Australian Government
Department of Health
Therapeutic Goods Administration

COVID-19 vaccines not registered in Australia but in current international use – TGA advice on "recognition"

Executive summary-Edition 2-1 November 2021

TGA Health Safety Regulation

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Executive summary

This report provides an updated assessment by the Therapeutic Goods Administration (TGA) of the protection offered by particular COVID-19 vaccines that are administered in certain countries but are not currently registered in Australia. It is based on individual assessment of published data and in a number of cases regulatory information provided to the TGA in confidence. This advice is subject to change as new information becomes available.

This information is advice only and does not represent assessment for regulatory approval within Australia. It will support decisions made by Government to support incoming travel across Australia's international borders in the coming months. It will be updated regularly as new evidence on the effectiveness of the currently reported vaccines emerges, and as assessments on other vaccines is completed or are obtained by the TGA. While certain vaccines may be considered by the TGA as "recognised" decisions on inbound travel are made by the Department of Home Affairs. State and Territory governments or organisations such as universities may apply additional considerations around vaccine requirements post-border.

The advice has compared the data for selected vaccines not registered in Australia with data on efficacy and protection offered by the vaccines approved for use in Australia. This assessment is based on data for two dose schedules of the vaccines not registered in Australia, although public health officials may wish to consider whether a post-arrival booster dose of another vaccine should be considered.

In its first assessment published on 1 October 2021, the TGA assessed six vaccines that are currently not registered in Australia:

- Peoples Republic of China - Coronavac (Sinovac), BBIBP-CorV (Sinopharm), and Convidecia (Cansino)
- India – Covishield (AstraZeneca-Serum Institute of India), Covaxin (Bharat Biotech)
- Russian Federation - Sputnik V (Gamaleya Research Institute)

Of these vaccines, Coronavac (Sinovac) and Covishield (AstraZeneca-Serum Institute of India) were Recognised for the purposes of travel into Australia effective 1 October 2021.

This assessment updates the Recognition status of two vaccines, and determines that they now be considered "recognised" by the TGA:

- BBIBP-CorV (Sinopharm)
- Covaxin (Bharat Biotech).

Potential use of this information

Identifying incoming travellers as being fully vaccinated against COVID-19 (or alternatively not fully vaccinated) helps achieve two main outcomes. Effective vaccination reduces the probability that an incoming traveller would:

1. **transmit COVID-19 infections to others while in Australia.**
2. **become acutely unwell due to COVID**, potentially requiring acute healthcare services.

How the estimates were determined

The protection offered by a vaccine against a person requiring hospital care if they develop COVID is either directly measured in Vaccine Efficacy and Effectiveness (VE) data from clinical trials, or inferred from protection against 'severe' infection. VE measures the reduction in the

odds of a person developing infection or hospitalisation, after vaccination, compared to unvaccinated people with the same exposure to COVID. Vaccine Efficacy trials directly measure the protection a vaccine offers against a person becoming infected with COVID when exposed to the virus. This can be used as an imperfect surrogate for reducing the chance of transmitting COVID because a person must first be infected with COVID to transmit it. There are also challenges in making accurate comparisons between the effectiveness of vaccines, given the inconsistent effectiveness measures, study confounders and efficacy end points used in clinical trials.

Vaccines approved in Australia

Effectiveness information has been assessed for the four vaccines that are TGA approved for use in Australia (Registered Vaccines) for the sake of completeness and to provide comparative data. **All TGA approved vaccines are recognised for incoming travellers.**

Vaccine	Outcome prevented	Average Vaccine Efficacy
AstraZeneca (Vaxzevria)	Symptomatic Infection	65%
AstraZeneca (Vaxzevria)	Severe infection/hospitalisation	85%
Pfizer (Comirnaty)	Symptomatic Infection	81%
Pfizer (Comirnaty)	Severe infection/hospitalisation	88%
Moderna (Spikevax)	Symptomatic Infection	86%
Moderna (Spikevax)	Severe infection/hospitalisation	81%
Janssen (COVID-19 Vaccine Janssen)	Symptomatic Infection	66%
Janssen (COVID-19 Vaccine Janssen)	Severe infection/hospitalisation	85%

Table 1. Vaccine Efficacy of TGA-registered vaccines, adapted from National Centre Immunisation Research and Surveillance update to ATAGI on 13 September 2021

Of the four vaccines currently granted provisional regulatory approval in Australia, the minimal average vaccine effectiveness (VE) from two doses of Vaxzevria (AstraZeneca) has been used as the minimal effectiveness comparator based on Vaxzevria's published results. **The average VE against symptomatic infection is 65% and severe infection and/or hospitalisation is 85%.**

Recommendations regarding recognition of TGA-registered vaccines

Four COVID-19 vaccines have been granted provisional approval in Australia from the following sponsors:

1. Pfizer Australia Pty Ltd (Comirnaty)
2. AstraZeneca Pty Ltd (Vaxzevria)
3. Janssen-Cilag Pty Ltd (COVID-19 Vaccine Janssen)
4. Moderna Australia Pty Ltd.(Spikevax)

TGA and ATAGI (Australian Technical Advisory Group on Immunisation) consider people to be fully vaccinated with Comirnaty, Vaxzevria and Spikevax if a) they have completed a two dose schedule of Comirnaty, Vaxzevria or Spikevax with the two doses at least 14 days apart, or received a single dose of COVID-19 Vaccine Janssen and b) at least 7 days has elapsed since completing their vaccination schedule.

TGAs updated recommendations on recognition of vaccines not registered in Australia

Coronavac (Sinovac) showed an average VE against symptomatic infection of 64% and an average VE against hospitalisation of 90%.

- VE against symptomatic infection (surrogate for transmission) of 54%, 54%, 64%, 66% and 84% in five studies.
- VE against severe infection/hospitalisation of 100%, 100%, 88% and 73% in four trials.

The standard schedule of Coronavac is 2 doses administered 14-28 days apart.

Based on regulatory, published and pre-print data this suggests the efficacy of Coronavac is comparable to the Australian-approved vaccines, although marginally lower in protection against symptomatic infection.

TGA thus considers that the Coronavac (Sinovac) vaccine is a 'recognised vaccine'.

BBIBP-CorV (Sinopharm China) showed an average VE against symptomatic infection of 65%. VE against severe infection/hospitalisation has been estimate at 79 % in people under 60 years of age.

- VE against symptomatic infection (surrogate for transmission) of 50% and 79% from two studies.
- VE against severe infection/hospitalisation of 79% in people under 60 years of age based on information provided in confidence to TGA.

Based on published, pre-print data and information provided by the WHO in confidence to the TGA, this suggests that the average efficacy of BBIBP-CoV against symptomatic or severe infection/hospitalisation infection are in a similar range to Australian-approved vaccines.

The TGA considers BBIBP-CorV (Sinopharm) is a 'recognised vaccine' for people under 60 years of age at the time of entry into Australia. In this case TGA has recognised a slightly lower (6 %) vaccine effectiveness against severe infection/hospitalisation than Australian-approved vaccines due to the lower absolute risk of severe disease/hospitalisation in younger people contracting COVID-19 compared to those over 60.

Covishield (AstraZeneca/Serum Institute of India) is manufactured using the same ChAdOx1-S recombinant virus as the AstraZeneca (Vaxzevria) vaccine to produce the same dose of virus in the final product. The two are considered interchangeable by the World Health Organisation. TGA considers COVISHIELD to have the same clinical efficacy as Vaxzevria for this assessment. Two major global regulators, the UK Medicines and Health products Regulatory Agency and Health Canada have provided regulatory approvals for the AstraZeneca vaccine manufactured by the Serum Institute of India. These regulators are recognised in regulation as "Comparable Overseas Regulators" by the TGA.

Therefore, the clinical efficacy and effectiveness data for Vaxzevria (AstraZeneca) are relevant in this case. The average VE against symptomatic infection is 65% and severe infection and/or hospitalisation is 85%.

TGA thus considers that the Covishield (AstraZeneca/Serum Institute of India) vaccine is a "recognised vaccine.

Covaxin (Bharat Biotech, India) showed an average VE against symptomatic infection of 78% and an average VE against hospitalisation of 94%.

- VE against symptomatic infection (surrogate for transmission) of 78% in one study.
- VE against hospitalisation of 91% in two studies.

The standard schedule of Covaxin is two doses administered 28 days apart.

Because additional information has now been provided in confidence by the sponsor to TGA that supports the efficacy and effectiveness of Covaxin, TGA considers that Covaxin is a 'recognised vaccine'.

Sputnik V (Gamaleya Institute, Russian Federation) showed an average VE against symptomatic infection of 92% and VE against hospitalisation of 100%.

- VE against symptomatic infection (surrogate for transmission) of 92% from one study.
- VE against hospitalisation of 100% from one study.

Because this is only a single study, and TGA has not yet been provided with a regulatory dossier, TGA has not reached a conclusion on whether Sputnik V be a 'recognised vaccine'.

For **Convidecia (Cansino)**, there are currently no published or pre-print studies on which to base an assessment of the efficacy of Convidecia and the TGA has not yet been provided with a regulatory dossier.

Because there is insufficient data to evaluate the efficacy of the vaccine, **TGA has not yet reached a conclusion on whether Convidecia (Cansino) should be a 'recognised vaccine'.**

For the unregistered vaccines that are granted recognition, effective vaccination would be considered to extend from 7 days after the last dose of the schedule (which is currently two doses (except for Janssen)), but may be a booster doses six to twelve months after the last dose of the schedule. This is based on generalising the data from duration of immunity studies reviewed in the absence of specific studies in the unregistered vaccines.

Assessment of vaccination status in schedules containing vaccines not registered in Australia

The use of TGA-registered vaccines in Australia to complete vaccine schedules commenced with vaccines not registered in Australia should follow the advice of ATAGI.

ATAGI has considered several issues arising from the Recognition of vaccines not currently registered in Australia including:

- The appropriate advice for people who have received vaccines that are not Recognised (either because TGA has not Recognised them or they are not registered in Australia) and wish to become fully vaccinated to undertake activity in Australia.
- The status of mixed-product schedules where both products are Recognised vaccines (e.g. Sinovac/Comirnaty).

The determination of the vaccination status of a person who has received a Recognised vaccine (e.g. fully vaccinated, partially vaccinated, requiring a booster etc) will follow ATAGI's advice on these matters.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	TGA	1 November 2021

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