

# **Systems Requirements for Computerized Medicine Registration, Mozambique Ministry of Health**

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Systems for Improved Access  
to Pharmaceuticals and Services

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## **About SIAPS**

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

## **Recommended Citation**

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## **Key Words**

Mozambique, medicine registration, web-based registration software

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## ACRONYMS AND ABBREVIATIONS

CD	compact disc
CTD	Common technical document
LNCQM	Laboratorio Nacional de Controle de Qualidade de Medicamentos
PD	Pharmacy Department
SIAPS	Systems for Improved Access to Pharmaceuticals and Services [Program]
SOP	standard operating procedure

## BACKGROUND

Health products regulation encompasses the pre-marketing evaluation, marketing authorization, and post-marketing surveillance of medicines, vaccines/biologics, medical devices, and other health products to ensure compliance to established standards of product quality, safety, and effectiveness. Country National Medicines Regulatory Authorities are challenged to improve their regulatory processes to achieve greater efficiency, ensure transparency, and communicate with all involved participants concerning regulatory information.

Despite efforts to computerize medicines registration in developing countries, many countries still use limited tools or manual processes. There is a need for an electronic tool for the entire regulatory processes including registration, licensing, inspection, quality control, pharmacovigilance, and medicine information. If the tool is built in modules where the respective databases are owned and updated by each unit that handles the function and then shares data across the entire regulatory authority and consumers, regulatory processes and functions will be more efficient.

In 2012, the US Agency for International Development-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program conducted a comprehensive assessment of regulatory systems in Mozambique and addressed the challenges of the current information system being used by the Mozambique Ministry of Health Pharmacy Department (PD) for medicine registration and other regulatory functions. The assessment showed that all processes and documents for medicines registration in the current system are managed manually. Recommendations for changes include introducing an online computerized information management system to handle the registration process that can significantly improve the efficiency of registration and reduce the backlog by tracking the process, enhancing communications, and improving document management.

To address this gap, SIAPS was asked to do a follow-on assessment to evaluate the PD's information system and related technical assistance needs for product registration as well as other regulatory functions (pharmacovigilance, inspection, and quality control). SIAPS then collaborated with the department to analyze system requirements to define data elements and identify an appropriate tool that is compatible with local technology and capacity.

### Key Objectives

- Evaluate process and identify gaps in the current registration system
- Develop a roadmap to implement a web-based registration system to improve efficiency, transparency, and governance of the regulatory system

## **Findings**

### ***Application Process***

#### *Paper-Based Manual Registration System*

Currently, all steps of the registration process are managed and performed manually. The system requires applicants to come with the two paper copies of dossiers (and compact discs [CDs]) and spend one day with the PD staff to go over the dossier and ensure there is no missing document or element. There is no tracking system to monitor timeline for registration.

#### *Revised SOPs, Guidelines, and Forms Pending Approval*

The current dossier format is not compliant with international standards, common technical document (CTD), International Nonproprietary Name or Anatomical Therapeutic Chemical code. There is also no application form. The PD, with support from SIAPS, recently developed new guidelines, standard operating procedures (SOPs), and a checklist for a complete, abbreviated registration (for locally manufactured, already introduced, or priority medicines), and application process (for products that have already been introduced in the United States, European Union, South Africa, and Brazil). These have yet to be approved and implemented in Mozambique.

#### *SOPs for Renewal and Exceptional Registration*

There are three types of registration applications—new, renewal, and variation. Once a new application for registration is approved, the registration is valid for five years and the marketing authorization holder should submit the application for renewal. However, there is no application form, guideline, or SOP available for renewal process.

#### *Data Elements for Application*

In the absence of the application form, the SIAPS team and the registration unit staff reviewed the checklists that have been newly developed for complete, abbreviated, and recognized registration (Form Code SOP R01-A—Receiving validation form complete; R01-B—Receiving validation form abbreviated; R01-C, Receiving validation form recognized) to define data elements.

### ***Screening and Evaluation***

Currently, the screening process takes one day in the presence of an applicant. The PD is planning to use the newly developed screening checklists Form Code SOPs R01-A, B, C for validation/screening.

After the registration unit staff members screen and validate the dossier, they perform a pharmaceutical evaluation of Part 2 chemical and pharmaceutical documentation, using the checklist—Form Code SOP R02 Evaluation Report for Pharmaceutical Products: Quality Part. Then, in principle, the dossier is sent to external reviewers who clinically evaluate Part 3

documentation on security and Part 4 documentation on efficacy. There is no summary report used by external reviewers. Once the evaluation is completed, the Technical Committee for Therapeutics and Pharmaceuticals reviews for approval or rejection. The current evaluation goes as follows—screening/validation, pharmaceutical evaluation, and then clinical evaluation.

According to regulations, applicants are required to submit samples for quality control testing. However, registration unit staff confirmed that the samples are not sent to the Laboratório Nacional de Controle de Qualidade de Medicamentos (LNCQM) and quality control test results are not required for approval.

## **Document Management**

The PD does not have an efficient document management system or sufficient storage space for hard-copy dossiers, which has made it challenging to maintain an organized system.

Hard-copy dossiers are placed in the PD storage room, without any regard for any storage, identification, tracking, inventory, or numbering system, which makes it almost impossible to retrieve the information. Currently, the PD is packing the dossiers together by name of importer to send them to new storage outside the PD for archiving and is planning to expand the storage space with improved inventory management.

## **Quarterly Report and Indicators**

The PD shared its quarterly update report for third quarter of 2012. However, the department currently doesn't have any measures to monitor timeline for registration. Indicators included in the quarterly report are—

- Number of applications submitted per month
- Number of registrations authorized per month
- Number of registrations authorized per importers per month
- Total number of registrations authorized to date
- Total number of registrations rejected to date
- Total number of registrations withdrawn by the importer
- Total number of registrations cancelled/total number of registrations authorized
- Total number of applications waiting for further information/clarification from applicant
- Total number of applications under CTD review
- Total number of applications undergoing clinical evaluation
- Total number of applications undergoing pharmaceutical evaluation
- Total number of applications to be evaluated
- Number of health products (cosmetics, nutritional supplements, medical devices, disinfectants) submitted, approved, waiting for approval, in analysis, and waiting for further clarification/information from applicant.

## **Current Register**

The PD was previously using the World Health Organization-supported SIAMED system for product registration; however, the system has not functioned for several years. In its place, the registration unit has been using an Excel<sup>®</sup>-based database (annex A) to capture basic information on applications and registered products. Because of limited data and functions of the current database, the information system is not able to generate all of the pertinent information needed to properly monitor and evaluate the process and products and inform applicants, stakeholders, and the public efficiently.

## **IT Infrastructure and Support**

The PD does not have IT personnel who handle network administration, troubleshooting, or equipment maintenance. However, the department has a good network capacity to support the establishment of a shared drive.

SIAPS recommended taking the following actions (annex B) before adapting and implementing the online registration software—

- Approve and implement new SOPs and guidelines in compliance with international standards. Once those are finalized and approved, data requirements should be further validated for any change. The newly revised guidelines for registration also need further technical review to ensure that they comply with international standards, such as CTDs.
- Registration process and requirements for renewal and variation of registration should be developed. Also, SIAPS recommended improving registration process by introducing parallel review (of pharmaceutical evaluation and clinical evaluation) and having quality control systems (either by conducting a quality control test in LNCQM) or developing measures/criteria/strategies to ensure product quality) in place. The recommended registration process mapping is presented in annex C.
- SIAPS recommended improving document management by upgrading inventory management of hard-copied dossiers (i.e., numbering in alphabetical order of generic name or importer) with the PD's current plan of storage expansion. Web-based registration software will include a field to link each application to physical location of hard-copies of dossiers. SIAPS also recommended creating shared folders to store electronic dossiers submitted on CDs, so that any staff in the PD can easily access to information. The data contained in the Excel-based register needs to be reviewed for missing elements, then validated, and exported to the web-based registration.
- SIAPS recommended strengthening IT infrastructure, personnel, and support. There are currently IT personnel working in Central Medical Store which is located in the next building and other departments within the Ministry of Health who can support the PD.

Based on the findings and discussion, SIAPS developed the roadmap (figure 1) to initiate the implementation of the new web-based regulatory information tool with focus on registration

module and presented it to the PD. Implementation will involve adapting the tool based on agreed upon data elements, procuring the required hardware and/or software, identifying in-country IT support and maintenance, pilot testing the program(s), finalizing the software, training users, and then launching the system. SIAPS will develop training and instructional materials to serve as references for users and maintenance providers. Once the registration module is fully implemented and used, the PD may expand the tool to support other functions such as inspection, licensing, pharmacovigilance, and quality control.

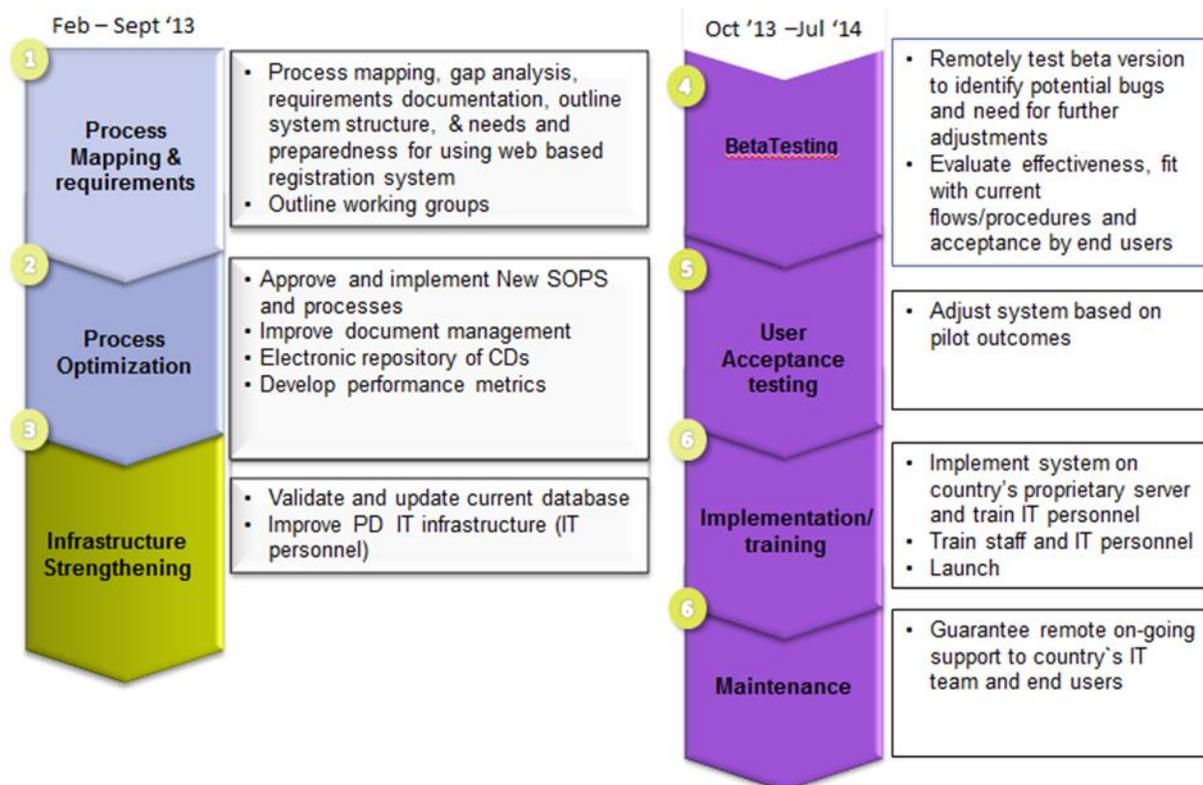


Figure 1. Roadmap to implement web-based registration software

Table 1. Follow-up Actions Needed

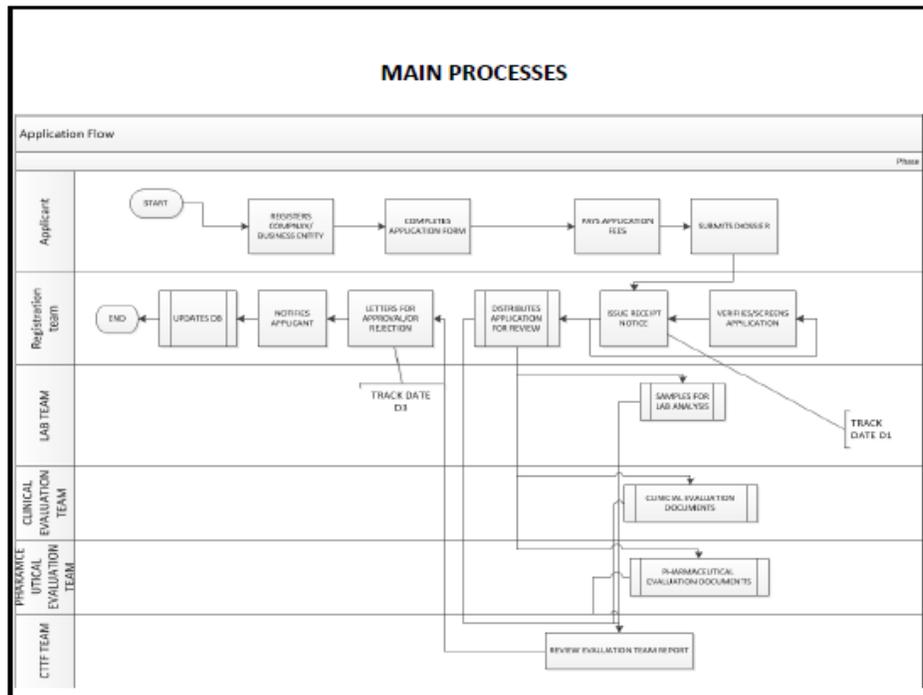
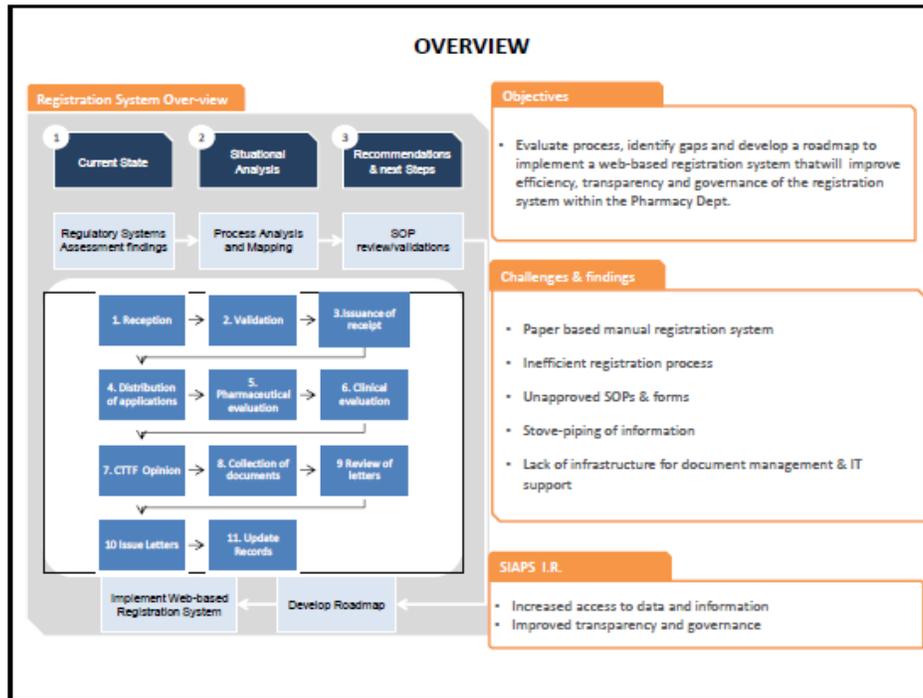
Actions	Person(s) Responsible	Estimated Completion	Location of Work
Approve process flow and mapping	PD	04/2013	
Review the international standards (i.e., CTD) and modify new guidelines, SOPs, and checklist, if necessary	Qawwas, Botwe, and PD	04/2013	Mozambique
Approve and implement new guidelines, SOPs, and checklist	PD	05/2013	
Improve inventory management and strengthen IT infrastructure (i.e., electronic repository, physical)	PD	06–07/2013	Mozambique

<b>Actions</b>	<b>Person(s) Responsible</b>	<b>Estimated Completion</b>	<b>Location of Work</b>
location of dossier hard copies)			
Review and update current database	PD (local consultant)	08/2013	
Validate any changes in process, form, and data requirements and adapt web-based registration software (PharmaDex) for PD	Choi, Srivastava, and Qawwas	09/2013	US/Arlington
Pilot-test PharmaDex	PD and Srivastava	10/2013	Mozambique with remote support
Finalizing the tool/user acceptance testing	PD and Srivastava	12/2013	
Launch of the online-based registration tool (engaging all stakeholders/importers) and user training	PD, Qawwas, Choi, and Srivastava	01/2014	Mozambique (STTA)

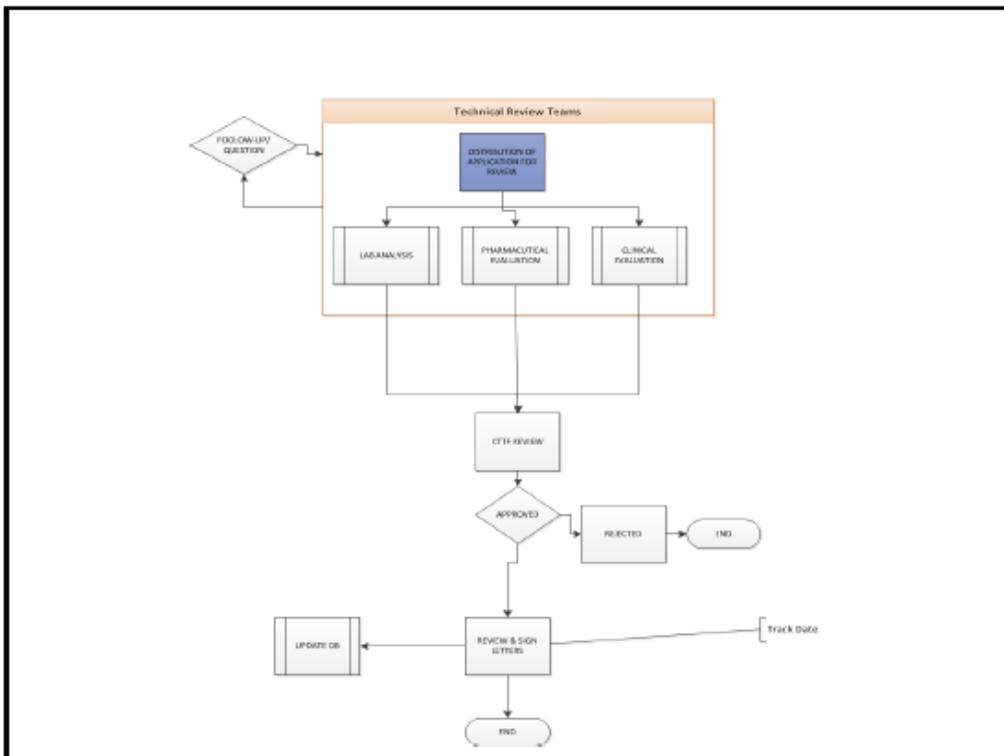
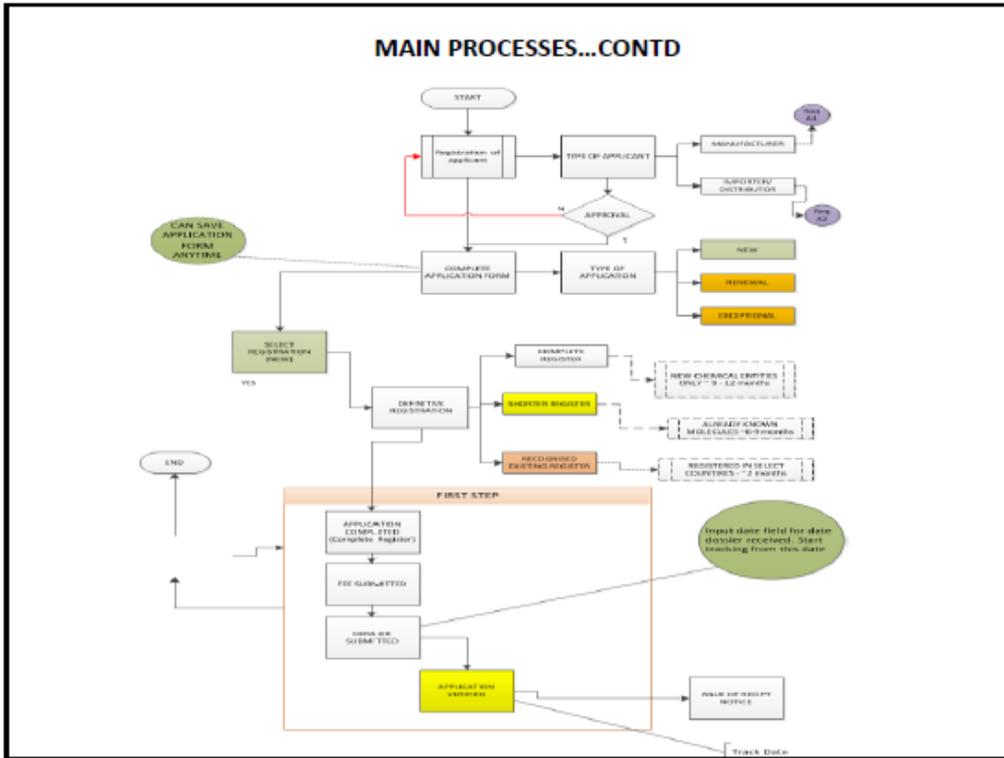
## ANNEX A. HEADINGS OF CURRENT EXCEL-BASED REGISTER

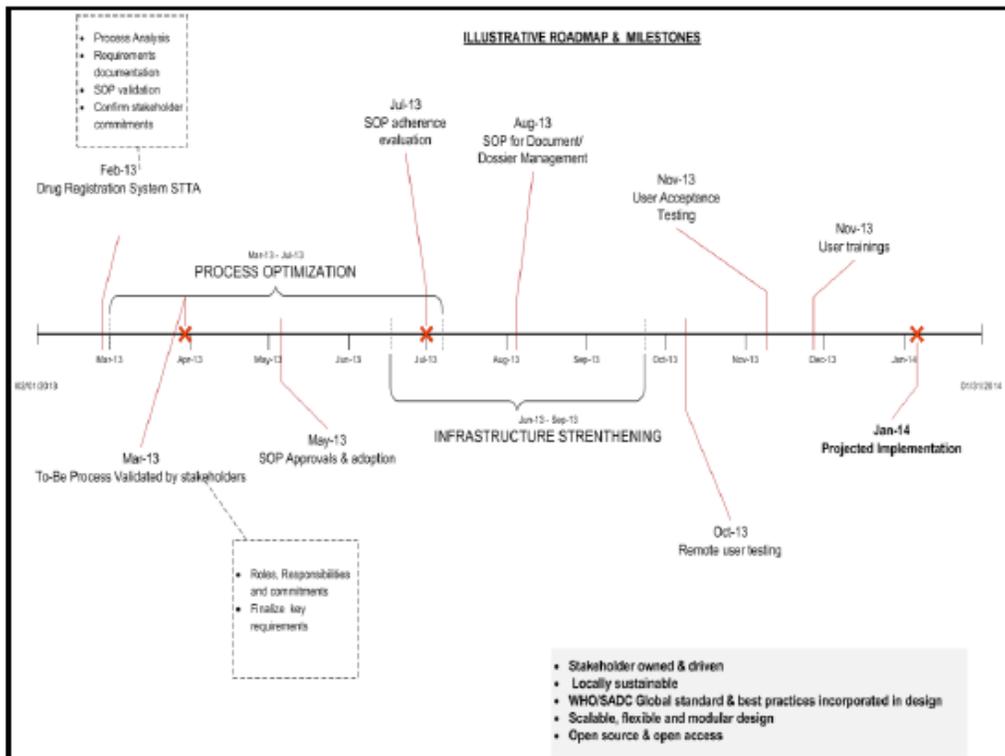
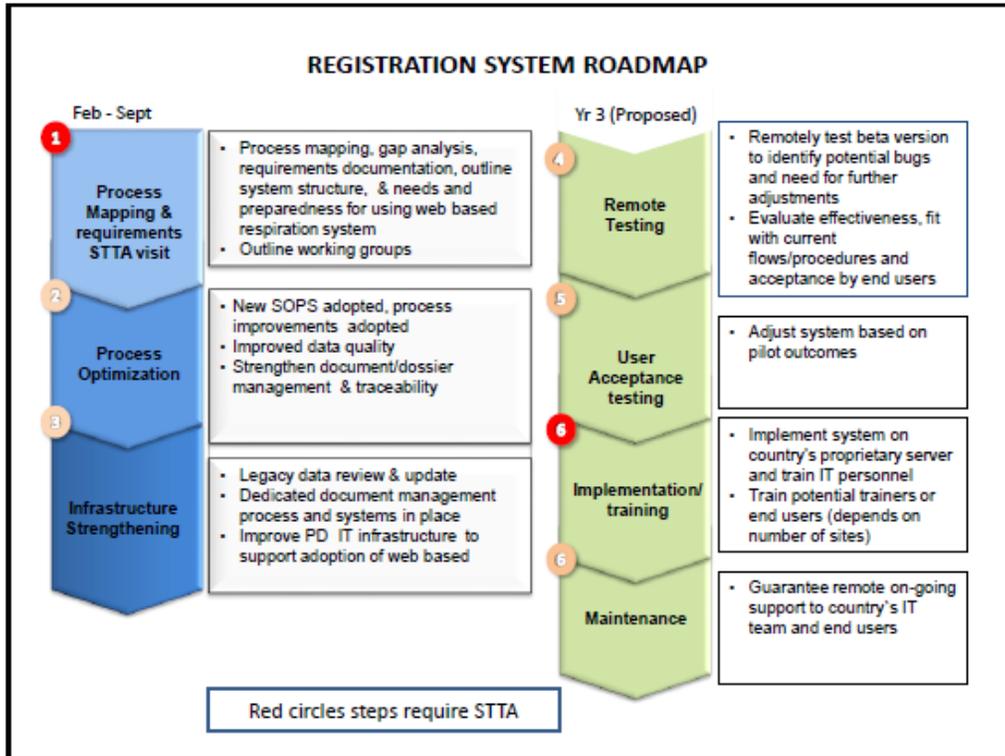
<b>Title of headings</b>
Importer Name
Trade or Generic Name
Medicine Name
Active ingredients
Dose
Dosage form
Package
Manufacturer
Date of entry
Registration status
Type of registration process
Evaluator/PD
Evaluator/Clinical
Fees Class
Authorization date
Registration fees amount
Payment of Fees
Date of payment
Transfer of ownership
Payment
Date
Registration Retention fees for 2012
Date
Registration Retention fees for 2011
Date
Registration Retention fees for 2009
Date
Registration Retention fees for 2010
Date
Product cancelation date
Renew date
Approval date
Fees paid
Payment date
Inclusion
Request for change date
Amendments requested
Payment of the application for amendment
Authorization of Amendment
Response date to the appeal
Cancellations date

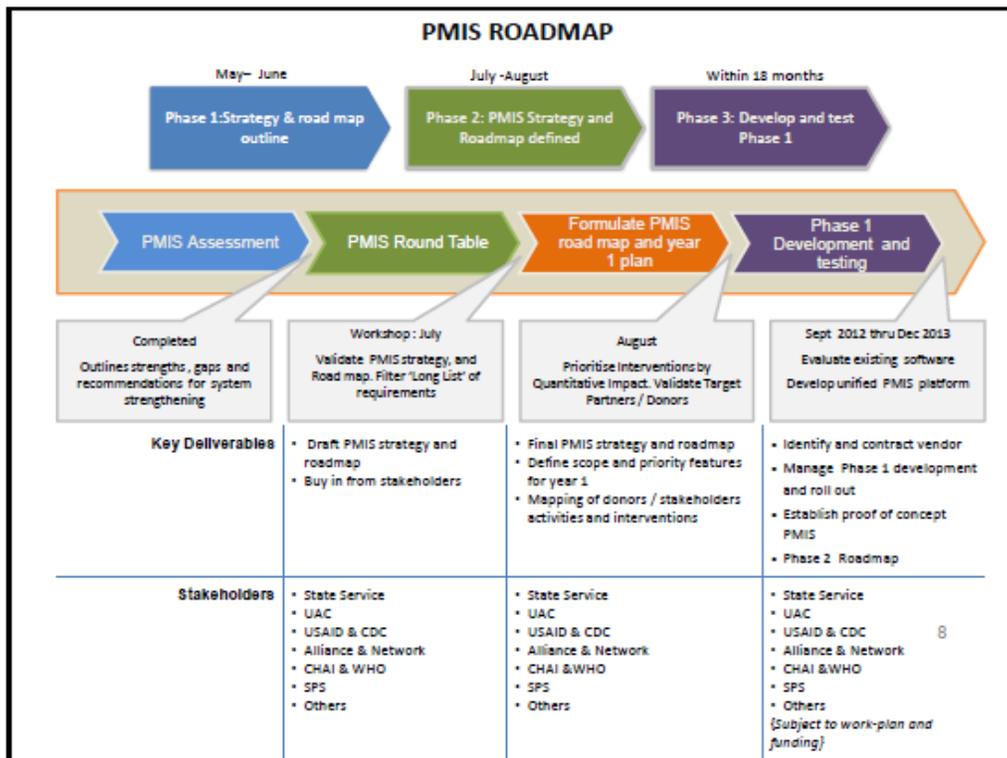
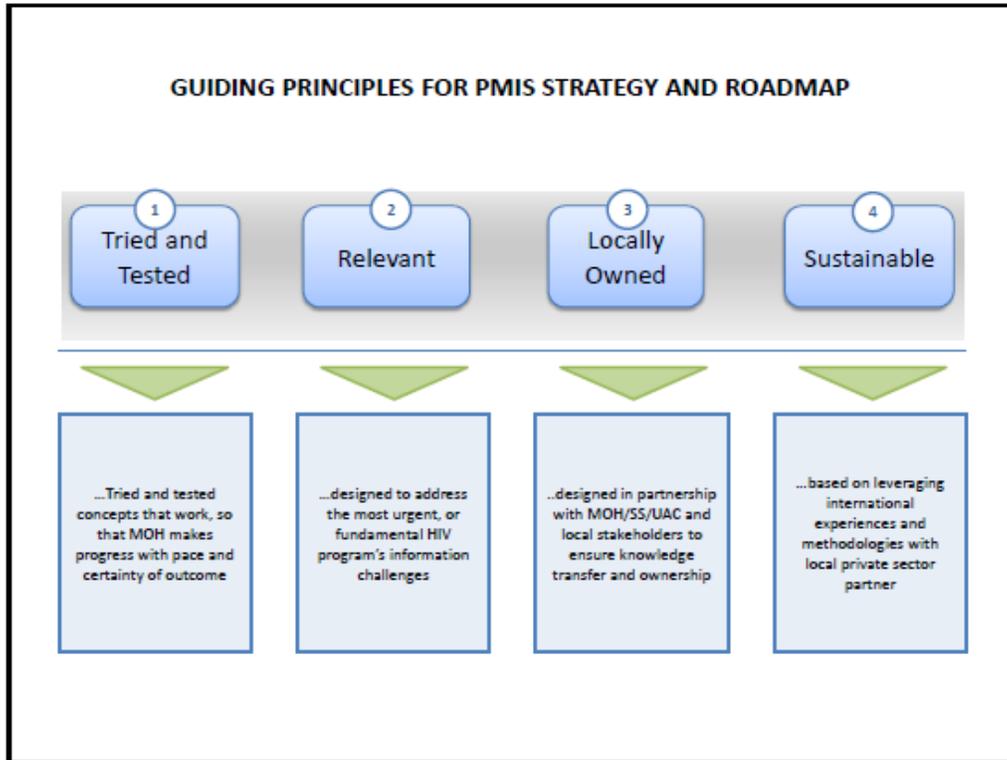
## ANNEX B. PHARMACY DEPARTMENT DEBRIEF





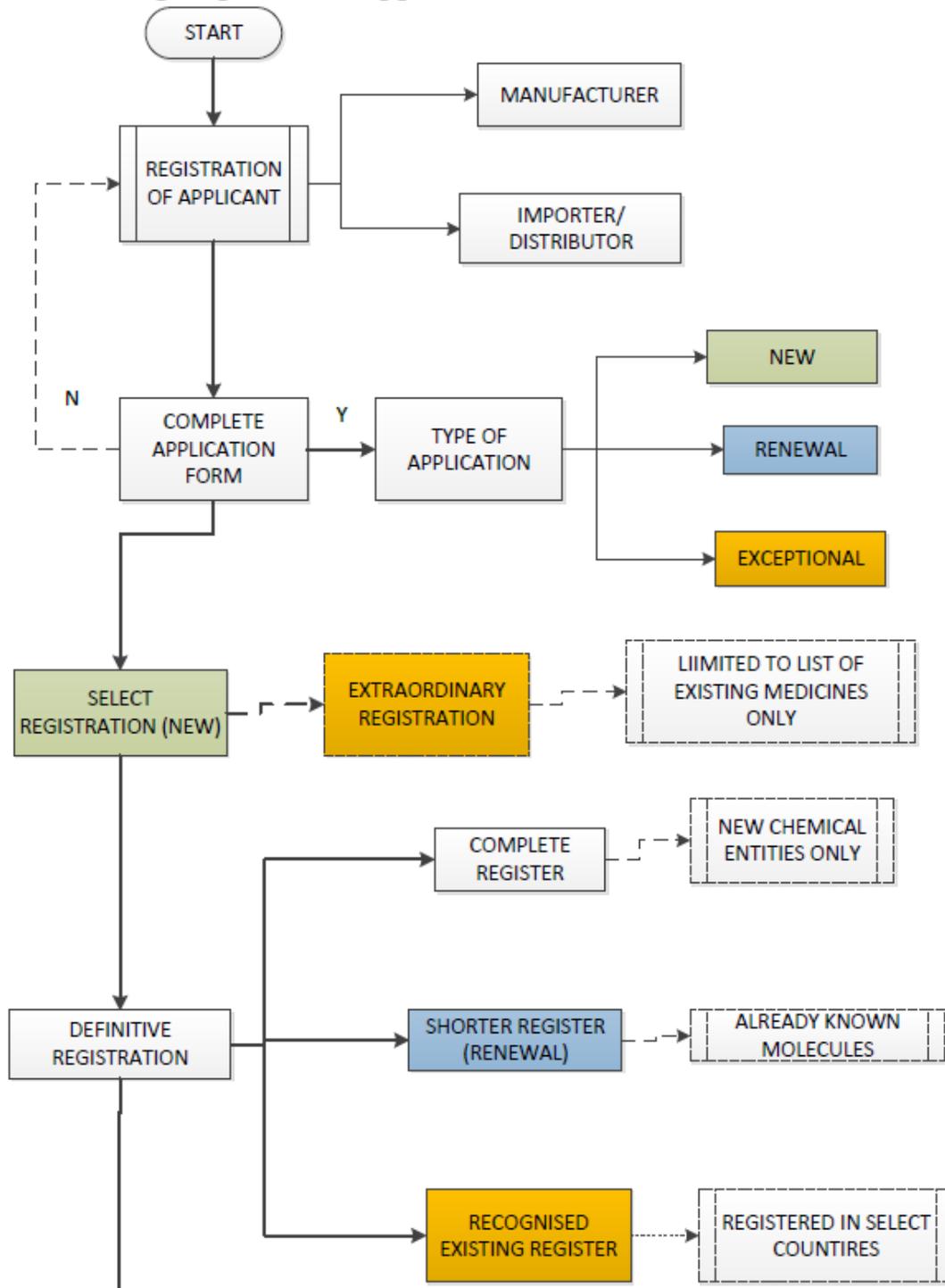


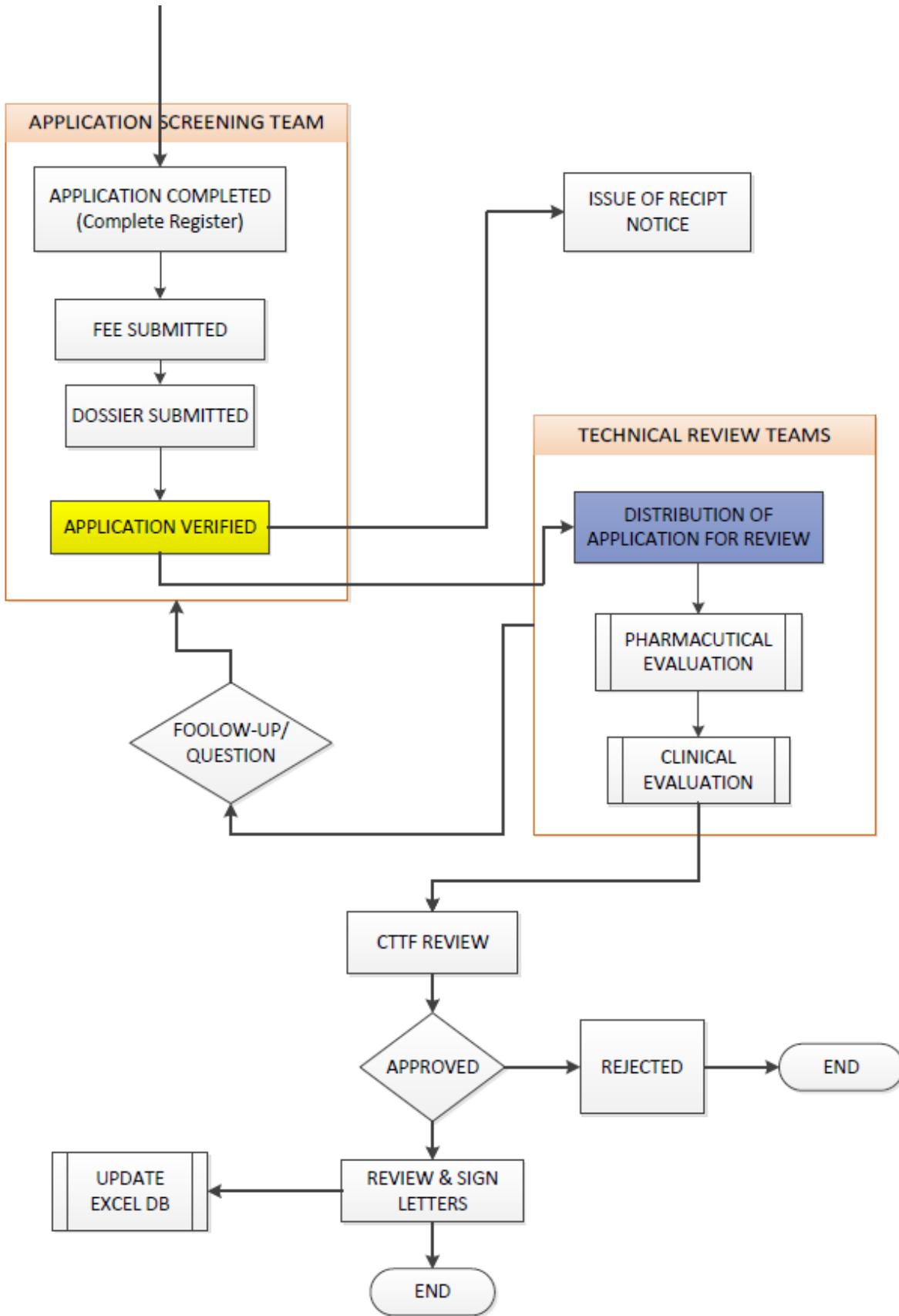




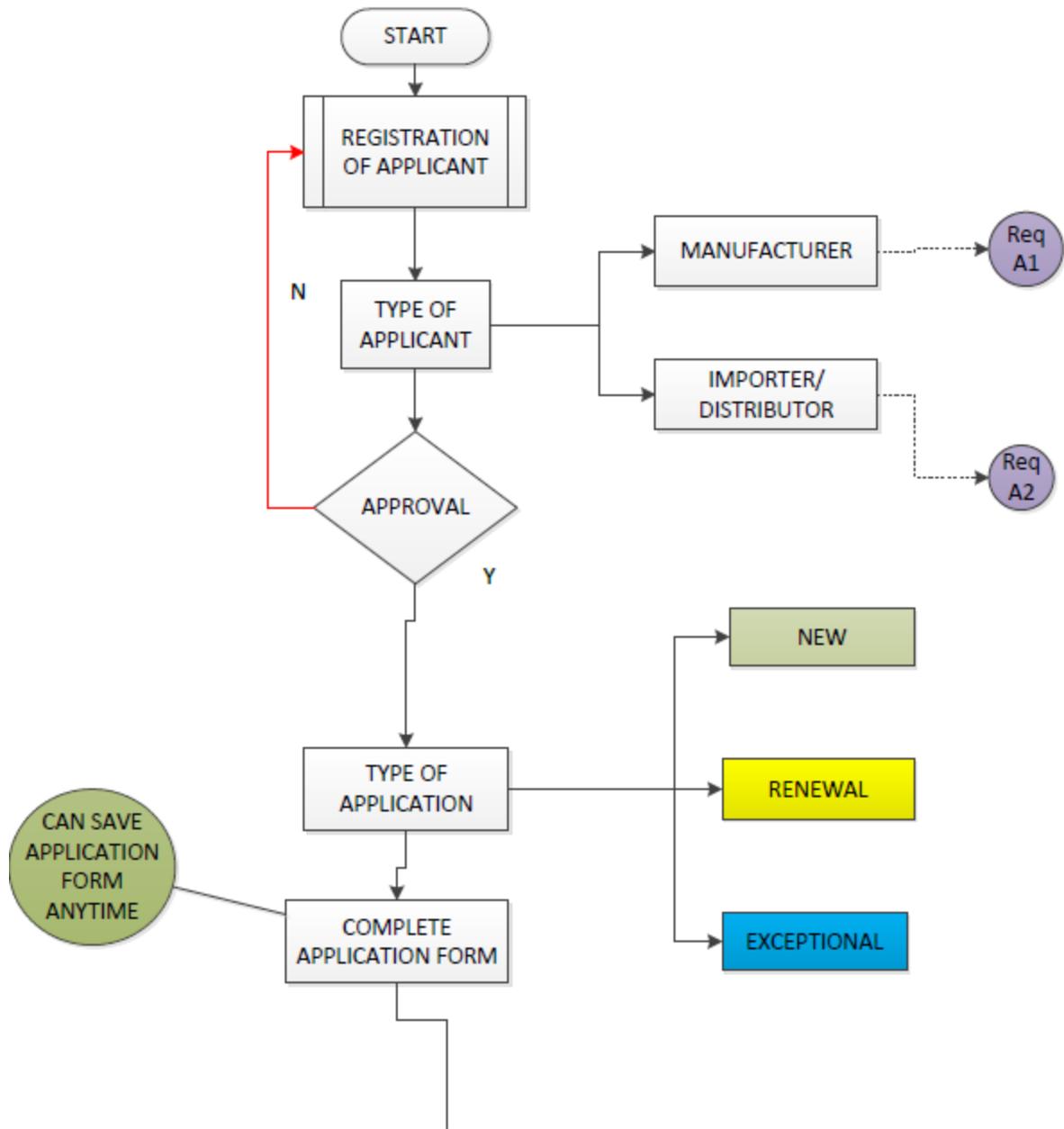
## ANNEX C. RECOMMENDATIONS FOR PROCESS MAPPING

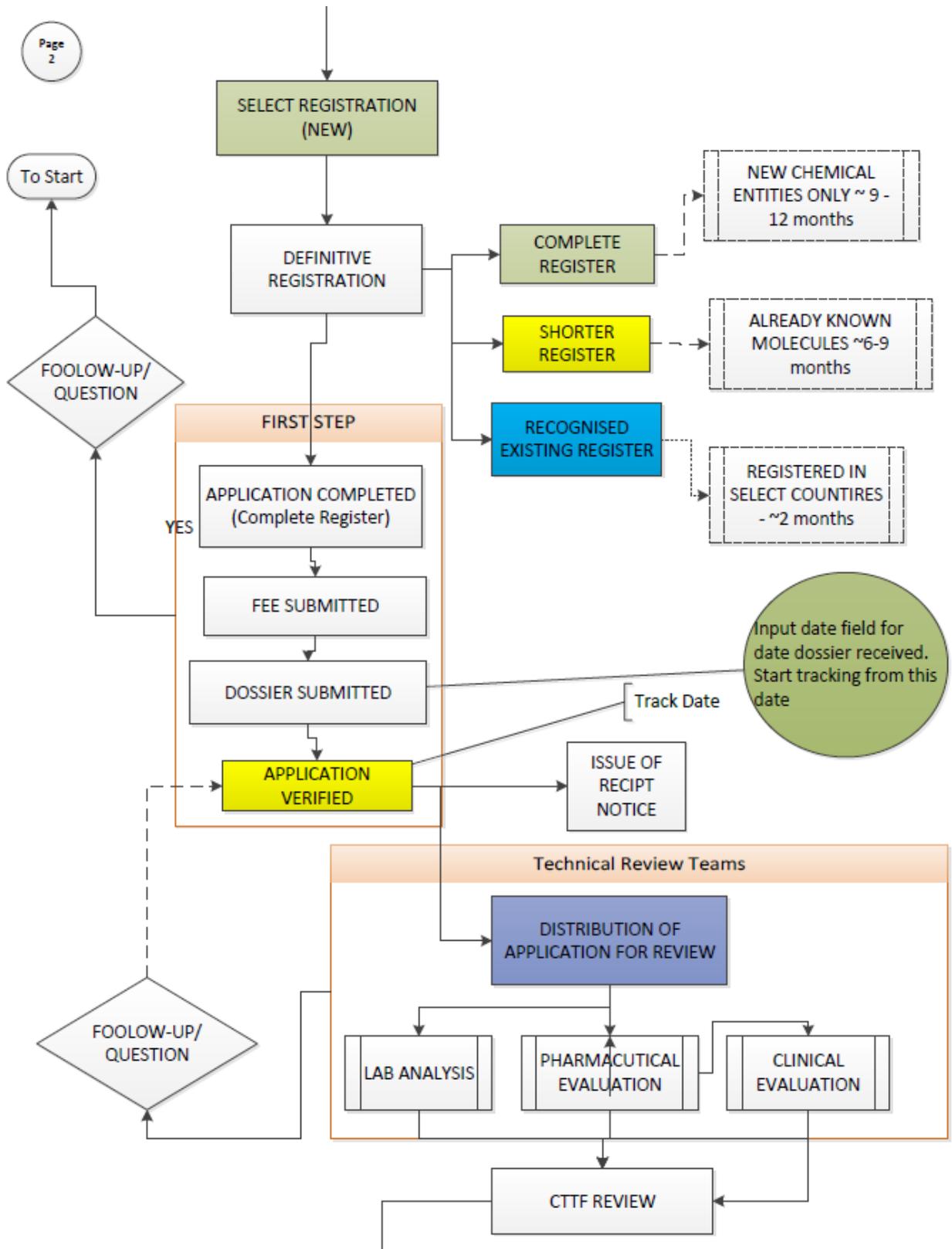
### Drug Registration Application Flow -As-Is



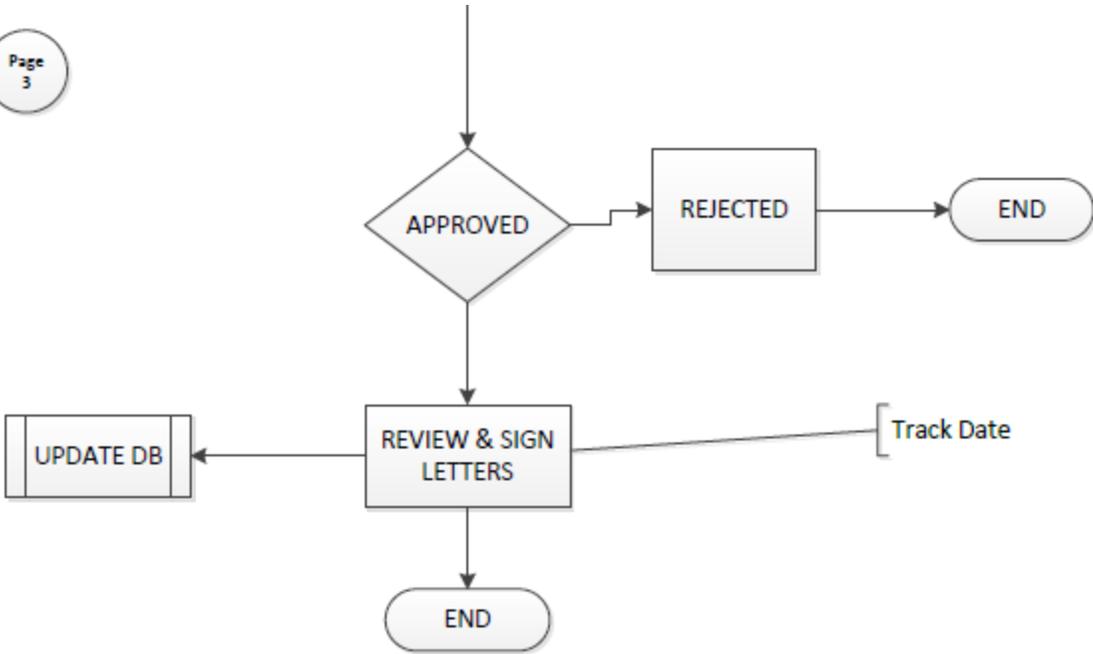


### Drug Registration Application Flow -To-Be









## Application Review Check List

