Enabel
Implementing on behalf of #TEAMEUROPE

ADDENDUM N°2 to the Tender document RWA21001-10055

Dear Sir, Madam,

With reference to the above-mentioned Tender Document (TD) launched on 19 March 2026, and further to addendum N°1 concerning the extension of submission deadline, please be informed of the following.

Further to the questions raised by bidders, please find attached a table compiling the responses for your consideration.

We also take this opportunity to correct a discrepancy identified between the number of person-days indicated in Article 5.7 (200 person-days) and Article 6.2 (227 person-days – Price Form). The Tender Documents are therefore amended accordingly, with revisions applied in particular to Article 6.2:

Revision of Tender Form – Prices (art 6.2)
The quantities have been adjusted to a maximum of 200 person-days, replacing the previously indicated 227 person-days. In addition, bidders are required to submit a detailed breakdown of the proposed financial offer, to be included as an annex to the Financial Proposal.

Please note that all other terms, conditions, and clauses of the initial Tender Document that are not explicitly modified by this Addendum remain unchanged and fully valid.

We appreciate your understanding and continued collaboration.

Kind regards,

Evariste SIBOMANA
Enabel Rwanda - Contract Officer

RWA21001-10055 - "**DEVELOPMENT OF THE PHARMACEUTICAL TRACK AND TRACE SYSTEM COMPLIANT WITH EPCIS STANDARDS" – CLARIFICATION Q/A**

#	QUESTIONS	CLARIFICATIONS
1.	**Tenderers – Evaluation** *Concerning section 3.4.7.4 (Award criteria), could you please clarify if there is a specific minimum score or "cut-off" point for the technical evaluation?* *Specifically, is there a threshold below which a proposal would be considered non-responsive and subject to preliminary rejection?* *Please confirm the technical evaluation scoring criteria for firm requirements. Will prior experience in GS1 standards/EPCIS (including serialization and track-and-trace implementations) be considered as part of the technical evaluation, or is this only reflected indirectly through the general experience requirements?* *Could you please indicate the expected number of bidders to be shortlisted for the negotiation phase?* *Could you please provide more detail on minimum qualifying thresholds, especially for technical evaluation?* *Is there a minimum technical score cutoff required to proceed to financial evaluation?*	The evaluation will be conducted in accordance with the procedure and criteria defined in the tender documents (notably articles 3.4.7.1 to 3.4.7.6). Only compliant tenders meeting the selection requirements will be evaluated on the basis of the award criteria. At the award stage, the final ranking will be based on the combined technical and financial scores, as stated in the tender documents. No pre-established minimum score applies; tenders will be comparatively assessed based on the defined award criteria. Then the contracting authority may decide to shortlist a maximum of three tenderers for negotiations. However, the contracting authority may also decide not to enter into negotiations, in which case the initial tender shall be considered the final tender. The Contracting Authority reserves the right not to award the contract.
2.	**Briefing** *We request the contracting authority to kindly confirm whether a pre-bid conference or technical briefing session will be conducted to address common queries.*	Not Planned.
3.	**Clarification and refinement – Negotiation** *During negotiations, will both technical and financial components be open for refinement, or only financial aspects?*	In accordance with art. 3.4.7 of the tender documents and the applicable public procurement rules, the Contracting Authority may request clarifications or refinements from tenderers regarding their technical proposals and may negotiate the financial aspects of their tenders. However, clarifications and negotiations shall not alter the minimum requirements, the subject-matter of the contract, or the award criteria.

		The Contracting Authority also reserves the right not to conduct negotiations and to base the award on the initial tenders.
4.	**Applicant Eligibility – International restriction and local representative** *As an International company invited by Enabel, we work in close partnership with a local partner. Given the objectives of this tender, does Enabel have a preference or requirement regarding which entity should act as the lead applicant?* *We would like to ensure our bidding structure—whether headed by the International entity or the local partner—is best aligned with your procurement guidelines for this specific contract.* *Are there any nationality or country-of-registration restrictions on consortium members, or may firms from any country participate?* *We wanted to confirm our understanding that bidding companies do not need to have a local representative office in Rwanda, as long as they are a legally registered company elsewhere.*	The Contracting Authority does not prescribe any specific entity to act as lead applicant. In principle, participation is open, subject to the Contracting Authority's KYC assessment and any applicable donor requirements. There is no requirement to have a local representative.
5.	**International bank guarantees** *Kindly confirm whether international bank guarantees are acceptable and if local institutions are preferred.*	International or local bank guarantees are acceptable, provided that they comply with the requirements set out in Article 4.6 of the Tender Documents. No preference shall be given in this regard.
6.	**International submission** *Considering global participation, would the authority consider allowing secure digital submission in addition to physical submission?* *We request the contracting authority to kindly clarify if any flexibility is available in case of courier delays beyond bidder control. We also request the authority to give provision for electronic submission of bid* *Can we submit electronically through a secure FTP for e.g.?*	Pursuant to Section 3.4.4 (How to submit tenders), Each tenderer may submit only one tender, which must be provided in *three hard copies* (one original and two copies) and *one soft copy that is strictly identical to the hard copy*, *submitted in one or more PDF files on a USB stick*; failure to submit both the required hard and soft copies may result in rejection of the tender. The Contracting Authority does not foresee allowing digital submission.
7.	**Submission – envelopes** *Should we separate the Technical Submission from the Commercial, by putting in different envelopes?*	This is not mandatory. However, tenderers are requested to follow the guidance set out in the tender documents notably section 7.
8.	**Financial proposal** *Please confirm whether the financial proposal must strictly follow the pricing template provided (expert fees and reimbursables only), or whether bidders are permitted to include additional cost line items (e.g. software/platform/licensing components) where such*	The financial proposal shall strictly adhere to the pricing template provided. Any cost elements not explicitly included in the template shall be deemed included in the relevant expert fees (see Article 3.4.3.1).

	costs are not explicitly captured within the prescribed structure. *In case additional cost components are not to be listed separately, please confirm whether such costs should be incorporated within the expert fee rates.* *There are other costs apart from the person days, such as software licenses for example. How do you want us to account for them, as the financial tender form doesn't cater for this.*	NB: Tenderers are requested to provide a detailed cost breakdown for transparency and clarity. Please refer to Amendment No. 2 of the Tender Documents.
9.	**Validity of the bids** *In case of extension beyond 120 days, would bidders be allowed to revise pricing or account for cost escalations?*	Bidders are bound by their tender for a period of 120 days from the submission deadline, as specified in the Tender documents (cf. art. 3.4.2.). In case an extension of the tender validity period is required, this will be subject to mutual agreement. Any request for extension will clearly specify whether bidders are allowed to maintain or revise their financial offer.
10.	**Pricing** *Given pricing is in EUR, could you clarify how currency fluctuation risks (especially for local costs) should be managed?*	All prices must be quoted in EUR as specified in the Tender Specifications. Bidders are deemed to have included in their financial offer all costs, risks, and contingencies related to the execution of the contract.
11.	**Taxes-duties** *We request the contracting authority to please confirm whether local taxes, duties, or regulatory fees in Rwanda are reimbursable or to be included in the bid price.*	Pursuant to section 3.4.3.1 of the tender documents (Elements Included in the Price), the service provider shall be deemed to have included in the unit and global prices all charges and taxes generally applied to the services. Only international travel costs and any applicable visa costs shall be considered reimbursable. Cf. also art. 6.2 of the tender documents and the Amendment 2.
12.	**Person-days** *Can the total person days exceed 200, subject to adequate justification?* *Please confirm whether the level of effort (man-days) reflected in the pricing template represents a fixed ceiling, or whether bidders may propose adjustments where justified by their technical approach*	The person-days indicated in the pricing template represent fixed maximum effort levels to be distributed. Bidders are expected to adhere to these ceilings
13.	**Revision** *Given project duration and uncertainties, would the authority consider limited price adjustment mechanisms*	As specified in the tender documents (art. 4.8.2), price revisions are not permitted under this contract.

	for major external factors (e.g., inflation)? Could you clarify the methodology for compensation in such cases and any predefined caps?	Bidders are therefore expected to include in their financial offer all costs, risks, and contingencies related to contract execution, including potential impacts from inflation or other external factors. Any contract modifications, if applicable, would be strictly limited to the conditions set out under the applicable public procurement rules.
14.	**Lump sum** *What is the significance of specifying person days, since the contract will be a fixed lumpsum rather than a time and material? Is it just meant as a quantification measure?*	Although the contract is lump-sum, person-days are included only as a reference to quantify the expected level of effort. They support planning, scope clarity, and bid comparability, without affecting the fixed-price payment structure, which remains based on deliverables.
15.	**Approval** *Kindly confirm whether approval timelines could impact payment schedules and how delays (if any) will be handled.*	Ref. to section 4.15.1. of the tender documents.
16.	**Cap** *We respectfully request clarification on whether there is a cap on liability, aligned with industry best practices. Could you provide more detail on the penalty calculation methodology and maximum exposure limits?*	The Tender Specifications do not provide for any limitation or overall cap on the Contractor's liability. The Contractor remains fully liable for the proper performance of the contract. Penalties and delay fines shall be applied in accordance with the applicable public procurement framework, including the General Implementing Rules (GIR), depending on the nature of the non-performance (delay or defect), and without prejudice to any additional damages where applicable.
17.	**Joint Venture/consortium Experience** *If a Joint Venture or Consortium submits a proposal for this tender, will Enabel permit the technical and non-technical capacity requirements to be met by combining the experience and past projects of the JV members?* *For a Joint Venture (JV) or Consortium established specifically for this project (a newly formed legal entity), will the 'minimum of 7 years of experience' requirement be waived, provided that the lead partner or one of the collective members meets this threshold?* *We are preparing a tender in the form of a consortium/temporary association and kindly request*	In case of a Joint Venture (JV) or Consortium, the required experience and financial capacity may be assessed based on the combined capacities of all members. However, each key expert must, of course, individually meet the required qualifications and experience (cf. Art. 5.9.2 of the tender documents). Bidders shall clearly indicate the roles, responsibilities, and contributions of each member, and comply with all formal requirements applicable to JV/Consortium

	clarification on the following points regarding the application of selection criteria to consortium members: *1. Are the selection criteria — specifically the minimum 7 years of experience in software development, the requirement for at least three (3) similar completed assignments, and the minimum cumulative turnover of €100,000 — assessed on an individual basis per consortium member, or may they be satisfied collectively across all members of the consortium?* *2. Is it required that the designated group leader individually meet all minimum selection criteria, or is it sufficient for the consortium as a whole to meet them?*	submissions, including the submission of a Power of Attorney designating the lead entity. Please refer to the Tender Documents, in particular section 7: *Legal Identification Form*: completed and signed by each member; *Financial Identification Form*: completed by the lead member; *Declaration on Honour and Integrity*: signed by all members; *Technical and Financial Offers*: signed by the authorized representative; *Supporting administrative documents* (e.g. criminal record, tax and social security clearance): provided for each member.
18.	**Joint Venture Agreement Requirements** *For a Joint Venture formed for this project would it suffice at the time of submission that only a JV Agreement is in place. And could Enabel clarify any mandatory requirements or minimum criteria that must be included in the JV Agreement?* *Specifically, we would like to confirm whether there are standard clauses required regarding:* *a) The designation of a Lead Partner with authority to bind the JV;* *b) The joint and several liability of all partners;* *c) The specific share of participation;* *d) Formal distribution of tasks among members*	See above – these elements are indeed necessary - The Contracting Authority reserves the right to require formalisation of the arrangement (if necessary) prior to contract signature.
19.	**Acceptance of individual JV/Consortium member payments** *If JV/Consortium members are incorporated from different countries, will it be accepted that invoices from each of them are presented directly, under the assumption that these are:* *1) Administratively consolidated and submitted by the Managing JV member / Prime in the consortium* *2) Add up to the agreed amount in the financial proposal* *3) Clear payment instructions for each of the JV members are agreed upon during contract finalization*	Payments will be made exclusively to the lead member (or designated contracting party) of the Joint Venture/Consortium, who remains fully responsible for contractual and financial coordination. Separate invoicing or direct payments to individual members are not permitted.
20.	**Technical Selection Criteria and Certification Requirements** *In recruiting experts, our company's policy emphasizes demonstrated technical skills, professionalism, and proven client value over formal certifications. In this context, could you clarify the specific weight assigned to*	While skills and experience remain essential, the Contracting Authority recalls that the minimum qualification and degrees and certification requirements defined in the tender documents

	"valid" or "recognized" certifications within the technical evaluation score? *Some requirements are quite specific, and do not necessarily match the technologies used in the proposed solution. How will the evaluation process assess experts with respect to skills maching the technologies used, but not matching those listed in the RFP material?* *May bidders propose additional relevant technical expertise beyond those listed in the ToRs?*	constitute selection criteria and must be complied with as such. Experts whose profiles do not meet these minimum requirements, including where specific certifications are required, will result in the rejection of the tender at the selection stage. Bidders may, however, propose additional relevant technical expertise where they consider it necessary to ensure the quality and successful delivery of the assignment.
21.	**Decision making** *We request the contracting authority to kindly request clarification on the decision-making structure during project execution, specifically whether approvals (technical, financial, and contractual) will be handled by the Rwanda office or require validation from Enabel HQ in Belgium.* *From a contractual perspective, can you confirm that the contracting authority is Enabel Rwanda?* *Could you clarify the escalation mechanism beyond the managing official for key decisions or disputes?*	As stated in art. 1.2. of the tender document, the contracting authority of this public procurement contract is Enabel, the Belgian Agency for international cooperation. Enabel Rwanda, as implementing entity of the Kwigira project, leads the entire process under this tender, in close partnership with the relevant stakeholders and beneficiaries, as required for implementation and validation.
22.	**Applicable law** *In case of overlap or conflict between Belgian laws, EU regulations, and local Rwanda regulations, could the contracting authority clarify the order of precedence to be followed?* *Considering the project is executed in Rwanda, would the authority consider arbitration mechanisms or local dispute resolution support to ensure practical handling of disputes?*	As stipulated in Section 1.8 of the tender documents, the contract shall be governed by and interpreted in accordance with Belgian law. The parties shall perform their obligations in good faith to ensure the proper execution of the contract, in line with the objectives set out in the tender documents.
23.	**Data protection** *Given the applicability of GDPR and local data regulations, could you confirm whether Rwanda-specific data protection laws also apply and how conflicts (if any) should be handled?*	As the contract will be implemented in Rwanda, with the final beneficiaries being Rwandan public institutions, applicable Rwandan data protection and privacy legislation shall apply and must be complied with as the primary regulatory framework governing data processing within Rwanda. Without prejudice to Article 1.3, GDPR principles shall be considered, where relevant, to the extent that, in the context of the assignment, they do not conflict with applicable Rwandan law.
24.	**Data hosting**	As the system will be owned by a Rwandan government entity, it must be hosted

	We request the contracting authority to kindly clarify if there are any restrictions or preferences regarding data hosting location (e.g., within Rwanda, EU, or approved cloud providers). Could you elaborate on how compliance with these obligations will be monitored and what governance mechanism will be used for enforcement during project execution?	either in the National Data Center or on an accredited cloud infrastructure, in compliance with applicable national ICT and cybersecurity standards (see Section 5.3.6 of the tender documents). Compliance with these requirements will be monitored by the Contracting Authority through regular reporting, technical validation of deliverables, and oversight by the relevant stakeholders. Any non-compliance may result in corrective measures in line with the contractual provisions.
25.	**Scale** *Given the scale (~2000+ entities), could the authority confirm whether the 10-month implementation timeline is fixed or subject to refinement based on detailed project planning?* *Kindly confirm whether onboarding of all ~2,000 entities is expected within project duration or phased beyond it.*	The 10-month implementation timeline remains sufficient for the defined scope, as the current objective is to develop the pharmaceutical track-and-trace system, establish the required APIs for future integration, and conduct a soft launch. . The onboarding of the approximately 2,000 entities will be implemented in phases, with only an initial subset covered during the project period and the remaining entities onboarded in subsequent phases beyond the project duration.
26.	**Software Licensing and Deployment Model** *Our understanding is that the tender aims for a closed deployment of the solution. However, PSQR operates on a yearly licensing model for the use of our technology. Given that the tender scope is limited to a 10+6 month implementation and support duration, how does a recurring licensing model fit within the financial and contractual expectations of this project?* *We wish to ensure our commercial proposal aligns with Enabel's long-term requirements for the solution's operation.*	The 10-month implementation period + 6 months of post-implementation support refers specifically to the contract/project management and oversight provided by Enabel, which is supporting the Rwanda FDA in establishing the full pharmaceutical track-and-trace system. Therefore, while Enabel managed contract has a fixed duration of 10+6 months**,** the long term operational and financial arrangements will fall under the direct management of the beneficiary institution after project completion.
27.	**Subcontracting**	No maximum percentage for subcontracting is defined in the Tender Specifications .

	Kindly confirm whether there is any limit on subcontracting (%) and whether specialized partners (e.g., GS1/EPCIS experts) are encouraged.	Subcontracting, including the use of specialized expertise (e.g., GS1/EPCIS), is permitted, provided that roles are clearly defined and the Contractor remains fully responsible (cf. 4.2 and 6.1.3 of the tender documents.). The proposed setup, including the use of subcontractors and specialized partners, will be assessed as part of the technical evaluation, in particular under the methodology and overall implementation strategy, in line with the award criteria.
28.	**Ecosystem** *Could you clarify whether data sharing with ecosystem stakeholders (e.g., manufacturers, distributors) is permitted under defined governance?*	Data sharing will be strictly governed by established rules, frameworks, and applicable national regulations. Only authorized ecosystem stakeholders will be allowed to access or exchange data in accordance with the approved governance structures.
29.	**IP** *While we understand IP transfer, could you confirm whether bidders retain rights to reusable frameworks, accelerators, and non-project-specific components?* *With regards to IP, our typical practice is that the contracting party will be licensed to use the proprietary software, however the right of distribution of this software would still lie with the winning contractor. Please confirm if this is acceptable.*	Intellectual property rights are governed by the provisions set out in the tender document (cf. art. 5.6).
30.	**Onsite-remote** *Could you provide guidance on the expected proportion of onsite vs remote effort, especially during deployment phases?* *We agree that it will be beneficial to have on-site resources during design and go live, but to be cost effective we propose to be completely remote during development.*	Ref. to the table in art. 5.5. of the tender document.
31.	**Deliverables** *Kindly share detailed acceptance criteria and KPIs for deliverables and system performance.* *Could you provide clear acceptance criteria for each deliverable to ensure alignment during execution?*	Please refer to the deliverables in section 5.5 and Performance requirements of the system in section 5.4.1 of the tender documents.

32.	**System** *We request access to current system architecture, data flows, and existing integrations to better assess implementation complexity.*	Currently, there is no existing end-to-end pharmaceutical track-and-trace system in operation. The ecosystem consists only of siloed dispensing and management systems used by regulators, manufactures/exporters, distributors, and retailers, which cannot be shared at this stage. The architecture and system design for the national track-and-trace solution will be included as part of the project deliverables, as specified in Section 5.5 of the tender document.
33.	**Documentation** *We request availability of API documentation, data standards, and integration readiness status for each system.* *We request the contracting authority to please provide the list of existing applications at every level - warehouses, facilities, etc*	For security and confidentiality purposes, API documentation and integration specifications cannot be shared at this stage. Relevant technical information will be provided to the successful bidder during the implementation phase Please refer to the section 5.2.2 for the list of systems identified for the first phase of integration
34.	**Processing** *Kindly clarify whether digitization of manual processes is within scope or only system enablement is expected.* *We request the contracting authority to please provide the quantum of manual data entry needed and at which level - i.e. warehouses, pharmacies, health facilities, etc.* *We would also like to bring this to the notice of contracting authority that manual data constitutes of manually keyed in data and not paper-based data*	The scope of the assignment is limited to system enablement, including system configuration, setup, and support for the integration of the systems listed in Art 5.2.2 an Art 5.3. At this stage, the contracting authority is not able to provide detailed estimates of the volume of manual data entry required at different levels. The contracting authority takes note of the clarification provided. However, for the purposes of this assignment, the scope remains limited to system enablement.
35.	**Non-functional requirements** *We request detailed non-functional requirements including scalability and security standards.*	For non-functional requirements, please refer Section 5.4.2 of the tender document.
36.	**Post-implementation support**	Refer to Article 5.3.9 and 5.8 of the tender documents.

	Would 6 months post go live support start after soft launch, or official go live? *We note that while the RFP outlines system expectations and post-implementation support, it does not specify measurable Service Level Agreements (SLAs) or performance benchmarks (e.g., system uptime, response times, incident resolution timelines). We kindly request clarification on whether such SLAs will be defined by the contracting authority or if bidders are expected to propose them as part of their solution.*	Tenderers are also invited to clarify or complement their offers by providing additional details where deemed necessary.
37.	**Source code** *Kindly confirm expectations regarding source code handover, documentation depth, and long-term maintainability.*	Please refer to the deliverables in section 5.6 which detail the ownership of the source code and documentation
38.	**Nodes** *We request the authority to please confirm whether there be more nodes in the future.*	Additional nodes may be added in the future. The initial scope covers only the core nodes for the first implementation phase, with expansion possible as the ecosystem grows or new stakeholders are onboarded. Any new nodes will be integrated in accordance with the system's established integration framework and interoperability standards.
39.	**Systems** *We request the contracting authority to please provide the list of national systems needed to be integrated (other than Rwanda Electronic Single Window, Rwanda Medical Supply system, IRIMS platform, RSSB reimbursement system, and Electronic Medical Records)*	The current scope includes integration only with the systems listed in the tender document (as detailed in Section 5.2.2).
40.	**Languages** *We request the authority to please provide the list of languages the solutions should support.* *Please confirm that all deliverables will be in English.*	The system is required to operate primarily in English under the current scope. Future enhancements may extend support to additional languages, including Kinyarwanda, French, and any other languages as determined by the system owner.
41.	**Training** *We request the authority to provide approximate number of users to be trained*	The approximate number of users to be trained is outlined in the tender document. Please refer to Section 5.5, which provides details on the end users and system administrators who are expected to receive training under the project scope
42.	**Hardware** *We request the authority to please clarify the hardware capabilities such as barcode scanner, etc available at each node.*	The hardware capability details for each node, cannot be shared at this stage. Further specifications, if required, will be communicated at an appropriate phase of the project.
43.	**GS1 compliancy**	GS1 compliance guidelines and regulations have been established and are actively

	Are the pharmacies and other nodes mentioned in the RFP already GS1 compliant	enforced. Regular assessments are conducted, and the most recent reports indicate that approximately 70% of pharmacies and other relevant nodes are currently GS1 compliant
44.	**Development** *Can you please clarify if the Track & Trace system should be designed/ developed entirely by the bidder OR if the Track & Trace system should expand/build on an existing system used/piloted by Rwanda FDA*?	There is currently no Track and Trace system. The successful bidder will be responsible for gathering requirements, designing, developing, and deploying the system as specified in the tender document. Ref. refer to Art. 5.3 regarding the task to be performed and Art. 5.2 concerning the project objectives.
45.	**Integration** *For integration with national systems (e.g. RMS ERP, IRIMS, EMRs, RSSB, Customs), please confirm whether the bidder's role is limited to providing APIs/interfaces OR is there also an expectation to modify or enhance the existing systems as part of the scope?*	The scope of the bidder's responsibility is limited to designing and exposing APIs/interfaces and performing system integration with the existing stakeholders' systems, in accordance with the technical specifications and access provided by the respective system owners.
46.	**Onboarding** *Confirm that winning contractor will not be responsible for onboarding supply chain partners onto the platform.*	The scope of the contractor does not include onboarding of supply chain partners. The contractor's responsibility is limited to providing the platform and any necessary technical enablement, as defined in the tender document.
47.	**Registration** *Is there a Drug registration system already in place for integration with the Track and Trace GTIN?* *Is there a facility licensing system already in place for integration with the Track and Trace GLN?*	A Drug Registration System is already in place and will be used for integration with the Track and Trace system for GTIN related data. The successful bidder will be required to integrate with the existing system through defined APIs/interfaces, in accordance with the tender requirements. No enhancement or modification of the existing Drug Registration System is within the bidder's scope. A Facility Licensing System is already in place and will be used for integration with the Track and Trace system for GLN-related data.
48.	**GS1** *Are products already serialized using GS1 standards i.e. with SGTINs?*	Under process.
49.	**Aggregation** *Is aggregation already in place using SGTINs and SSCCs (Serial Shipping Container Code)?*	No. Aggregation using GS1 standards, including SGTINs and SSCCs (Serial Shipping Container Codes), is not currently in place. Aggregation in accordance with GS1 standards shall be implemented as part of

		the Track and Trace system under this project.
50.	**Track and Trace** *Are Track and Trace related regulations already published? if yes can this be shared?*	Track and Trace related regulations, including the Rwanda National Traceability Strategy and other relevant regulatory and technical documents, have already been published and are publicly available online.
51.	**Customs systems** *The RFP mentions "Customs system (Rwanda Electronic Single Window). Is there a similar system for Local manufacturers?* Could you clarify the current integration status between Rwanda FDA systems and the customs platform (e.g., Rwanda Electronic Single Window)? • Is there an existing automated data exchange mechanism? • Is regulatory approval from Rwanda FDA required as part of the importation process prior to customs clearance?	The Customs system referenced in the RFP (Rwanda Electronic Single Window) applies specifically to imported products. Currently, there is no equivalent national system for for overseeing locally manufactured products comparable to the Customs system. Locally manufactured products are regulated and managed through the Integrated Regulatory Information Management System (IRIMS). Integration between Rwanda FDA systems and the customs platform (e.g., Rwanda Electronic Single Window), currently in progress. All import licenses are authorized by Rwanda FDA
52.	**RSSB** *Is RSSB reimbursement system related to insurance claim reimbursements?*	Yes.
53.	**Records** *Is National Electronic Medical Records (dispensing data) already integrated with all health care facilities?*	Under process.
54.	**RMS system** *Please explain the usage of Rwanda Medical Supply (RMS) system.* *Could you please clarify the official role and responsibilities of Rwanda Medical Supply (RMS) within the national pharmaceutical track and trace ecosystem? In particular, we would appreciate insight into its involvement in product ownership, distribution, and traceability processes.* *Should Rwanda Medical Supply (RMS) be considered as a core stakeholder actively performing supply chain operations within the system (i.e., generating EPCIS events), or as an external system to be integrated (e.g., via ERP integration)?* *Are there centrally managed warehouses operated by RMS or other public entities from which pharmaceutical products are distributed nationwide? If so, could you provide further details regarding their operational role*	Refer to Art 5.2.2 of the tender document please also refer to the official website. https://www.rms.rw/ for further details. Rwanda Medical Supply (RMS) should be considered a core stakeholder actively performing supply chain operations, including the generation of EPCIS events, as it is the main distributor for public health facilities. Technically, RMS will participate in the track and trace ecosystem through integration of its existing systems (e.g., ERP/WMS) with the national track and trace system, rather than operating as a standalone external system. .

	and expected interaction with the track and trace system?	
55.	**Export operations** *Could you elaborate on the standard procedure for pharmaceutical export operations?* • *Are export activities restricted to specific stakeholder types (e.g., manufacturers or designated warehouses)?* • *Or are all licensed stakeholders permitted to perform export operations within the system?*	Refer to Art 5.2.2 of the tender document concerning the specific objectives of the assignment. more information regarding Rwanda FDA import guidelines, please refer to the official website. https://www.rwandafda.gov.rw/
56.	**Landing page** *Is there an expectation to design and develop a dedicated landing page or public-facing portal for the Pharmaceutical Track and Trace System, or should this functionality be incorporated into the existing Rwanda FDA web portal?*	Please refer to the project objectives Art 5.2 and Task to be performed Art. 5.3.
57.	**Operational ownership** *Could you please clarify how operational ownership and data ownership will be structured among Rwanda FDA, Rwanda Medical Supply (RMS), and other stakeholders? In particular, we would appreciate clarification regarding ownership and governance of:* • *Inventory data* • *EPCIS event data* • *Data reconciliation processes across integrated systems*	Operational ownership of inventory data remains with the respective supply chain operators, such as Rwanda Medical Supply (RMS) and other licensed stakeholders, while Rwanda FDA retains regulatory oversight and national-level governance, particularly for EPCIS traceability data generated by stakeholders during supply chain activities. Each stakeholder is responsible for the accuracy of data originating from its own systems, with the national track and trace system serving as the authoritative reference for traceability events and cross-system reconciliation, supported by governance and reconciliation processes that will be further defined during the implementation phase with the selected bidder.
58.	**Imported and locally manufactured products** *What percentage of products are imported vs locally manufactured?* *Are un-registered products allowed to be imported in mandatory scenarios?*	Information on the proportion of imported, locally manufactured pharmaceutical products is publicly available on the Rwanda FDA official website (www.rwandafda.gov.rw). Product importation procedures for both registered and un-registered guidelines are available on the Rwanda FDA official website ((www.rwandafda.gov.rw).
59.	**Products registered** *What is the number of medical products registered by Rwanda FDA?*	Information on registered products is publicly available on the Rwanda FDA official website (www.rwandafda.gov.rw).
60.	**Model** *Are you interested in a SaaS based model vs perpetual license?*	No specific preference can be indicated between a SaaS-based model and a perpetual license at this stage . Bidders are

		encouraged to propose solutions that best meet the functional, technical, sustainability, and cost considerations outlined in the requirements, clearly specifying the proposed licensing and deployment model.
61.	**Infrastructure** *Will you be able to provide the required infrastructure such as VMs etc. or are there government approved cloud providers which we can use?*	The approach to infrastructure provisioning will be determined in alignment with government policies and deployment requirements.
62.	**Portal** *Can you provide samples and/or potential rule complexity for the Notification Portal and Engine based on predefined alert triggers?*	At this stage, detailed samples and specific rule complexities for the Notification Portal and Engine are not yet defined. These requirements will be elaborated and finalized at a later stage of the project, during detailed requirements gathering and solution design, in collaboration with the selected vendor.
63.	**Tracking** *We interpret that Integration with the National Electronic Medical Records implies "Patient Tracking", is that true?*	The scope and purpose of any EMR integration will be defined based on approved use cases and system interoperability needs. Further details, including the nature and extent of data exchange, will be clarified at a later stage in line with regulatory, privacy, and project requirements.
64.	**Data Migration** *Migrating existing relevant data is asked for. Is data already cleansed/classified? What is the amount of data?*	The requirement includes migration of relevant existing data, however, at this stage, detailed information regarding data cleansing status, classification, and data volumes is not finalized. These details will be assessed and shared with the successful bidder during the implementation and detailed design phase, following a joint review of available data sources and quality.
65.	**Mobile app** *Are native mobile application(s) required?*	Not required for this phase