medsafe operates. He outlined options for the approvals process (parallel, rolling and abbreviated assessments) while ensuring that it acts independently to ensure the vaccines meet internationally-agreed standards for safety and quality. Discussion included: • Medsafe operates in a global context, and has strong international links. Regular meetings enable the sharing of the latest information and discussion on how products may be regulated. • Medsafe considers approvals from other regulators (particularly the EMA, the US FDA, and the Australian TGA) when reviewing applications, although approval elsewhere is not a guarantee of approval in New Zealand. • Developers may submit to all regulatory agencies simultaneously, or seek approval from one of the larger regulatory agencies first. Medsafe has been encouraging developers approaching the Australian regulator to submit at the same time. • Medsafe has assessors ready to assess COVID-19 vaccine candidates. **Q**: Any COVID-19 vaccine would be likely to require provisional consent as the need for early access could mean it is still undergoing clinical assessment. Is there any indication of the timeframes for this process? **A**: This will depend on a range of factors. This is an issue faced globally, and it's important to balance the need for early access with ensuring any vaccine meets internationally acceptable safety standards. Medsafe will not cut any regulatory corners. It is looking at 'rolling submissions' where these are being used by others, e.g. the Europeans, as a way of ensuring the earliest decisions are reached on submissions. **Q**: Does Medsafe review individual patient data and critical safety data as part of a 'reliance' approval? **A**: Medsafe receives and reviews the full set of data (CDT data), it does not re-calculate clinical trial statistics from raw data.	Chris James
6. Proposed 'Science Summary' template The template for the proposed Candidate Summaries was presented and feedback requested. Discussion included: • Justine Daw acknowledged the need to close-off the Science Review Panel documentation to assist purchasing decisions before full and complete information was known. The Science Summaries will capture more up to date information, as new information comes to light. They will be updated regularly, and aim to ensure later decisions can be informed through date-stamped summary information. These updates will be available to the STAG to review and likely used by other Taskforce agencies as needed.	

• The STAG highlighted that the Science Summaries would ideally include formulation details and packaging information for each candidate, as well as storage requirements, to aid with immunisation projections and planning. [*Comment: The template will include this information, although the intent was that the document initially include only public information. We will discuss this and resolve among the MBIE team*]. **Action** MBIE will present a populated mock-up at the next STAG meeting to provide a more comprehensive view of the content to be captured by the Science Candidate Summary.	
Discussion	
7. Global WHO Solidarity Protocol for COVID-19 vaccine trials *WHO's newly launched solidarity trials for COVID vaccines* The Chair confirmed receipt of the WHO circular on solidarity trials for COVID-19 vaccines, and that a response would be prepared. The STAG agreed that the limited Covid-19 prevalence in New Zealand meant there was little we could assist with at the moment, but that we should keep involved in the conversation, and may be better able to contribute in the post-licensing phases.	Ian Town
8. Draft decision-making framework for clinical trials via VAANZ Platform Justine Daw presented a proposed decision-making framework for clinical trials in NZ of international COVID-19 vaccine candidates identified through the VAANZ platform. The Taskforce has asked for a summary on how these decisions will be made, noting there are close to 200 vaccine candidates in development globally. The framework will be finalised following Taskforce comment and input. Justine Daw noted the need to ensure the VAANZ approach aligns with the broader Taskforce programme objectives by prioritising collective activity and resources, as appropriate. Comments on the draft decision-making framework were welcomed. Discussion included: • In terms of decision-making, the Taskforce will make decisions on which candidates will progress to clinical trials in New Zealand, with the STAG's Science Review Panel providing science input to inform Taskforce decisions. • There was support for the current proposal to prioritise a small range of priority APA and COVAX candidates, while still retaining flexibility (i.e. to consider candidates with ties to domestic manufacturing capability). **Q:** The current timeframes (with VAANZ trials scheduled to occur before October 2021) seem very short. Is this feasible? **A:** The Taskforce aims to be flexible with the contract settings, and there is potential to extend the funding dedicated to clinical trials. This is yet to be explored fully to ensure best value from the investment, and is likely to be informed early in 2021 once the situation clarifies in respect of clinical trial prospects in New Zealand. [Budget sensitive] There have been very early discussions regarding the possibility of a budget bid to support Phase IV trials. This is still to be worked through as a Taskforce discussion, and is not guaranteed.	Justine Daw

Q: How much focus does the VAANZ platform have on international outreach? **A:** Developing research collaborations with international research teams is one of the primary objectives of the Platform.	
9. Questions for STAG comment **Q:** Are animal virus vectors likely to deliver any materially different immune responses to human ones? If so, what and why? **A:** Generally speaking, there is lower likelihood that animal virus vectors have circulating immunity in humans, and so they are more reactogenic and immunogenic. This is also because they have not co-evolved with human immune systems. We will need to be mindful of how we engage with communities on animal virus vectors, if they are used. It may be worth doing some research in the communities on this. **Action:** Taskforce Communications team to consider this as part of the research being scoped. The team will be invited back to the STAG when the programme is shaped up to update the STAG and seek comment.	Justine Daw
10. Meeting close	Ian Town