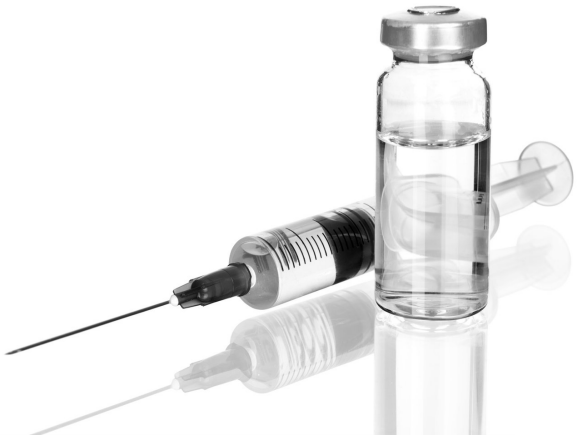
BioSpectrum the business of Bio & Health Sciences ASIA EDITION

NZ seeks additional Janssen COVID-19 vaccine data

19 April 2021 | News

The pause of the rollout in the US and Europe has also been discussed with Janssen



New Zealand's medicines regulator, Medsafe has requested additional information from Janssen, ahead of making a decision about whether to approve the pharmaceutical company's COVID-19 vaccine.

After receiving information from the US Food and Drug Administration (FDA) related to cases of blood clots reported in the US, Medsafe has issued a number of additional requests for data from Janssen. The pause of the rollout in the US and Europe has also been discussed with Janssen.

Medsafe group manager Chris James says Medsafe expects to provide an update on the Janssen approval process in the next two to three weeks.

'This will allow us time to investigate the data we receive so that when we do make a decision, we can reassure the New Zealand (NZ) public about the safety and efficacy of the vaccine.

'We continue to receive information from our regulatory colleagues, which includes the FDA in the US and Therapeutic Goods Administration in Australia, who are also assessing the Janssen vaccine.

'Medsafe has a robust system in place for evaluating the safety and quality of medicines and vaccines for use in New Zealand, and will continue to make decisions based on the most up to date information,' says Chris James.