REQUEST FOR BID SERVICES

BID DETAILS

BID NUMBER: **SAHPRA/2026/PHARMACOVIGILANCE DIGITIZATION SOLUTION/RFB006**

CLOSE **Date:** **31 MARCH 2026**
Time: **11:00**

DESCRIPTION: **REQUEST FOR BID FOR PHARMACOVIGILANCE DIGITIZATION SOLUTION, INCLUDING MAINTENANCE AND SUPPORT FOR A PERIOD OF 36 MONTHS WITH AN OPTION TO RENEW FOR ADDITIONAL 24 MONTHS**

BRIEFING SESSION: Yes [X] No [ ]
See Section A-1 Paragraph 2 on Bid Submission Conditions and Instructions that the Bidder needs to take note of.

DETAILS OF BIDDER

Organisation/individual: .....

Contact person: .....

Telephone/ Cell number: .....

E-mail address: .....

GLOSSARY

Award	Conclusion of the procurement process and final notification to the effect to the successful bidder
B-BBEE	Broad-based Black Economic Empowerment in terms of the Broad-based Black Economic Empowerment Act, 2003 (Act No. 53 of 2003) and the Codes of Good Practice issued thereunder by the Department of Trade and Industry
Bid	Written offer in a prescribed or stipulated form in response to an invitation by SAHPRA for the provision of goods, works or services
Contractor	Organisation with whom SAHPRA will conclude a contract and potential service level agreement subsequent to the final award of the contract based on this Request for Bid
Core Team	The core team are those members who fill the non-administrative positions against which the experience will be measured.
DTI	Department of Trade and Industry
EME	Exempted Micro Enterprise in terms of the Codes of Good Practice
GCC	General Conditions of Contract
IP	Intellectual Property
SAHPRA	South African Health Products Regulatory Authority
Original Bid	Original document signed in ink, or Copy of original document signed in ink, or Submitted Facsimile of original document signed in ink
Originally certified	To comply with the principle of originally certified, a document must be both stamped and signed in original ink by a commissioner of oaths.
SCM	Supply Chain Management
SLA	Service Level Agreement

DOCUMENTS IN THIS BID DOCUMENT PACK

Bidders are to ensure that they have received all pages (53) of this document, which consist of the following sections:

SECTION A

Note: Documents in this section are for information to/instruction of bidders and must be returned with bids.

- ❒ Section A 1: Bid Submission Conditions and Instructions
- ❒ Section A 2: Specifications and Requirements
- ❒ Section A 3: Evaluation Process/Criteria
- ❒ Section A 4: Contract Form (Rendering of Services) (Parts 1 & 2)/Letter of Acceptance/Formal Contract
  (The pro forma contract is only included for Bidders to take note of the contents of the contract that will be entered into with the successful contractor)

SECTION B

Note: Documents in this section must be completed and returned or supplied with bids.

- ❒ Section B 1: Special Conditions of Bid and Contract: Special conditions that the Bidder needs to accept
- ❒ Section B 2: Declaration of Interest (SBD 4)
- ❒ Section B 3: Preference Points Claim Form in terms of the Preferential Procurement Regulations, 2022 (SBD 6.1)
- ❒ Section B 4: Invitation to Bid (SBD 1)
- ❒ Section B 5: Pricing Schedule (Goods and Services) (SBD 3.1)

SECTION A

(This section must be returned as part of the bid document)

BID SUBMISSION CONDITIONS AND INSTRUCTIONS

CONDITIONS AND INSTRUCTIONS THAT BIDDERS NEED TO TAKE NOTE OF

1 FRAUD AND CORRUPTION

1.1 All providers are to take note of the implications of contravening the Prevention and Combating of Corrupt Activities Act, Act No 12 of 2004 and any other Act applicable.

2 BRIEFING SESSION

A non- compulsory virtual briefing session will be from 11h00- 12h00 on Thursday, 12 March 2026- Microsoft teams link below: -
https://teams.microsoft.com/meet/35227190612405?p=jrwIIiMN8UW37UdNXL
Meeting ID: 352 271 906 124 05
Passcode: BL9dB2Nr

3 CLARIFICATIONS/ QUERIES

3.1 Any clarification required by a bidder regarding the meaning or interpretation of the Terms of Reference, or any other aspect concerning the bid, is to be requested in writing (e-mail) from precious.mnguni@sahpra.org.za by not later than **Monday, 16 March 2026**. Telephonic requests for clarification will not be accepted. The questions and answers will be uploaded on SAHPRA website on **Friday, 20 March 2026.** The bid number should be mentioned in all correspondence.

Contact details for Precious Mnguni
E-mail- precious.mnguni@sahpra.org.za

4 SUBMITTING BIDS

4.1 **<u>One (1) original document plus two (2) copies and one (01) USB must be handed in/ delivered to:</u>**

Loftus Park, Building A,
402 Kirkness St
Arcadia
Pretoria
0083

No posted, faxed or e-mailed bids will be accepted

Bidders should ensure that bids are delivered before the closing date and time to the correct physical address mentioned above. If the bid is late, it will not be accepted for consideration.
*** Refer to Paragraph 5 below**

1. Bids can only be delivered and deposited into the tender box or handed in at second floor any time during office hours (**08:30 to 16:00 Mondays to Fridays**) before or on the closing date. *Receipt of bid documents outside of these hours cannot be guaranteed.*

2. Bids submitted or handed in at any other address than the one stated above will not be considered.

4.1 Bids should be submitted in a sealed envelope, marked with:

- ❒ BID NUMBER **(SAHPRA/2026/PHARMACOVIGILANCE DIGITIZATION SOLUTION/RFB006)**
- ❒ Closing date and time (31 MARCH 2026 @ 11:00 am)
- ❒ The name and address of the Bidder.

4.2 Documents submitted on time by bidders shall not be returned.

5 LATE BID SUBMISSIONS

5.1 Bids received late shall not be considered. A bid will be considered late if it arrived even one second after 11:00 am or any time thereafter. The tender (bid) box shall be closed at exactly 11:00 am of the closing date and bids arriving late will not be considered under any circumstances. Bids received late shall be returned unopened to the bidder. Bidders are therefore strongly advised to ensure that bids be despatched at such a time that will accommodate of any unforeseen events that may delay the delivery of the bid.

5.1 The official Telkom time, which can be observed by dialling 1026 from any phone, will be used to verify the exact closing time.

6. BID VALIDITY

The bid is valid for ninety (90) days from closing date.

7. GENERAL CONDITIONS OF CONTRACT

The General Conditions of Contract must be accepted. The GCC can be downloaded from the Treasury Website. Please refer to the link below:

http://www.treasury.gov.za/divisions/ocpo/sc/GeneralConditions/General%20Conditions%20of%20Contract.pdf

1. INTRODUCTION

The South African Health Products Regulatory Authority (SAHPRA / The Authority) is the regulatory authority responsible for the regulation of health products intended for human and animal use, the conduct of clinical trials, as well as the licensing of manufacturers, wholesalers, and distributors of medicines and medical devices, radiation emitting devices, and radioactive nuclides.

The legislative mandates of SAHPRA are derived from the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended (herein after referred to as "the Medicines Act"), and other relevant legislation, regulations, and policies.

In terms of the Medicines Act, the objectives of the Authority are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration, and control of medicines, scheduled substances, clinical trials, medical devices, and radiation emitting devices, and related matters that are in the public's interest.

SAHPRA transitioned into a public entity on 1 February 2018. Previously, the Authority was known as the Medicines Control Council (MCC), a sub-programme of the National Department of Health (NDOH).

SAHPRA charges fees for various services rendered in terms of its mandate. These fees are gazetted, and applicants pay fees prior to submission of application. Payment received are allocated in a clearing account (unallocated) until matched to an application where it's added to the deferred income / income received in advance listing. Revenue is recognised on service rendered.

2. PURPOSE

This proposal outlines the scope, rationale, objectives and a high level-description of the Pharmacovigilance Platform, which forms part of the foundation of the Regulatory Information Management Ecosystem (RIMeS) for the organization and stakeholders. The RIMeS project is part of SAHPRA's IT and Digital Transformation Strategy which was developed specifically to align IT priorities with those of the organization itself. The aim of the different interventions is to accelerate SAHPRA's digital transformation with the resulting improvement in operational efficiencies and service delivery.

2.1 DURATION

The appointed service provider will be required to start immediately after signing the contract and provide the required services for a period of 36 months, with an option to renew for additional 24 months subject to satisfactory annual review of service provider performance.

2.2 SCOPE OF WORK

The scope of work by the bidders is to provide following:

<u>The larger RIMeS project of SAHPRA consist of several components:</u>

- an engagement portal (middleware tool) that manages service requests for various SAHPRA service task e.g. licensing of new establishments, GMP certificate requests, etc.
- third party software tools e.g. a document management system that facilitates the health product application submission administration and evaluation processes – integrated through the Portal (middleware layer)

- A data warehouse and analytics platform that facilitates reporting and analytics for the organisation across the various business processes.

SAHPRA conducted a business process mapping and re-engineering project between 2019 and 2021 to define its modernization priorities and identify existing process bottlenecks and deficiencies. The initiative revealed significant challenges arising from paper-based processes and the lack of an integrated information management and reporting system. Analysis of the business process maps highlighted numerous opportunities where a digital system could introduce automation and intelligence, thereby reducing human intervention and minimizing errors.

THE RATIONALE

SAHPRA must modernize its core business processes, strengthen institutional capacity, and enhance operational efficiency to ensure the continued and effective delivery of its mandate while meeting the expectations of its stakeholders.

Historically, SAHPRA (formerly the Medicines Control Council) has faced significant operational challenges due to the absence of an integrated information management and workflow system, coupled with inefficient, paper-based processes. These limitations contributed to a backlog of over 2,000 applications accumulated over more than two decades, an issue inherited by SAHPRA upon its establishment.

While considerable progress has been made in addressing this backlog, the absence of a fully integrated digital system to support SAHPRA's regulatory functions remains a critical gap. Implementing such a system is essential to sustaining efficiency gains, preventing future backlogs, and enabling SAHPRA to fulfil its regulatory mandate effectively and transparently.

The objective of the RIMeS would be to automate and digitalise multiple core business activities related to the process of registration of all categories of health products – in particular then a Pharmacovigilance platform that will form part of the IMS ecosystem.

THE NEED: A PHARMACOVIGILANCE MODULE as part of the SAHPRA RIMeS

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem. A Pharmacovigilance software database offers alerts for first cases, follow-up cases, and reports submission to fulfill regulatory timeline compliance. Any pharmacovigilance safety database must be deposited up to date with the most advanced regulatory requirements and certified to meet international standards and business requirements. Safety databases expedite the reporting of individual and aggregate safety data to authorities and third parties and provide critical information for detecting safety signals and the ongoing evaluation of the risk-benefit profile of the company's products.

External experts and technical assistance are required for the acquisition of a highly customizable off-the-shelf (COTS) software tool. This tool should include:

- Training of Trainers (ToT) conducted by the software provider;
- Comprehensive user manuals and supporting documentation; and
- Ongoing technical support to ensure successful implementation, customization, and maintenance.

- **Data Collection** - reports are received from health care professionals (HCPs), Patients/End users, Manufacturers, veterinarians and Distributors through a mobile and/or web based application, Holders of Certificate of Registration (HCRs) and user facility such as Primary Health Care centres, Hospitals, Laboratories etc – as part of Public or Private sector treatment sites. Data collection also includes reports arising from: Clinical Trials (CT) and Section 21 (S21) health products authorized through section 21 .
- **Streamlined Case Management, Data Processing with Risk Assessment**– integrated with Medsafety reporting App plus allowing for automated allocation of cases, and interactive case management between SAHPRA team and health care workers.
- **Signal Detection** – with source data from Health Product Safety Event Reporting tool, VigiBase, Clinical Trials and SAHPRA Engagement portal submission
- **Enable Integrated Signal Management** – to track and resolve safety signals from any data source with audit-ready and intuitive tools including automated ASPR communication.
- **Enable Advanced Data Analytics** – to uncover patterns, correlations, trends, patient preferences (where applicable) and additional insight to help the organization make informed decisions.
- **Public Access and Transparency** – allowing the organisation to publish data/information around certain safety information and recalls to be accessed by other NRAs and members of the public.
- **Regional Decentralisation** - Enable the system to segregate data and control access based on the region in which an ICSR is submitted.
- **Vigilance Related Activities – The proposed system should allow for submission, assessment and tracking of the following Pharmacovigilance documents: -**

1. Regulatory actions –
   - Professional Information / Patient Information Letter (PI/PIL), Dear Healthcare Professional Letter (DHCPL),
   - Risk-management plans request & review
   - Request and submission of scientific comments
   - Periodic Safety Update Reports / Periodic Benefit Risk Assessment Report submission, request & review
2. Pharmacovigilance inspection resolution letter in terms of Good Clinical Practice (GCP) inspection – resolution letter (summary of key findings)
3. Pharmacovigilance System Master File
4. Qualified Person Responsible for Pharmacovigilance (QPPV) information

Functional Requirements

1) Data Collection

a) *Data collection*:
   i) Obtain case reports from various sources, including healthcare professionals, patients, clinical trials, literature, and spontaneous reporting systems. This should include veterinary and medical device specific reporting sources such as: Veterinarians, academia and research institutions, end users and licence holders)
   ii) The system shall allow users to enter, store, and retrieve adverse event reports in a structured format.

b) *Data Entry and Receipt*:
   i) Users should be able to upload case reports manually or import data from external sources (*e.g., E2B R3 files for orthodox and biological products, FDA3500A forms and IMDRF prescript information for Medical Devices and IVDs, VEDDRA and Eudravigilance prescripts*

for data collection on veterinary medicines, TGA "Blue Card" prescript/information for Complementary Medicines, and various structured XML files as relate to the product category -- TBC).

ii) The system shall support the management of case information, including patient demographics, medical history, drug or device exposure details, and adverse event descriptions and tests and laboratory test results.
Ensure accurate and consistent data entry to maintain data integrity – where relevant force-controlled vocabulary – IDMP compliant data standard, IMDRF/ UDI, VEDDRA clinical terminologies.

c) Enable two-way communication between the system and users through:
- Acknowledgments of reports submissions
- Alerts based on predefined conditions or attributes (e.g., status changes, critical updates)
- Reminders for upcoming deadlines, follow-ups, or required actions
- Provide reporters with secure access to retrieve copies of previously submitted reports, including the ability to view submission history and download or print reports

d) The system shall allow users to submit follow-up reports that are linked to previously submitted ICRS entries. This includes:

- Selecting a prior ICRS submission as the reference case
- Providing updated information, new developments, or additional documentation
- Maintaining a clear relationship between the original report and all associated follow-ups for traceability
- Displaying a timeline or history of all related submissions for each case

e) The system shall provide the ability to validate ICRS (Individual Case Safety Report) submissions before final submission. This includes:

- Automated validation of required fields, data formats, and logical consistency (e.g., date fields, category selections)
- Real-time error messages or prompts to guide the user in correcting incomplete or incorrect entries
- Summary review screen allowing the user to confirm all entered data before final submission
- Optional validation against business rules or workflows, such as duplicate case detection or compliance checks

f) Enable manufacturers and distributors to create, submit, track, and manage Individual Case Safety Reports (ICSRs) within the system to ensure compliance with regulatory reporting requirements including which should include reviewers request additional details or documentation, manufacturers/distributors responding directly through the platform, attaching new evidence or clarifications and follow-up submissions are linked to the original ICSR for full traceability.

g) Automatically detects duplicates using a scoring/search feature (exclude follow ups apply for CT only).

2) Case Management

a) *Case Triage*:
   i) System should prioritize incoming case reports based on predefined factors such as seriousness of the adverse event, potential impact on patient safety, and regulatory reporting requirements. Assign appropriate urgency levels to ensure timely evaluation and response to high-priority cases.

b) *Data Quality Review*:
   i) Check information fields and identify missing/inconsistent data and automatically send communication back to the reporter to request updated information.
   ii) Allow Operator to further verify the accuracy and completeness of information and resolve any discrepancies or issues before further processing.
   iii) Automatically detects duplicates using a scoring/search feature

c) *Case Assessment*:
   i) Allow operator to evaluate each case report to determine its clinical significance and potential causality with the implicated drug or medical product. Assess the seriousness, expectedness, and causality of adverse events using established criteria and guidelines (potential to automate this through AI)
   ii) Users should have the ability to search and filter case reports based on various criteria (e.g., date range, drug name, dosage form, species, breed, disciplines, adverse event type, province/ district name, name of capturer or MRO the report is assigned to, company name, SAHPRA allocated number in case of Clinical trials, received from (healthcare professional/ companies/ consumers).
   iii) Should allow for Follow Up Management
   iv) The system shall support both automatic and manual allocation of ICRS (Incident Case Reporting System) cases, with full end-to-end tracking through a workflow management system. This includes:
      1. Case Allocation
         - Automatic allocation based on predefined rules (e.g., case type, seriousness criteria (fatal, life-threatening hospitalisation, incapacitating), region, workload balancing)
         - Manual allocation by authorized personnel with the ability to assign or reassign cases
      2. Workflow Management
         - Track each case through its entire lifecycle: submission, review, action, closure, and submission to VigiBase (medicines and vaccines).
         - Visual workflow or status indicators showing current stage and responsible party
         - Timestamped activity logs for auditability and accountability
      3. Notifications & Escalations
         - Automated alerts for pending actions, overdue cases, or escalations
         - Role-based visibility and permissions throughout the workflow

3) Artificial Intelligence (AI)

a) AI-based Case Coding:

i) The system shall integrate an AI tool for automated case coding, which assigns standardized medical terms (MedDRA and WHO Drug Dictionary, VEDDRA,) to reported adverse events. Utilize coding dictionaries and tools to facilitate accurate and consistent coding.

ii) Users should have the option to review and validate AI-generated codes before finalization.

b) Narrative Writing:

i) Using Natural Language Processing (NLP) and ML techniques/models to assist with the compilation of detailed narratives summarizing the clinical course and context of each adverse event report.

ii) Should include relevant information such as medical history, concomitant medications, treatment interventions/ laboratory tests results, and outcomes to provide context for subsequent analysis and review.

*c) AI Translation *:*

i) Provide AI translation for narrative transformation between languages

d) AI Trend Analysis – analyse large datasets from clinical reports, social media, and medical literature to detect emerging trends in ADRs earlier than traditional methods.

e) AI Image Interpretation for:

- Image Preprocessing: Clean and enhance scanned images for clarity.
- Feature Extraction: Use Computer Vision to detect relevant clinical signs (e.g., lesion size, ECG abnormalities).
- Automated Classification: Classify image content (normal vs. abnormal) or quantify severity.
- Integration: Extracted image insights are linked to the patient case report.

f) Use AI-powered Natural Language Processing (NLP) and Machine Learning (ML) models to automate and standardize causality assessment.

g) Reading Submitted Electronic Documents to:

- Document Parsing: Use Optical Character Recognition (OCR) for scanned documents and NLP for digital texts.
- Information Extraction: Extract critical fields such as patient demographics, medication details, adverse event descriptions, lab values, and treatment outcomes.
- Data Structuring: Convert unstructured text into structured data fields required for ICRS forms.
- Validation: Cross-check extracted data with submission criteria to ensure completeness and accuracy.

4) **Product Dictionary Management**

The system should include a comprehensive dictionary of health products, including pharmaceutical products, ingredients, substances, and related entities (Admin Routes, Pharm Forms, ATCs, etc.). Key features include:

a) **Product Index**: Maintain a catalog of all possible name variations for medicinal products and devices.

b) **Term-Based Coding**: Allow review of coding for reported drugs, substances, and devices, including misspellings and synonyms.

c) **Substance Management:** Enable searching and managing substances by name, type, preferred name, and other attributes.

d) **Admin Routes and Pharm Forms Management:** Allow users to manage and edit lists of routes of administration and pharmaceutical dosage forms.

e) **Integration with External Dictionaries:** The system should be able to import and update standard terminologies such as the WHO Drug Dictionary, EDQM, medical devices IMDRF / UDI and Veterinary medicines VEDDRA.

5) Event / Incidents Dictionary Management

- Medical Dictionary for Regulatory Activities (MedDRA) - specific standardized medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans. Products covered by the scope of MedDRA include pharmaceuticals, biologics, vaccines and drug-device combination products.
- IMDRF (International medical device regulatory forum)-compliant data structures and terminologies for medical device and IVD reporting, to facilitate sharing of regulatory information internationally for medical devices & IVD used by humans.
  UDI (Unique Device Identification) for device traceability and identification, aligned with IMDRF UDI guidance.

6) Signal Detection

a) The system shall support the application of biostatistical algorithms (e.g., PRR: Proportional Reporting Ratio, ROR: Reporting Odds Ratio & EBGM: Empirical Bayes Geometric Mean (EMEB5?) for largely Orthodox and Biological products and then also other biostatistical algorithms that might apply for Medical Device and IVDs, Complementary medicines and Veterinary medicines) for signal detection.
b) Users should be able to select specific algorithms and customize parameters for signal detection analysis.
c) System should utilize data mining algorithms, disproportionality analyses, and other signal detection techniques to identify emerging risks or patterns of concern.
d) The system shall provide interactive visualization tools to explore and interpret signal detection results.

Signal detection biostatistical methods:

<u>1. Orthodox Medicines (Human Pharmaceuticals)</u>

a. Reporting Odds Ratio (ROR)

- **Definition:** Measures the strength of association between exposure and adverse events, comparing the odds of a particular event occurring in patients using a drug to those not using it.
- **Usage:** Commonly used for disproportionality analysis in signal detection for pharmaceuticals. It compares the number of observed versus expected reports of an adverse event with a drug.

b. Proportional Reporting Ratio (PRR)

- **Definition:** A statistical measure that compares the proportion of a specific adverse event in a particular drug's reports to the proportion of the same event in all other drugs.
- **Usage:** Frequently used in pharmacovigilance systems to identify whether certain adverse events are more frequently reported with specific drugs than with others.

c. Bayesian Confidence Propagation Neural Network (BCPNN)

- **Definition:** A statistical model that combines Bayesian statistics and neural networks to predict adverse event risks by processing complex data.
- **Usage:** Used in large datasets to identify significant signals, with more flexibility in estimating rare events.

d. Empirical Bayes Geometric Mean (EBGM)

- **Definition:** A method that computes the geometric mean of the reporting ratios, adjusting for variability in reporting rates. It is especially used to detect disproportionate reporting.
- **Usage:** Used in large pharmacovigilance datasets, particularly in spontaneous reporting systems, to quantify signal strength.

e. Meta-Analysis Methods

- **Definition:** A statistical technique for combining the results of different studies to assess the overall risk.
- **Usage:** Applied to clinical trial data and observational studies to detect and confirm safety signals.

f. The "Chi-Square Test" or Fisher's Exact Test

- **Definition:** Used to test the association between categorical variables (such as drug exposure and adverse event occurrence).
- **Usage:** Can be used for smaller datasets or rare adverse events in spontaneous reporting systems.

g. Data Mining Techniques

- **Definition:** Algorithms such as tree-based methods, clustering, and association rule mining that analyze large datasets to identify patterns indicative of potential signals.
- **Usage:** Applied in both clinical trial databases and spontaneous reporting systems.

2. Medical Devices

a. Proportional Reporting Ratio (PRR)

- **Definition:** Same as for human medicines, used for medical devices to compare the frequency of adverse events in devices vs. all other medical devices.
- **Usage:** Frequently used in regulatory systems for post-market surveillance of medical devices to detect disproportionate reporting.

b. Bayesian Methods

- **Definition:** A set of statistical techniques that allow for updating the probability of a signal as new data comes in, based on prior knowledge.
- **Usage:** Used in medical device surveillance to handle sparse data and improve signal detection over time.

c. Surveillance Methods (Cox Proportional Hazards Model)

- **Definition:** A statistical model used to identify the relationship between the occurrence of adverse events and device characteristics over time.
- **Usage:** Used for cohort-based studies in device surveillance, particularly useful in clinical trials.

d. Cumulative Incidence Curves

- **Definition:** A method for estimating the probability of an adverse event over time.
- **Usage:** Used in monitoring the long-term safety of medical devices.

e. Relative Reporting Rate (RRR)

- **Definition:** Measures the proportion of adverse events relative to the total number of device incidents.
- **Usage:** Helps in assessing whether specific adverse events are over-represented for medical devices.

3. Veterinary Products (Veterinary Pharmaceuticals, Biologicals & Devices)

a. Empirical Bayes Geometric Mean (EBGM)

- **Definition:** Similar to its use in human medicines, EBGM is used in veterinary pharmacovigilance to identify disproportionate adverse event reporting.
- **Usage:** Particularly useful for veterinary products, given the unique nature of reporting systems and the types of adverse events reported.

b. Reporting Odds Ratio (ROR)

- **Definition:** As in human pharmaceuticals, ROR is used in veterinary pharmacovigilance to measure the association between a veterinary product and reported adverse events.
- **Usage:** Commonly applied in signal detection in animal drug safety data.

c. Proportional Reporting Ratio (PRR)

- **Definition:** Used to identify adverse events that occur more frequently with a specific veterinary product.
- **Usage:** Similar to its use in human medicines, applied to the veterinary domain to identify disproportionality in reporting.

d. Surveillance Systems

- **Definition:** Models that track and analyze adverse events over time using time-series analysis or survival models.
- **Usage:** Used in veterinary pharmacovigilance to monitor long-term safety and performance of veterinary medicines or devices.

e. Dose-Response Modeling

- **Definition:** This method involves assessing the relationship between the dose of the veterinary product and the occurrence of adverse events.
- **Usage:** Primarily used in clinical trials for veterinary products, it helps to identify adverse events related to dosage.

4. General Statistical Approaches for Signal Detection (Across All Product Types)

a. Disproportionality Analysis

- **Definition:** Analyzes whether the occurrence of a particular adverse event is significantly higher in a specific product or device compared to other products.
- **Usage:** Commonly applied across all types of products, including medicines, medical devices, and veterinary products.

b. Kaplan-Meier Survival Analysis

- **Definition:** A method for estimating the time to the occurrence of an adverse event or failure.
- **Usage:** Used in clinical trials for both human and veterinary medicines as well as medical devices to monitor the time to adverse events.

c. Logistic Regression

- **Definition:** A statistical technique for modeling the relationship between one or more independent variables (e.g., exposure to a drug or device) and a binary outcome (e.g., presence or absence of an adverse event).
- **Usage:** Can be applied across product types to model adverse event risks.

The statistical methods used in signal detection differ slightly across orthodox medicines, medical devices, and veterinary products. Methods like ROR, PRR, IC and EBGM are commonly used for all three categories, but the specific context, regulatory requirements, and reporting systems shape how these methods are applied. Signal detection in medical

devices may also incorporate survival analysis, while veterinary products often make use of specialized methods for managing unique data types, including dose-response modeling.

7) Aggregate Reporting & Dashboards

The system must be capable of generating various aggregate reports and dashboards for analyzing ICSR and device incident data. Key functionalities include:

- **Configurable Queries**: Allow users to configure query criteria based on various parameters including product, event, and patient attributes.
- **Output Formats**: Support extraction of results into various formats such as listings and interactive dashboards.
- **Data Filtering**: Allow users to apply filters and customize data columns on the fly.
- **Templated Reports**: Utilize Word-based templates for formatted outputs (e.g., DSUR, PADER, CIOMS II Line Listing).
- **Document Management**: Provide features to store document outputs and apply electronic signatures
- **Incorporate data from other sources for example** for example, STATS SA data (total population for each province) For veterinary products, data should be incorporate from Animal Health (Act 35/1984).

8) Requirements Intelligence

- The system must be able to manage global and local regulatory requirements, guidelines, and partner obligations. Key functionalities include:
  - **Requirement Logging**: Log and control revisions of regulatory documents, with categorization and implementation tracking.
  - **Rule Management**: Maintain rules for ICSR reporting, device incidents, PV system master file, and periodic safety reports, line listings.
  - **Integration**: Link rules to requirement documents and allow for data transfer to and from other systems.
  - **Impact Assessment**: Assess the impact of new or changed requirements and manage necessary actions.

9) Vigilance Related Activities – The proposed system should allow for submission, assessment and tracking of the following Pharmacovigilance documents: -

9.1. Professional Information / Patient Information Letter (PI/PIL), Dear Healthcare Professional Letter (DHCPL),
9.2. Risk-management plans request & review
9.3 Request and submission of scientific comments
9.4 Periodic Safety Update Reports / Periodic Benefit Risk Assessment Report submission, request & review
9.5 Pharmacovigilance inspection resolution letter in terms of Clinical Trials – Good Clinical Practice (GCP) inspection resolution letter (summary of key findings)
9.6 Pharmacovigilance System Master File

- **Main Body and Annex Management**: The system must support managing the Main Body document and various Annexes, including document version control and generating reports.
- **Document Review**: Support review and approval of workflows for PSMF documents**.**
- **PDF and Reports Generation**: Allow conversion of documents to PDF format, including merging of annexes.
- **Data Management: The system must capture data lock points, audit log notes, and generate inspection reports and responsible personnel related to PSMF documents.**
- **Flag outstanding CAPAs that are due for submission from inspected company**
- **Inspection documents/pictures: The system should be able to save requested documents from the company**

9.7 Qualified Person Responsible for Pharmacovigilance (QPPV) information

10) Regional Decentralization

The system must be capable of isolating ICSRs and all related data to:

- Support regional pharmacovigilance (PV) activities effectively.
- Ensure compliance with regional data privacy and regulatory requirements.
- Enable region-specific access controls, allowing only authorized users within a designated region to view, process, or manage relevant ICSRs.

11) Interoperability

a) *Data Standards*
   i) The case reports should follow the E2B (R3) data standard as defined by the European Medicines Agency (EMA), and the relevant FDA3500A/IMDRF format, VICH format and TGA Blue Card format
   ii) XML data integrations with the AMA, NDOH should be provisioned for to allow for cases to be shared with other entities – including data sharing for relevant flagged products to UMC for the VigiFlow data.
   iii) Aligning with the data standards of the African Medicines Agency (AMA) will be taken into account.

b) *Integrations*
   i) The integrations below are not an exhaustive list – but cites at minimum the key items:
      (1) REST-based APIs for integration with VigiMobile and/or Med Safety to allow for events being reported in South-Africa via the Med Safety App to be automatically pulled into the PV module to enable interactive case management.
      (2) Direct integration needed with MedDRA and/or the SNOMED ontology including VEDDRA for veterinary medicines.
      (3) Direct integration needed with the WHO's Drug Dictionary (WHO-DD).
      (4) Integration with AMA
      (5) Integration with NDOH/NHI Patient Care systems.
      (6) Integration with IMDRF
      (7) VigiBase to allow seamless sharing of ICSR data with the WHO Programme for International Drug Monitoring (PIDM)

Sharing of AE reports/data with applicants – HCRs/Applicant facing

Non-Functional Requirements

1) Performance

a) The system shall be capable of handling a large volume of case reports efficiently, with minimal latency in data processing.
b) Response times for data retrieval and analysis tasks should be within acceptable limits, even during peak usage periods.

2) Cloud Hosting

a) The solution should be hosted in a SOC-3 compliant South African based Data Centre or SAHPRA's Cloud environment, to align with POPIA requirements.
b) The hosting provider should be ISO9001 and ISO27001 certified.

3) Security

a) The system shall implement robust data security measures to protect sensitive information in compliance with relevant regulations (e.g., GDPR, HIPAA).
b) User access to different system functionalities and data should be controlled through role-based access controls (RBAC).
c) The system should comply with GxP, audit trail, CFR 21 part 11, and EU Annex 11 requirements.

4) Usability

a) The user interface shall be intuitive and user-friendly, with features such as guided workflows, tooltips, and context-sensitive help.
b) Module based navigation
c) Task management – where user can view and manage tasks associated with different workflows
d) The system shall support multi-language capabilities to accommodate users from diverse linguistic backgrounds.
e) A dedicated data collection interface should be developed used a Progressive Web App (PWA) architecture underpinned by the ability to allow zero-rated data access for health care workers in the public sector.
f) Template Management: The system must allow for the management of document templates, including the use of placeholders
g) System should allow for configurable workflows that can be adapted.
h) Electronic Signatures: The system must support electronic signatures for end-to-end processes.
i) Notifications**:** The system should provide notifications for tasks and deadlines.
j) Audit Trails: The system should maintain detailed audit trails of all activities, including user actions and data changes.
k) Data Validation: The system must have built-in validation rules to ensure data quality
l) Training manuals for internal users should be developed and provides and quick reference/how-to guides for external parties as relevant.
m) Training for SAHPRA Tier 1 and Tier Support person should be provided.

5) Constraints

a) The system development should adhere to regulatory requirements governing pharmacovigilance systems (e.g., ICH and VICH guidelines, IMDRF/FDA regulations, ICH guidelines).
b) The software system should be compatible with common operating systems and web browsers to ensure broad accessibility.

Project Resource Allocation and Costing

Project Background:

1. The proposals should outline the approach, provisional timetable and proposed resource schedule that informs the costing based on the above functional and non-functional requirements.
2. The proposal should allow for data standardisation/normalisation support up to 60 hours per category of Health Products
3. The proposal should detail the Project Milestones and related payment points and should reflect a Modular approach.

The implementation will follow a modular approach, ensuring flexibility, scalability, and phased delivery of functionality across all regulatory domains within SAHPRA's mandate:

A) Base Platform and Functional Requirements

The initial phase will focus on developing and deploying the base digital platform, incorporating core functional requirements (Modules 1 through 6) applicable across the various categories of health products regulated by SAHPRA, including:

1. Orthodox and Biological Medicines
2. Medical Devices and In Vitro Diagnostics (IVDs)
3. Veterinary Medicines
4. Complementary Medicines

This approach enables standardized functionality while allowing customization and optimization for each product category.

NB: The implementation of the Veterinary Medicine functional requirements can be done on a phase-in approach (not on the initial implementation phase) and should be included in the costing.

B) Non-Functional Requirements

All **non-functional requirements** including system performance, security, scalability, interoperability, usability, and compliance with relevant ICT and data protection standards will be incorporated across all modules to ensure a robust and sustainable platform.

C) System Maintenance and Support

Following implementation, the solution will be supported through a 36-month maintenance and support period, providing Tier 3 (vendor-level) support to ensure system stability, performance optimization, updates, and continuous improvement.

 # Note the cost breakdown in this granular way is required to assist in defining the value of each sprint to ascertain funding flows required for the total project OR part of project covering for example only 1 Health Product category or 2 Health Products etc.

Proposed Resources to consider:

Pharmacovigilance Subject Matter Expert

- A Pharmacoepidemiologist/medical doctor/Other expert with in-depth knowledge and expertise in pharmacovigilance, the science of monitoring the safety of medications (for all health products OR specific Product disciplines) AND experience with Pharmacovigilance software tools.

  Responsibilities:

- Provide input into the user requirement for a software tool to assist with the case management, signal detection and communication with rapporteurs and holders of certificate of registration
- Provide workflow processing input from a Regulator's perspective in terms of best practice work procedures with Review and analyse safety data related to the project throughout the development process.
- Assist with development of system guidelines for the different modules – to standardise work practices and be retained as system guidelines.
- Conduct Training with SAHPRA staff

Business Analyst

- Analyses business requirements, completes detailed market research on best practice standards with regards to work practices within Pharmacovigilance units within other Regulators to have a broad and comprehensive understanding of the ways of working and what business practices could be adopted refined within SAHPRA to transitions to more efficient work processing (engagements with other regulatory authorities that SAHPRA have Agreements with could be considered and any other contacts could be used) to also translates business requirements then into a optimal business process and transcribe them into technical specifications for the development team.

  Responsibilities:
  - Elicit and document business needs and requirements.
  - Define the scope and functionality of the project.
  - Create user stories and acceptance criteria.
  - Liaise between stakeholders and the development team.

UX/UI Designer

- Designs the user interface (UI) and user experience (UX) for the project, focusing on usability and user satisfaction.

  Responsibilities:
  - Conduct user research to understand user needs and behaviours.
  - Develop wireframes, prototypes, and mock-ups of the user interface.
  - Ensure the design is intuitive, user-friendly, and aesthetically pleasing.
  - Collaborate with developers to ensure a smooth transition from design to implementation.

Front-end Software Engineer

- Develops the user interface (UI) of the project, focusing on the visual elements and interactivity.

  Responsibilities:
  - Write front-end code using HTML, CSS, and JavaScript frameworks.
  - Implement the UI design specifications created by the UX/UI designer.
  - Ensure the UI is responsive and works across different devices and browsers.
  - Integrate with the back-end developed by the back-end developers.

Back-end Software Engineers

- Develops the server-side logic and functionalities of the project.

  Responsibilities:
  - Design and implement the database structure.
  - Write server-side code to handle data processing and business logic.
  - Ensure the back-end is secure, scalable, and performant.

- Integrate with any necessary external APIs or services.
- AI/ML developers for Case Triage, Data Cleansing, Auto-Coding and Classifications

Data Scientists

- Analyse data to extract insights and inform decision-making.
  - Responsibilities:
  - Develop and implement data analysis models and algorithms.
  - Clean, prepare, and analyse data relevant to the project.
  - Identify trends and patterns in the data.
  - Communicate insights and recommendations to stakeholders.

AI Engineer

- Collaborate with stakeholders to understand the business problem
- Translate the problem into a solvable AI or ML task
- Define success metrics (e.g., accuracy, precision, business KPIs)
- Identify relevant datasets and sources
- Clean, normalize, and prepare data for modelling
- Handle data labelling (manual or automated)
- Work with structured and unstructured data
- Select appropriate algorithms (e.g., regression, neural networks, transformers)
- Evaluate model performance using validation techniques
- Ensure models remain compliant with regulations and ethical standards

Project Manager:

- Leads and oversees the project execution, ensuring it is completed on time, within budget, and meets project goals.
  - Responsibilities:
  - Develop and manage the project plan and schedule.
  - Manage project resources and budget.
  - Track project progress and identify and mitigate risks.
  - Facilitate communication and collaboration among stakeholders.

ALL BIDDERS MUST TAKE NOTE OF THE EVALUATION PROCESS THAT WILL BE FOLLOWED

3. EVALUATION PROCESS

3.1. COMPLIANCE WITH MINIMUM REQUIREMENTS

3.1.1 All bids duly lodged as specified in this Request for Bid will be examined to determine compliance with bid requirements and conditions. Failure to comply with or submit any of the following items may render a bid non-responsive and not be evaluated further.

Reference	Description	Compliant?	
		YES	NO
Part 1	Signed Special Conditions of Bid and Contract		
Part 2	Tax Compliance Requirements		
Part 3	Completed and signed Declaration of Interest (SBD 4)		
Part 5	Completed and signed Invitation to Bid (SBD 1)		

Part 7	Proof of registration on the CSD or MAAA number If there will be subcontracting, proof of CSD registration of the sub-contractor must be submitted		

3.1.2 Failure to comply with or submit pricing schedule (SBD 3.1) will render a bid non-responsive and not be evaluated further.

Reference	Description	Compliant?	
		YES	NO
Part 6	Completed Pricing Schedule in the prescribed format (SBD 3.1)		

3.1.3 Bidders must submit their proposal by the closing date and time. Proposals submitted after the closing date and time will be disqualified from further evaluation.

3.1.4 Hard-copy proposals must be recorded in the tender submission register at SAHPRA reception. Hard-copy proposals not recorded on the tender submission register at SAHPRA reception will be disqualified from further evaluation.

3.2 DETERMINATION OF SCORE FOR FUNCTIONALITY

3.2.1 The evaluation criteria and weights for mandatory, functionality and presentation as indicated in the table below will apply.

Mandatory Requirements	Provide evidence/page No. and/or location	Yes= evaluate further No=Don't evaluate further
PART 1:		
a. The bidder must be an accredited reseller or partner or original developer, accredited by the Original Equipment Manufacturer (OEM) or Original Software Manufacturer (OSM) to supply, maintain, and support the Pharmacovigilance (PV) Software, or provide a signed letter affirming such authorization.		
b. The Bidder must comply with all Product/Service Functional requirements by completing and signing Annex A.		

If the condition above is not met, bidder will be not evaluated further.

Technical Evaluation Criteria	Provide evidence/page no and/or location	Maximum points to be Awarded
PART 2: Bidders Capability and Experience		
1. **Reference letters.**		30

The bidder must have provision a vigilance information system(s) for three (3) customers in the last ten (10) years Provide a letter(s) from Institutions that conduct vigilance regulatory activities to whom the Information system(s) was delivered to this effect. Each letter must be dated, signed and on a letterhead of the customer and indicate: a) The customer Company name and physical address. b) Customer contact person's name, telephone number and email address. c) Project <or Service> scope of work relating to e.g., Individual Case Safety Report (ICSR) management/ processing, signal management etc but non-exhaustive. d) Project start and end date. The Bidder must provide reference details from customers to whom the PV Solution/Software was supplied, maintained and supported in the past ten (10) years from the closing date of this bid. *Evaluation:* 0 point = zero/ one reference letter 15 points = two reference letters 30 points = three or more reference letters		
2. **Experience of the Project Manager:** The recommended project manager CV **detailing the experience and expertise** including the number of years in enterprise software development, deployment, support and maintenance, which is verifiable *Evaluation:* **20 points** = 10 years and above of project experience as the Project Manager in system development, support with Project Management Professional (PMP) Certification, Prince 2 or other methodology would advantageous **10 points** = 5 - <10 years of project experience as the Project Manager in system support **0 point** = 0 - <5 years of project experience as the Project Manager in system support		20
3. **Experience of the Technical Lead.** The recommended technical lead CV **detailing the experience and expertise** including the number of years in enterprise software		20

development, deployment, support and maintenance, which is verifiable *Evaluation:* **20 points** = Over 10 years of experience as a Software Developer, specializing in application development and customization, with extensive expertise in API integration, system enhancement, and artificial intelligence (AI) solutions. **10 points** = 5 - <10 years of software development as the Software Developer in system development/enhancement with extensive expertise in API integration, system enhancement, and artificial intelligence (AI) solutions. **0 point** = 0 - <5 years of software development as the Software Developer in system development/enhancement with extensive expertise in API integration, system enhancement, and artificial intelligence (AI) solutions.		
4. **Experience of the Business Analyst** The recommended business analyst CV **detailing the experience and expertise** including the number of years in enterprise software development, deployment, support and maintenance, which is verifiable *Evaluation:* **10 points** = Over 10 years of experience as a Business Analyst in system development, specializing in conducting stakeholder interviews to gather and analyse business needs, developing process models and visualizations to optimize workflows, and leveraging data analysis tools for research, insights, and problem-solving. **5 points** = 5 - <10 years of business analyst experience as the Business Analyst in system development and/or customization **0 point** = 0 - <5 years of business analyst experience as the Business Analyst in system development and/or customization		10
5. **Project Implementation Plan** The bidder must submit a comprehensive support management methodology and approach, accompanied by a **detailed project implementation plan.** This plan should outline the deployment of resources and demonstrate how the following key milestones will be achieved: • Established processes and governance structures for continuous improvement		20

• Framework and procedures for solution rollout • Demonstrated skills and expertise required to maintain ongoing support and drive continuous enhancements and skills transfer • Provision of technical architecture *Evaluation:* **20 points** = Comprehensive plan outlining all key milestones **10 points** = Proposal not comprehensive, have respond to 50% of key milestones. **0 point** = No project plan, respond less than 50% of key milestones.		
Total		100

Minimum threshold: To be eligible to proceed to the next stage of the evaluation (Demo/ presentation) the bidder must achieve a minimum threshold score of **70 points.**

Technical Proof of Concept (Demonstration) requirements
Technical Proof of Concept (PoC) will be conducted in two phases, as outlined below:

Phase 1: System Demonstration
• Objective:
The purpose of Phase 1 is to allow the bidder to present a technical demonstration of the proposed solution to the Evaluation Committee.

• Scope:
The demonstration should focus on showcasing the core functionality of the system in alignment with the specified requirements outlined in the tender documentation.

• Key Expectations:
- The bidder must demonstrate how the system meets the technical specifications and functional requirements.
- The presentation should highlight key features and capabilities that align with the needs of the end users.
- The bidder must provide a clear user guide or walkthrough, enabling committee members to understand how to navigate and operate the system effectively.
- Demonstrations must be live (not prerecorded), and the system should reflect a realistic, working environment.

Phase 2: System Piloting
• Objective:
The purpose of Phase 2 is to allow the Evaluation Committee to test and evaluate the proposed system in real-world scenario, ensuring that it performs as expected under actual operating conditions.

• Scope:
The pilot will simulate typical use cases and workflows based on organizational needs, giving evaluators an opportunity to interact directly with the system.

• Key Expectations:
- The pilot system must allow Evaluation Committee members to:
  - ✓ Perform core functions independently.
  - ✓ Assess system performance, usability, and reliability.
  - ✓ Technical support must be available from the bidder during the pilot phase to address queries and issues in a timely manner.

System Demonstration and Presentation	
Functions: **Reporter facing - data collection functionalities:** 1. **Online Portal** - Public-facing, user-friendly web interface for reporters, responsive design compatible with mobile and desktop devices and multi-language support (if applicable). 2. **User Registration** - Secure self-registration process with identity verification as needed, capture of relevant user profile information (e.g., role, organization, contact details) and optional approval workflow for account activation. 3. **User authentication and access management -** Role-based authentication (e.g., reporter, reviewer, administrator), support for modern authentication protocols (OAuth2, SAML, MFA) and password management and account recovery features. 4. **Ability to submit online application** - Dynamic, user-guided forms with validation and conditional logic, file upload support for attachments (e.g., documents, images), auto-save, draft, and resume later functionality and unique submission ID and confirmation receipt. 5. **Communication & Notifications** - Automated email/SMS notifications for key actions (e.g., submission confirmation, status updates), In-portal messaging or announcement area and configurable templates and communication rules. 6. **Coding Functionalities** - Integration of coding tools for standardized data entry (e.g., product codes, incident types), Autosuggestion or search-enabled dictionaries for consistent classification and support for international and local coding standards (e.g., MedDRA, ICD, SNOMED, etc.).	**40**

7. **Industry facing and data extraction** **40 points**= All seven functions met **20 points**= Five functions met **0 point**= 0- four functions	
Official facing major functionalities: 1. **Application eligibility checks -** Automated validation of applicant criteria based on predefined rules and policies, Real-time eligibility determination with integration to external databases and registries and audit trails for all decisions. 2. **Allocation process, case management and end to end tracking** - Intelligent allocation of cases/resources based on predefined logic (e.g., priority, region, expertise), full lifecycle case management with status updates, task assignments, and SLA monitoring and end-to-end tracking and traceability of every application or case. 3. **Product and Incident Dictionary Managemen**t - Centralized repository for maintaining standardized definitions, classifications, and codes for products and incidents, version control and approval workflows for updates and support for regulatory taxonomies and coding systems. 4. **Document management** - Secure document upload, storage, versioning, and retrieval with metadata tagging and classification for searchability and Role-based access control and audit logging for compliance. 5. **Signal Detection** - Real-time monitoring and detection of anomalies, trends, or early warning signals using statistical or AI models, Alerts and notifications for predefined thresholds or patterns. 6. I**ntegration Capabilities with Flexibility -** API-driven architecture for interoperability with internal and external systems, support for various integration methods: REST, SOAP, file-based, event-driven, and is scalable and configurable integration framework to adapt to evolving needs. 7. **Artificial Intelligence (AI) -** AI-powered decision support (e.g., application assessment, risk scoring).	**60**

8. **Dashboard and Reporting** - Interactive dashboards for real-time data visualization and monitoring, AI-enhanced analytics for trend identification, forecasting, and KPI tracking and customizable reports for operational, strategic, and regulatory needs. Data extraction **60 points**= All eight functions met **40 points**= Six functions met **0 point**= 0 – five functions	
Total	100

a. The score for functionality shall be calculated as follows:

i. The score of each panel member shall be added together and divided by the number of panel members to establish the average score obtained by each individual bidder for functionality.
ii. The overall minimum technical threshold is **60 points** (functional and presentation). Bidders that do not meet the minimum technical threshold will not be evaluated further for price and specific goals.

b. PRICE AND SPECIFIC GOALS POINTS

i. All remaining bids will be evaluated as follows:

ii. The 80/20 preference point system will be applied. Points for price and specific goals will be awarded in accordance with the stipulations in the Preference Point Claim Form in terms of the Preferential Procurement Regulations, 2022.

iii. If appropriate, implied contract price adjustments will be made to the cost proposals of all remaining bids.

iv. The point scored for the specific goals for each acceptable bid will now be added to the price point.

v. The bid must be awarded to the supplier that obtained the highest preference points or may be awarded to a supplier that did not score the highest points only in accordance with section 2(1)(f) of the PPPFA.

c. ADJUDICATION OF BID

i. The relevant award structure will consider the recommendations and make the final award. The successful bidder will usually be the service provider scoring the highest number of points.

ii. The bid must be awarded to the supplier that obtained the highest preference points or may be awarded to a supplier that did not score the highest points only in accordance with section 2(1)(f) of the PPPFA.

CONTRACT FORM: RENDERING OF SERVICES

THIS FORM MUST BE FILLED IN DUPLICATE BY BOTH THE SERVICE PROVIDER (PART 1) AND THE PURCHASER (PART 2). BOTH FORMS MUST BE SIGNED IN THE ORIGINAL SO THAT THE SERVICE PROVIDER AND THE PURCHASER WOULD BE IN POSSESSION OF ORIGINALLY SIGNED CONTRACTS FOR THEIR RESPECTIVE RECORDS.

PART 1 (TO BE FILLED IN BY THE SERVICE PROVIDER)

1. I/we hereby undertake to render services described in the attached bidding documents to SAHPRA in accordance with the requirements and task directives/proposals specifications stipulated in Bid Number SAHPRA/2026/PHARMACOVIGILANCE DIGITIZATION SOLUTION/RFB006 at the price/s quoted. My/our offer/s remain binding upon me/us and open for acceptance by the Purchaser during the validity period indicated and calculated from the closing date of the bid.

2. The following documents shall be deemed to form and be read and construed as part of this agreement:

2.1 Bidding documents, viz

- ❒ Invitation to bid
- ❒ Proof of tax compliance status
- ❒ Pricing schedule(s)
- ❒ Filled in terms of reference/task directive/proposal
- ❒ Preference claim form for Preferential Procurement in terms of the Preferential Procurement Regulations
- ❒ Bidder's Disclosure form
- ❒ Special Conditions of Contract

2.2 General Conditions of Contract

2.3 Other (specify)

3. I/we confirm that I/we have satisfied myself as to the correctness and validity of my/our bid; that the price(s) and rate(s) quoted cover all the services specified in the bidding documents; that the price(s) and rate(s) cover all my obligations and I accept that any mistakes regarding price(s) and rate(s) and calculations will be at my own risk.

4. I/we accept full responsibility for the proper execution and fulfilment of all obligations and conditions devolving on me/us under this agreement as the principal liable for the due fulfilment of this contract.

5. I/we declare that I/we have no participation in any collusive practices with any bidder or any other person regarding this or any other bid.

6. I confirm that I am duly authorised to sign this contract.

NAME (PRINT)	.....	WITNESSES	
CAPACITY	.....	1	.....
SIGNATURE	.....	2	.....
NAME OF FIRM	.....	DATE:	.....
DATE	.....		

CONTRACT FORM: RENDERING OF SERVICES

PART 2 (TO BE FILLED IN BY THE PURCHASER)

1. I …… in my capacity as …….. accept your bid under reference number …….. dated …….. for the rendering of services indicated hereunder and/or further specified in the annexures.

1. An official order indicating service delivery instructions is forthcoming.

2. I undertake to make payment for the services rendered in accordance with the terms and conditions of the contract within 30 (thirty) days after receipt of an invoice.

DESCRIPTION OF SERVICE	PRICE (ALL APPLICABLE TAXES INCLUDED)	COMPLETION DATE	TOTAL PREFERENCE POINTS CLAIMED	POINTS CLAIMED FOR EACH SPECIFIC GOAL

3. I confirm that I am duly authorised to sign this contract.

SIGNED AT ..... ON .....

NAME (PRINT) .....

SIGNATURE .....

OFFICIAL STAMP		WITNESSES 1 ..... 2 ..... DATE: .....

SECTION B

This section must be completed and returned or supplied with bids as prescribed.

SPECIAL CONDITIONS OF BID AND CONTRACT
Return as Part 1

	SPECIAL CONDITIONS
1	**GENERAL**
1.1	The Bidder must clearly state if a deviation from these special conditions is offered and the reason therefor. If an explanatory note is provided, the paragraph reference must be indicated in a supporting appendix to the application submission.
1.2	Should Bidders fail to indicate agreement/compliance or otherwise, the SAHPRA will assume that the Bidder is in compliance or agreement with the statement(s) as specified in this bid.
1.3	Bids not completed in this manner may be considered incomplete and rejected.
1.4	SAHPRA shall not be liable for any expense incurred by the Bidder in the preparation and submission of a bid.
2	**CANCELLATION OF PROCUREMENT PROCESS**
2.1	This procurement process can be postponed or cancelled at any stage at the sole discretion of SAHPRA provided that such cancellation or postponement takes place prior to entering into a contract with a specific service provider to which the bid relates.
3	**BID SUBMISSION CONDITIONS, INSTRUCTION AND EVALUATION PROCESS/CRITERIA**
3.1	The Bid submission conditions and instructions as well as the evaluation process/criteria have been noted.
4	**NEGOTIATION AND CONTRACTING**
4.1	SAHPRA have the right to enter into negotiation with one or more Bidders regarding any terms and conditions, including price(s), of a proposed contract.
4.2	Under no circumstances will negotiation with any Bidders, including preferred Bidders, constitute an award[1] or promise/ undertaking to award the contract.
4.3	SAHPRA shall not be obliged to accept the lowest or any bid, offer or proposal.
4.4	A contract will only be deemed to be concluded when reduced to writing in a formal contract and Service Level Agreement (if applicable) signed by the designated responsible person of both parties. The designated responsible person of SAHPRA is the CEO.
4.5	SAHPRA also reserves the right to enter into one contract with a Bidder for all required functions or into more than one contract with different Bidders for different functions.

[1] See GLOSSARY.

5	**ACCESS TO INFORMATION**
5.1	All bidders will be informed of the status of their bid once the procurement process has been completed.
5.2	Requests for information regarding the bid process will be dealt with in line with the SAHPRA SCM Policy and relevant legislation.
6	**REASONS FOR REJECTION**
6.1	SAHPRA shall reject a proposal for the award of a contract if the recommended Bidder has committed a proven corrupt or fraudulent act in competing for the particular contract.
6.2	The SAHPRA may disregard the bid of any bidder if that bidder, or any of its directors: ❒ Have abused the SCM system of the SAHPRA. ❒ Have committed proven fraud or any other improper conduct in relation to such system. ❒ Have failed to perform on any previous contract and the proof exists. Such actions shall be communicated to the National Treasury.
7	**GENERAL CONDITIONS OF CONTRACT**
7.1	The General Conditions of Contract must be accepted.
8	**ADDITIONAL INFORMATION REQUIREMENTS**
8.1	During evaluation of the bids, additional information may be requested in writing from Bidders. Replies to such request must be submitted, within 2 (two) working days or as otherwise indicated. Failure to comply, may lead to your bid being disregarded.
8.2	No additional information will be accepted from any individual Bidder without such information having been requested
9	**CONFIDENTIALITY**
9.1	The bid and all information in connection therewith shall be held in strict confidence by Bidders and usage of such information shall be limited to the preparation of the bid. Bidders shall undertake to limit the number of copies of this document.
10	**INTELLECTUAL PROPERTY, INVENTIONS AND COPYRIGHT**
10.1	Copyright of all documentation relating to this contract belongs to the client. The successful Bidder may not disclose any information, documentation or products to other clients without the written approval of the accounting authority or the delegate.
10.2	This paragraph shall survive termination of this contract.
11	**NON-COMPLIANCE WITH DELIVERY TERMS**

11.1	As soon as it becomes known to the contractor that he/she will not be able to deliver the services within the delivery period and/or against the quoted price and/or as specified, SAHPRA must be given immediate written notice to this effect. SAHPRA reserves the right to implement remedies as provided for in the GCC.
12	**WARRANTS**
12.1	The Contractor warrants that it is able to conclude this Agreement to the satisfaction of SAHPRA.
13	**PARTIES NOT AFFECTED BY WAIVER OR BREACHES**
13.1	The waiver (whether express or implied) by any Party of any breach of the terms or conditions of this contract by the other Party shall not prejudice any remedy of the waiving party in respect of any continuing or other breach of the terms and conditions hereof.
13.2	No favour, delay, relaxation or indulgence on the part of any Party in exercising any power or right conferred on such Party in terms of this contract shall operate as a waiver of such power or right nor shall any single or partial exercise of any such power or right under this agreement.
14	**RETENTION**
14.1	On termination of this agreement, the contractor shall, on demand hand over all documentation provided as part of the project and all deliverables, etc., without the right of retention, to SAHPRA.
14.2	No agreement to amend or vary a contract or order or the conditions, stipulations or provisions thereof shall be valid and of any force and effect unless such agreement to amend or vary is entered into in writing and signed by the contracting parties. Any waiver of the requirement that the agreement to amend or vary shall be in writing, shall also be in writing.
15	**CENTRAL SUPPLIER DATABASE**
15.1	It is a requirement that all suppliers/ services providers to SAHPRA shall be registered on the National Treasury Central Supplier Database (CSD).
15.2	Bidders are therefore required to register as a supplier on the CSD before submitting a bid. The CSD website can be accessed on the following link: http://ocpo.treasury.gov.za/Pages/default.aspx
15.3	No bid will be awarded, and a contract concluded with a bidder who is not registered on the CSD.
16	**FORMAT OF BIDS**
16.1	Bidders must complete all the necessary bid documents and undertakings required in this bid document. Bidders are advised that their proposal should be concise, written in plain English and simply presented.

16.2	**Bidders are to set out their proposal in the format prescribed hereunder**. This means that the proposal must be structured in the parts noted below. Information not submitted in the relevant part, may not be considered for evaluation purposes.
16.3	**Part 1: Special Conditions of Bid and Contract**
16.3.1	Bidders must initial each page and sign the last page and return the Special Conditions of bid and Contract (Section B-1). Bids submitted without a completed Special Conditions of Bid form **may** be deemed to be non-responsive.
16.4	**Part 2: Tax Compliance**
16.4.1	Bidders must ensure compliance with their tax obligations. Bidders are required to submit their unique personal identification number (PIN) issued by SARS to enable the organ of state to view the taxpayer's profile and tax status. Application for tax compliance status (TCS) or PIN may also be made via e-filing. In order to use this provision, taxpayers will need to register with SARS as e-filers through the website www.sars.gov.za. Bidders may also submit a printed TCS together with the bid. In bids where consortia/ joint ventures/ sub-contractors are involved; each party must submit a separate proof of TCS/ PIN/ CSD number. Where no TCS is available, but the bidder is registered on the Central Supplier Database (CSD), a CSD number must be provided. Bids submitted without any one of the above particulars, **may** be deemed to be non-responsive.
16.5	**Part 3: Declaration of Interest**
16.5.1	**Each party** to the bid must complete and return the "Declaration of Interest" (Section B-3). Bids submitted without a complete and signed Declaration of Interest **may** be deemed to be non-responsive.
16.6	**Part 4: Preference Points Claim Form in terms of the Preferential Procurement Regulations 2022**
16.6.1	Bidders must complete, sign and return the full "Preference Points Claim Form" (Section B-4) document. Quotes submitted without a completed and signed Preference Points Claim Form and a valid BEE certificate/ valid affidavit/ director(s)' certified ID copy/ CSD report will be awarded zero points for preference (specific goals).

16.7	**Part 5: Invitation to Bid**
16.7.1	Bidders must complete, sign and return the full "Invitation to Bid" (Section B-5) document. Bids submitted without a completed and signed Invitation to Bid **<u>may</u>** be deemed to be non-responsive.
16.8	**Part 6: Pricing Schedule**
16.8.1	All costs related to the bid are to be allowed for in the pricing schedule and in the format prescribed and must be returned as part of the submission (Section B-6). Bids submitted without a price or with an incomplete price, or with a price which is not in the prescribed format, **<u>will</u>** be deemed to be non-responsive.
16.8.2	Price for thirty-six (36) months of the contract must be firm and must be indicated in the format prescribed. Price for additional two years (year 4 and 5) must also be provided.
	❒ VAT: Value Added Tax must be included and shown separately.
16.9	**Part 7: Registration on the CSD**
16.9.1	In this part, bidders must submit proof of their registration of the Central Supplier Database. Bids submitted without the required proof, **<u>may</u>** be deemed to be non-responsive.

I/we herewith accept all the above-mentioned special conditions of the bid. If I/we do consider a deviation therefrom, I have noted those as per the instruction in paragraph 1 (General) above.

Name of Bidder: _____

Signature of Bidder: _____

Date: _____

BIDDERS DISCLOSURE (SBD 4)
Return as Part 3

1. PURPOSE OF THE FORM

Any person (natural or juristic) may make an offer or offers in terms of this invitation to bid. In line with the principles of transparency, accountability, impartiality, and ethics as enshrined in the Constitution of the Republic of South Africa and further expressed in various pieces of legislation, it is required for the bidder to make this declaration in respect of the details required hereunder.

Where a person/s are listed in the Register for Tender Defaulters and / or the List of Restricted Suppliers, that person will automatically be disqualified from the bid process.

2. Bidder's declaration

2.1 Is the bidder, or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest2 in the enterprise, employed by the state?
YES/NO

2.1.1 If so, furnish particulars of the names, individual identity numbers, and, if applicable, state employee numbers of sole proprietor/ directors / trustees / shareholders / members/ partners or any person having a controlling interest in the enterprise, in table below.

Full Name	Identity Number	Name of State institution

2.2 Do you, or any person connected with the bidder, have a relationship with any person who is employed by the procuring institution? **YES/NO**

2.2.1 If so, furnish particulars:
……
……

2.3 Does the bidder or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest in the enterprise have any interest in any other related enterprise whether or not they are bidding for this contract?
YES/NO

2.3.1 If so, furnish particulars:

[2] the power, by one person or a group of persons holding the majority of the equity of an enterprise, alternatively, the person/s having the deciding vote or power to influence or to direct the course and decisions of the enterprise.

……
……

3 DECLARATION

I, the undersigned, (name)……. in submitting the accompanying bid, do hereby make the following statements that I certify to be true and complete in every respect:

3.1 I have read, and I understand the contents of this disclosure;

3.2 I understand that the accompanying bid will be disqualified if this disclosure is found not to be true and complete in every respect;

3.3 The bidder has arrived at the accompanying bid independently from, and without consultation, communication, agreement or arrangement with any competitor. However, communication between partners in a joint venture or consortium3 will not be construed as collusive bidding.

3.4 In addition, there have been no consultations, communications, agreements, or arrangements with any competitor regarding the quality, quantity, specifications, prices, including methods, factors or formulas used to calculate prices, market allocation, the intention or decision to submit or not to submit the bid, bidding with the intention not to win the bid and conditions or delivery particulars of the products or services to which this bid invitation relates.

3.4 The terms of the accompanying bid have not been, and will not be, disclosed by the bidder, directly or indirectly, to any competitor, prior to the date and time of the official bid opening or of the awarding of the contract.

3.5 There have been no consultations, communications, agreements, or arrangements made by the bidder with any official of the procuring institution in relation to this procurement process prior to and during the bidding process except to provide clarification on the bid submitted where so required by the institution; and the bidder was not involved in the drafting of the specifications or terms of reference for this bid.

3.6 I am aware that, in addition and without prejudice to any other remedy provided to combat any restrictive practices related to bids and contracts, bids that are suspicious will be reported to the Competition Commission for investigation and possible imposition of administrative penalties in terms of section 59 of the Competition Act No 89 of 1998 and or may be reported to the National Prosecuting Authority (NPA) for criminal investigation and or may be restricted from conducting business with the public sector for a period not exceeding ten (10) years in terms of the Prevention and Combating of Corrupt Activities Act No 12 of 2004 or any other applicable legislation.

[3] Joint venture or Consortium means an association of persons for the purpose of combining their expertise, property, capital, efforts, skill and knowledge in an activity for the execution of a contract.

I CERTIFY THAT THE INFORMATION FURNISHED IN PARAGRAPHS 1, 2 and 3 ABOVE IS CORRECT.

I ACCEPT THAT THE STATE MAY REJECT THE BID OR ACT AGAINST ME IN TERMS OF PARAGRAPH 6 OF PFMA SCM INSTRUCTION 03 OF 2021/22 ON PREVENTING AND COMBATING ABUSE IN THE SUPPLY CHAIN MANAGEMENT SYSTEM SHOULD THIS DECLARATION PROVE TO BE FALSE.

…… ……

Signature Date

…… ……

Position Name of bidder

PREFERENCE POINTS CLAIM FORM IN TERMS OF THE PREFERENTIAL PROCUREMENT REGULATIONS 2022 (SBD 6.1)

Return as Part 4

NB: BEFORE COMPLETING THIS FORM, TENDERERS MUST STUDY THE GENERAL CONDITIONS, DEFINITIONS AND DIRECTIVES APPLICABLE IN RESPECT OF THE TENDER AND PREFERENTIAL PROCUREMENT REGULATIONS, 2022

1. GENERAL CONDITIONS

1.1 The following preference point systems are applicable to all bids:
- the 80/20 system for requirements with a Rand value of up to R50 000 000 (all applicable taxes included); and
- the 90/10 system for requirements with a Rand value above R50 000 000 (all applicable taxes included).

1.2 To be completed by the organ of state

a) The applicable preference point system for this tender is the 80/20 preference point system.

b) 80/20 preference point system will be applicable in this tender. The lowest/ highest acceptable tender will be used to determine the accurate system once tenders are received.

1.3 Points for this tender (even in the case of a tender for income-generating contracts) shall be awarded for:
(a) Price; and
(b) Specific goals

1.4 To be completed by the organ of state:
The maximum points for this bid are allocated as follows:

	POINTS
PRICE	80
Specific Goals	20
Total points for Price and Specific goals	100

1.5 Failure on the part of a bidder to submit proof of specific goals claim as stipulated on paragraph 4 below together with the bid, will be interpreted to mean that preference points claimed.

1.6 The organ of state reserves the right to require of a tenderer, either before a tender is adjudicated or at any time subsequently, to substantiate any claim in regard to preferences, in any manner required by the organ of state.

2. DEFINITIONS

(a) **"tender"** means a written offer in the form determined by an organ of state in response to an invitation to provide goods or services through price quotations, competitive

tendering process or any other method envisaged in legislation;

(b) **"price"** means an amount of money tendered for goods or services, and includes all applicable taxes less all unconditional discounts;

(c) **"rand value"** means the total estimated value of a contract in Rand, calculated at the time of bid invitation, and includes all applicable taxes;

(d) **"tender for income-generating contracts"** means a written offer in the form determined by an organ of state in response to an invitation for the origination of income-generating contracts through any method envisaged in legislation that will result in a legal agreement between the organ of state and a third party that produces revenue for the organ of state, and includes, but is not limited to, leasing and disposal of assets and concession contracts, excluding direct sales and disposal of assets through public auctions; and

(e) **"the Act"** means the Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000).

3. FORMULAE FOR PROCUREMENT OF GOODS AND SERVICES

3.1. POINTS AWARDED FOR PRICE

3.1.1 THE 80/20 OR 90/10 PREFERENCE POINT SYSTEMS

A maximum of 80 or 90 points is allocated for price on the following basis:

80/20 **or** **90/10**

$$Ps = 80\left(1 - \frac{Pt - P\,min}{P\,min}\right) \text{ or } \quad Ps = 90\left(1 - \frac{Pt - P\,min}{P\,min}\right)$$

Where

Ps = Points scored for price of tender under consideration

Pt = Price of tender under consideration

Pmin = Price of lowest acceptable tender

3.2. FORMULAE FOR DISPOSAL OR LEASING OF STATE ASSETS AND INCOME GENERATING PROCUREMENT

3.2.1. POINTS AWARDED FOR PRICE

A maximum of 80 or 90 points is allocated for price on the following basis:

80/20 **or** **90/10**

$$Ps = 80\left(1 + \frac{Pt - P\,max}{P\,max}\right) \text{ or } \quad Ps = 90\left(1 + \frac{Pt - P\,max}{Pmax}\right)$$

Where

Ps = Points scored for price of tender under consideration

Pt = Price of tender under consideration

Pmax = Price of highest acceptable tender

4. POINTS AWARDED FOR SPECIFIC GOALS

4.1. In terms of Regulation 4(2); 5(2); 6(2) and 7(2) of the Preferential Procurement Regulations, preference points must be awarded for specific goals stated in the tender. For the purposes of this tender the tenderer will be allocated points based on the goals stated in table 1 below as may be supported by proof/ documentation stated in the conditions of this tender:

4.2. In cases where organs of state intend to use Regulation 3(2) of the Regulations, which states that, if it is unclear whether the 80/20 or 90/10 preference point system applies, an organ of state must, in the tender documents, stipulate in the case of—

(a) an invitation for tender for income-generating contracts, that either the 80/20 or 90/10 preference point system will apply and that the highest acceptable tender will be used to determine the applicable preference point system; or

(b) any other invitation for tender, that either the 80/20 or 90/10 preference point system will apply and that the lowest acceptable tender will be used to determine the applicable preference point system,

then the organ of state must indicate the points allocated for specific goals for both the 90/10 and 80/20 preference point system.

Table 1: Specific goals for the tender and points claimed are indicated per the table below.

(Note to organs of state: Where either the 90/10 or 80/20 preference point system is applicable, corresponding points must also be indicated as such.

***Note to tenderers: The tenderer must indicate how they claim points for each preference point system.*)**

SAHPRA SPECIFIC PREFERENTIAL PROCUREMENT GOALS					
Description / Goals		**Allocated points**		**Evidence or Proof of claim**	**Number of points claimed (80/20 system) (To be completed by the tenderer)**
		Preference Point System			
Category A: Promotion of SMMEs		**80/20**	**90/10**	- Valid BBBEE certificate - Valid affidavit - Director(s)' certified ID copy - CSD report	
1.	100% Black owned EME and QSE	20	10		
2.	At least 51% Black owned EME and QSEs	18	9		
3.	Zero and less than 51% Black owned EME and QSEs	16	8		
Category B: Promotion of Historically Disadvantaged Individuals -HDI (Large enterprises)		**BBBEE Level**	**Preference Point System**	**Evidence / proof of claim**	
			80/20	**90/10**	
4.	<u>% Ownership</u> a) 30% - 100% Black women b) 51% - 100% Black youth c) 51% - 100% Black people with - disability	All levels	20	10	- CSD report - Valid affidavit - Valid BBBEE certificate - Directors(s) certified ID copy - Declaration / proof of disability issued by medical practitioner.
	a) 51% - 100% Black	1	18	9	
		2	16	8	
		3	14	7	
		4	12	6	
		5	8	5	

		6	6	4		
		7	4	2		
		8 and Non-compliant	0	0		
Category C: Promotion of BBBEE Contributors - large enterprises		**BBBEE Level**	**Preference Point System**		**Evidence / proof of claim**	
			80/20	**90/10**		
10.	Nonblack and Non-HDI enterprises	1	12	6	Valid BBBEE certificate	
		2	10	5		
		3	8	4		
		4	6	3		
		5 to non-compliant	0	0		

4. BID DECLARATION

DECLARATION WITH REGARD TO COMPANY/FIRM

4.3. Name of company/firm.....

4.4. Company registration number: .....

4.5. TYPE OF COMPANY/ FIRM

- ϒ Partnership/Joint Venture / Consortium
- ϒ One-person business/sole propriety
- ϒ Close corporation
- ϒ Public Company
- ϒ Personal Liability Company
- ϒ (Pty) Limited
- ϒ Non-Profit Company
- ϒ State Owned Company

[TICK APPLICABLE BOX]

4.6. I, the undersigned, who is duly authorised to do so on behalf of the company/firm, certify that the points claimed, based on the specific goals as advised in the tender, qualifies the company/ firm for the preference(s) shown and I acknowledge that:

i) The information furnished is true and correct;

ii) The preference points claimed are in accordance with the General Conditions as indicated in paragraph 1 of this form;

iii) In the event of a contract being awarded as a result of points claimed as shown in paragraphs 1.4 and 4.2, the contractor may be required to furnish documentary proof to the satisfaction of the organ of state that the claims are correct;

iv) If the specific goals have been claimed or obtained on a fraudulent basis or any of the conditions of contract have not been fulfilled, the organ of state may, in addition to any other remedy it may have –

(a) disqualify the person from the tendering process;

(b) recover costs, losses or damages it has incurred or suffered as a result of that person's conduct;

(c) cancel the contract and claim any damages which it has suffered as a result of having to make less favourable arrangements due to such cancellation;

(d) recommend that the tenderer or contractor, its shareholders and directors, or only the shareholders and directors who acted on a fraudulent basis, be restricted from obtaining business from any organ of state for a period not exceeding 10 years, after the *audi alteram partem* (hear the other side) rule has been applied; and

(e) forward the matter for criminal prosecution, if deemed necessary.

.....

SIGNATURE(S) OF TENDERER(S)

SURNAME AND NAME.....

DATE: .....

ADDRESS: .....

.....

INVITATION TO BID

Return as Part 5

YOU ARE HEREBY INVITED TO QUOTE FOR REQUIREMENT OF SAHPRA					
BID NUMBER:	SAHPRA/2025/PHARMACOVIGILANCE DIGITIZATION SOLUTION/RFB002	CLOSING DATE:	**31 MARCH 2026**	CLOSING TIME:	**11:00 am**
DESCRIPTION	**REQUEST FOR BID FOR DESTRUCTION OF PHARMACOVIGILANCE DIGITIZATION SOLUTION FOR A PERIOD OF THIRTY-SIX (36) MONTHS**				

BIDDING PROCEDURE ENQUIRIES MAY BE DIRECTED TO		**TECHNICAL ENQUIRIES MAY BE DIRECTED TO:**	
CONTACT PERSON	**Precious Mnguni**	CONTACT PERSON	**Precious Mnguni**
TELEPHONE NUMBER		TELEPHONE NUMBER	
FACSIMILE NUMBER	**N/A**	FACSIMILE NUMBER	**N/A**
E-MAIL ADDRESS	precious.mnguni@sahpra.org.za	E-MAIL ADDRESS	precious.mnguni@sahpra.org.za

SUPPLIER INFORMATION					
NAME OF BIDDER					
POSTAL ADDRESS					
STREET ADDRESS					
TELEPHONE NUMBER	CODE		NUMBER		
CELLPHONE NUMBER					
FACSIMILE NUMBER	CODE		NUMBER		
E-MAIL ADDRESS					
VAT REGISTRATION NUMBER					
SUPPLIER COMPLIANCE STATUS	TAX COMPLIANCE SYSTEM PIN:		**OR**	CENTRAL SUPPLIER DATABASE No:	MAAA
B-BBEE STATUS LEVEL VERIFICATION CERTIFICATE	TICK APPLICABLE BOX] ☐ Yes ☐ No		B-BBEE STATUS LEVEL SWORN AFFIDAVIT		[TICK APPLICABLE BOX] ☐ Yes ☐ No

[A B-BBEE STATUS LEVEL VERIFICATION CERTIFICATE/ SWORN AFFIDAVIT (FOR EMES & QSEs) MUST BE SUBMITTED IN ORDER TO QUALIFY FOR PREFERENCE POINTS FOR B-BBEE]

ARE YOU THE ACCREDITED REPRESENTATIVE IN SOUTH AFRICA FOR THE GOODS /SERVICES /WORKS OFFERED?	☐Yes ☐No [IF YES ENCLOSE PROOF]	ARE YOU A FOREIGN BASED SUPPLIER FOR **THE GOODS /SERVICES /WORKS OFFERED?**	☐Yes ☐No [IF YES, ANSWER THE QUESTIONNAIRE BELOW]

QUESTIONNAIRE TO BIDDING FOREIGN SUPPLIERS

IS THE ENTITY A RESIDENT OF THE REPUBLIC OF SOUTH AFRICA (RSA)?	☐ YES ☐ NO
DOES THE ENTITY HAVE A BRANCH IN THE RSA?	☐ YES ☐ NO
DOES THE ENTITY HAVE A PERMANENT ESTABLISHMENT IN THE RSA?	☐ YES ☐ NO
DOES THE ENTITY HAVE ANY SOURCE OF INCOME IN THE RSA?	☐ YES ☐ NO
IS THE ENTITY LIABLE IN THE RSA FOR ANY FORM OF TAXATION?	☐ YES ☐ NO

IF THE ANSWER IS "NO" TO ALL OF THE ABOVE, THEN IT IS NOT A REQUIREMENT TO REGISTER FOR A TAX COMPLIANCE STATUS SYSTEM PIN CODE FROM THE SOUTH AFRICAN REVENUE SERVICE (SARS) AND IF NOT REGISTER AS PER 2.3 BELOW.

TERMS AND CONDITIONS FOR BIDDING

1.	**BID SUBMISSION:**
1.1.	BIDS MUST BE DELIVERED BY THE STIPULATED TIME TO THE CORRECT ADDRESS. LATE BIDS WILL NOT BE ACCEPTED FOR CONSIDERATION.
1.2.	**ALL BIDS MUST BE SUBMITTED ON THE OFFICIAL FORMS PROVIDED–(NOT TO BE RE-TYPED) OR IN THE MANNER PRESCRIBED IN THE BID DOCUMENT.**
1.3.	THIS BID IS SUBJECT TO THE PREFERENTIAL PROCUREMENT POLICY FRAMEWORK ACT, 2000 AND THE PREFERENTIAL PROCUREMENT REGULATIONS, 2022, THE GENERAL CONDITIONS OF CONTRACT (GCC) AND, IF APPLICABLE, ANY OTHER SPECIAL CONDITIONS OF CONTRACT.
1.4.	**THE SUCCESSFUL BIDDER WILL BE REQUIRED TO FILL IN AND SIGN A WRITTEN CONTRACT FORM (SBD7).**
2.	**TAX COMPLIANCE REQUIREMENTS**
2.1	BIDDERS MUST ENSURE COMPLIANCE WITH THEIR TAX OBLIGATIONS.
2.2	BIDDERS ARE REQUIRED TO SUBMIT THEIR UNIQUE PERSONAL IDENTIFICATION NUMBER (PIN) ISSUED BY SARS TO ENABLE THE ORGAN OF STATE TO VERIFY THE TAXPAYER'S PROFILE AND TAX STATUS.
2.3	APPLICATION FOR TAX COMPLIANCE STATUS (TCS) PIN MAY BE MADE VIA E-FILING THROUGH THE SARS WEBSITE WWW.SARS.GOV.ZA.
2.4	BIDDERS MAY ALSO SUBMIT A PRINTED TCS CERTIFICATE TOGETHER WITH THE BID.
2.5	IN BIDS WHERE CONSORTIA / JOINT VENTURES / SUB-CONTRACTORS ARE INVOLVED, EACH PARTY MUST SUBMIT A SEPARATE TCS CERTIFICATE / PIN / CSD NUMBER.
2.6	WHERE NO TCS PIN IS AVAILABLE BUT THE BIDDER IS REGISTERED ON THE CENTRAL SUPPLIER DATABASE (CSD), A CSD NUMBER MUST BE PROVIDED.
2.7	NO BIDS WILL BE CONSIDERED FROM PERSONS IN THE SERVICE OF THE STATE, COMPANIES WITH DIRECTORS WHO ARE PERSONS IN THE SERVICE OF THE STATE, OR CLOSE CORPORATIONS WITH MEMBERS PERSONS IN THE SERVICE OF THE STATE."

NB: FAILURE TO PROVIDE / OR COMPLY WITH ANY OF THE ABOVE PARTICULARS MAY RENDER THE BID INVALID.

SIGNATURE OF BIDDER: ……

CAPACITY UNDER WHICH THIS BID IS SIGNED: ……
(Proof of authority must be submitted e.g., company resolution)

DATE: ……..

PRICING SCHEDULE (SBD 3.1)

Goods and Services

Return as Part 6

NAME OF BIDDER: .....

OFFER TO BE VALID FOR 90 DAYS FROM THE CLOSING DATE OF QUOTATION

The pricing schedule as indicated below must be completed in the format provided. No alterations to this pricing schedule will be allowed and the bids of bidders who do so will be regarded as non-responsive and will not be evaluated.

Bidders may attach separate spreadsheets with their calculations, but all costs musts eventually be consolidated and summarised into the format required.

YEAR 1					
Item No.	**Description**	**Unit**	**Quantity**	**Unit Price ZAR (Excl. VAT)**	**Total Price ZAR (Excl. VAT)**
1.	Implementation and configuration costs of the solution	Sum	1		
2.	Maintenance and supports	Monthly	12		
3.	License and Subscription costs	Annually	unlimited		
4.	Transactions	Annually	unlimited		
5.	IT training and Certification	Once-Off	3 x IT personnel		
6.	Change Management and Awareness (includes user training)	Once-Off (Month)	1		
	SUB-TOTAL				
	VAT				
	TOTAL COST FOR YEAR 1 (VAT INCLUDED)				

YEAR 2					
Item No.	**Description**	**Unit**	**Quantity**	**Unit Price ZAR (Excl. VAT)**	**Total Price ZAR (Excl. VAT)**
1.	Maintenance and support	Monthly	12		
2.	License and Subscription costs	Annually	unlimited		
3.	Transactions	Annually	unlimited		
	SUB-TOTAL				
	VAT				

	TOTAL COST FOR YEAR 2 (VAT INCLUDED)	

YEAR 3					
Item No.	**Description**	**Unit**	**Quantity**	**Unit Price ZAR (Excl. VAT)**	**Total Price ZAR (Excl. VAT)**
1.	Maintenance and supports	Monthly	12		
2.	License and Subscription costs	Annually	unlimited		
3.	Transactions	Annually	unlimited		
	SUB-TOTAL				
	VAT				
	TOTAL COST FOR YEAR 3 (VAT INCLUDED)				

YEAR 4					
Item No.	**Description**	**Unit**	**Quantity**	**Unit Price ZAR (Excl. VAT)**	**Total Price ZAR (Excl. VAT)**
1.	Maintenance and supports	Monthly	12		
2.	License and Subscription costs	Annually	unlimited		
3.	Transactions	Annually	unlimited		
	SUB-TOTAL				
	VAT				
	TOTAL COST FOR YEAR 4 (VAT INCLUDED)				

YEAR 5					
Item No.	**Description**	**Unit**	**Quantity**	**Unit Price ZAR (Excl. VAT)**	**Total Price ZAR (Excl. VAT)**
1.	Maintenance and supports	Monthly	12		
2.	License and Subscription costs	Annually	unlimited		
3.	Transactions	Annually	unlimited		
	SUB-TOTAL				
	VAT				
	TOTAL COST FOR YEAR 5 (VAT INCLUDED)				

SUMMARY	
Total cost for year 1	
Total cost for year 2	
Total cost for year 3	
TOTAL COST FOR 3 YEARS WITH VAT	

Total cost for year 4	
Total cost for year 5	
TOTAL COST FOR OPTIONAL 2 YEARS WITH VAT	

Bidder Representative Signature .....

Title: .....

Name: .....

Date: .....

SAHPRA
South African Health Products Regulatory Authority

DECLARATION

BID NUMBER: SAHPRA/2026/ PHARMACOVIGILANCE DIGITIZATION SOLUTION/RFB006

BID DESCRIPTION: REQUEST FOR BID FOR PHARMACOVIGILANCE DIGITIZATION SOLUTION, INCLUDING MAINTENANCE AND SUPPORT FOR A PERIOD OF 36 MONTHS WITH AN OPTION TO RENEW FOR ADDITIONAL 24 MONTHS.

No	TECHNICAL PRODUCT/SERVICE FUNCTIONAL REQUIREMENTS	Compliant?	
		YES	NO
1	The system provides a structured electronic form for capturing Individual Case Safety Report (ICSR) data in compliance with ICH E2B(R3) standards. It includes the following key functionalities: Validation of Minimum Criteria for a Valid ICSR, Adverse Event Coding, Product Coding, Support for Additional Coding Dictionaries.		
2	The system offers comprehensive vigilance case management functionality to support the end-to-end processing of adverse event (AE) and product complaint reports. This includes the initial evaluation to determine urgency and appropriate handling, thorough review and validation of data for accuracy, completeness, and consistency from various sources (e.g., reporters, clinical sites, safety databases), and scientific and medical assessment to evaluate causality, seriousness, expectedness, and regulatory reportability.		
3	The system demonstrates AI capabilities corresponding to one or more features outlined in Section 3 (Artificial Intelligence).		
4	The system can accommodate Product Dictionary Management to support vigilance activities, as detailed in Sections 4 and 5 of the Functional Requirements.		
5	The system incorporates advanced signal detection capabilities tailored for pharmacovigilance and vigilance activities as indicated in section 6.		
6	The system is capable of generating a variety of aggregate reports and dashboards for analyzing ICSR and device incident data, with the ability to incorporate additional data sources for comprehensive and comparable reporting. Key functionalities include configurable queries, multiple output formats, data filtering, templated reports, and document management.		
7	The system is designed to manage global and local regulatory requirements, guidelines, and partner obligations across jurisdictions. It ensures organizations remain compliant by centralizing, tracking, and		

No	TECHNICAL PRODUCT/SERVICE FUNCTIONAL REQUIREMENTS	Compliant?	
	evaluating regulatory changes and their operational impact. Key functionalities include Requirement Logging, Rule Management, Integration, and Impact Assessment.		
8	The system is capable of being customized to support other vigilance-related activities conducted in relation to organizational or regulatory requirements.		
9	The system has the ability to decentralize vigilance activities by isolating ICSRs to support regional vigilance operations, as indicated in Section 10.		
10	The system has the ability to incorporate vigilance-related standards and integrate with related systems, featuring API readiness for seamless connectivity.		
11	Has the capability for two-way communication between the system and users through: Acknowledgments of reports submissions, alert based on predefined conditions or attributes, reminders for upcoming deadlines, follow-ups, or required actions and Provide reporters with secure access to retrieve copies of previously submitted reports, including the ability to view submission history and download or print reports		

I, the undersigned, being duly authorized to act on behalf of the company, hereby certify that all technical product/service functional requirements, as defined, are **fully** met by the proposed solution.

Name: _____

Designation: _____

Company Name: _____

Date: _____

Signature: _____