<u>newzealand</u>.govt.nz

Covid-19 Vaccine Strategy Science and Technical Advisory Group

Minutes – Wednesday 27 January 2021 (Confidential)

Date & time	10:30 am to 12:00 pm, Wednesday 27 January	
Attendees	Ian Town (Chair) David Murdoch (Deputy Chair) Sue Crengle Graeme Jarvis Peter McIntyre Nikki Moreland Helen Petousis-Harris Nikki Turner James Ussher Ian Frazer Matire Harwood, John Taylor	Chriselle Braganza (MBIE) Simon Rae (MBIE) Caroline McElnay (MoH) Chris James (Medsafe) Dan Bernal (MoH) Fiona Callaghan (MoH) Kris Golding (MoH) Allison Bennet (MoH) Sarah Mitchell (MoH)
		V

lten	n for discussion	Led by	
Administration			
1.	Apologies Matire Harwood, John Taylor	lan Town	
2.	Introductions All attendees provided a brief introduction.	Everyone	

Updat		
3.	Immunisation planning and transition	lan Town
	lan Town gave an update on the Immunisation Programme underway at Ministry of Health (MoH) and the transition process from MBIE to MoH.	
	Key points were:	
	 Seven workstreams have been identified at MoH, each of which will be involved in individual activities including landing the vaccines, storage, logistics, staff training, and sequencing etc. 	
	 A phased handover is underway from MBIE to MoH, ranging from contract management to roll-out. This is a well-advanced, cross- agency piece of work that will be subject to written agreements. 	

 In anticipation of the leadership role transferring to MoH, measures have been taken to galvanise internal efforts towards the Immunisation Programme, which sits broadly within the COVID directorate.

Chris James

4. Medsafe approvals

Medsafe has been working with the four vaccine developers for several months to understand the timelines for generating data. To streamline this process, Medsafe has allocated dedicated assessors to each of the four vaccine candidates, all of which are rolling assessments. At the end of an assessment for each vaccine, Medsafe consults a ministerial expert advisory group, medicines assessment advisory committee(MAAC), for recommendations and advice.

Key points were:

- Data from Pfizer has been assessed as available and there have been no roadblocks to date. Questions have been sent to Pfizer for extra information, with quick turnaround of answers within a week. A risk-benefit analysis will be prepared by the Ministry and provided to Medsfae/MAAC for review. A meeting has been set with MAAC for 2nd February, with the approval dependent on MAAC's recommendation. The approval will most likely be provisional, which means that conditions can be put onto the approval that requires Pfizer to provide updated clinical data as it becomes available.
- A formal application has been received from Janssen but little clinical data is currently available, with more expected in February.
- Medsafe have started assessing data from AstraZeneca informally, with a formal application yet to be received.
- Medsafe has initiated conversations with Novavax's contracted company in NZ, however data is yet to be provided for assessment.
- Medsafe is working with MoH to gain support for conducting post-market monitoring of the vaccines to identify safety signals rapidly and to inform the Immunisation Programme.

Discussion points:

- Medsafe does not stipulate explicitly which groups the vaccine can be given to. Approval will be based on the data available, for Pfizer the current indication is likely to be 16+.
- The delicate nature of the Pfizer vaccine and the need for it to be handed carefully including cold chain was discussed. Medsafe will work with the Immunisation Programme to ensure that logistical information is conveyed to people who need to administer the vaccine.
- Medsafe is closely linked with the global regulatory community and uses expertise and assessments from regulatory colleagues. They have also been working closely with the Australia's Therapeutic Goods Administration, including discussing technical assessments and questions for the vaccine developers.
- It will be crucial to have effective media communication around provisional approvals for vaccines to ensure public confidence. Medsafe is working with communications teams to ensure this occurs.

Discussion

5. Decision to Use Framework and Terms of Reference

Town

Kris Golding/Ian

Kris Golding provided an overview of the Decision to Use Framework that will be presented to Cabinet shortly. This Framework addresses the need to provide advice on which vaccines in the portfolio can be best used for particular reasons within the Immunisation Programme.

Key points were:

- The Framework centres around four key questions that cover the context and timeline for the decision, the key pieces of information that will build the foundations of advice, and the risks and benefits.
- The STAG/new expert advisory group (EAG) is expected to provide advice on key pieces of information such as science, clinical and technical assessments of the vaccine, including who to use the vaccine for (i.e. specific population groups such as children).
- The COVID-19 Immunisation Implementation Advisory Group (IIAG) have been involved in the sequencing framework and will be consulted for advice on operational use, e.g. processes and implementation.
- lan Town acknowledged the STAG's ongoing commitment to providing vaccine advice and recommendations. The STAG will be briefed about the processes and timelines and will be asked to reconvene urgently on short notice to provide advice on deployment of the first tranche of vaccines.

Discussion points:

- Sue Crengle recommended that Te Tiriti o Waitangi assessments should be included within all groups instead of a separate group to avoid risk of marginalisation. Ian Town explained that the IIAG is very focussed on treaty and equity issues and will provide advice on these issues in parallel with the EAG.
- Clear media communication and availability of transparent science advice
 will be key to ensuring public confidence on the vaccines in our portfolio,
 especially considering the speed at which the vaccines were developed.
 Work is underway towards this and will feed into the national immunisation
 campaign. Māori providers and leaders will also be included in the
 communication campaign.
- There was some concern regarding overlap between roles of the IIAG and the new EAG in providing advice. The terms of reference (TOR) will be updated accordingly to accurately reflect the roles of the advisory groups.
- It was noted that it would be good for the STAG to have an update from the IIAG with regards to where things stand so that they are appropriately informed.

Actions:

- 1) Ian Town to send out explanation of the role of the IIAG along with the meeting minutes to the STAG.
- 2) Kris/Allison to debrief on the Framework and ensure that the risk of leaving out Te Tiriti o Waitangi issues is mitigated.
- 3) The TOR will be fine-tuned to capture the roles of the IIAG and the new EAG more clearly.

	4) MoH has developed an A3 roadmap summarising the critical decision points and will share these with the STAG.	
6.	Surveillance and research Ian Town gave a brief overview of the cohort surveillance work proposed by Dr Fran Priddy from Vaccine Alliance Aotearoa New Zealand (VAANZ), which includes aspects discussed in the 2 December 2020 workshop on Surveillance, post-marketing and associated needs for NZ and Polynesia. A second workshop will be held in the near future with STAG members and researchers from primary and secondary care to discuss this research and the proposal from VAANZ. This work will also set expectations on New Zealand's contributions to the international literature from outcomes of our Immunisation Programme.	lan Town
7.	Vaccine questions for the STAG and new expert advisory group MoH has been receiving vaccine questions from various sources, including the Prime Minister. These can be straightforward questions or really deep technical questions, which are currently being addressed by the Science and Technical Team but will eventually need to be answered by qualified experts as part of an expert advisory group (EAG). Ultimately, MoH needs to sign off on a decision and requires the STAG/EAG to land on a position for these questions. Examples of questions were sent to the STAG before the meeting and they were requested to comment. Key points: An immunisation training package is being put together and there are some pressing questions that also require advice and answers. It was noted that timeframes are generally very tight and the questions may need to be answered offline via email rather than during meetings.	Caroline McElnay
8.	Other matters No other matters were raised.	lan Town
9.	Meeting close	lan Town