

Headline:

Shots, symptoms and side effects: How regulators ensure the safety of COVID vaccines

Blurb: Medicines regulators constantly monitor the safety of COVID-19 vaccines by tracking reactions among people who have gotten the jab. Each case is investigated to see if the symptoms are caused by the vaccine, in which case the response will be listed as a side effect.

Bullets:

- Medicines regulators look out for consumers and constantly monitor the safety of health products.
- Drug companies have to submit regular safety updates on their COVID jabs to regulatory bodies to track reactions among people who have been vaccinated.
- Each case is investigated by the regulator and then only if it is scientifically linked to the vaccine is it called a side effect.

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How do you know if a vaccine or medication is safe?

That's what medicines regulators are there for.

They look out for consumers and vet medicines.

Our regulator is called the South African Health Products Regulatory Authority (Sahpra).

Sahpra constantly monitors the safety of COVID jabs.

The regulator asks drug companies to submit regular safety updates.

These reports track reactions among people who have been vaccinated.

Not all of the reactions are caused by the vaccines themselves — some are due to other factors such as illnesses a person has.

The reactions fall into 3 categories.

1. An adverse event

An adverse event is any type of reaction someone has after taking a medication or getting a vaccine.

This response isn't necessarily caused by the product.

2. An adverse event of special interest

Regulators and manufacturers have a watchlist of possible reactions to look out for.

The list is based on things they've seen after people received jabs that use similar ingredients or the type of technology used to make the shots.

Symptoms of the infection that the vaccine is designed to fight off are also added to the list.

All the potential reactions are called adverse events of special interest because they have to be closely watched.

The symptoms are a guide of what to look out for when monitoring how people are doing after vaccination.

Each case has to be investigated to see if the timing of the reaction was a coincidence or caused by the vaccine.

3. A side effect

If a reaction is scientifically linked to the vaccine then the reaction is listed as a side effect.

Some side effects occur more often than others, which is why the use of medications is carefully monitored and controlled.

Jabs sometimes have serious side effects — but these are extremely rare.

That means they occur in fewer than 1 in 10 000 people.

Very rare side effects are mostly only picked up once registered jabs have been rolled out.

Because they are so rare they only emerge when millions of people have been jabbed.

Sahpra looks out for these reactions to know if there are any new risks people should be aware of.

In summary: An adverse event is not the same thing as a side effect.

It's merely any reaction someone experienced after vaccination and not necessarily caused by the jab.

Only if such an event has been scientifically linked to the shot, it's called a side effect.