Government of the Republic of Trinidad and Tobago

Ministry of Health

PROCUREMENT UNIT

#4-6 Queens Park East, Port of Spain 101002

REQUEST FOR PROPOSAL

December 4th, 2025

The Procurement Unit of the Ministry of Health (MOH) invites suitably qualified firms to submit proposals for the following:

- **Design, Development, Implementation and Maintenance of a web-based Drug Registration Management System**

Proposals should be submitted on or before **Wednesday 14th January, 2026** at **11.00 a.m.** Please see Terms of Reference at Appendix I.

All quotations must be valid for at least ninety (90) days.

If you require any further information or clarification, please feel free to contact the Procurement Unit at 217 – 4664 ext 14803 - 14808 or via email at procurement@health.gov.tt.

Sincerely

Aviann Boodoo-Redhead
Procurement Officer (Ag)
Procurement Unit
Ministry of Health

INSTRUCTION TO BIDDERS – GENERAL

1. All proponents MUST be registered with the Office of the Procurement Regulator.
2. All quotations are to be submitted via hard copy. Envelopes must be addressed to the Permanent Secretary, Ministry of Health and must be deposited in the Tenders Box located in the Ground Floor at # 4-6 Queen's Park East, Port of Spain **ON OR BEFORE: 11.00 am on Wednesday 14th January, 2026.**
3. Submission should be one original and two (2) copies.
4. All requests for clarifications are to be submitted via email to procurement@health.gov.tt no later than ten (10) days before submission deadline.
5. Quotations shall remain valid for ninety (90) days from submission deadline. The Ministry reserves the right to request an extension of this validity period if necessary.
6. Proponents must have a minimum of five (5) years' experience in software development preferably in health information systems and/or regulatory platforms.
7. The contract will be awarded to the **most responsive and technically qualified bidder** whose proposal offers the **best overall value** to the Ministry, in accordance with the Public Procurement and Disposal of Public Property Act.
8. The Ministry reserves the right to:
    a. Reject any or all proposals
    b. Cancel the procurement process
    c. Accept any proposal in whole or in part
    d. Negotiate with the preferred bidder prior to award

Instruction to Bidders – Proposal Submission Requirements

1. Submissions should include the following Legal documents:
    a. Company Registration Documents
    b. BIR Clearance Certification
    c. NIS Clearance Certification
    d. VAT Certificate and VAT Clearance
2. Interested International suppliers must be registered on the Office of the Procurement Regulator Depository

ADDITIONAL DOCUMENTATION

1) Cover Letter

a) Name of the firm or individual
b) Contact information
c) Signature of authorized representative
d) Statement of interest in the project

2) Executive Summary

a) Summary of the proposed solution
b) Brief overview of relevant experience

3) Company Profile and Experience

a) Background and history of the company
b) Summary of experience with similar ICT projects (5) years or greater
c) Client Reference in similar projects (at least [3] recent clients) as per Appendix B – Client Reference Form

4) Technical Proposal

a) Detailed description of the proposed approach/methodology
b) Compliance with specifications in Appendix A
c) Project Management Plan inclusive of:
    i) Work plan and deliverables
    ii) Project schedule (GANTT chart) identifying project milestones and deliverables

iii) Communications Management Plan

iv) Stakeholder Management Plan

v) Risk Management Plan

vi) Quality Management Plan

vii) Change Control Plan

viii) Roles and responsibilities of project team

d) Draft Training Plan

e) Documentation detailing all hardware, software and licenses specifications

f) Draft Service-Level Agreement (SLA) and Exit Management Plan

5) Project Team

a) Names and qualifications of key personnel

b) CVs/resumes of team members

c) Role on the project

6) Cost Proposal

a) Detailed cost breakdown

b) Pricing assumptions and payment schedule

c) Any optional/add-on services and their costs

Checklist for Bidders

Bidders are required to complete the following checklist to ensure all required information and documentation are included in their submission.

Item Id	Item	Check Mark (✓)
1.	Name of the firm or individual	☐
2.	Contact information	☐
3.	Signature of authorized representative	☐
4.	Statement of interest in the project	☐
5.	Summary of the proposed solution	☐
6.	Brief overview of relevant experience	☐
7.	Background and history of the company	☐
8.	Summary of experience with similar ICT projects (5 years or greater) in software development preferably in health information systems and/or regulatory platforms.	☐
9.	Client references for similar projects (at least 3 recent clients) as per Appendix B – Client Reference Form	☐
10.	Detailed description of the proposed approach/methodology	☐
11.	Compliance with specifications outlined in the Functional and Non-Functional Requirements	☐
12.	Work plan and deliverables	☐
13.	Project schedule (GANTT chart) identifying milestones and deliverables	☐
14.	Draft training plan	☐
15.	Documentation detailing all hardware, software, and license specifications	☐
16.	Draft Service-Level Agreement (SLA) and Exit Management Plan with Local Support	☐
17.	Names and qualifications of key personnel (with CVs/resumes and project roles)	☐
18.	Price Structure table (with any additional costing for full functionality)	☐
19.	Company Information table	☐
20.	Pricing assumptions and payment schedule	☐
21.	Any optional/add-on services and their costs	☐

APPENDIX I

Terms of Reference
for a
Drug Registration Management System
for New and Supplemental Drugs

Table of Contents

1(868) 217-4664
Ext. 11000-11142
www.health.gov.tt
ict@health.gov.tt

Introduction

The Chemistry Food and Drugs Division (CFDD) is responsible for the administration and enforcement of the Food and Drugs Act No. 8 of 1960 & Regulations and the Pesticides and Toxic Chemicals Act No. 42 of 1978 & Regulations. The Food and Drugs Act prohibits the sale and advertisement of harmful, unfit or impure food and regulates the standards for food, drugs and cosmetics. The CFDD also serves as secretariat for the Drug Advisory Committee (DAC) which is responsible for:

- The Registration of New Drugs, and
- The Registration of Supplemental Drugs.

The CFDD has managed the drug registration process for over thirty (30) years with the use of a traditional paper-based system, receiving and processing both new and supplemental drug applications (Refer to Appendix C, D and E). New Drug Submission applications are received and processed for drugs that have not been registered in Trinidad and Tobago and Supplemental Drug applications for drugs which are already registered in Trinidad and Tobago, but for which post registration changes have been made. These applications with accompanying documents are stored in physical filing cabinets, making it increasingly difficult to keep up with the growing volume of registrations, which has more than tripled over time. Without modernization, maintaining these records will soon become unmanageable.

To address these challenges, the implementation of an automated, user-friendly and efficient Drug Registration Application is essential. This system will:

- Enhance customer satisfaction
- Optimize employee efficiency
- Streamline registration tracking

The Ministry of Health (MoH) is also seeking to implement online payments which will replace the existing cash payment method thereby expediting the drug application process. Through these digital transformation initiatives, the MoH will move closer to achieving its Vision 2030 healthcare objectives and reinforcing its commitment to modernizing Trinidad and Tobago's health sector. The project for the implementation of the online Drug Registration System for New and Supplemental Drugs is projected for completion on a phased basis:

1. **Phase 1:** Implementation of a web based system for the registration of new and supplemental drugs.

2. **Phase 2:** Implementation and integration of an online payment solution to support the new and supplemental drug registration system.

NB:

✓ *Please note that this tender is for phase 1 only (the design of the solution should take into consideration phase 2).*

Objectives

The objective is to Design, Develop, Implement and Maintain a web-based system of a Drug Registration and Supplemental Management System**,** that supports the end-to-end new drug registration and supplemental process from application submission to product approval and database management. The various forms and current process can be seen in Appendix C, D and E.

The key objectives of this project phase are listed below:

1. To enhance and transform the Business Services of the CFDD thereby ensuring greater compliance, while enabling timely and precise processing of new and supplemental drug registrations.
2. To create an online Drug Registration System for New and Supplemental Drugs which allows for the retrieval of records, application processing and progress tracking.
3. To ensure accurate retrieval of drug information and approvals from CFDD.
4. To reduce average application processing within six (6) months of system launch through automated workflows and integrated data validation.
5. To enable real-time tracking and status updates for 100% of submitted applications within the system, with alerts for pending actions and document requirements.

Scope of Services

The proponent shall be required to perform the following services as **part of Phase 1** of the project, but not limited to:

- Supply and implement an online solution for New and Supplemental Drug Registration to be used by the MoH's internal and external clients.
- Provide a Project Management Plan.
- Facilitate working sessions to validate all processes and requirements.
- Facilitate User acceptance testing with issue tracking and fixes.
- Facilitate fixes based on testing done by Trinidad and Tobago Cyber Security Incident Response Team (TT-CSIRT).
- Ensure that all data stores are implemented locally at the MoH.
- Provide all software, and licenses required to support the application.
- Provide all hardware specifications required to support the application.
- Provide Training for all personnel responsible for supporting & operating the application.

- Provide a Post-Implementation local support period of three (3) months to the MoH prior to the actual start of the Maintenance period.
- Provide a Maintenance Period of twelve (12) months with an option for renewal.
- Provide a Service-Level Agreement (SLA) for the maintenance period and Exit Management Plan in collaboration with the MoH.
- Provide Support via E-mail, remote access, phone and/or online chat 24x7x365 as part of the SLA;

Deliverables

The proponent shall be required to deliver the following:

- Supply and implement a web-based application for registering, processing and tracking of New and Supplemental Drug registrations, that meets but is not limited to the requirements listed in Appendix A;
- An online application that allows for the creation of user profiles for an Applicant and MoH staff.
- An online application that is interoperable with existing MoH platforms;
- Project Management Plan inclusive of, but not limited to:
    - Scope Management Plan
    - Identifying any project considerations including, assumptions and constraints
    - Project schedule including GANTT chart clearly identifying project milestones and deliverables;
    - Communications Management Plan;
    - Resource Management Plan
    - Stakeholder Management Plan;
    - Risk Management Plan;
    - Quality Management Plan;
    - Change Control Plan;
- Facilitation of working sessions with the MoH to ensure that all requirements are captured and incorporated into the final application;
- Training of personnel responsible for supporting & operating the application as identified by the MoH, such as (Administrators, Super users, ICT personal, all categories of end users, etc);
- Training guides in formats such as videos, PDFs, Docx inclusive of:
    - Administrators, Super users, ICT personal and End user guides;
- All software and licenses required to support the solution;
- Documentation detailing all hardware, software and license specifications required to support the application;

- Test scenarios and Test cases documentation for the application with various user groups;
- Installation and configuration of all software and/or hardware required for the application;
- Documentation on all application design inclusive of, but not limited to troubleshooting, administration configuration, system architecture and coding documentation (where applicable);
- Sample SLA for the Maintenance Period and the Exit Management Plan.

NB:

✓ *All documentation shall be provided in English*

✓ *All work done as part of the project whether created by the developer individually or as part of a team, including coding, designs, and any related materials, will be the exclusive property of the Ministry of Health.*

Duration of Project

All works and services shall be completed nine (9) months after the award of the contract.

The Post-Implementation Support provided shall be three (3) months after deployment of the solution

The Maintenance Period shall be for a period twelve (12) months on the expiration of the post Implementation local support

Costing

Costing shall include 12.5% VAT (where applicable) in Trinidad and Tobago currency ONLY.

A breakdown of the Price Schedule detailing the various costs for the solution and all associated costs as per the following items are required:

The proponent must provide two (2) Cost Options for the Ministry's consideration as follows:

Cost Option A (Solution Hosted by Proponent within Trinidad and Tobago)

This cost option shall entail the proponent providing a fully hosted solution at a certified datacentre within Trinidad and Tobago (including 3-month post-implementation support), with the option to migrate the hosted solution to an on-premise platform provided by MoH after the initial 12 months of the contract. The proponent should outline all of the cost items associated with this option. This option must also include:

- Twelve (12) month Maintenance Period for all applications
- Payment schedule linked to deliverables
- Cost for Migration

Cost Option B (Solution Hosted by MoH)

This option must also include:

- Costing for Licenses and all Software (modules, where applicable)
    - Please include the software license Model being supplied either perpetual or subscription
        - If subscription based, please include the initial period being supplied
- Twelve (12) month Maintenance Period for all applications
- Payment schedule linked to deliverables
- Costing for installation and configuration of the solution on the Ministry's hosting environment (including 3-month post-implementation support)
- Proponent must provide a listing of all hardware required to host the solution

Ownership of Data

The proponent agrees that all data and documentation as a result of this solution belong exclusively to the Ministry of Health.

Payment Schedule

The contract price for this consultancy shall be fixed. This price must be all inclusive of items required for the deployment of a solution to meet the functional requirements identified.

It is proposed that the consultant be paid upon successful completion of each phase of the project milestones as captured below.

Milestone	Percentage
• Mobilization Fee	**10**
• Validation that all system requirements are met as stated in Appendix A. • Build, Configure, Customize, Test and Stabilize Environment	**50**
• Training and User Guides • Deploy Solution to Production • Successful Operation • Project Close-off	**40**

Evaluation Criteria

The Ministry will evaluate the responses based on multiple criteria and will select the best overall solution to fit its needs. The Ministry is not obligated to select the lowest price bidder.

Evaluation Criteria	Points	Threshold
1. Functional & Non-Functional Requirements	**25**	**70%**
2. Experience I. Experience of five (5) years or greater in ICT solutions in software development preferably in health information systems and/or regulatory platforms. II. Client Reference - Demonstrated competence (Refer to Appendix B) III. Team Composition and Professional Certificates/Qualifications	**10**	**70%**
3. Project Management Methodology and Work Plan	**20**	**70%**
4. Support and Maintenance Plan i. SLA and Exit Management Plan ii. One-year on-going iii. Support and Maintenance	**10**	**70%**
5. Suitability of the transfer of knowledge (training) program: i. Training Plan	**10**	**70%**
6. Costing	**25**	
TOTAL	**100**	**70%**

Costing will be evaluated on the basis of price with the lowest overall price receiving the maximum score of 25. All other proposals will be scored on the difference in the price of the lowest price expressed as a percentage (%) and ranked accordingly. The formula for this evaluation is as follows:

$$p = y * (x / z)$$

where:

p = points for the financial proposal being evaluated.

y = maximum number of points for the financial proposal.

x = price of the lowest-priced proposal.

z = price of the proposal being evaluated

Appendices

Appendix A – Technical Requirements

Response Code	Description
Y - Included	Feature is delivered as standard functionality in the proposed version of the software and can be demonstrated by the vendor.
F - Future	The feature is not currently included but will be available in a future release. Please indicate the time frame (e.g., 12 months).
C - Customer Customization	Not included. Tools are provided for customization at no additional cost.
V - Vendor Customization	Not included. Vendor provides customization at an additional cost.
T - Third Party	Feature is provided by a third-party partnering arrangement. Indicate any preferred partner agreements.
N - Not Available	Requirements cannot be met.

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ID	Requirement	Code	Comments
A	**General Requirements**		
A.1	The solution shall allow for the registration of an Applicant (Agent, Manufacturer, Importer and Distributor) and creation of a user profile. <u>Fields to register an Applicant inclusive of but not limited to:</u> - Company Type (Agency, Distributor, Manufacturer, Importer) - Name of Company - Company Address - Name of Contact Person - Telephone Contact of Contact Person - Email Address of Contact Person		
A.2	The solution shall allow for the creation of a MoH user and a user profile. <u>Fields to register MoH personnel inclusive of but not limited to:</u> - Name - Job Title - Email - Role (Inspector, Approved, Administrator, Executive, Reviewer)		
A.3	The solution shall include for a Dashboard Interface with key information inclusive of but not limited to; Applicant – biodata, submitted applications, queried applications, completed applications. MoH user – assigned applications, work-in-progress applications, completed applications.		
A.4	The solution shall incorporate the capability to capture electronic signatures.		

ID	Requirement	Code	Comments
A.5	The solution shall support the electronic submission of both New Drug and Supplemental Drug applications, including the secure upload of accompanying dossiers.		
A.6	The solution shall assign a unique identifier to each company registered within the application.		
A.7	The solution shall assign a unique system-generated identifier for each new application. This identifier shall remain visible in the application for the duration of its lifecycle.		
A.8	The solution shall incorporate data validation mechanisms to verify all submitted information for completeness, with the capability to automatically issue alerts for incomplete applications.		
A.9	The solution shall automatically record timestamps of key transactions e.g. when an application is received, when an application is approved, when an application is updated.		
A.10	The solution shall allow for the automatic generation of email and in-app notifications upon the completion of key transactions.		
A.11	The solution must detect and highlight potential duplicate receipt numbers, issuing alerts to the MoH user upon processing new application requests.		
A.12	The solution shall allow applications to be distributed to the team of Inspectors, with the capability to reassign applications. This includes reassigning new applications in response to changes within the team.		
A.13	The solution shall incorporate a countdown mechanism that clearly indicates the time remaining for inspectors to complete the approval process at different stages. MoH to determine the timer value with start and stop period.		

ID	Requirement	Code	Comments
A.14	The solution shall permit Inspectors and Approvers to record and update the status of each application (approved, deferred, or rejected) along with the corresponding justification for their decision. Inspectors should also be able to modify an application's status at any stage of the process.		
A.15	The solution shall provide continuous tracking of each application, with status updates and tracking information accessible to both MoH user and Applicant.		
A.16	The solution shall capture and store the MoH user's (Inspector or Approver) full name and the job title, assigned to review an application.		
A.17	The solution shall allow for workflow management where MoH users can view, assign and track applications by status, add internal notes and flag applications.		
A.18	The solution shall be designed to accept documents in a variety of formats, including but not limited to PDF, JPEG, and PNG.		
A.19	The solution shall allow for the scheduling of appointments with the Applicant as required.		
A.20	The solution shall allow for a New Drug to be registered only once.		
A.21	The solution shall allow for multiple Supplemental Drug registrations.		
A.22	The solution shall allow for the association of a supplementation drug to an existing Drug		
A.23	The solution shall allow an Applicant to cancel an application.		

B	Permissions, Security & Audit Trails		
B.1	The solution shall enforce granular access control on all actions, ensuring users have the minimum necessary privileges to perform their duties (Principle of Least Privilege).		
B.2	The solution shall enforce strong authentication for all users attempting to access the system, ensuring only authorized individuals gain entry.		
B.3	The solution shall enforce robust authorization controls, ensuring authenticated users can access data and generate reports relevant to their defined roles and responsibilities.		
B.4	The solution shall employ strong encryption mechanisms (at rest, in transit, and in use) to protect the confidentiality and integrity of all data.		
B.5	The solution shall implement Role-Based Access Control (RBAC) to centrally manage user permissions based on roles, streamlining administration and enhancing security.		
B.6	Administrators shall be able to configure detailed and layered access rights and security policies based on organizational units (e.g., site location, department) to align with operational needs and segregation of duties.		
B.7	User sessions shall automatically terminate after a configurable period of inactivity of thirty (30) minutes.		
B.8	The solution shall implement an account lockout mechanism with a configurable threshold (e.g., three failed login attempts) to mitigate brute-force attacks, requiring administrator intervention or a secure reset process for reactivation.		
B.9	The solution shall maintain a comprehensive and tamper-proof audit trail of all system operations performed by individual users, including creation, reading, updating, deletion, and archiving of information, with precise timestamps and user identification.		

B.10	The solution shall provide System Administrators with comprehensive audit logs/reports detailing: • Specific actions performed. • The unique identifier of the user who performed the action. • The precise date and time of the action.		
B.11	Where applicable and based on data sensitivity, the solution shall employ data masking or pseudonymization techniques to protect sensitive data in non-production environments or reports with broader access.		
B.12	The solution shall facilitate regular security audits of user permissions and access controls through reporting and review capabilities to ensure ongoing adherence to policies.		
B.13	The solution shall ensure audit log integrity through mechanisms preventing tampering and unauthorized modification.		
B.14	The solution shall be capable of integrating with a centralized Security Information and Event Management (SIEM) system for comprehensive log analysis, correlation, and alerting.		
B.15	The solution shall define and enforce data retention policies for audit logs in accordance with legal, regulatory, and organizational requirements.		
B.16	The solution shall provide alerting capabilities for security-relevant events (e.g., suspicious login activity, unauthorized access attempts) to enable timely response.		
B.17	For privileged actions, the solution shall implement Just-In-Time (JIT) access, granting temporary elevated privileges only when necessary and for a limited duration.		
B.18	The solution shall incorporate User and Entity Behaviour Analytics (UEBA) capabilities to detect anomalous activities indicative of potential security threats or insider risks.		

B.19	For sensitive documents or reports, the solution shall implement watermarking capabilities to track origin and discourage unauthorized distribution.		
B.20	If the system handles highly sensitive data, the solution shall implement Data Loss Prevention (DLP) mechanisms to prevent data exfiltration.		
B.21	The solution shall provide secure data deletion or shredding methods for permanent data removal when required.		
B.22	The solution shall incorporate a dedicated and secure administration portal, accessible only through internal network channels, logically and physically separated from the public web front-end.		
B.23	The solution shall enforce strong central authentication for all administrator accounts upon login, preferably integrating with a centralized identity management system.		
B.24	The solution shall allow the MoH the capability to create and manage user accounts (administrator and end-user roles) with clearly defined and distinct permission levels based on the principle of least privilege and separation of duties.		
B.25	The solution shall utilize Transport Layer Security (TLS) encryption (latest secure version) for all data transmission between web browsers and servers.		
B.26	The solution shall allow users to securely reset their passwords through a process that enforces strong password policies (e.g., minimum length, complexity, history).		
B.27	The solution shall provide super administrator accounts with the capability to securely reset passwords and reactivate disabled user accounts, with appropriate auditing.		
B.28	The solution shall enforce multi-factor authentication (MFA) for all administrator accounts (and preferably for all users), with email being a minimum requirement initially, and stronger methods considered for later phases		

B.29	The solution shall allow administrators to retrieve accidentally deleted records through a mechanism like versioning or a recycle bin with defined retention policies.		
B.30	The solution shall allow Administrator accounts to adhere to the principle of least privilege, with distinct administrative roles possessing the minimum necessary privileges.		
B.31	The solution shall enforce secure configuration baselines for all system components and provide mechanisms to detect and alert on deviations.		
B.32	The solution shall facilitate regular vulnerability scanning of all system components and provide clear reporting and remediation guidance for identified vulnerabilities.		
B.33	The solution shall implement security hardening measures for all layers (OS, web server, database, application) to minimize the attack surface.		
B.34	The solution shall integrate with or include Intrusion Detection/Prevention System (IDS/IPS) capabilities to monitor and block malicious activity.		
B.35	The solution shall define and implement secure procedures for the disposal or sanitization of sensitive data at its end of life.		
B.36	The solution shall enforce the principle of separation of duties for critical administrative tasks to prevent single points of failure and reduce the risk of abuse.		
B.37	The solution shall guarantee the need for comprehensive security awareness training for all users and shall be a documented requirement, with the system potentially providing reminders or access to training resources.		
B.38	The solution shall aim to adhere to established security baselines and hardening guides (e.g., CIS Benchmarks) where applicable.		
B.39	The solution shall implement encryption keys, robust secure key management practices (generation, storage, rotation, access control).		

B.40	The search functionality shall be implemented securely to prevent vulnerabilities such as information disclosure or denial-of-service attacks.		
B.41	The solution shall enforce strong multi-factor authentication (MFA) as a standard method to verify user identities at login, utilizing at least two distinct authentication factors for all users. For administrators, email-based MFA is a minimum initial requirement, with stronger methods to be considered in later phases.		
C	**Access and Interoperability**		
C.1.	The solution shall be built on open standards to ensure easy interoperability with other systems.		
C.2.	The solution shall be capable of secure integration with the organization's existing email system for essential functions (e.g., notifications, password resets).		
C.3.	The solution shall be capable of a secured integration with other critical organizational applications via secure APIs and data exchange protocols.		
C.4.	The solution shall provide a secure "forget password and password reset feature" with an automated, time-limited reset mechanism securely communicated to the user (e.g., email, SMS if MFA enabled).		
C.5.	The solution shall ensure web access compatibility with the latest stable versions of major browsers (e.g., Edge, Firefox, Chrome, Safari) and common mobile devices, ensuring security and functionality across platforms.		
C.6.	The solution shall be fully accessible from a range of mobile devices (phones and tablets) with a responsive and secure user interface.		
C.7.	The solution shall allow for the secure retrieval, storage, and access of documents or images stored remotely, ensuring data integrity and confidentiality.		

C.8.	The system shall be designed to maintain a minimum uptime of 99.5% for availability, with appropriate monitoring and redundancy measures.		
C.9.	The solution shall display a user-friendly and informative error page during critical issues, without revealing sensitive system details.		
C.10.	The solution shall have a context-sensitive built-in help menu or user guide.		
C.11.	The solution shall be designed for intuitive use, minimizing or eliminating the need for extensive user training for common tasks.		
C.12.	The solution shall provide clear and helpful validation prompts to guide users and prevent errors.		
C.13.	The solution shall be easy to understand and logically organized interface, tailored to the needs and roles of various user groups.		
C.14.	The solution shall provide a fully responsive user interface that adapts seamlessly to various screen sizes and devices (tablet, mobile, desktop).		
C.15.	The solution shall enforce strong security measures, including robust authentication with integrations of other systems via APIs.		
C.16.	The solution shall implement robust input validation and sanitization on all user-supplied data to prevent common web application vulnerabilities (e.g., SQL injection, XSS).		
C.17.	The solution shall allow for file uploads and downloads, implement comprehensive security measures to prevent malicious file uploads and ensure the integrity and confidentiality of downloaded files.		
C.18.	The solution shall the implement certificate pinning for mobile applications or critical API integrations, as a requirement to prevent man-in-the-middle attacks.		

D	**Usability**		
D.1.	The solution shall display an error page to users when the solution is experiencing critical issues.		
D.2.	The solution shall have a built-in help menu to assist users.		
D.3.	The system shall be intuitive and user-friendly, enabling users to operate it effectively with minimal or no training.		
D.4.	The solution shall allow validation prompts to users.		
D.5.	The solution shall be easy to understand and organized in a structured way for the various user groups.		
D.6.	The solution shall provide a responsive interface for multiple devices such as tablet, mobile and desktop.		
E	**Scalability, Maintainability and Performance**		
E.1	The solution shall be available 24 hours a day, 7 days a week) except for maintenance		
E.2	The solution shall be able to accommodate/ process a minimum of 200 applications per month		
E.3	The solution shall be modular, allowing for updates and bug fixes.		
E.4	The solution shall support a minimum of 100 concurrent users, with no performance degradation and scalable to accommodate additional users as required		
E.5	The solution shall ensure pages load within 3-5 seconds under normal network conditions.		
E.6	The system shall handle peak load periods of up to 5 times the normal traffic with minimal performance degradation		
E.7	The solution shall have a response time of five (5) seconds or less for all transactions under normal system load.		

E.8	No user submissions and/or uploads, shall be lost during peak periods; automatic queuing shall be used where needed.		
E.9	The system shall scale to accommodate growth from hundreds of thousands to millions of records without redesign.		
F	**Searching and Retrieving**		
F.1	The solution shall enable advanced search capabilities.		
F.2	The solution shall display the total count of records matching the search criteria.		
F.3	The solution shall provide clear notification if no records match the search criteria.		
F.4	The solution shall allow users to order, filter, and sort search results		
F.5	The solution shall include records with attached documents in search results where applicable.		
F.6	The solution should highlight searched keywords within the displayed search results.		
F.7	The solution shall enforce rate limiting on search queries to ensure system stability and fair usage		
F.8	The system shall ensure that users can only view search results for data they are explicitly authorized to access, enforcing access controls at the search result level.		
G	**Reporting**		
G.1	The solution shall generate a list of applications that are approved, deferred and rejected.		
G.2	The solution shall allow for graphical representation for various reports.		
G.3	The solution shall create a downloadable list of applications to be sent to the respective Committee/Board within a specific date range.		

G.4	The solution shall generate a list as it relates to users.		
G.5	The solution shall provide reporting dashboards based on user roles		
G.6	The solution shall allow for reports to be printable.		
G.7	The solution shall provide flexible reporting facilities for the administrator and users		
G.8	The solution shall allow for the users to select specific fields to create reports and also facilitate any ad hoc reporting requests		
G.9	The solution shall allow for the customization of reports according to user defined templates		
G.10	The solution shall be able to produce regular periodic reports and one-off reports		
G.11	The solution shall provide the capability to export data to an MS Excel file and other formats specified by the client		
G.12	The solution shall provide reports on any drug registration attributes at any given point in time based on user stipulated time frame		
G.13	The solution shall generate a list of all completed new and supplemental drugs and cancelled applications.		
H	**Back-up and Recovery**		
H.1	The solution shall provide automatic and regularly scheduled back-up and recovery procedures for all system data and configurations.		
H.2	The solution shall allow authorized Administrators to define and schedule automated back-up routines, including frequency, type, and retention policies.		
H.3	The solution shall allow authorized Administrators to perform manual back-ups on demand.		
H.4	The solution shall allow authorized Administrators to restore the system to a specific point in time using available backups, ensuring data integrity.		
H.5	The solution shall support transactional-based recovery mechanisms to ensure data consistency in the event of system failures.		

H.6	The solution shall provide clear and informative flags or reports to administrators regarding any errors during backup or restore processes.		
H.7	The solution shall allow authorized Administrators to perform integrity checks on data updates that were unable to be recovered or rebuilt.		
H.8	The solution shall support file compression for backups to optimize storage and transfer efficiency.		
H.9	The solution shall provide plain English error messages during backup and recovery, including descriptions and recommended actions.		
H.10	The solution shall allow authorized Administrators to specify default locations for both secure remote (off-site) and local (on-site) backups.		
H.11	The solution shall allow for scheduling of backups to external hardware or secure cloud storage.		
H.12	The solution shall implement version control for system configurations to allow for rollback to previous stable states.		
H.13	The solution shall provide a facility whereby all of the data collected and stored in the system can be exported in a usable standard data export format so that the Ministry can import that data into other data systems for analytics and recordkeeping.		
H.14	All backups, both on-site and off-site, shall be encrypted to ensure data confidentiality.		

Appendix B – Client Reference Form

Company Name:	
Contact Name:	
Contact Position:	
Contact Number and e-mail	
Date:	

Reference being provided for: _____

Goods / Services Supplied: _____

Date Contract started: _____

Date Contract ended: _____

To be completed by the Proponent's Reference:

Please circle the appropriate answer on the table below. If the Proponent's rating is poor or below average, please explain under "Comments".

COMMITMENT	EVALUATION					COMMENTS
How would you describe the quality of service by the vendor?	Excellent	Above average	Average	Below average	Poor	
How would you describe the quality of the project delivered and their ability to meet your original expectations?	Excellent	Above average	Average	Below average	Poor	
How did the vendor perform in accordance with your original schedule, budget and scope expectations?	Excellent	Above average	Average	Below average	Poor	
How would you describe the quality of post-implementation/ training provided by the vendor?	Excellent	Above average	Average	Below average	Poor	

Would you engage this vendor again? Yes [ ] No [ ]

Would you recommend this vendor? Yes [ ] No [ ]

Were there any challenges or delays? Yes [ ] No [ ]

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If you have answered "NO" to either of the first two questions or "YES" to the last question, please use the Additional Comments section below to explain how the vendor can improve their service, and why you would not recommend or use their service in future or why there were any challenges or delays.

Additional Comments:

_____

_____

_____

_____

_____

_____ _____

Signature and Delegation of Reference **Date:**

_____

Company Stamp

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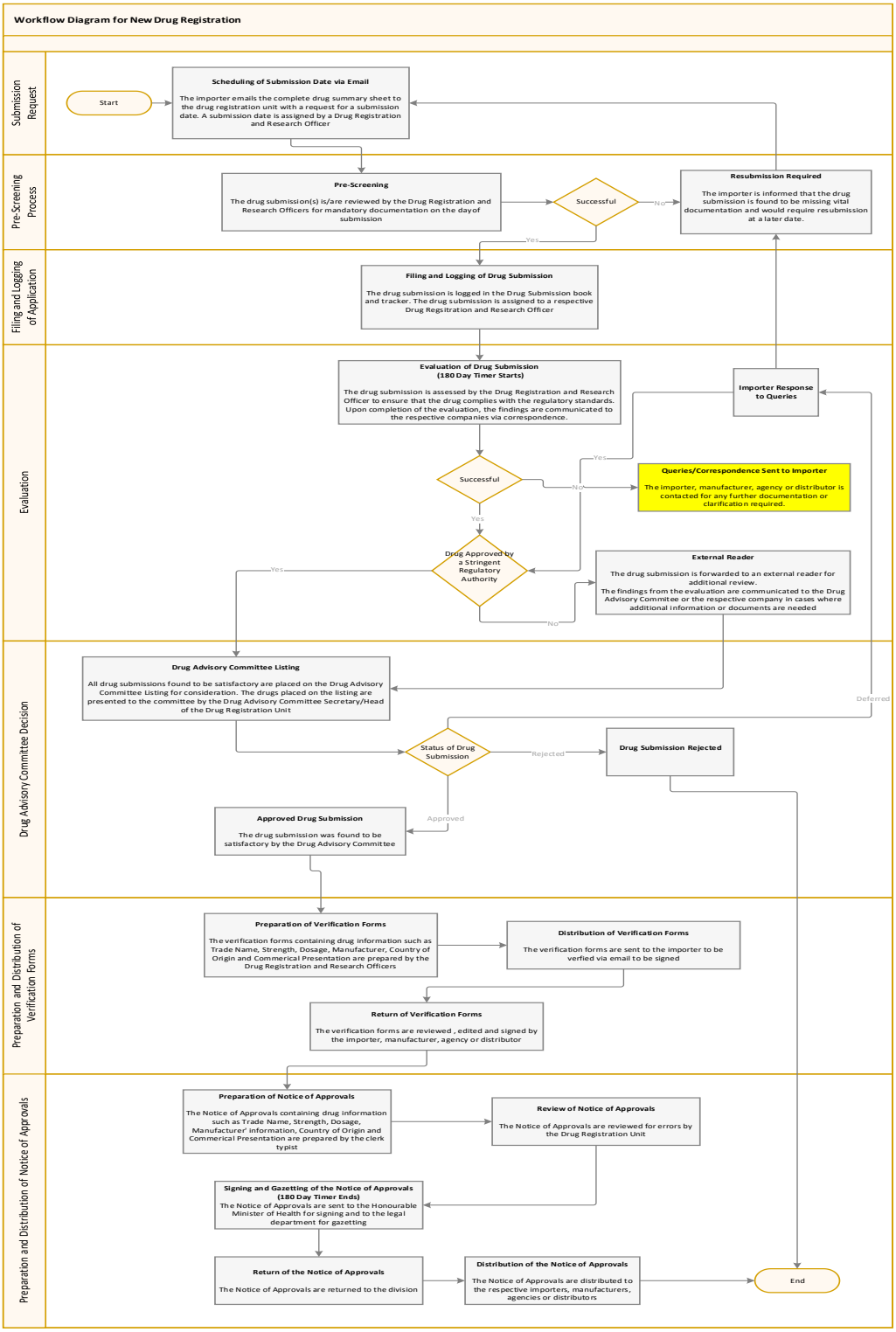
Appendix C – Current State Process Flow



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Appendix D – Current New Drug Registration Form

GOVERNMENT OF REPUBLIC OF TRINIDAD AND TOBAGO

MINISTRY OF HEALTH

CHEMIST- FOOD AND DRUGS DIVISION

NOTICE TO IMPORTERS/MANUFACTURERS

Applications accepted by Appointment only.

No late submission would be accepted.

The following requirements are needed for Pre-evaluation:

- Completed Form A, B and C
- Payment Receipt
- Dossiers - Administrative
  Chemical
  Pharmaceutical
  Other

For further information please see - Detailed Requirements for New Drug Submission.

Failure to comply would result in non-acceptance of application.

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FORM A

GOVERNMENT OF REPUBLIC OF TRINIDAD AND TOBAGO

MINISTRY OF HEALTH

CHEMISTRY- FOOD AND DRUGS DIVISION

NEW DRUGS/SUPPLEMENTAL SUBMISSION CHECKLIST

Checklist to be completed by Applicant

Importer/Manufacturer: .....

Date of Appointment: .....

Receipt No: .....

Product Information		
Trade Name:	**Form:**	**Strength:**
Nature of Drug:	**Classification:** ☐ Chemical Generic ☐ Chemical Brand ☐ Innovator Biologic ☐ Biosimilar Biologic	**Condition for Sale:**

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Commercial Presentation:	☐ Herbal ☐ Other---------- ----	
Reference Product (if applicable) & Manufacturer:		

Please complete the following:			**FOR OFFICIAL USE ONLY**		
Administrative Documentation			File Number:		
	Yes	**No**	**Yes**	**No**	**Comments**
Is this drug being sold in the Country of Origin?	☐	☐	☐	☐	
Has this drug been withdrawn in any country/district?	☐	☐	☐	☐	
Is this drug the same drug approved by the Reference Authority?	☐	☐	☐	☐	
Has any change been made? (name, form, strength, commercial presentation, route of administration)	☐	☐	☐	☐	
Has these changes been approved and by which regulatory agency?	☐	☐	☐	☐	
Completed Application Form	☐	☐	☐	☐	

Stringent Regulatory Approval SRA Name: Issue Date:	☐	☐	☐	☐	
Free Sale Certificate or Certificate of Pharmaceutical Product (CPP) Reference Authority:	☐	☐	☐	☐	
Apostille	☐	☐	☐	☐	
Attested	☐	☐	☐	☐	
Validity Date	☐	☐	☐	☐	
Chemical Documentation					
	Yes	**No**	**Yes**	**No**	**Comments**
Specifications	☐	☐	☐	☐	
Method of Analysis	☐	☐	☐	☐	
Certificate of Analysis - Original (Finished Product)	☐	☐	☐	☐	1. Lot: Exp:

Stability Data (Zone IVA) Shelf life:	☐	☐	☐	☐	1. Lot: Exp: 2. Lot: Exp: 3. Lot: Exp:
Disintegration	☐	☐	☐	☐	
Dissolution Profile	☐	☐	☐	☐	
Three (3) Samples	☐	☐	☐	☐	
Active Ingredient(s)					
	Yes	**No**	**Yes**	**No**	**Comments**
Specifications	☐	☐	☐	☐	
Method of Analysis	☐	☐	☐	☐	
Certificate of Analysis (each active ingredient) - Original	☐	☐	☐	☐	
Certificate of Analysis (each excipient) - Original	☐	☐	☐	☐	
GMP Certificate – Raw Materials (Disregard if manufacturer is the same)	☐	☐	☐	☐	

Sample of Active Ingredient - One (1) gram each (if required)	☐	☐	☐	☐	
Pharmaceutical Documentation					
	Yes	**No**	**Yes**	**No**	**Comments**
Pharmacodynamic Data	☐	☐	☐	☐	
Pharmacokinetic Data	☐	☐	☐	☐	
Pharmacotherapeutic Data	☐	☐	☐	☐	
Toxicity Data	☐	☐	☐	☐	
Immunogenicity Data (if applicable)	☐	☐	☐	☐	
Adverse Event Reports (Within the last 5 years with summary reports)	☐	☐	☐	☐	
Risk Management Plan	☐	☐	☐	☐	
Periodic Safety Update Records/ Public Assessment Reports	☐	☐	☐	☐	

(PSUR/PAR) (most recent with summary reports)					
Pharmacovigilance Plan/ Post-Marketing Surveillance Plan	☐	☐	☐	☐	
Manufacturing Documentation					
	Yes	**No**	**Yes**	**No**	**Comments**
Manufacturing/Unit Composition Formula	☐	☐	☐	☐	
Brief Manufacturing Direction/Procedure	☐	☐	☐	☐	
Brief Manufacturing Controls	☐	☐	☐	☐	
Sampling and Testing Procedure (including Batch Release Certificate and reporting criteria)	☐	☐	☐	☐	Batch Release Certificate? Yes ☐ No ☐
GMP Certificate	☐	☐	☐	☐	
Packaging Materials (Containers and Closures)	☐	☐	☐	☐	
Ink and Printing (Ink composition and safety)	☐	☐	☐	☐	
Artwork	☐	☐	☐	☐	

Labelling	☐	☐	☐	☐	Lot ☐ Expiry ☐ Address ☐ Country of Origin ☐ Special storage conditions stated? Yes ☐ No ☐ NA ☐ Non-compliance:
Package Inserts	☐	☐	☐	☐	NA ☐

Decision: [Check the appropriate box]

☐ Application Accepted ☐ Application Rejected

☐ Decision deferred pending further information ☐ Application Incomplete

Follow-up Notes:

.....

Importer/Representative

.....

CFDD

.....

Date

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FORM B

NEW DRUG SUBMISSION FORM

Second Schedule, Division 3, Food and Drugs Act Chap 30:01

To: The Chief Chemist/Director of Food and Drugs,

4 – 6 Queen's Park East, Port of Spain, Trinidad.

We hereby make the New Drug Submission for .....

and attach the following information IN DUPLICATE:

(a) a description of the New Drug, its proper name and trade name; [ ]

(b) a statement of all ingredients, route of administration, dosage, claims to be made, contra-indication and side-effects (if known), and description of pharmaceutical form in which it is to be sold; [ ]

(c) details of tests applied to control potency, purity and safety of new drugs; [ ]

(d) labels and samples of the new drug in the finished pharmaceutical form; (Note 1) [ ]

(e) samples of the components - active ingredient(s); [ ]

(f) certificates as specified in (g) to (j) in para. 3 (f) (i)-(v) Div.3, of the Second Schedule of the Food and Drugs Regulations; [ ]

Canada	[ ]	United Kingdom	[ ]
F.D.A., U.S.A.	[ ]	Australia	[ ]

(g) certificates from State or City authorities in the United States respecting the sale

and conditions of sale in the United States; [ ]

(h) certificates in English Language recognised as having adequate experience and facilities for assessing the safety of new drugs by the Ministries of Health in

Belgium	[ ]	Netherlands	[ ]	Denmark	[ ]
France	[ ]	Sweden	[ ]		

(i) certificates (with English translation) from other authorities in

..... (2);

(j) detailed reports of animal test [ ] and/or clinical trials [ ] to establish the safety of the new drug (Note 2).

We undertake to inform you of any change made in the conditions of use, labelling, pharmaceutical form, dosage, or strength, purity, quality of the drug which makes them significantly different to those given in this submission, (para. 5 of this Division of the Regulations).

We also undertake to inform you of any report of unexpected side-effects, injury, toxicity, or sensitivity reaction associated with the use of this New Drug in any way (para. 9 of this Division of the Regulations).

....

Date Importers/Manufacturers Agent

in Trinidad and Tobago

NEW DRUG SUBMISSION FORM

(TYPE OR FILL IN BLOCK LETTERS)

TRADE NAME .....

FORM .....

INGREDIENTS:

(SEE NOTES)

	QUANTITY OR %		QUANTITY OR %
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

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CLAIMS, INDICATIONS

KNOWN CONTRA INDICATIONS SIDE-EFFECTS

DOSAGE

MANUFACTURER (Complete Name & Address)	NAME: ADDRESS:
IMPORTER/AGENT (Complete Name & Address)	NAME: ADDRESS: PHONE:

Notes: The pharmaceutical form (tablet, capsule, cream, elixir, injection etc.,) must be indicated. Different strengths in the same form (e.g. 1.5 and 10 mg tablets) must be treated separately.

Active ingredients must be listed before inactive ingredients. Quantities should be given in appropriate units, or in percentages (for creams, liquids), or in amounts per ml or per ampoule.

FOR OFFICIAL USE ONLY

CONDITION OF SALE:

1. FREE SALE
2. THIRD SCHEDULE
3. CONTROLLED
4. DEFERRED

COMMENTS:

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FORM C

For Official Use

Receiving No:

Control No:

DAN No:

Worksheet

To be filled out by Applicant upon presentation of New Drug Submission/Supplemental Submission

(1) Name of Drug/Form/Strength :.....

(2) Name and Address of Manufacturer or :.....

Distributor:.....

(3) Phone Number (if local manufacturer):.....

(4) Country of Origin:.....

(5) Name & Address of Importer:.....

.....

(6) Phone Number:.....

(7) List of ingredients (Active Only)

NAME	QUANTITY	NAME	QUANTITY

(8) Claims/Indications:.....

.....

.....

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Appendix E - Supplemental Drug Registration Form

SUPPLEMENT TO NEW DRUG SUBMISSION

VARIATION OF FORMULA/NEW CLAIM/NEW PACKAGING*

To: Chief Chemist/Director of Food and Drugs
Chemistry/Food and Drugs Division
4-6 Queen's Park East,
Port of Spain

I/We*……..

*(State Name of Importer/Manufacturer/Agent in Trinidad and Tobago)**

of…….....

(State Address)

Hereby make a supplementary New Drug Submission in DUPLICATE for the drug ……

……...

(State Name of New Drug)

in support of the changes indicated below :

(a) Name/Mark	☐	*(f)* Route of administration	☐
(b) Formulation	☐	*(g)* Packaging	☐
(c) Condition of Use	☐	*(h)* Label	☐
(d) Indications for Use	☐	*(i)* Pharmaceutical form	☐
(e) Dosage	☐	*(j)* Any other change	☐

Description of other changes which made the drug different from that in the original New Drug Submission

……

……

The following information is attached in support of the changes indicated:

(a) Samples of the drug with the changes indicated above in the finished pharmaceutical form in which it is to be sold. ☐

(b) Samples of components of the new drugs as the Director may require. ☐

(c) Certificate of compliance issued to the manufacturer by the authorized Government Agency in the country of origin. ☐

(d) Technical literature, describing the changes made to the new drug including tests and results of tests supporting that the quality, potency, efficacy and safety of the new drug are not affected. ☐

(e) Any other information that may be required by the Director. ☐

I/We* undertake to inform you of any report of unexpected side effects, toxicity, sensitivity or other adverse reactions associated with the clinical uses, studies, investigations and tests in respect of the new drug or resulting from the material changes made.

Date ……. ……

Importer/manufacturer/Agent in

*Trinidad and Tobago**

*Delete as applicable

End of Document

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