MEDIA RELEASE

SAHPRA Earns a Regulatory Accolade of Note

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Pretoria, 25 August 2023 – The South African Health Products Regulatory Authority (SAHPRA) has been designated as a Regional Centre of Regulatory Excellence (RCORE) for Vaccines Regulatory Oversight for a period of four (4) years in the following functions:

- Overarching Regulatory Systems
- Marketing Authorisation and Registration
- Vigilance
- Market Surveillance and Control
- Licensing of Premises
- Regulatory Inspections
- Laboratory Access and Testing
- Clinical Trials
- Lot Release

The rationale behind the African Union Development Agency, New Partnership for Africa's Development (AUDA-NEPAD) designating RCOREs is to support continent-wide regulatory systems strengthening through leveraging capacity in better resourced regulators. The reality of medicine regulatory capacity limitation on the continent continues to hinder access to essential medicines as well as limit progress in regulatory harmonisation efforts. The intention is to address this regulatory gap and ensure the acceleration and strengthening of regional medicines regulatory harmonisation initiatives. RCOREs are required to support regulatory workforce strengthening through training in

regulatory functions and enhance skills through hands-on training and exchange programmes amongst National Medicines Regulatory Authorities.

About RCOREs

The Regional Centres of Regulatory Excellence (RCOREs) is an initiative of the AUDA- NEPAD. As part of its mandate to strengthen regulatory capacity development in Africa, AUDA-NEPAD through its AMRH programme has designated 11 RCOREs in eight different regulatory functions which include:

1. Pharmacovigilance
2. Training in core regulatory functions
3. Quality assurance and quality control of medicines
4. Medicine registration and evaluation, quality assurance/quality control and clinical trials oversight
5. Licensing of the manufacture, import, export, distribution and inspection and surveillance of manufacturers, importers, wholesalers and dispensers of medicine
6. Clinical trials oversight
7. Registration and evaluation and clinical trials oversight
8. Medicine evaluation and registration

Read here for more information on the regulatory functions of RCOREs.

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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.