

MEDIA RELEASE

Update on COVID-19 vaccines

Embargo: Immediate release

Pretoria, 26 October 2023 – The South African Health Products Regulatory Authority (SAHPRA) currently has four (4) COVID-19 vaccines which are under review, the COMIRNATY Bivalent paediatric and adult vaccines, mRNA (COMIRNATY Bivalent Infant DTU vaccine), and non-mRNA vaccine Coviccine.

SAHPRA has so far registered three (3) mRNA vaccines: COMIRNATY, Pfizer COVID -19 Adult RTU, and Pfizer COVID- 19 Paediatric DTU.

SAHPRA has to date registered eight (8) COVID-19 vaccines namely, Covovax COVID-19 vaccine, COVID-19 vaccine (BBIBP-CortV-Vaccine) MC Pharma, COVID-19 vaccine (vero-cell) inactivated LHC Pharma, Comirnaty vaccine, Pfizer /BNT COVID -19 Vaccine Paedatric DTU, Pfizer /BNT COVID-19 Vaccine Adult RTU, COVID-19 Vaccine Janssen, and Coronavac.

"We continue to review the registration of these vaccines as SAHPRA plays its role in the fight against COVID-19. SAHPRA will continue to play its part in ensuring the quality, safety and efficacy of all health products, including all vaccines to ensure that the South African public is protected at all times," indicates SAHPRA CEO, Dr Boitumelo Semete-Makokotlela.

Please note: Vaccines are registered in terms of Section 15 of the Medicines and Related Substance Act (Act 101 of 1965 as amended), with conditions. This means that these products are not under Emergency Use Authorisation but have a full registration.

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About SAHPRA:

SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and

registering) all health products. This includes clinical trials, complementary medicines,

medical devices and in-vitro diagnostics (IVDs). Furthermore, SAHPRA has the added

responsibility of overseeing radiation control in South Africa. SAHPRA's mandate is outlined

in the Medicines and Related Substances Act (Act No 101 of 1965 as amended) as well as the

Hazardous Substances Act (Act No 15 of 1973).

SAHPRA has three pillars to ensure that medicines, medical devices and IVDs meet the

requisite standards to protect the health and well-being of all who reside in South Africa:

Safety

Efficacy

Quality

It is these three pillars that define the ethos of SAHPRA.

Notes to Editors:

SAHPRA will post this media release on our website. Navigate to the News section on the website.

A podcast will be recorded and posted on the home page. Scroll don the home page to "SAHPRA TV and Podcasts". Podcasts appear on the right-hand side.

Should you request an interview for television, please send your request to media@sahpra.org.za and copy yuveng@sahpra.org.za. Include your discussion points in your request.

Updates on vaccine registration can be accessed here:

Vaccines - News and updates (sahpra.org.za) - https://www.sahpra.org.za/news-and-

updates/vaccines-news-and-updates/