MEDIA RELEASE

SAHPRA receives Accolade from the World Health Organisation (WHO)

Embargo: Immediate release

Pretoria, 5 October 2022 –The South African Health Products Regulatory Authority (SAHPRA) has recently been ranked by the World Health Organisation (WHO) at a functional level of maturity (Level 3) according to WHO's global classification system for national medical products regulatory authorities. This means that SAHPRA has a stable, well-functioning and integrated regulatory system to ensure the quality, safety, and efficacy of vaccines that are registered by SAHPRA.

WHO confirmed SAHPRA's attainment of maturity level three (ML3) for vaccine regulation — the third of four levels in the WHO's classification. Maturity level four (ML4) is the highest. As a fairly new instituted independent regulatory authority, this is indeed a noteworthy accolade for SAHPRA.

SAHPRA and the National Control lab must be commended for reaching ML4 for the Lot Release function. This function is critical in ensuring that the vaccines made available in the country meet the highest quality requirements. ML4 represents a regulatory function that is advanced, well-functioning and is continuously improving. To put in context, this status compares to that of the US and Singapore as examples.

"We commend the tireless efforts of SAHPRA staff members and stakeholders in ensuring the integrity and rigour of the health products registration processes. This achievement is testament to the role the regulator has played in ensuring that vaccines that are safe, efficacious and of a high quality are available in South Africa. SAHPRA will continue to be an agile and responsive African health products regulator, whilst working towards the aim of being a globally recognised regulator and an enabler of access to safe, effective and quality health products," indicates SAHPRA CEO, Dr Boitumelo Semete-Makokotlela.

Issued by:

Dr Boitumelo Semete

CEO

Boitumelo.semete@sahpra.org.za

For further enquiries /information contact:

Media contact:

Mr Yuven Gounden

Cell: 066 1202 669

E-mail: yuveng@sahpra.org.za

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.