The South African Health Products Regulatory Authority (SAHPRA), is the National Medicines Regulatory Authority established in terms of the *Medicines and Related Substances Act, 1965, (Act No. 101 of 1965) as amended*, to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, clinical trials and medical devices, and related matters in the public interest.

This procurement will be managed by Supporting Health Initiatives (SHI), a Division of Wits Health Consortium Pty Ltd (WHC) for and on behalf of SAHPRA. SHI is dedicated to promoting and enabling public health activities that lead to new, significant advancements in healthcare and related fields and does this by providing resources, collaborative opportunities and project management support to partners and funders. SHI has developed a strong track record of delivering on assignments in Africa. SHI's operations and business teams have demonstrated capacity to quickly align with partners, distribute funds, and oversee implementation.

Specialist:	Specialist Pharmacovigilance
Contract: Ending	31 December 2026, with possible extension based on performance.
Location:	Pretoria, South Africa (Hybrid)
Reference:	SAHPRA 034/2024
Remuneration:	Competitive, depending on experience.

Why Join Us?

This role offers a unique opportunity for international subject matter experts to collaborate with SAHPRA in a hybrid working environment, contributing to pharmacovigilance excellence in South Africa and globally. As a specialist, you will play a critical role in advancing safety standards for health products, driving strategic initiatives, and shaping global best practices

Key Responsibilities include but are not limited to:

- Strategic Leadership: Provide technical leadership on pharmacovigilance (PV) strategies informed by local and international reports, interventions, and guidelines from the WHO and other National Regulatory Authorities (NRAs).
- Regulatory Decision-Making: Make or recommend regulatory decisions on vaccines and biological products based on comprehensive reviews and assessments.
- Signal Detection and Investigation: Conduct signal detection, investigate adverse events, and analyse safety data from diverse sources to support informed decision-making.
- Capacity Building: Lead training and development initiatives to enhance pharmacovigilance expertise among SAHPRA staff and stakeholders.
- Global Collaboration: Represent SAHPRA in international forums and collaborate with global regulatory bodies to advance pharmacovigilance frameworks and practices.

Performance Expectation include but are not limited to:

- Foster a culture of pharmacovigilance awareness within the organization.
- Create and maintain effective pharmacovigilance systems and processes that ensure the timely detection, assessment, understanding, and prevention of adverse drug reactions .
- Timely submission of required safety reports to regulatory authorities and other relevant stakeholders.
- Develop and deliver training programs that enhance the knowledge and skills of staff, fostering a culture of pharmacovigilance excellence.

- Utilize advanced signal detection methodologies to proactively identify emerging safety issues.
- Contribute to a robust peer review process that identifies potential safety and efficacy concerns in a timely manner.
- Consistently deliver high-quality, evidence-based clinical assessments that meet deadlines and contribute to well-informed regulatory decisions.
- Collaborate effectively with multidisciplinary teams on PV-related projects.
- Strong analytical and communication skills to interpret safety data and communicate complex information effectively.
- Lead and mentor teams in a dynamic regulatory environment.
- Manage multiple priorities and deadlines efficiently with strong organizational skills.
- Proactively identify areas for improvement within SAHPRA's PV system.
- Conduct thorough reviews and assessments of vaccines and biological products.
- Make informed regulatory decisions on these products based on safety data analysis.
- Provide sound recommendations to support the decision-making process.
- Adhere to South African data protection laws and SAHPRA's specific data protection policies

Application Criteria:

Qualifications and Expertise

- Essential:
    - MBChB degree with a Master's in Public Health or Clinical Pharmacology (NQF) Level 09) as evaluated by South African Qualifications Authority (SAQA), with
    - Registration with the professional bodies.
    - At least 10 years of experience in public health programs or clinical research.
    - Active participation in regional or international regulatory associations or advisory bodies

- Preferred:
    - A PhD in public health or pharmacology.
    - Experience in hybrid or remote collaborative work environments

Core Competencies

- Comprehensive knowledge of pharmacovigilance legislation, regulations, and global standards.
- Advanced analytical and communication skills to address complex safety issues innovatively.
- Ability to mentor and lead multidisciplinary teams in dynamic regulatory environments.
- Strong organizational skills and the ability to manage multiple priorities effectively.

What We Offer

- **Hybrid Working Model:** Flexibility to work remotely with periodic travel to South Africa, supported by cutting-edge digital tools.
- **Global Impact:** Collaborate on projects that advance pharmacovigilance standards and public health globally.
- **Professional Growth:** Engage with leading experts in pharmacovigilance and regulatory science.
- **Collaborative Environment:** Be part of a diverse, innovative team committed to improving health outcomes worldwide.

Application Process

Submit your application via email to SHIproposals@supportinghi.co.za, by c.o.b 17 January 2025.

Applications must include:

- A detailed cover letter and curriculum vitae.
- Certified copies of qualifications, including professional registrations.
- A copy of a valid driver's license.

Please note: Applications must clearly state the position and reference number. Late or incomplete submissions will not be considered.

Diversity and Inclusion: SAHPRA is an equal opportunity employer committed to fostering diversity in its workforce. Candidates from underrepresented groups and individuals with disabilities are encouraged to apply.

For inquiries: contact Ms. **Bafedile Rakgotho** at Bafedile.Rakgotho@sahpra.org.za (Note: Applications sent to this email will not be processed).

Only shortlisted candidates will be contacted.