SAHPRA/2023/TECHNOLOGY CONSULTING/RFB003

Questions and Answers

Questions	Answers
1. Just some verification on the solutions required as part of this Bid: Are bidders required to bid on all of the below solutions or are there some of these that are already in the process of being procured or have been procured already? The digital tools would include but is not limited to the following: • **RIMS Solution (Health Product Applications and Licensing Management)** – A comprehensive Regulatory Management solution for planning, tracking, document management and registration of products and establishments. Implements regulatory standards and formats for submission of application and amendments such as eCTD (**electronic common technical document**), ISO IDMP and other submission related standards for Vet and Medical Devices. • **Import/Export permit processing Solution** - a Management Information System (MIS) for national and international drug control with range of day-to-day drug control activities (import/export permits, licensing of companies, domestic transactions, company management) and exchange of data electronically on national and international levels.	The scope of the bid is limited to only this system. • **Stakeholder engagement** – platform to allow stakeholders to access specific datasets, track status of their requests, manage service requests and inquiries. • **Data Management platform** – data lake/warehouse with intelligent analytics, with management reporting related to key performance indicators, dashboard visualizer that is optimized also for mobile viewing. • **S21 and S36 applications and Imported/Exported/Manufactured batch & product tracking management solution (which includes safety alerts/recalls requests/"out-of-stock" alerts –** customized tool that allows applicants to log lot and qty information by product imported/exported/manufactured – update the tool with laboratory test results/i.e. lot release status, and if exported – log in the system quantity if exported with details of destination country and provide mechanism to manage S21 and S36 applications and provide visibility to key holders such as Port Health Bid No: **SAHPRA/2023/RFB 003 SOURCING OF A SERVICE PROVIDER TO PROVIDE TECHNOLOGY CONSULTING FOR A PERIOD OF SIXTY (60) MONTHS** SAHPRA Bid Document Section A 3: Evaluation Process/ Criteria Page 9

• **Pharmacovigilance Solution** – a drug monitoring, signal detection and analytics, as well as reporting tool for managing reports of adverse drug reactions of any other health products related problem, with automated reporting interface/integration to World Health Organization's UMC Vigiflow database. • **Clinical Trial Solution** – is a software system to manage clinical trials in the clinical research. The system maintains and manages planning, performing, and reporting functions, along with participant contact information, tracking deadlines and milestones. • **Stakeholder engagement** – platform to allow stakeholders to access specific datasets, track status of their requests, manage service requests and inquiries. • **Data Management platform** – data lake/warehouse with intelligent analytics, with management reporting related to key performance indicators, dashboard visualizer that is optimized also for mobile viewing. • **S21 and S36 applications and Imported/Exported/Manufactured batch & product tracking management solution (which includes safety alerts/recalls requests/"out-of-stock" alerts –** customized tool that allows applicants to log lot and qty information by product imported/exported/manufactured – update the tool with laboratory test results/i.e. lot release status, and if exported – log in the system quantity if exported with details of destination country and provide mechanism to manage S21 and S36 applications and provide visibility to key holders such as Port Health Bid No: **SAHPRA/2023/RFB 003 SOURCING OF A SERVICE PROVIDER TO PROVIDE TECHNOLOGY CONSULTING FOR**	• **Health Product Registration and Establishment licensing registry system** – software tool that manages data updates from inter alia core RIMS processing system etc. to reflect list of registered products, licensed establishments, and the registration/license statuses, and allows data extracts of permitted data fields to stakeholder systems such as National Department of Health (NDoH), Port Health, South African Revenue Services (SARS) etc.

A PERIOD OF SIXTY (60) MONTHS SAHPRA Bid Document Section A 3: Evaluation Process/ Criteria Page 9 • **Health Product Registration and Establishment licensing registry system** – software tool that manages data updates from inter alia core RIMS processing system etc. to reflect list of registered products, licensed establishments, and the registration/license statuses, and allows data extracts of permitted data fields to stakeholder systems such as National Department of Health (NDoH), Port Health, South African Revenue Services (SARS) etc. Furthermore, from the need analysis conducted key problem statement were identified: • A need to for a common stakeholder platform (self-service portal) to manage stakeholder related activities for all core business activities. • A need to integrate of all SAHPRA solution where required. • A need to manage fragmented data to eliminate tedious data collection and extraction. • Stakeholder platform for accessing health product related information – e.g., registered health products, approved Import Permits, licensed establishments. • Training platform to access CPD training topics and other training materials. **2.2 Scope of Work** 2.1.2 Solution Architecture (within 4 weeks after signing of the SLA) The scope of work by the bidders is to provide:	

• Review the proposed digital tools and craft an overall solutions architecture view with integration requirements. • Develop implementation plan along with development team. • Identify opportunities for custom developments based on software tools currently subscribed to – which allows for closed mapping and support of unique SAHPRA processes.	
2. We kindly request that you consider extending the deadline by a weeks, if at all possible.	The tender will not be extended. It is advertised for a minimum of 21 days which is in line with NT regulation.
3. The understanding of the RFP is the below requirement: Design, Supply, Implementation, Integration services and Support of Digital Tools/platforms inter alia Engagement Portal, Updates to website, Data Warehouse/lake & Analytics Tool, Data Dashboards and Reporting Solution – with the requisite integration layer between deployed digital tools to the South African Health Product Regulatory Authority (SAHPRA). However in a session yesterday with a specialised 3rd party vendor, he indicated the requirement was more around the Hosting requirements of a partially built system already. Please provide clarity on the actual requirement for SAPHRA please….	Section 2.2 (**Scope of work**) of the bid document, clearly illustrate the deliverables required from this bid and sub section 2.2.3 provide software development activities/work required however that work is limited to the following solution. • **Stakeholder engagement** – platform to allow stakeholders to access specific datasets, track status of their requests, manage service requests and inquiries. • • **Data Management platform** – data lake/warehouse with intelligent analytics, with management reporting related to key performance indicators, dashboard visualizer that is optimized also for mobile viewing. • **S21 and S36 applications and Imported/Exported/Manufactured batch & product tracking management solution (which includes safety alerts/recalls requests/"out-of-stock" alerts –** customized tool that allows applicants to log lot and qty information by product imported/exported/manufactured – update the tool with laboratory test results/i.e. lot release status, and if exported – log in the system quantity if exported with details of destination country and provide mechanism to manage S21 and S36 applications and provide visibility to key holders such as Port Health Bid No: **SAHPRA/2023/RFB 003 SOURCING OF A SERVICE PROVIDER TO PROVIDE TECHNOLOGY CONSULTING FOR A PERIOD OF SIXTY (60) MONTHS** SAHPRA Bid Document Section A 3: Evaluation Process/ Criteria

	Page 9 • **Establishment licensing registry system** – software tool that manages data updates from inter alia core RIMS processing system etc. to reflect list of registered products, licensed establishments, and the registration/license statuses, and allows data extracts of permitted data fields to stakeholder systems such as National Department of Health (NDoH), Port Health, South African Revenue Services (SARS) etc. Furthermore, the functional requirement for the required development work is specified in Section 2.3 **Business Requirements Functional**
4. With regards to SAHPRA/2023/RFB 003, MMT Inland require clarification on the following clause indicated in the General Conditions of Contract (GCC) Clause 7 makes reference to Performance Security that can be found in the Special Conditions of Contract (SCC), however there is none indicated on there. Please advise if Performance Security is applicable for this RFP or will this be discussed in the contractual phase.	Yes, this will be discussed in the contractual phase.

Question and Answer for No5

1. Would the acceptance of the tender proposal be influenced by this ongoing fee structure, and if so, could you provide some guidance on how this should be factored into our submission?

Response:

The bid is open/none restrictive, as long as the proposed solution (whether a customizable off the shelf solution or custom solution) addresses the functional requirements in the specification document .

. You should factor all customzable activities as per the delivirables indicated on the pricing schedule and perhaps extend the pricing schedule table to reflect licensing fees.

2. On the requirement below, are you able to advise what kinds of data sources we could expect to work with?

Response:
We are currently in the process of acquiring system to automate our process and therefore we don't have sight of facts regarding data sources. However, there are part of distributed data source in various format within the organisation in different databases format, as well as spreadsheets, the expectation is that all the data will be converted to meaning format during this project.

3. What communication platform is currently used or preferred for 2-way communications (system level, email etc)?

Response: Email and SMS.

4. Not all of the listed function requirements are documented (e.g. Recall Notification) - are we able to get a small write-up on the purpose of each of these features?
Response: All function and features are similar to Section 3.2.4. with minor differences.

5. What is the current technology stack?

Response: We prefer Microsoft .Net Framework or Spring Framework.

6. Is MS SQL a prerequisite and if so, why?

SAHPRA has acquired microsoft licensing for all our operational technological activities (such as office, Exchange,icluding MS SQL ,Azure etc.) so from a financial cost saving perspective we prefer that the proposed solution is aligned to this.

7. What is the size of the current user base?

Response: Internally, we have 400 users and contracted 200 users, however, with those who will be consuming our services externally, some services are for the general public, hence we are unable to provide numbers.

8. Can you kindly provide a list of all the solutions (internal and external) that you see as being in scope for integration?

Response: The scope is as follows:

• Import/Export permit processing Solution - a Management Information System (MIS) for national and international drug control with range of day-to-day drug control activities (import/export permits, licensing of companies, domestic transactions, company management) and exchange of data electronically on national and international levels.

• Pharmacovigilance Solution – a drug monitoring, signal detection and analytics, as well as reporting tool for managing reports of adverse drug reactions of any other health products related problem, with automated reporting interface/integration to World Health Organization's UMC Vigiflow database.

• Clinical Trial Solution – is a software system to manage clinical trials in the clinical research. The system maintains and manages planning, performing, and reporting functions, along with participant contact information, tracking deadlines and milestones.

• Stakeholder engagement – platform to allow stakeholders to access specific datasets, track status of their requests, manage service requests and inquiries.

• Data Management platform – data lake/warehouse with intelligent analytics, with management reporting related to key performance indicators, dashboard visualizer that is optimized also for mobile viewing.

• S21 and S36 applications and Imported/Exported/Manufactured batch & product tracking management solution (which includes safety alerts/recalls requests/"out-of-stock" alerts – customized tool that allows applicants to log lot and qty information by product imported/exported/manufactured – update the tool with laboratory test results/i.e. lot release status, and if exported – log in the system quantity if exported with details of destination country and provide mechanism to manage S21 and S36 applications and provide visibility to key holders such as Port Health
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9. Do you require external stakeholders to be able to access this, sign up, attend, and receive their CPD points via the system? Ie, a complete LMS?
Response: Yes.
10. Can SAHPRA provide a list of the software tools they are already subscribed to, in order to determine if that fits in with the desired technology stack?
Response: Refer to question 5.
11. Kindly confirm that SAPHRA will carry all 3rd party fees re the Payment Gateway

Response: This should be factored in your proposal.

12. Can a list be provided?
- RIMS Solution (Health Product Applications and Licensing Management) – A comprehensive Regulatory Management solution for planning, tracking, document management and registration of products and establishments. Implements regulatory standards and formats for submission of application and amendments such as eCTD (electronic common technical document), ISO IDMP and other submission related standards for Vet and Medical Devices.

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- Clinical Trial Solution – is a software system to manage clinical trials in the clinical research. The system maintains and manages planning, performing, and reporting functions, along with participant contact information, tracking deadlines and milestones.

and all those tha will be procured during the implementation of this project.

13. It is our concern that saving such large files inside the DB files would be detrimental to the DB performance.

Response: No files are to be stored in the database. Some file submissions via the stakeholder engagement portal will be consumed by other solutions inergrated with the proposed solution.

14. Does this imply that the public is also a potential “role-player”. Please identify the key role-players (internal and external) that you see accessing the system.

Response: The stakeholder portal primary purpose is to allow all SAHPRA stakeholders to engage with the platform through submitting or requesting various services. These services relate to requesting to register a product, licencing of establishment, permit to use unregistered medicine etc. As a result, external stakeholder access has to be defined based on the type of services a user has selected during registration of a profile.

15. Confirm that SAHPRA will be responsible for SQL fees as well as hosted environment (infrastructure, telecommunication, etc)
Reponse: SAHPRA is responsible.
16. Will SAHPRA provide the infrastructure?
Response: SAHPRA will provide infrastructure. However, the proposal of the specifications and configuration is the responsibility of the bidder.

Question and Answer for No 6

Question 1

Please provide a number of data sources and details about each data source on the following:
- Type of Data Sources (is it RDBMS or semi-structured data like JSON?)
- Technology and Version of the Source Database: (Ex: SQL Server, Oracle)
- Frequency of data feeds from the data sources: (Daily, weekly, etc)

Response:

- Technology and Version of the Source Database: (Ex: SQL Server, Oracle)?

- We are in a process of acquiring specialized solutions to digitize most of the core business tasks, as indicated in the bid briefing session these systems are:
    - **RIMS Solution (Health Product Applications and Licensing Management)** – A comprehensive Regulatory Management solution for planning, tracking, document management and registration of products and establishments. Implements regulatory standards and formats for submission of applications and amendments such as eCTD (**electronic common technical document**), ISO IDMP and other submission-related standards for Vet and Medical Devices.

- **Import/Export permit processing Solution** - a Management Information System (MIS) for national and international drug control with a range of day-to-day drug control activities (import/export permits, licensing of companies, domestic transactions, company management) and exchange of data electronically on national and international levels.

- **Pharmacovigilance Solution** – a drug monitoring, signal detection and analytics, as well as reporting tool for managing reports of adverse drug reactions of any other health products related problem, with automated reporting interface/integration to World Health Organization's UMC Vigiflow database.

- **Clinical Trial Solution** – is a software system to manage clinical trials in clinical research. The system maintains and manages planning, performing, and reporting functions, along with participant contact information, tracking deadlines and milestones.

- From the above list, only the Import/Export permit solution has an Oracle 19c Database backend, and the rest are on MS SQL Server 2019. (These solutions are not in operation as yet)
- There are also data scattered around in several various formats, such as spreadsheets, and MS SQL that would be retained to the proposed solution in the bid.

Frequency of data feeds from the data sources: (Daily, weekly, etc)?

- Daily

Question 2

Please provide a number of tables /views/files for each data source.

Response: Information is not available at this stage.

Question 3

Please provide for historical data size of each source.

Response:

Question 4

Please provide daily incremental data size of each source

Response:
Information is not available at this stage.

Question 5

Please share if you have any preference for Reporting and Visualization tools such as Power BI, Tableau, etc.

Response:
Power BI

Question 6

Reports: Please share the complexity level of reports

Response:
No data structure or database design of the sources are available as yet to make such determination.

Question 7

Training: Please specify the number of people to be trained and their location

Response:

- For business functional requirements, because the functions are specific to a business unit the number will be determined during requirements gathering for such specific function. However, the number of use bases in SAHPRA is 500.
- For **Section 2.3.2 Data Management Requirement,** a minimum of 10 users

Question 8

What are the current integration Technologies and tools that SAPHRA uses or has licenses for currently? This will help us to understand how existing Technology investments can be leveraged.

Response:
No solutions are currently in operation to interface data exchange for our core business operations however SAHPRA has an E3 license for Microsoft-related technology for all other operations.

Question 9

Is SAPHRA targeting both Android and iPhone users; what is the expected user base of Mobile users?
Response:
Some services are for the public; hence we are unable to provide numbers.

Question 10

Are there any Technologies of preference for Development e.g. Angular/ React/ Vue, Microsoft .Net/ Java, Oracle/ PostgreSQL/ SQL Server etc.?

Response:
We prefer Microsoft .Net Framework or Spring Framework with MS SQ database backend.

Question 11

How many concurrent users are expected on the Stakeholder engagement portal once Live, and what is the expected growth over the next three years

Response:
Kindly refer to the response to Question 9.

Question 12

What are the file formats (e.g. MS WORD, MS Excel, PDF etc.) of S21 and S36 applications

Response:

- For (S21 and S36) requests, file formats are primarily PDF,
- We also indicated a max file size limit for submission requests, that is to accommodate dossier submission requests based on several International specifications such as eCTD and others (https://ich.org/page/ich-electronic-common-technical-document-ectd-v40)

- The expectation is that the stakeholder portal interfaces with the specialised solution that SAHPRA is in the process of acquiring, in the absence of any specialized solution to process submission requests the bidder is to provide such a solution.

Question 13

Has the technology/ product for RIMS already been decided? If yes, can you provide details?
Will the RIMS be ready for integration before the project starts?

Response:
No decision as yet, but our intention is to execute both projects either simultaneously or at least not more than a month apart to allow the successful bidder to gauge issues of operations and interfacing requirements.

Question 14

What is the Financial/ ERP system to integrate with?

Response:
We in process of exploring Sage Evolution functionality, no concrete decision yet.

Question 15

Does SAPHRA have a Business Process Management system already implemented?

Response:

- The Business process is decentralised to the business-specific solutions. (Example. RIMS execute all Medicine Registration Process and others)
- The expectation is the same for all the business function requirements indicated on this bid.

Question 16

Are any Monitoring / Alerting tools already in use at SAPHRA?

Response:

- There is none. However, for the proposed solution we prefer that the stakeholder engagement portal manage all alerts for external stakeholders through integration with specialized internal solutions indicated in Question 1**.**
- For internal alerts, the business-specific function should assume the responsibility of managing alerts that includes solutions acquired through this bid.