COVID-19 Vaccines and Treatments for Australia Science and Industry Technical Advisory Group summaries

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# 16 August 2020

SITAG considered recent updates to the international landscape for vaccines and treatments.

SITAG agreed that the Oxford-AstraZeneca COVID-19 vaccine candidate would be an appropriate investment for the Australian Government. SITAG supported a letter of intent with AstraZeneca and indicated it would support the Government entering into a process to reach a binding purchase agreement with AstraZeneca.

SITAG was made aware of the strategy of the Australian Government and supported its participation in the COVID-19 Vaccines Global Access (COVAX) Facility.

# 24 August 2020

SITAG considered recent updates to the international landscape for vaccines and treatments.

SITAG confirmed its support for entering into a binding Advance Purchase Agreement (APA) for the Oxford-AstraZeneca COVID-19 vaccine candidate.

SITAG supported the Government entering into an agreement with Seqirus to support manufacturing of the University of Queensland (UQ)/Seqirus COVID-19 vaccine.

SITAG noted the need for appropriate indemnity clauses within contractual arrangements with vaccine developers and manufacturers to share the risk of high-volume manufacturing during clinical trials and to support earliest access to vaccines.

# 9 September 2020

SITAG considered recent updates to the international landscape for vaccines and treatments.

SITAG considered options for Australia’s COVID-19 vaccine portfolio and agreed that diversification of the portfolio was a priority, and that both experienced and more novel technology platforms should be included.

SITAG was provided with an overview of mRNA vaccines, noting unique storage considerations, stability of candidates and manufacturing. SITAG discussed the role of a new technology, delivery and implementation mechanisms in the context of a pandemic, and noted that a framework comprised of key criteria to determine appropriate investments was prudent.

SITAG agreed that it was important to explore onshore manufacturing capacity and capability for vaccines after the receipt of information from the COVID-19 Vaccine and Treatment Manufacturing Audit following the Request for Information.

# 17 September 2020

SITAG considered recent updates to the international landscape for vaccines and treatments.

SITAG considered a vaccination prioritisation framework for advance investments in COVID-19 vaccines. SITAG supported ongoing discussions with Pfizer, Novavax, Janssen and Moderna in relation to their vaccine candidates.

SITAG agreed that APA discussions should continue with Pfizer and Novavax as a priority.

SITAG agreed that further evidence was required to consider investments in new treatments for COVID-19, given treatment options were complex with numerous therapeutic approaches targeting different stages of the disease.

# 2 October 2020

SITAG considered recent updates to the international landscape for vaccines and treatments.

SITAG considered principles for investment in COVID-19 treatments, and agreed that a draft framework for treatments would be brought forward for discussion at a future SITAG meeting.

SITAG was provided with an update on negotiations with Pfizer, Novavax and Janssen.

SITAG agreed that the Government should enter into APA’s with Pfizer and Novavax.

# 7 October 2020

SITAG considered recent updates to the international landscape for vaccines and treatments.

SITAG discussed different vaccine technology platforms, including mRNA and protein vaccines, and the potential that each offered for longer term investment and options for manufacturing these in Australia.

SITAG noted Australia’s strong capacity and capability in manufacturing protein-based vaccines, and less capacity to manufacture mRNA, viral vector, inactive and attenuated virus vaccines. SITAG also noted that considering long term opportunities for investment, there was benefit in the Government further considering newer technology platforms, such as mRNA.

# 25 November 2020

SITAG considered recent updates to the international landscape for vaccines and treatments.

SITAG discussed the Australian COVID-19 Vaccine and Treatment Strategy and the importance of therapeutics in combatting COVID-19. SITAG agreed that the limited evidence for treatments did not support investments in supply of COVID-19 treatments at this stage.

SITAG supported Australia’s participation in COVID-19 treatments global platform trials, and the development of an assessment tool to assist Government’s future decision making regarding treatment options. SITAG supported the Government considering support for the development of some treatments in Australia through participation in clinical trials.

SITAG noted an update on the COVAX Facility and agreed priority should be given to purchasing additional doses of vaccines from the manufacturers with existing APAs with Australia rather than purchases made through the COVAX Facility.

# 8 December 2020

SITAG considered recent updates to the international landscape for vaccines and treatments.

SITAG discussed the HIV-diagnostic interference observed following administration of the UQ/Seqirus COVID-19 vaccine during Phase 1 trials. Members agreed that the diagnostic interference issue with the vaccine candidate made it unsuitable for distribution and administration in Australia nor for donation or resale to Australia’s regional partners.

SITAG members supported the proposal that Government should pursue additional AstraZeneca doses manufactured by CSL, through the existing AstraZeneca APA and by amendment to the separate CSL funding agreement for onshore manufacturing of AstraZeneca doses.

SITAG supported the proposal that Government should explore additional Novavax doses and discussed other candidate options to secure whole-of-population coverage.

# 12 January 2021

SITAG considered recent updates to the international landscape for vaccines and treatments.

SITAG received an update from ATAGI on its vaccine prioritisation advice.

SITAG noted an update relating to the Moderna COVID-19 vaccine candidate and the GlaxoSmithKline (GSK) therapeutic candidate VIR-7831.

# 17 February 2021

SITAG was provided with an update on plans for the vaccine roll out. This update included further information on the ATAGI clinical guidance, including the priority groups.

SITAG had a discussion on manufacturing, including fill and finish capacity and the potential for mRNA manufacturing in Australia. SITAG also received a presentation on the business case for mRNA manufacturing in Australia.

SITAG was provided with an update on the Moderna vaccine, J & J vaccine and Novavax vaccine, including available data.

# 26 March 2021

SITAG considered recent updates to the international landscape for vaccines and treatments.

SITAG discussed viral variants of COVID-19 and variant-specific vaccines and noted that Novavax announced it was considering a variant vaccine candidate.

SITAG considered updates provided on clinical trial data for COVID-19 therapeutics, including anti-viral monoclonal antibodies, immunomodulators and anti-viral small molecules. Based on the limited data available at the time, SITAG did not recommend the Government purchase a supply of COVID-19 therapeutics.

SITAG discussed the benefits and risks of having multiple vaccine manufacturing facilities onshore and were supportive of continuing discussions on available options.

# 21 April 2021

SITAG considered recent updates to the international landscape for vaccines and treatments.

SITAG was provided with an update on the COVID-19 vaccine roll out program recalibration.

SITAG expressed its support for purchasing Moderna vaccines due to the security associated with diversity of supply, promising protection against the variants, and potential supply needed for vaccinating children.

SITAG discussed onshore manufacturing and supported ongoing negotiations with Moderna and an approach to market. SITAG discussed the challenge of fill and finish for increasing vaccine supply.

SITAG supported the proposal that the Government should not pursue an APA for the Johnson & Johnson/Janssen vaccine at this time because existing supplies of adenovirus vaccines were adequate.

# 27 June 2021

SITAG was informed of the provisional registration of the Janssen vaccine by the Therapeutic Goods Administration (TGA). SITAG agreed that its recommendation to the Government not to purchase the vaccine was not changing because Australia had adequate supplies of adenoviral vector vaccines at the time.

# 1 July 2021

SITAG considered recent updates to the international landscape for vaccines and treatments.

SITAG discussed the Department’s COVID-19 Rapid Health Technology Assessment (HTA) process for therapeutics, and noted the TGA’s approach to assessing therapeutics, noting both would be inputs to inform the Advisory Group’s future considerations.

SITAG was updated on the approach to market for onshore mRNA manufacturing.

SITAG agreed it was likely at least one booster dose would be required annually and discussed different approaches by vaccine manufacturers to the development of boosters, including variant specific boosters. SITAG indicated its support for Government to use Moderna doses as booster doses. SITAG also indicated its support for the Government to purchase additional Pfizer doses for 2022 – 2023 to maintain a diverse vaccine portfolio and provide appropriate population coverage for primary and booster doses

# 22 July 2021

SITAG discussed GSK’s Sotrovimab treatment and supported a strategic Government investment in the monoclonal antibody.

# 3 August 2021

SITAG considered recent updates to the international landscape for vaccines and treatments. The chair noted the Government had made a strategic investment in GSK's Sotrovimab monoclonal antibody.

SITAG was provided with a further briefing on the rapid HTA process for COVID-19 treatments. SITAG discussed a diverse investment profile for treatments at all stages of disease and a variety of mechanisms.

# 20 August 2021

SITAG discussed GSK’s Sotrovimab treatment and supported a further strategic Government investment in the monoclonal antibody.

# 6 September 2021

SITAG considered recent updates to the international landscape for vaccines and treatments.

SITAG discussed treatment options, and supported the Government investing in a diverse portfolio of treatments. SITAG supported investment in antivirals from Pfizer and MSD, a monoclonal antibody treatment from Regeneron and further purchases of Sotrovimab from GSK.

SITAG supported the formation of a sub-group of SITAG to advise on the clinical usage of purchased treatments.

# 29 October 2021

SITAG considered recent updates to the international landscape for COVID-19 vaccines and treatments and was provided with an update on Australia’s vaccine roll out.

SITAG discussed current investment in and future requirements for treatment options, was provided with an update on the rapid HTA evaluation findings and considered treatments that would best suit the model of care moving forward. SITAG suggested additional modelling for Sotrovimab would be required to inform any additional investment.

SITAG supported additional purchases of Remdesivir to support supply in the National Medical Stockpile (NMS) if and when required

# 19 November 2021

SITAG considered GSK's Sotrovimab and supported a further strategic Government investment in the monoclonal antibody.

SITAG also discussed AstraZeneca's Evusheld® treatment and supported a strategic Government investment in the combined monoclonal antibody treatment.

# 22 December 2021

SITAG considered recent updates to the international landscape for COVID-19 vaccines and treatments, and was provided with an update on Australia’s vaccine roll out.

SITAG was provided with an overview of Australia’s epidemiology and Omicron variant in Australia, and presented with updated modelling from the Doherty Institute.

SITAG was also provided with an update on treatments by the TGA. SITAG provided its support for investigating additional purchases of Sotrovimab and Evusheld®.

# 12 January 2022

SITAG considered recent updates to the international landscape for COVID-19 vaccines and treatments.

SITAG was provided an overview of the work of the COVID-19 Clinical Evidence Taskforce and the rapid HTA report for COVID-19 treatments.

SITAG was also provided with a regulatory update on vaccines and treatments by the TGA.

SITAG provided its support for investment in additional purchases of Sotrovimab, Remdesivir, Paxlovid®, and Evusheld®.

# 18 March 2022

The SITAG considered recent updates to the international landscape for COVID-19 vaccines and treatments.

SITAG was presented with an overview of the Government’s winter preparedness planning, including the approach to COVID-19 and influenza.

SITAG was also provided with a regulatory update on vaccines and treatments by the TGA.

SITAG was presented with supply and demand modelling of COVID-19 treatments and considered if further treatment purchases are necessary for Australia for 2022 and 2023. These considerations of SITAG are ongoing.

# 24 March 2022

SITAG considered recent updates to the international landscape for COVID-19 vaccines and treatments.

SITAG considered emerging efficacy data for COVID-19 treatments against the Omicron BA.2 variant.

SITAG was presented with supply and demand modelling of COVID-19 treatments in Australia, and considered further treatment purchases necessary for Australia for 2022 and 2023.

SITAG supported additional purchases of Paxlovid and Remdesivir, to be made available for Australia’s treatment approach in 2022.

# 15 June 2022

SITAG considered recent updates to the international landscape for COVID-19 vaccines and treatments. SITAG considered emerging efficacy data for COVID-19 treatments against the Omicron BA.2 variant.

SITAG was presented with supply and demand modelling of COVID-19 treatments in Australia, and considered further treatment purchases necessary for Australia for 2022 and 2023.

SITAG supported additional purchases of Paxlovid and Remdesivir, to be made available for Australia’s treatment approach in 2022.

# 5 August 2022

SITAG considered the approach to securing new COVID-19 variant vaccines as they become available by manufacturers.

SITAG supported the inclusion of Pfizer’s and Moderna’s variant-specific vaccines into Australia’s vaccine strategy as soon as they become available, to ensure Australia has a diverse vaccine portfolio to provide protection against variants of concern.