SAHPRA/2022/REGULATORY INFORMATION MANAGEMENT SYSTEM/RFB004

Questions and answers

QUESTIONS	ANSWERS
1. Where are the main challenges with existing application submission and review processes?	Manual submission and upload of dossiers Multiple platforms for data collection and segregated data Manual and Separate tracking mechanism Reporting.
2. Are the current submission and reviewal processes documented in a manner that would enable rapid system workflow configuration, or are workshops required to support the elicitation of workflows.	The organization recently engaged in Enterprise Architecture (EA) process mapping in preparation for this tender.
3. Are SAHPRA review processes standardised or variable across commodity categories (e.g. medicines v.s. devices) and within categories (e.g. originators v.s. generics). If variable, how many processes are there?	There are variable across commodities the review process is not standardized. The variable range between 7 to 8 processes.
4. Are any review processes available to share with bidders as an example of the workflow configuration requirements?	Yes
5. Is it expected that the workflow will be required to inform or trigger tasks in licensing or other functional areas in SAHPRA?	Yes

6. Validation Tool: Is the purpose of the validation tool to digitise the Validation Template (or similar) and automate the workflow to assess and evaluate administrative and technical information?	Yes
7. Who is the expected user of the validation tool? SAHPRA users only? Or submitting organisations? Should this tool be accessed separately from the solution?	SAHPRA users for now, with time and maturity eventually submitting organizations as well.
8. Is the solution expected to be used for initial registrations only, or does it include post-registration amendments?	The solution is expected to include post registration and Amendments.
9. Are SAHPRA applicants expected to interact with the system and receive automated notifications regarding the status of their application (e.g. stage of workflow, requests for information etc.)	Yes, and have readily available API's to enable integration with other internal applications.
10. Are inspections triggered automatically and do findings from inspections automatically form part of evaluation workflows?	No, there is no direct inspection request that would trigger or inform other parts of the evaluation process.
11. The document management system refers to the ability to generate data regarding the creation and editing of a document. Is the system also required to digitise and codify the underlying submission data?	eCTD/Dossier related documents are not expected to be modified nor expect to generate any documents within such submission. However, there are documents which are to be produced and shared during processing of submission such as evaluation reports, inspection reports committee reports etc. These are the documents that would require the use of document management system.
12. Is there an existing electronic database that enables SAHPRA to review applications?	There is an existing solution for review (evaluation) of applications supplemented with tracking tools.

13. Does SAHPRA have existing business intelligence functionality to (amongst others): a) track submission statuses b) Identify process efficiencies and bottlenecks c) review applications based on any pre-defined criteria (e.g. applicant history, fast track, disease area, competition levels, etc.)	None.
14. Is it possible to share the templates that will be stored for applicants to utilise?	The Template will be shared to the successfully bidder.
15. eCTD requirements specify submissions for Medicines. What is the SAHPRA process and requirement for Medical devices and other related submissions (Veterinary etc.)	The Medical devices process for SAHPRA will be shared with the successful bidder.
16. What system is currently in use by SAHPRA, and is the existing system able to integrate with new systems through an API connection? a) Can the existing system API endpoints be shared?	The current SAHPRA systems were implemented to address pain points. A way forward on the systems will be discussed and finalized with the successful bidder.
17. Is the system required to integrate with any procurement and supply chain information systems to support improved medicine availability?	Nope, However the system is expected to have/or integrate with a payment mechanism/gateway for submissions which requires payments. Furthermore, a financial module is required to manage all revenue triggered points in the process flows.
18. During the briefing session it was noted that an offline system is required to support inspections. Is this system already in place and available to integrate with workflows?	Nope.
19. Who is the expected user of the validation tool? SAHPRA users only? Or submitting organisations? Should this tool be accessed separately from the solution?	Primarily for SAHPRA users, with time and maturity would make it available to applicants.

20. Per mandatory requirement, a demonstration of the solution is required. When is it expected that this demonstration will be provided, and when will the SAHPRA specific information noted be provided?	SAHPRA will provide specific information for the demonstration before appointment.