



REQUEST FOR BID SERVICES

BID DETAILS

BID NUMBER: SAHPRA/2022/REGULATORY INFORMATION MANAGEMENT SYSTEM/RFB004

CLOSE **Date:** 06 March 2023
 Time: 11:00

DESCRIPTION: **REQUEST FOR BID TO SUPPLY, IMPLEMENT, MAINTAIN AND SUPPORT AN ELECTRONIC SUBMISSION AND MANAGEMENT SOLUTION FOR A PERIOD OF 60 MONTHS**

BRIEFING SESSION: Yes 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 (42) 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 not 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)
- Annexure A: Detailed description of A Grade office accommodation

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 5: Preference Points Claim Form in terms of the Preferential Procurement Regulations, 2022 (SBD 6.1)
- Section B 6: Invitation to Bid (SBD 1)
- Section B 7: Pricing Schedule (Professional Services) (SBD 3.1)

SECTION A

(This section must not 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

- 2.1 Briefing Session

- 2.2 A briefing session will be held from **12:00 to 14:00 on 22 February 2023**.

- 2.3 Briefing session to be held on MS Teams, link https://teams.microsoft.com/l/meetup-join/19%3ameeting_ZTI1Mjk4NjltMjBjMi00ZDRhLThlYWUtZThkNGZmNGY4MWUw%40thread.v2/0?context=%7b%22Tid%22%3a%22a238ae09-e326-4cc0-9ae3-df134f7ebad9%22%2c%22Oid%22%3a%22d71dcbdd-1d6a-44b0-b91e-8efd1aa60854%22%7d

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 **27 February 2023**, Telephonic requests for clarification will not be accepted. Questions and answers will be posted on our website only, by **01 March 2023**.

Contact details: Precious Mnguni

Telephone: 012 501 0418

E-Mail: precious.mnguni@sahpra.org.za

4 SUBMITTING BIDS

- 4.1 **One (1) original document, two (2) hardcopies and one (1) electronic copy on a storage device (USB) must be handed in/ delivered to:**

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**

Section A 1: Bid Submission Conditions and Instructions

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.

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

- Bid number (SAHPRA/2022/REGULATORY INFORMATION MANAGEMENT SYSTEM/RFB004)
- Closing date and time (06 March 2023 @ 11:00 am)
- The name and address of the Bidder.

4.3 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.

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

6 GENERAL CONDITIONS OF CONTRACT

6.1 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>

DETAILED SPECIFICATIONS/ REQUIREMENTS LIST

TERMS OF REFERENCE TO SUPPLY, IMPLEMENT, MAINTAIN AND SUPPORT AN ELECTRONIC SUBMISSION AND MANAGEMENT SOLUTION

1 BACKGROUND TO THE PROJECT

- 1.1 The South African Health Products Regulatory Authority (SAHPRA) was established as a public entity in terms of the Medicines and Related Substance Amendment Act, 2008 (Act No, 72 of 2008), in February 2018, replacing the Medicines Control Council (MCC). SAHPRA as a regulator, applies standards laid down by the Medicines and Related Substances Act, which govern the manufacture, distribution, sale, and marketing of medicines.
- 1.2 As a health products regulator, SAHPRA currently receives various electronic submissions for the registration of different categories of medicines as well medical devices, some of these submissions are prepared in the Electronic Common Technical Document for the Registration of Medicines (eCTD) as prescribed.
- 1.3 SAHPRA requires an enterprise software solution for the submission, management, review and tracking of electronic submission for applications to register medicines and medical devices that conforms to various electronic submission formats as per the different guidelines inter alia latest **eCTD format, VNeS, fillable PDF, IMDRF specified electronic formats etc. specification.**

2 CONTRACT PERIOD

- 2.1 The contract period shall be for a maximum of 60 months

3 ROLE AND OBJECTIVES

- 3.1 Service provider roles and responsibilities as per requirements below. SAHPRA staff to support the project throughout.

4 SCOPE OF WORK AND SPECIFICATIONS

- 4.1 Supply, installation, support and maintenance of an electronic submission management and evaluation solution, that includes an online submission portal or integration with existing portal, submission management and review system, as well as an integrated document management platform for a period/subscription/license for 60 months. **User Requirements Annexure attached.**
- 4.2 Provide the Infrastructure as Service (IaaS) and/or Software as a Service (SaaS) for the duration of the service of 60 months. E.g., Microsoft Azure or Amazon Web Services may be used for cloud deployment. **Cloud Residence strictly in-country, South Africa**

Section A 3: Evaluation Process/ Criteria

- 4.3 Full configuration of workflows and automation in line with SAHPRA’s business processes.
- 4.4 Full Migration of the current environments and legacy data, configurations and data to the new environment where required.
- 4.5 Possible custom development of required components that do not form part of the standards software solution, e.g., Online Submission Portal. **Refer to the User Requirements Annexure for details.**
- 4.6 Ongoing Training and support – training for super users and the SAHPRA users will be critical at Implementation stages – therefore a detailed training plan and training method must be provided as part of the proposed project plan.
- 4.7 On-site Project Support for the key implementation phases

5 WHERE SERVICE/S IS/ARE REQUIRED

- 5.1 SAHPRA

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

EVALUATION PROCESS

1. COMPLIANCE WITH MINIMUM REQUIREMENTS

- 1.1 All bids duly lodged as specified in the Request for Bid will be examined to determine compliance with bid requirements and conditions. Bids with obvious deviations from the requirements/conditions will be eliminated from further consideration.
- 1.2 Failure to comply with or submit any one of the following items, will render a bid nonresponsive and will 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		
Part 4	Preference Points Claim Form in terms of the Preferential Procurement Regulations 2022		
Part 5	Completed and signed Invitation to Bid		
Part 6	Completed Pricing Schedule in the prescribed format		
Part 7	Compliance with Minimum Requirements		
Part 8	Proof of registration on the CSD		

2. DETERMINATION OF SCORE FOR FUNCTIONALITY

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

MANDATORY REQUIREMENTS	Evidence Of Compliance	Provide file location or Page no.	Yes/No
<p>1. BIDDER EXPERIENCE AND CAPABILITY REQUIREMENTS</p> <p>The bidder must have provided a similar ICT software solution (which includes a document management, case management and evaluation management software tool) to an organisation within the Health Product Industry (either Regulatory Authorities or Pharmaceutical Companies or medical devices) during the past ten (10) years with no implementation older than 36 months.</p>	<p>The bidder must provide a minimum of two (2) award or reference letters of affirmation from other organisation within the Health Product Industry (either Regulatory Authorities or Pharmaceutical Companies or medical devices) to whom the service(s) were delivered. Each letter must be dated, signed and on a letterhead of the customer and indicates:</p> <ul style="list-style-type: none"> a) The customer Company name and address. b) Include a description of the scope of work. c) Project Start and End Date 	<p>Page no.</p>	<ul style="list-style-type: none"> • Yes – Proceed • No – Do not evaluate further
<p>2. LOCAL PRESENCE/REPRESENTATION</p> <p>Bidder must have a presence in South Africa or an unconflicted local partner with the relevant technical expertise to support the project and the service over the contract period.</p>	<p>Proof of presence in South Africa must be provided.</p> <ul style="list-style-type: none"> a) Proof of local presence b) Proof of a partnership or agreement or contract. c) CV and certification for relevant technical expertise to support the project 	<p>Page no.</p>	<ul style="list-style-type: none"> • Yes – Proceed • No – Do not evaluate further
<p>3. ACCESS & TRAINING FOR IT STAFF TO MAINTAIN AND COMPLETE BASIC CONFIGURATION CHANGES</p>	<p>Provide training to the nominated in-house SAHPRA ICT staff members that equips the IT staff to complete basic config changes – to suit the evolving SAHPRA business environment – within defined and agreed parameters.</p> <ul style="list-style-type: none"> a) Provide any form of declaration that OEM training, and certificate will be provided to SAHPRA staff (e.g., letter). b) An example of these basic config and change parameters which can be configured by SAHPRA staff -- must be provided. 	<p>Page no.</p>	<p>Yes – Proceed</p> <p>No – do not evaluate further</p>
<p>4. eCTD and eSubmissions COMPONENT</p> <p>Does the solution have an eCTD component – compliant with eCTD v3.2 or will be able to meet requirements as communicated by the ICH (International Conference for Harmonisation) and any other e-</p>	<p>Provide proof of ICH version compliance and a demonstration of the eCTD – SAHPRA specific information will be provided for the demo.</p>	<p>Page no.</p>	<ul style="list-style-type: none"> • If “Yes” – Proceed • If “No” – Do not evaluate further

<p>submission format that is currently used or will be introduced for future Health Product Registration processes Is the software tool also kept up to date if there are any ICH version updates?</p>			
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Functional Criteria	Provide evidence/page no and/or location	Maximum to be Awarded
<p>1. Can the software tool integrate with an existing stakeholder/customer portal to be able to:</p> <p>a) Allow applicants to submit all forms of application including related uploads. E.g., eCTD and eSubmission formats through the existing portal and then via configured API transfer the documents, files and information to the document/case management and review tool – keeping track of the unique sequential service reference number.</p> <p>Refer User Requirements Annexure for details (Req ID: SP-1) and Refer User Requirements Annexure for details (Req ID: SM1 to SM17, PA-1 to PA-11).</p>	<p>Page no.</p>	<ul style="list-style-type: none"> • No information provide – 0 • Cannot integrate with existing portal, must use proprietary portal to receive information/documents and provide sequential reference number, providing a unique sequential reference number - 10 • Can integrate with existing portal to receive information/documents and provide sequential reference number, providing a unique sequential reference number - 20
<p>2. Is the solution’s eCTD component able to</p> <p>a) Perform automated validation of submitted application based on ZA criteria, perform submission structure reviews, generate review reports.</p> <p>b) Integrate with online submission portal for tracking activities in this component.</p> <p>c) Able to extend the component to handle other form of application with their own specific rule set (Criteria)</p> <p>Refer User Requirements Annexure for details (Req ID: SE-1 to SE-23, SV1 to SV-3, SI-1 to SI-5, PA-1 to PA-11).</p>	<p>Page no.</p>	<ul style="list-style-type: none"> • Does not meet any criteria - 0 • Meets only one criterion - 5 • Meets only two criteria - 10 • Meets all three criteria - 20
<p>3. Does the solution have an online web log-on function that will allow users (regardless of geographical location) management access to be able to:</p> <p>A) Review and manage submitted applications, track activities (which include decision making committee outcomes), update application status and respond to queries.</p> <p>Refer User Requirements Annexure for details (Req ID: SMS1 to SMS17, PA-1 to PA-11).</p>	<p>Page no.</p>	<ul style="list-style-type: none"> • Non-compliance - 0 • Instance on premise and requires VPN log-on - 5 • Secure web-based platform - 10

Section A 3: Evaluation Process/ Criteria

<p>4. Does the Solution have user management and access control component?</p> <ul style="list-style-type: none"> Unlimited user creation without licensing limitations Users self-profile management, user grouping management, categorization, and Access Control List (ACL) functionalities. <p>Refer User Requirements Annexure for details (Req ID: UMAC-1 to UMAC-5).</p>	<p>Page no.</p>	<ul style="list-style-type: none"> Non-compliance - 0 Meets UMAC 1,2,3 and 4 only - 10 Meets UMAC 1,2,3,4 and 5 criteria - 20
<p>5. Does the system have a reporting component?</p> <ul style="list-style-type: none"> to track individual activities and responses, searching and filter functionalities and custom data aggregation for decision making and planning. <i>NB – Basic report refers to specific customized general report</i> <i>Rich report refers to specific customized report</i> <p>Refer User Requirements Annexure for details (Req ID: R-1 to R-5).</p>	<p>Page no.</p>	<ul style="list-style-type: none"> Non-compliance - 0 Basic report and dashboards available with no customisation - 5 Rich report and dashboards with no customisation – 10 Rich report and dashboards with customisation - 20
<p>6. Is the solution capable of cloud deployment e.g., Amazon Web Services or Azure</p>	<p>Page no.</p>	<ul style="list-style-type: none"> No proof provided- 0 Proof of Cloud hosting platform to be provided via an industry certificate. (OEM) Original Equipment Manufacturer or equivalent (Verification certificates) -10
<p>TOTAL</p>		<p>100</p>

2.2 The score for functionality shall be calculated as follows:

- 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 supplier for functionality.
- Supplier will need to obtain a **minimum threshold of 70 points** on functionality for them to qualify into the next stage which is price and B-BBEE.

2.3 PRICE AND B-BBEE STATUS LEVEL POINTS

- 2.3.1 All remaining bids will be evaluated as follows:
- 2.3.2 The 80/20 preference point system will be applied in terms of the Preferential Procurement Regulations, 2022.
- 2.3.3 If appropriate, implied contract price adjustments will be made to the cost proposals of all remaining bids.

Section A 3: Evaluation Process/ Criteria

- 2.3.4 The point scored for the B-BBEE status level certificate for each acceptable bid will now be added to the price point.
- 2.3.5 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.

3. ADJUDICATION OF BID

- 3.1 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.
- 3.2 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/2022/REGULATORY INFORMATION MANAGEMENT SYSTEM/RFB004 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
 - Tax clearance certificate
 - Pricing schedule(s)
 - Filled in terms of reference/task directive/proposal
 - Preference Points Claim Form in terms of the Preferential Procurement Regulations, 2022
 - Declaration of interest
 - Declaration of bidder's past SCM practices
 - 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)

CAPACITY

SIGNATURE

NAME OF FIRM

DATE

WITNESSES	
1
2
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 (VAT INCL)	COMPLETION DATE	B-BBEE STATUS LEVEL OF CONTRIBUTION

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 are 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.

Section B 1: Special Conditions of Bid and Contract

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: <ul style="list-style-type: none"> <input type="checkbox"/> Have abused the SCM system of the SAHPRA. <input type="checkbox"/> Have committed proven fraud or any other improper conduct in relation to such system. <input type="checkbox"/> 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,

Section B 1: Special Conditions of Bid and Contract

	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	Bidders are therefore required to submit proof of their registration on the CSD, or if not yet registered, provide proof of their application to be registered, with their bid.
15.4	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.

Section B 1: Special Conditions of Bid and Contract

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. <u>Information not submitted in the relevant part, may not be considered for evaluation purposes.</u>
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 will 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, will 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-2). Bids submitted without a complete and signed Declaration of Interest will 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-5) document. In addition, a valid BEE certificate must be submitted.

Section B 1: Special Conditions of Bid and Contract

	Quotes submitted without a completed and signed Preference Points Claim Form and a valid BEE certificate will be awarded zero points for preference.
16.7	Part 5: Invitation to Bid
16.7.1	Bidders must complete, sign and return the full “Invitation to Bid” (Section B-6) document. Bids submitted without a completed and signed Invitation to Bid will be deemed to be non-responsive.
16.8	Part 6: Pricing Schedule
16.8.1	All costs related to the proposed project are to be allowed for in the pricing schedule and in the formats prescribed and must be returned as part of the submission (Section B-7). Bids submitted without a price or with an incomplete price, or with a price which is not in the prescribed format, will be deemed to be non-responsive.
16.8.2	Rates for the full duration must be firm and must be indicated in the formats prescribed.
	<input type="checkbox"/> VAT: Value Added Tax must be included and shown separately.
16.9	Part 7: Compliance with Minimum Requirements
16.9.1	Bidders must complete, sign, and return the full “Compliance with Minimum Requirements” (Section B-8) document. Bids submitted without a completed and signed Compliance with Minimum Requirements will be deemed to be non-responsive.
16.10	Part 8: Registration on the CSD
16.10.1	In this part, bidders must submit proof of their registration, or proof that they have applied for registration on the Central Supplier Database. Bids submitted without the required proof, will 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: _____

Section B 2: Declaration of Interest

BIDDER'S DISCLOSURE- SBD4
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:
.....
.....

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:

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.

Section B 2: Declaration of Interest

- 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.

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

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.

PREFERENCE POINTS CLAIM FORM IN TERMS OF THE PREFERENTIAL PROCUREMENT REGULATIONS 2022

Return as Part 4

NB: BEFORE COMPLETING THIS FORM, BIDDERS MUST STUDY THE GENERAL CONDITIONS, DEFINITIONS AND DIRECTIVES APPLICABLE AS PRESCRIBED IN THE 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 The value of this bid is estimated to not exceed R50 000 000 (all applicable taxes included) and therefore the 80/20 preference point system shall be applicable;
- 1.3 Points for this bid shall be awarded for:
- (a) Price; and
 - (b) B-BBEE Status Level of Contributor.
- 1.4 The maximum points for this bid are allocated as follows:

	POINTS
PRICE	80
B-BBEE Status Level of Contributor	20
Total points for Price and B-BBEE must not exceed	100

- 1.5 Failure on the part of a bidder to submit proof of B-BBEE Status level of contributor together with the bid, will be interpreted to mean that preference points for B-BBEE status level of contribution are not claimed.
- 1.6 The purchaser reserves the right to require of a bidder, either before a bid is adjudicated or at any time subsequently, to substantiate any claim in regard to preferences, in any manner required by the purchaser.

2. DEFINITIONS

- (a) **“B-BBEE”** means broad-based black economic empowerment as defined in section 1 of the Broad-Based Black Economic Empowerment Act;
- (b) **“B-BBEE status level of contributor”** means the B-BBEE status of an entity in terms of a code of good practice on black economic empowerment, issued in terms of section 9(1) of the Broad-Based Black Economic Empowerment Act;
- (c) **“bid”** means a written offer in a prescribed or stipulated form in response to an invitation by an organ of state for the provision of goods or services, through price quotations, advertised competitive bidding processes or proposals;
- (d) **“Broad-Based Black Economic Empowerment Act”** means the Broad-Based Black Economic Empowerment Act, 2003 (Act No. 53 of 2003);
- (e) **“EME”** means an Exempted Micro Enterprise in terms of a code of good practice on black economic empowerment issued in terms of section 9 (1) of

- the Broad-Based Black Economic Empowerment Act;
- (f) **“functionality”** means the ability of a tenderer to provide goods or services in accordance with specifications as set out in the tender documents.
 - (g) **“prices”** includes all applicable taxes less all unconditional discounts;
 - (h) **“Proof of B-BBEE status level of contributor”** means:
 - 1) B-BBEE Status level certificate issued by an authorized body or person;
 - 2) A sworn affidavit as prescribed by the B-BBEE Codes of Good Practice;
 - 3) Any other requirement prescribed in terms of the B-BBEE Act;
 - (i) **“QSE”** means a qualifying small business enterprise in terms of a code of good practice on black economic empowerment issued in terms of section 9 (1) of the Broad-Based Black Economic Empowerment Act;
 - (j) **“rand value”** means the total estimated value of a contract in Rand, calculated at the time of bid invitation, and includes all applicable taxes;

3. POINTS AWARDED FOR PRICE

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

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

$$\begin{array}{ccc}
 \mathbf{80/20} & \mathbf{or} & \mathbf{90/10} \\
 P_s = 80 \left(1 - \frac{P_t - P_{\min}}{P_{\min}} \right) & \mathbf{or} & P_s = 90 \left(1 - \frac{P_t - P_{\min}}{P_{\min}} \right)
 \end{array}$$

Where

- P_s = Points scored for price of bid under consideration
- P_t = Price of bid under consideration
- P_{min} = Price of lowest acceptable bid

4. POINTS AWARDED FOR B-BBEE STATUS LEVEL OF CONTRIBUTOR

4.1 B-BBEE status level of contribution in accordance with the table below:

B-BBEE Status Level of Contributor	Number of points (90/10 system)	Number of points (80/20 system)
1	10	20
2	9	18
3	6	14
4	5	12
5	4	8
6	3	6
7	2	4
8	1	2
Non-compliant contributor	0	0

5. BID DECLARATION

5.1 Bidders who claim points in respect of B-BBEE Status Level of Contribution must complete the following:

6. B-BBEE STATUS LEVEL OF CONTRIBUTOR CLAIMED IN TERMS OF PARAGRAPHS 1.4 AND 4.1

6.1 B-BBEE Status Level of Contributor:= (maximum of 10 or 20 points)
(Points claimed in respect of paragraph 6.1 must be in accordance with the table reflected in paragraph 4.1 and must be substantiated by relevant proof of B-BBEE status level of contributor.

7. SUB-CONTRACTING

7.1 Will any portion of the contract be sub-contracted?

(Tick applicable box)

YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
-----	--------------------------	----	--------------------------

7.1.1 If yes, indicate:

- i) What percentage of the contract will be subcontracted?%
- ii) The name of the sub-contractor
- iii) The B-BBEE status level of the sub-contractor
- iv) Whether the sub-contractor is an EME or QSE

(Tick applicable box)

YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
-----	--------------------------	----	--------------------------

v) Specify, by ticking the appropriate box, if subcontracting with an enterprise:

Designated Group: An EME or QSE which is at last 51% owned by:	EME √	QSE √
Black people	<input type="checkbox"/>	<input type="checkbox"/>
Black people who are youth	<input type="checkbox"/>	<input type="checkbox"/>
Black people who are women	<input type="checkbox"/>	<input type="checkbox"/>
Black people with disabilities	<input type="checkbox"/>	<input type="checkbox"/>
Black people living in rural or underdeveloped areas or townships	<input type="checkbox"/>	<input type="checkbox"/>
Cooperative owned by black people	<input type="checkbox"/>	<input type="checkbox"/>
Black people who are military veterans	<input type="checkbox"/>	<input type="checkbox"/>
OR		
Any EME	<input type="checkbox"/>	<input type="checkbox"/>
Any QSE	<input type="checkbox"/>	<input type="checkbox"/>

8. DECLARATION WITH REGARD TO COMPANY/ FIRM

8.1 Name of company/firm:

Section B 5: Preference Points Claim Form to the Preferential Procurement Regulations 2011

8.2 VAT registration number:

8.3 Company registration number:

8.4 TYPE OF COMPANY/ FIRM

(Tick applicable box)

- Partnership/ Joint Venture/ Consortium
- One person business/ sole propriety
- Close corporation
- Company
- (Pty) Limited

8.5 DESCRIBE PRINCIPAL BUSINESS ACTIVITIES

.....
.....
.....
.....

8.6 COMPANY CLASSIFICATION

(Tick applicable box)

- Manufacturer
- Supplier
- Professional service provider
- Other service providers, e.g. transporter, etc.

8.7 Total number of years the company/firm has been in business:

8.8 I/ we, the undersigned, who is/ are duly authorised to do so on behalf of the company/firm, certify that the points claimed, based on the B-BBE status level of contributor indicated in paragraphs 1.4 and 6.1 of the foregoing certificate, qualifies the company/ firm for the preference(s) shown and I/ we 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 6.1, the contractor may be required to furnish documentary proof to the satisfaction of the purchaser that the claims are correct;
- iv) If the B-BBEE status level of contributor has been claimed or obtained on a fraudulent basis or any of the conditions of contract have not been fulfilled, the purchaser may, in addition to any other remedy it may have –
 - (a) disqualify the person from the bidding process;
 - (b) recover costs, losses or damages it has incurred or suffered as a result of that person's conduct;

Section B 5: Preference Points Claim Form to the Preferential Procurement Regulations 2011

- (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 bidder or contractor, its shareholders and directors, or only the shareholders and directors who acted on a fraudulent basis, be restricted by the National Treasury 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.

<p>WITNESSES</p> <p>1.</p> <p>2.</p>	<p>.....</p> <p style="text-align: center;">SIGNATURE(S) OF BIDDERS(S)</p> <p>DATE:</p> <p>ADDRESS:</p> <p>.....</p> <p>.....</p>
--	---

INVITATION TO BID Return as Part 5

YOU ARE HEREBY INVITED TO QUOTE FOR REQUIREMENT OF SAHPRA					
BID NUMBER:	SAHPRA/2022/REGULATORY INFORMATION MANAGEMENT SYSTEM/RFB002	CLOSING DATE:	06 March 2023	CLOSING TIME:	11:00 am
DESCRIPTION	REQUEST FOR BID TO SUPPLY, IMPLEMENT, MAINTAIN AND SUPPORT AN ELECTRONIC SUBMISSION AND MANAGEMENT SOLUTION				
BIDDING PROCEDURE ENQUIRIES MAY BE DIRECTED TO			TECHNICAL ENQUIRIES MAY BE DIRECTED TO:		
CONTACT PERSON	Precious Mnguni		CONTACT PERSON	Precious Mnguni	
TELEPHONE NUMBER	012 501 0418		TELEPHONE NUMBER	012 501 0418	
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] <input type="checkbox"/> Yes <input type="checkbox"/> No		B-BBEE STATUS LEVEL SWORN AFFIDAVIT	[TICK APPLICABLE BOX] <input type="checkbox"/> Yes <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No [IF YES ENCLOSE PROOF]		ARE YOU A FOREIGN BASED SUPPLIER FOR THE GOODS /SERVICES /WORKS OFFERED?	<input type="checkbox"/> Yes <input type="checkbox"/> No [IF YES, ANSWER THE QUESTIONNAIRE BELOW]	
QUESTIONNAIRE TO BIDDING FOREIGN SUPPLIERS					
IS THE ENTITY A RESIDENT OF THE REPUBLIC OF SOUTH AFRICA (RSA)?				<input type="checkbox"/> YES <input type="checkbox"/> NO	
DOES THE ENTITY HAVE A BRANCH IN THE RSA?				<input type="checkbox"/> YES <input type="checkbox"/> NO	
DOES THE ENTITY HAVE A PERMANENT ESTABLISHMENT IN THE RSA?				<input type="checkbox"/> YES <input type="checkbox"/> NO	
DOES THE ENTITY HAVE ANY SOURCE OF INCOME IN THE RSA?				<input type="checkbox"/> YES <input type="checkbox"/> NO	
IS THE ENTITY LIABLE IN THE RSA FOR ANY FORM OF TAXATION?				<input type="checkbox"/> YES <input type="checkbox"/> 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

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 insert any additional items they deem necessary.

Bidders may attach separate spreadsheets with their calculations, but all costs must 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.	Supply of Software	Sum	1		
2.	License Fee	Sum	1		
3.	Training of users and Certification	Users	3		
4.	Implementation Support	Months	12		
5.	Technical Maintenance and Support of the system (3rd Level)	Months	12		
6.	Other: Ad hoc improvement support				
SUB-TOTAL					
VAT					
TOTAL COST FOR YEAR 1 (VAT INCLUDED)					

Section B 7: Pricing Schedule

YEAR 2					
Item No.	Description	Unit	Quantity	Unit Price ZAR (Excl. VAT)	Total Price ZAR (Excl. VAT)
1	Implementation Support	Months	12		
2	Technical Maintenance and Support of the system (3rd Level)	Months	12		
3	Other: Ad hoc improvement support				
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	Implementation Support	Months	12		
2	Technical Maintenance and Support of the system (3rd Level)	Months	12		
3	Other: Ad hoc improvement support				
SUB-TOTAL					
VAT					
TOTAL COST FOR YEAR 3 (VAT INCLUDED)					

Section B 7: Pricing Schedule

YEAR 4					
Item No.	Description	Unit	Quantity	Unit Price ZAR (Excl. VAT)	Total Price ZAR (Excl. VAT)
1	Implementation Support	Months	12		
2	Technical Maintenance and Support of the system (3rd Level)	Months	12		
3	Other: Ad hoc improvement support				
SUB-TOTAL					
VAT					
TOTAL COST FOR YEAR 2 (VAT INCLUDED)					

YEAR 5					
Item No.	Description	Unit	Quantity	Unit Price ZAR (Excl. VAT)	Total Price ZAR (Excl. VAT)
1	Implementation Support	Months	12		
2	Technical Maintenance and Support of the system (3rd Level)	Months	12		
3	Other: Ad hoc improvement support				
SUB-TOTAL					
VAT					
TOTAL COST FOR YEAR 2 (VAT INCLUDED)					

SUMMARY	
Total cost for year 1	
Total cost for year 2	
Total cost for year 3	
Total cost for year 4	
Total cost for year 5	
TOTAL COST FOR 5 YEARS	

Annexure A

Electronic Submission Management and Review System - User Requirement Specifications (URS)

General Requirements			
Req ID	Title	Description	Priority
GEN-1	Web Client	Solution should be available as a web-based client for remote use.	Critical
GEN-2	System Configuration	Solution should allow options to setup system parameters to meet local requirements.	High
GEN-3	COTS with Experience	Solution should be a Commercial Off The Shelf solution with proven experience at other major world authorities.	Critical
GEN-4	System Security	Solution should conform to major world security standards e.g. the U.S. CFR 21 Part 11, GAMP5, etc. IT security audits and regulatory compliance	Critical
GEN-6	Application Security	Solution should confirm to confirm to vulnerability resistance on the application layer e.g SAST and DAST?	Critical
GEN-7	Cloud hosted solution certification/validation	Cloud Servers must be in SA, services must be POPIA compliant A Cloud transparency report and/or penetration test compliancy from 3rd party	Critical
User Management and Access Control			
Req ID	Title	Description	Priority
UMAC-1 (NonNeg1)	Users	Solution must allow for the creation of unlimited users without license constraints i.e. should provide a concurrent license model.	Critical
UMAC-2 (NonNeg2)	Groups	Solution should allow the categorisation of users into groups. Permissions in the ACLs should be assignable to groups.	Critical
UMAC-3 (NonNeg2)	Profiles	Solution should allow users to be assigned to one or more profiles controlling the access in general to functionality.	Critical
UMAC-4 (NonNeg3)	ACLs	Solution should allow central control of Access to content during the different stages via Access Control Lists which should be editable centrally.	Critical
UMAC-5 (NonNeg4)	Changes to ACLs	Solution must allow editing of ACLs and new permissions must be applied to all content immediately after ACLs are updated.	Critical

Section B 7: Pricing Schedule

Document Management			
Req ID	Title	Description	Priority
DMS-1	General Document Management	Solution should provide an integrated document management system configurable without software customisation (changes in the executable file) so that application related documents e.g., Evaluation Reports, Committee Decisions, Registration Certificates, etc. can be displayed and made accessible together with the related submissions.	Critical
DMS-2	Document Workflow	Solution should allow the definition of basic document workflow configurable without software customisation (changes in the executable file).	Critical
DMS-3	Document Templates	Solution should provide a way of storing and centrally managing templates for documents to be created within the system.	Critical
DMS-4	Documents from Templates	Solution should be able to create new documents within the system based on centrally managed templates.	Critical
DMS-5	Document Template Variables	Solution should be able to automatically insert values into documents created from a stored template based on the properties of the document e.g. Application Number, Applicant, Proprietary Name, Author, etc.	High
DMS-6	Document Configuration Independence	Solution should make it possible for the Authority to make changes to the configuration including document types, document templates, properties and workflow independently without software updates or software vendor consulting or assistance (assuming adequate training).	Critical
DMS-7	Related Documents	Solution should be able to create documents so that properties from a related submission are automatically applied to the related documents created e.g., Evaluation Reports, Committee Decisions, etc.	Critical
DMS-8	Document Upload	Solution should provide functionality so that documents created externally can be uploaded into the system.	High
DMS-9	Document Versioning	Solution should allow documents to be versioned and document history should show a connection between the versions as part of the overall document structure.	Critical
DMS-10	Document Formats	Solution should enable multiple formats of a document to be stored for each version.	Critical
DMS-11	PDF Rendering	Solution should provide an option to render documents to PDF format using centralised settings conform to general eCTD requirements.	High

Section B 7: Pricing Schedule

Submission Portal (Development/Integrations)			
Req ID	Title	Description	Priority
SP-1	Submission Portal Development	Extend SAHPRA's current online application portal to include electronic submission of dossiers directly to the management and review system.	
Submission Management Configuration			
Req ID	Title	Description	Priority
SMS-1	General Submission Management	Solution should provide an integrated submission management system configurable without software customisation (changes in the executable file) so that application types e.g., Pharmaceutical, Biological, Complimentary, APIMF submission tracking etc. can be defined.	Critical
SMS-2	Submission Properties	Solution should automatically adopt properties from the eCTD Envelope as provided by the applicant where required.	Critical
SMS-3	Submission Property Levels	Solution should allow properties for the submission to be definable at - the application level e.g. Application Number or INN, - the submission level e.g. Submission Type or Submission Status and - the sequence level e.g. Related Sequence Number, Sequence Type or Sequence Status.	Critical
SMS-4	Submission Workflow	Solution should allow the definition of basic submission workflow configurable without software customisation (changes in the executable file).	Critical
SMS-5	Submission Configuration Independence	Solution should make it possible for the Authority to make changes to the configuration including application types, properties and workflow independently without software updates or software vendor consulting or assistance (assuming adequate training).	Critical

Section B 7: Pricing Schedule

SMS-6	Basic Application Content Filters	Solution should allow functionality so that filters can be applied to applications that will: 1) Allow an evaluator to see the current status of the overall application with any replaced or deleted content removed from view, 2) Allow an evaluator to see only the content associated with the sequence being reviewed, 3) Allow an evaluator to see only the content associated with a submission e.g. the sequence being reviewed and any earlier related sequences of the same submission, 4) Allow an evaluator to see only the content associated with sequences included in submissions that have been approved e.g. all content replaced, added as new or deleted in submissions that were withdrawn or rejected should be ignored and not displayed.	Critical
SMS-7	Application Content Filter Configuration	Solution should enable the creation of additional filters as standard functionality and/or configuration (not software customisation) to show content based on submission or sequence properties.	High
SMS-8	Submission Management Explorer	Solution should provide a central hub where applications can be organised and displayed along with any related documentation e.g. evaluation reports, etc.	Critical
SMS-9	Submission Content Display	Solution should allow configuration of content displayed including columns and content grouping.	High
SMS-10	Workflow Management	Solution should allow all submission related content to be moved within the workflow both as a "bundle" of information as well as individual documents and sequences.	High
SMS-11	Submission Content Filters	Solution should allow configuration of filters to be applied to submission related content, both documents and sequences.	High
SMS-12	Submission Search Filters	Solution should enable the creation of search filters as a standard functionality for administrative users. Functionality to create and edit the search filters should not be available to all users.	Critical
SMS-13	Submission Assignment Search Filters	Solution should provide search filters so users can quickly find submissions assigned to them for evaluation.	Critical
SMS-14	Submission Assignment	Solution should have a means to assign teams and/or individual evaluators, portfolio managers, etc to submissions.	Critical

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SMS-15	Leaf Review Status Configuration	Solution should allow the configuration without customisation of a review status that can be applied to individual leafs or sections.	High
SMS-16	Leaf Review Status Filters	Solution should allow the configuration without customisation of filters for leaf review statuses that will show only the content associated with the status defined.	High
SMS-17	Search Filter Result Configuration	Solution should allow all column headings to be configurable without software customisation.	High
Submission Evaluation			
Req ID	Title	Description	Priority
SE-1	Submission Shortcuts	Solution should enable evaluators to create shortcuts on their desktops to allow quick access to submission assigned to them. When activated, login, user validation and access permissions must be required and checked before submission is opened.	Medium
SE-2	Multiple Submission Outlines	Solution should enable the display of multiple submission outlines so that the evaluator can i.e. review both the eCTD Module 2 and eCTD Module 3 content expanded in two separate displays.	Medium
SE-3	Multiple Content Windows	Solution should enable multiple content windows. Windows should be movable and detachable, enabling the user to place them on separate screens.	Critical
SE-4	Favourites	Solution should allow the user to bookmark pages to a favourites section for quick access.	Medium
SE-5	Bookmarks	Solution should allow the users to open and close the bookmark pane in the content windows to access the PDF bookmarks.	Critical
SE-6	Content Search	Solution should allow the user to search words or phrases within the submission content.	Critical
SE-7	Content Search Highlights	Solution should allow the user to highlight all results of a content search to help certain words or phrases to stand out in a document.	High
SE-10	Lifecycle Application View	Solution should enable the user to only see the latest content submitted in the application as a whole i.e. non of the content replaced or deleted.	Critical
SE-8	Lifecycle Submission View	Solution should enable the user to only see content related to the sequences in a particular submission.	Critical
SE-9	Lifecycle Sequence View	Solution should enable the user to only see content submitted in a particular sequence.	Critical

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SE-11	Lifecycle Approved View	Solution should enable the user to only see sequences associated with submissions that have been approved, not those rejected, withdrawn or still under review.	Critical
SE-12	Sequence History	Solution should provide an overview of the sequence history of all sequences provided. The sequence history should be displayed both in chronological order by sequence as well as grouped by submission where each submission is listed separately with all associated sequences. Information about the sequences and submissions should be displayed e.g. status. The sequence history should be available from within the submission, it should not be necessary to return to the submission explorer for history information.	High
SE-13	Annotation Highlights	Solution should allow the evaluator to highlight text without editing or changing the submitted PDF file in any way (the MD5 Checksum cannot be altered). Highlights should be possible in multiple colours.	High
SE-14	Annotation Notes	Solution should allow the evaluator to create notes. Notes should allow the user to categorise comments and give detailed text. Notes should be possible in multiple colours.	Critical
SE-15	Annotation Filters	Solution should allow annotations to be filtered allowing an evaluator to see only their own annotations or also annotations from other evaluators. Filters should be able to also distinguish between Highlights, Notes and different colours.	High
SE-16	Annotation Export	Solution should allow the export of annotations in various formats including MS Excel or a tabular format into the Clipboard for pasting into MS Word.	Critical
SE-17	Hide Annotations	Solution should allow annotations to be hidden if excessive hyperlinks have been created on a page. A simple toggle function should be available to switch the displaying of annotations on and off.	High
SE-18	Leaf Review Status	Solution should enable each evaluator to mark each leaf or section with a configurable status.	High
SE-19	Hyperlink Targets	Solution should allow targets for hyperlinks to be opened 1) in the same content window 2) in a separate content window 3) in the native application configured on the PC/Laptop for that file type e.g. Adobe for PDF.	Critical

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SE-20	Hyperlink Dual Window Use	Solution should allow two content windows where the first window shows the source page for a hyperlink and the second shows the target page of hyperlinks activated.	High
SE-21	Hyperlink Creation	Solution should enable evaluators to create their own hyperlinks in the system. Such hyperlinks cannot be created by editing or changing the submitted PDF file in any way (the MD5 Checksum cannot be altered).	Medium
SE-22	Content Reuse Flag	Solution should be able to flag content identical to content used in other submissions based on MD5 Checksums.	High
SE-23	Content Reuse Referencing	Solution should enable applicants to reference content 1) Provided in other sections of the same sequence, 2) Provided in earlier sequences of the same application, 3) Provided in other applications.	Critical
Submission Validation			
Req ID	Title	Description	Priority
SV-1	Basic Validation	Solution should be able to validate all current requirements in the South African 2.22 Validation Criteria.	Critical
SV-2	Free Industry Validation Tool	Solution should be willing to provide a free version of a validation tool for industry use that will cover all basic validation requirements as defined in the South African 2.22 Validation Criteria.	High
SV-3	Advanced Validation	Solution should be able to handle advanced validation criteria that will reduce screening efforts and help automate quality control of incoming applications. This may include - Document Existence Checks based on Submission/Sequence types - Hyperlink Analysis ensuring the existence of hyperlinks in defined documents to pre-defined locations - Maintain central statistics on common validation issues - Maintain validation issues statistics per applicant <i>Consulting on additional ways advanced validation can help SAHPRA processes will be expected from a local service representative.</i>	Critical
Submission Importing			
Req ID	Title	Description	Priority
SI-1	eCTD Import	Solution must allow the import of eCTDs.	Critical

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SI-2	eSubmission Import	Solution must allow the import of eSubmissions.	Critical
SI-3	Folder Import	Solution must allow a generic import of any folder format determined as necessary. This may be an eSubmission format for Medical Devices (IMDRF-IVD and IMDRF-Non-IVD), for Complimentary Medicines, Veterinary related submissions, Cosmetics, etc.	Critical
SI-4	Envelope Information Import - eCTD	Solution must be able to extract information from the integrated envelope section of an eCTD.	Critical
SI-5	Envelope Information Import - eSubmission	Solution must be able to extract information from files found in a specified location of an eSubmission.	Medium
Process Automation			
Req ID	Title	Description	Priority
PA-1	Automation Flexibility	Solution must be able to connect to systems other than their own (assuming an API connection is available).	Critical
PA-2	Automation Experience	Solution must be able to provide examples of other automation projects at other major world authorities. References will be appreciated.	Critical
PA-3	Import Process	Solution must be able to automate the import process of submissions from the time they are uploaded to the portal including: - Submission Validation, - Virus Scan, - Automated Applicant Communication, - Import into the Evaluation System, - Assignment of the submission to evaluator teams.	Critical
PA-4	General Validation Statistics	Solution must be able to keep statistics of industry validation issues and provide regular reports on the most common issues encountered.	High
PA-5	Applicant Validation Statistics	Solution must be able to keep statistics of applicant specific validation issues and provide regular reports on the most common issues encountered.	High
PA-6	Evaluation Resource Assignment	Solution must be able to keep information of resource work load and automatically assign evaluation to appropriately qualified team members with available capacity.	Critical
PA-7	Pre-Submission Process	Solution must be able to manage processes such as the assignment of Application Numbers and automated communication surrounding expected application dates, etc.	Critical

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PA-8	Automated communication	Solution must be able to create and send automated communication to the applicants concerning validation results, evaluation process changes and evaluation results.	Critical
PA-9	Updated Management Dashboards	Solution must be able to create and update detailed status dashboards for management and portfolio managers and keep statistics on evaluation related timelines.	Critical
PA-10	Consolidated Reports	Solution should be able to automatically compile consolidated reports for the applicant based on documents created using standardised templates during the review process.	High
PA-11	Applicant Packages	Solution should be able to automatically compile, bundle, zip and send a pre-determined package of information to the applicant. Automated process should allow a review and approval of package by a pre-determined role e.g. portfolio manager.	High
Reporting			
Req ID	Title	Description	Priority
R-1	Dashboard	Solution should provide configurable dashboard functionality showing results based on configured properties for applications, submissions, sequences and documents.	Critical
R-2	Individual Dashboards	Solution should enable users to create and maintain their own dashboards independent of the present organisation templates	High
R-3	General Dashboards	Solution should enable the creation and sharing of general organisational dashboards/report templates to users or groups based on automated report batch-runs.	Critical
R-4	Search Filter Result Reports	Solution should allow reports to be created from any search results based on the content shown and the column headers selected in PDF, MS Excel or MS Word as a report	Critical
R-5	Report Formats	Solution should provide the options to create customized reports in PDF, MS Excel or as a tabulated format added to the clipboard to be pasted in MS Word.	Critical
Solution Provider Services			
Req ID	Title	Description	Priority

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SPS-1	Local Representation for Project Implementation Phase	Solution provider should have local representation based in South Africa for - Project Management for Project Implementation as per agreed project schedule. - Technical and Business Consulting for the business blueprint phase and - Training and support during the roll-out phase to the organisation.	Critical
SPS-2	International Expertise	Solution provider should have a detailed understanding of other eCTD regions, their guidance documents, specifications, validation criteria and business processes.	Critical
SPS-3	Project Management	Solution provider should be able to provide a local project manager. Monthly project meetings should be possible and, when necessary, face to face without international travel.	Critical
SPS-4	Business Consulting	Solution provider should be able to provide local business consulting including - General solution best practice use, - Workflow for business processes, - Specification updates, - Submission validation criteria updates, - Submission portal requirements, - Automation processes requirements, etc.	Critical
SPS-5	Technical Consulting	Solution provider should be able to provide local technical consulting to IT including - Solution setup and configuration, - Installations and updates, - System validation and testing, - Security, - Backup procedures, - Submission portal setup, - Automation process configuration, etc.	High
SPS-6	Training	Solution provider should be able to provide local training resources to support the SAHPRA training requirements of evaluators and any other solution users identified during the project.	Critical
SPS-7	eLearning	Solution provider should be able to provide SAHPRA specific eLearning modules to support the process and solution use training.	High
SPS-8	Support	Solution provider should be able to provide local support based in South Africa and focused on SAHPRA requirements. Monthly support meetings should be possible and, when necessary, face to face without international travel.	High

