Headline: [WATCH] A dummy’s guide to COVID vaccine approvals

Blurb: South Africa’s medicine regulator is working to approve COVID-19 vaccines quickly, but the process won’t skip any important steps.

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South Africa’s first doses of the Johnson & Johnson COVID vaccine arrived on 16 February 2021.

We’re expecting to receive up to 500 000 jabs from the company. These will be used as part of a research study among healthcare workers.

A further 11-million doses have been secured from the company by the department of health.

But these are for a wider roll-out and will need a different type of approval.

All medications in South Africa have to be approved by the country’s regulatory body, the South African Health Products Regulatory Authority (Sahpra).

Approvals can take anywhere from a week to several months depending on what kind of approval is needed.

Here are the three types of approval:

Emergency: Section 21 authorisation

This tool allows doctors to import medicines that have not been registered for use in the country — but only if there’s enough data to show the drug is safe to use.

Section 21 authorisation is used in cases where other treatment options have failed, or if there are none.

Section 21 is South Africa’s equivalent to emergency use authorisation granted by the Food and Drug Administration in the United States.

The authorisation can be granted for individual patients, or for bulk orders of a medicine when there’s more than one person who needs it.

The AstraZeneca COVID vaccine received Section 21 approval in South Africa.

Johnson & Johnson might submit an application for this type of approval.
The authorisation doesn’t mean the vaccine is registered in the country, just that it can be used in the meantime.

**The quickest: Clinical trial approval**

In order to test an intervention (like a vaccine) as part of a trial, Sahpra needs enough information to see that it’s safe and there needs to be some evidence indicating it can work.

Checking this level of information takes less time than a full review — meaning Sahpra can approve it in a few weeks.

For COVID vaccines this process takes three to four weeks. For non-COVID medicines the approval takes about 90 days.

The first 500 000 Johnson & Johnson jabs that are being used in a trial received this type of approval.

The Johnson & Johnson approval was given within five days — shorter than the three to four weeks normally required.

Because the vaccine had previously been approved for use in a clinical trial.

**The longest: Normal approval**

If Sahpra is the first regulator to review a medicine for approval, registration can take up to two years.

Generic medicines take half as long.

For both branded and generic medicines, the data submitted will go through three teams of Sahpra experts.

1. **Screening team:** To make sure only good quality applications make the cut.
2. **Evaluating team:** A two-person team to make sure there are no more questions for the manufacturer to answer.
3. **Advisory committee:** To review the most complex issues, flagged by the previous team.

Then, Sahpra will make the final decision on whether the medicine gets approved or not.

But during the COVID pandemic Sahpra found a way to do this a bit faster.

First off, all applications relating to COVID-19 jump straight to the front of the queue.
Any submissions for COVID vaccines are dealt with urgently by Sahpra and the body tries to conclude these as soon as possible.

But even on this accelerated timeline, Sahpra doesn't want to skip any steps or let anything unsafe slip through.

So instead, the regulator is using something called a 'reliance mechanism'.

This means that Sahpra can use review documents from other trusted regulatory bodies to shorten its own approval time.

But this only works if a vaccine receives approval elsewhere before submitting to South Africa.

In cases where trials are still ongoing or the data has not yet been released, a company can do something called rolling review.

This is where data is continuously submitted for checking by the regulatory body as it becomes available.

The Johnson & Johnson vaccine has applied for rolling review approval.

The review can then be done in stages, with Sahpra checking the safety and efficacy of a vaccine as the trial progresses instead of spending months checking all the data at once.

Once the process is complete, the vaccine will be fully registered for use.

The Johnson & Johnson jab may in the end have three types of approval:
(1) approval for use in a clinical trial
(2) (possible) approval for emergency use (if J&J applies for this while waiting for full approval)
(3) full approval and registration (via a rolling review application)