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The South African Health Products Regulatory Authority (Sahpra) is assessing whether it is necessary to start rolling out the Pfizer Comirnaty booster shot for those who need it.

The pharmaceutical giant submitted an application to Sahpra on 17 November for testing of the Covid booster shot.

Sahpra said it would now "commence with the assessment of data for the safety and efficacy of the third vaccine dose".

Sahpra chief executive Boitumelo Semete-Makokotlela said the organisation was committed to ensuring medicines met all required standards to ensure safety, efficacy and quality.

Semete-Makokotlela promised to provide details about the assessment outcomes in due course.

Initial data from the phase three clinical trial – conducted with more than 10 000 participants – found the third dose was safe and effective.

Why are booster shots needed?

The World Health Organisation (WHO) said booster shots are needed when immunity or clinical protection has fallen below a rate deemed sufficient.

The aim of a booster shot is to restore vaccine effectiveness.

"Over time, the immunity that you received and achieved as a result of being vaccinated starts to wane, it starts to deteriorate or go down over time," said WHO's Dr Katherine O'Brien.

She said there was a small proportion of people who don't respond to the vaccine, in the same way as a person without an immunocompromised condition.

J&J third dose

Last month, Sahpra and Johnson & Johnson (J&J) approved vaccine booster doses for all healthcare workers who received the first shot as part of the Sisonke study.

This was after the FDA recommended a second dose of the J&J vaccine for all Americans 18 years and older who received a single dose.

This year, the South African Medical Research Council, working with the department of health, Desmond Tutu Health Foundation, Caprisa and the pharmaceutical company came together to provide early access to J&J vaccines.

Vaccine hesitancy

Sahpra pharmacovigilance manager Mafora Matlala highlighted the need to mitigate vaccine hesitancy in South Africa.

"Covid is riskier; it's safer to take the vaccine," she said.

Monitoring the safety of Covid-19 vaccines – and additional booster shot data – is a critical priority for Sahpra.

– Additional reporting by SAnews.gov.za