Australian Government

Department of Health

TGA to give Australians confidence to get the COVID-19 jab

COVID-19 vaccines will play a major role in fighting the coronavirus pandemic.

Australia's Therapeutic Goods Administration (TGA) is responsible for assessing and approving COVID-19 vaccines for use in Australia. The TGA considers all the benefits and risks of a potential vaccine. The TGA's processes for determining the safety and effectiveness of vaccines are strict, broad – and independent.

But the TGA does not work alone. The TGA works closely with its regulatory counterparts around the world. They collaborate daily, making sure there is a shared knowledge that all can benefit from.

In deciding whether to approve a vaccine, the TGA assesses all of the scientific and clinical information available. This information comes from the vaccine's developer and other available evidence.

We will only approve a vaccine for use if it is safe and effective during and after clinical trials. It is critical the vaccine developer can show the vaccine can be produced in a high quality, consistent and controlled way.

If the TGA approves a vaccine, you can trust that it will work against COVID-19. The vaccine will reduce the number of people who become severely ill or who die from the virus.

Following approval, our role continues. We will continue to closely monitor vaccine safety and assess the quality of every batch in Australia.

As our highest priority, the TGA is conducting a full review of COVID-19 vaccines – but in a shorter time frame than normal.

The approach taken in Australia will make sure people have greater confidence in the vaccines. This will achieve the best possible public health result.

How have we managed to fast track the evaluation process of vaccines without any compromise to our standards? The TGA has been regularly accepting data from developers. We have worked with them to get fast answers to any questions.

We have different teams assessing different parts of the vaccine submissions. We also have increased the number of people working on vaccine regulatory reviews and safety. Our dedicated teams of experts worked through the festive period.

You may have heard the TGA considers thousands of pages of data and information when evaluating a vaccine. What exactly are we looking at?

We look at everything including the effectiveness of vaccines in a laboratory environment. We look at the manufacturing processes. We look at the vials of product that go to doctors' surgeries and hospitals, as well as clinical trial data, and detailed safety information.

The Australian Government expects to start vaccinating high priority Australian groups from mid-to-late February.

Our job at the TGA is to assure Australians these vaccines are safe, effective and have met our strict standards.

By Adjunct Professor John Skerritt, who leads the Therapeutic Goods Administration.