



Situation Analysis: Regulatory Data Management System of Philippines FDA

September 2016



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Situation Analysis: Regulatory Data Management System of Philippines FDA

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September 2016



This report is made possible by the generous support of the American people through the US Agency for International Development (USAID), under the terms of cooperative agreement number AID-OAA-A-11-00021. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

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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Kim, EunMi. 2016. *Situation Analysis: Regulatory Data Management System of Philippines FDA*. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

Key Words

Philippines FDA, medicine registration, regulatory data management system, IT solution

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ACRONYMS

| | |
|-------|--------------------------------------------------------------|
| AE | adverse event |
| eCTD | electronic common technical document |
| DOH | Department of Health |
| FDA | Food and Drug Administration |
| GMP | Good Manufacturing Practice |
| ICTMD | Information, Communication, Technology, Management Division |
| IT | information technology |
| NMRA | National Medicine Regulatory Authority |
| NQL | National Quality Laboratory |
| PAIR | Public Assistance Information and Receiving |
| PFDA | Philippines Food and Drug Administration |
| PMS | post-marketing surveillance |
| PSUR | periodic safety update report |
| PV | pharmacovigilance |
| SIAPS | Systems for Improved Access to Pharmaceuticals and Services |
| SOP | standard operating procedure |
| TB | tuberculosis |
| WPRO | Western Pacific Regional Office of World Health Organization |

ACKNOWLEDGMENTS

On behalf of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS), I would like to express my gratitude to the Philippines Food and Drug Administration (PFDA) for their support toward completing the assessment to understand the gaps in managing regulatory data, with a focus on the medicine registration data management system. In particular, I would like to acknowledge Ms. Nela Charade Puno, Director General, and Ms. Maria Lourdes Santiago, Deputy Director General of the PFDA, who has been supportive in providing all of the necessary information and in encouraging all PFDA staff to improve the regulatory data management system.

I would also like to express our gratitude to Mr. Abdel Raouf Qawwas from Technical Assistance for the Philippine Health Sector Reform Project for the information provided during the assessment.

I am also deeply appreciative of the support provided by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS)/Philippines staff, including Mr. Mehmood Anwar, SIAPS Country Program Director; Ms. Princess Christine Mangao-Alejandrino, SIAPS Technical Advisor; and Ms. Chesa Desano, SIAPS Information Technology (IT) Specialist, for their support in arranging meetings with stakeholders and collecting relevant information for conducting the situation analysis in the country.

EXECUTIVE SUMMARY

Background

SIAPS has worked together with the Philippines Department of Health in country to achieve the overall objective of enabling the PFDA to offer a more appropriate and easily accessible registration system that provides more timely access to quality anti-tuberculosis (TB) and other medicines.

The PFDA is mandated to ensure the safety, efficacy, and quality of pharmaceutical products. As per this directive, the PFDA must enhance its regulatory capacity and strengthen its capability with regard to licensing of drug establishments and the registration and monitoring of pharmaceutical products.

During consultation meetings with the PFDA, several issues were identified for improvement, including fragmented regulatory data management systems, redundant and inefficient processes, and disconnected electronic repositories. It was recommended to strengthen the regulatory system through an appropriate regulatory data management system, which would support the government in the establishment of a stronger e-governance system.

The goals of this situation analysis were to evaluate the current status of the PFDA's overall regulatory information management system, with a focus on medicine registration data management, and to develop recommendations and an action plan to cultivate a more robust regulatory information management system, including the required IT solutions to manage licensing of drug establishments and the registration of pharmaceutical products, as well as other operations of the PFDA.

Methods of Situation Analysis

Between August 15 and August 25, 2016, SIAPS conducted key informant interviews with PFDA officers and observed the major regulatory processes—from receiving applications to issuing official regulatory certificates—by visiting pertinent department offices (see annex A for a list of interviewees). After these interviews, SIAPS conducted a workshop to define the current challenges in performing daily work due to the current regulatory data management system. The basic questionnaire was provided to PFDA prior to the visit so that PFDA could provide the necessary information in advance.

During and after key informant interviews, PFDA officers demonstrated the workflow and explained current regulatory processes, including medicine registration, clinical trial approvals, post-marketing surveillance (PMS), licensing of premises, inspections of Good Manufacturing Practice (GMP) facilities, and testing samples at the National Quality Laboratory (NQL) and issuance of administrative sanctions. During the interviews, PFDA officers demonstrated the process of handling data, from creating tracking numbers to pulling final data from the intranet and each division or unit's data repository system.

Common areas reviewed during the interview process were as follows:

- **Legal framework:** If current laws and regulations define/restrict/allow the use, submission, and approval as a part of regulatory processes.
 - Availability of pertinent laws and regulations
 - Feasibility of the use of electronic submission and approval, including the issuance of official certificates, letters, and other regulatory documents
- **Current processes of regulatory functions:**
 - Process map and the flow of data in performing everyday work of regulatory functions
 - Availability of standard operating procedures (SOPs) and efforts to streamline processes
 - Challenges in performing everyday work caused by a limited regulatory data management system
- **Current regulatory data management system:** If PFDA has used any IT tools as part of regulatory processes, including the following:
 - Scope of regulatory data management system (medicine registration, clinical trials, quality laboratory, inspections, PMS, pharmacovigilance [PV], etc.)
 - Functions of IT tools used in different regulatory activities
 - Availability of SOPs that define the roles and processes of managing regulatory data
 - IT infrastructure, including servers, software, programmers, IT support staff, etc.
 - Security measures to protect confidential regulatory information
 - Interchangeability of IT tools in accessing data
 - Accessibility and control of regulatory data
- **User experience:**
 - Unmet needs: if there are any unmet needs to manage regulatory data as a part of regulatory processes
 - Access to necessary information to perform everyday work
 - Suggestions for improvements: if there are any suggestions to improve IT tools in order to improve the quality and efficiency of work

After conducting key informant interviews, a workshop was held to identify current problems in regulatory data management, with a focus on everyday work in performing regulatory functions. In total, 15 regulators participated in the workshop and presented their findings at the end of group discussions on finding roots causes and interventions for improvements.

Findings

Although there are limitations, current regulatory data management at the PFDA provides basic IT solutions for PFDA users in accessing regulatory data for various regulatory functions. The current IT system also provides basic services for industry applicants and the public in providing necessary information and scheduling of application. The PFDA has worked to continuously improve the regulatory data management system. However, the current regulatory data management system has not met the increasing demands of PFDA users due to the rapid increase in volume of regulatory work and various types of regulatory applications caused by the growth of relevant industries, such as food, cosmetics, and pharmaceuticals.

However, it has been identified that serious restrictions in performing regulatory work due to inefficient methods of managing regulatory data and accessibility to the data. The quality of regulatory data has not been well maintained due to the lack of manpower and the unclear designation of responsible staff.

- **Legal framework:** Current laws and regulations do not define or limit the use of electronically issued official certificates or letters from automated systems. The PFDA's legal department is responsible for issuing legal documents, including official certificates and letters. The legal interpretation and feasibility to adopt an electronic approval system requires further examination.
- **Current processes of regulatory functions:** Processes of each regulatory function are well defined. However, due to the lack of manpower and long and backlogs of applications, officers often have to work to fill others' responsibilities without sufficient knowledge of the respective SOPs.
- **Current regulatory data management system:** The PFDA has provided IT tools to staff to help expedite routine work. Different IT tools are provided to track applications, document inspection results, and record official certificates and letters. A separate JAVA based IT solution called eLTO (electronic License to Operate) became available in July 2016 for the licensing of premises, from submitting applications to approvals. Many other IT tools are under development or planned for other regulatory functions under the strong leadership of the PFDA.

However, the efficiency of the tools has often been diminished due to a fragmented data management system and difficulty navigating the data in order to perform routine regulatory work. Collaboration between the IT and technical teams has not been effective enough to improve IT tools due to lack of manpower and unclear roles and responsibilities in improving and maintaining regulatory data.

- **Users' experience:** PFDA users of IT tools are well trained to use current tools to perform their routine work. Although most tools are not necessarily user friendly in terms of their ease of use, users learned how to navigate the system to obtain necessary information using a document tracking number with a combination of different pathways, such as phone calls or emails. Overall, users agree that the current IT tools and data

management system are not user friendly and that it is difficult to obtain necessary regulatory data, particularly data that is older and not available in an electronic format.

Recommendations

In order to meet the increasing demands on the PFDA to perform regulatory work, a major upgrade of the current regulatory data management system is highly recommended.

- 1) Improving the quality of regulatory data:** Databases of registered medicines, health products, licensed premises, and other regulatory information should be improved in order to build a strong regulatory data management system. The availability of usable and searchable data will improve the accessibility of necessary regulatory data to assist regulators in performing their work in a more effective and efficient way. Current databases contain a large amount of scanned images of documents, which does not allow regulators to search information in an efficient manner.
- 2) Strengthening the protection of confidential information:** The PFDA needs to prepare for electronic submission of dossiers through the electronic common technical document (eCTD), which will require higher security protection of confidential information. Currently, the PFDA receives files through USB portable devices without providing clear instructions for naming or formatting files.
- 3) Human resource development:** The PFDA needs to designate full-time staff to manage regulatory data in order to build regulatory databases, starting with registered medicines. Staff should work closely with the IT department to select the data fields to transform unusable data to searchable data.
- 4) Online-based medicine registration system:** Currently, the PFDA receives applications when applicants visit the PFDA office to submit files of dossiers in order to file regulatory applications such as product registration applications. The PFDA can prepare for electronic submission of dossiers through eCTD via an online-based medicine registration system. In this way, the PFDA can easily build databases of registered products.
- 5) IT tools for other regulatory functions:** Once the PFDA strengthens the database of registered medicines, it can develop integrated IT tools for other regulatory functions, as these subsequent tools can have an access to a core database to search for necessary information.

A short-term, mid-term, and long-term improvement plan also need to be developed, as well as a long-term strategic plan, in order to strengthen the regulatory data management system.

Short-term plan (3 to 6 months): The short-term plan should include quality improvement of regulatory data, such as the list of registered products, licensed premises, clinical trials applications, inspection data, and other regulatory information. The quality of the data should be

based on the accessibility of necessary information that allows users to search in a more effective way. Scanned copies of old documents need to be reviewed and transformed into usable and searchable data for further improvement of regulatory data of registered medicines and other pharmaceutical products.

Current issues related with the long backlogs of medicine registration applications can be addressed by hiring additional technical reviewers while the PFDA improves the quality and accessibility to regulatory data. Alternatively, PFDA can also consider utilizing an external technical review committee which is composed of expert groups outside of the PFDA. However, establishing such technical committee can also take significant amount of time because the PFDA needs to develop a good review guidelines and analysis report templates to standardize the review process.

Mid-term plan (6 to 12 months): The mid-term plan should include the improvement of IT tools per regulatory function, such that they can meet the demands and expectations of users, through close collaboration between technical staff and IT developers. Important data should be shareable between different IT tools. Interchangeability of IT tools for sharing data should also be considered when developing and improving these tools. Core data should be maintained at the central level and should be shareable between departments, regardless of their IT tools.

Long-term plan (12 to 24 months): The long-term plan should include the integration of the existing regulatory data management system, which includes the completed eCTD for medicine registration. Currently, the PFDA accepts electronic files and reviews electronic dossiers. With the completed eCTD submission, reviewers can reduce the time needed to manage data related to medicine registration. With the launch of eCTD submission, a new integrated regulatory data management system can be incorporated to maximize the availability of a high volume of usable data. Security to protect confidential information should also be considered to ensure data protection. The country's IT infrastructure, including internet speed and transmission of a high volume of data, is one of the critical factors to be considered before launching eCTD for medicine registration.

INTRODUCTION

National Medicine Regulatory Authorities (NMRAs) in countries are responsible for ensuring the quality and safety of medicines and other health products for the public by checking and monitoring health products. The demand for NMRAs to control the manufacturing, import, and supply of health products has grown rapidly due to the increase in consumption and import from other countries. In many countries, NMRAs have faced challenges in pursuing routine regulatory work due to a lack of staff and technical resources. In order to overcome the challenges caused by the lack of technical staff and the growing demand on regulatory work, an efficient and effective regulatory data management system is necessary to save time and to improve the accuracy of routine regulatory mandates.

However, building a good regulatory data management system is challenging due to the complexity of regulatory work and the risks involved with inaccuracy and protection of confidential regulatory information. Many of routine regulatory works performed by NMRAs are interrelated. For example, the registration of a medicine is also related to inspection of premises, clinical trials, and PMS.

Current Challenges of PFDA

The PFDA has been trying to upgrade the regulatory data management system by launching a new document tracking system and e-portal services for renewals of registered products and applications for licensing of premises. However, the current regulatory data management system does not provide enough services for both regulators and external users, such as applicants and the public, due to the complexity of a fragmented IT system and limited access to quality databases to find the necessary information in an efficient manner. Due to the rapid increase in the workload of regulatory work, an efficient regulatory data management system as well as a high quality database of regulatory information are urgently needed to meet the challenges.

Development of long-term strategies as well as implementation plans should be done in order to guide staff and define roles and responsibilities to improve the regulatory data management system. Despite leadership changes, regulatory system development strategies need to be carried out to overcome the current challenges as well as to prepare for the future, including eCTD.

BACKGROUND

SIAPS has worked together with the Philippines Department of Health in country to achieve the overall objective of enabling the PFDA to offer a more appropriate and easily accessible registration system that provides more timely access to quality tuberculosis (TB) and other medicines.

The PFDA is mandated to ensure the safety, efficacy, and quality of pharmaceutical products. As per this directive, the PFDA must enhance its regulatory capacity and strengthen its capability with regard to licensing of drug establishments and the registration and monitoring of pharmaceutical products.

During consultation meetings with the PFDA, several issues were identified for improvement, including fragmented regulatory data management systems, redundant and inefficient processes, and disconnected electronic repositories. It was recommended to strengthen the regulatory system through an appropriate regulatory data management system, which would support the government in the establishment of a stronger e-governance system.

The goals of this situation analysis were to evaluate the current status of the PFDA's overall regulatory information management system, with a focus on medicine registration data management, and to develop recommendations and an action plan to cultivate a more robust regulatory information management system, including the required IT solutions to manage licensing of drug establishments and the registration of pharmaceutical products, as well as other operations of the PFDA.

The situation analysis was conducted in order to assess the existing drug registration processes and regulatory information management system, with a focus on drug registration. In conjunction with key stakeholders, the situation analysis also sought to identify key requirements and high-level specifications for a drug registration system given the local context and needs.

FINDINGS

The PFDA has been continuously improving the regulatory data management system over the past decade. Despite its efforts to create a comprehensive and integrated regulatory data management system, the Agency has not been completely successful.

Although there are some limitations in accessing regulatory data, current regulatory data management at the PFDA provides basic IT services for PFDA users in processing regulatory applications for various regulatory functions. The current IT system also provides basic services for industry applicants and the public in providing necessary information. However, the current regulatory data management system has not met the increasing demands of PFDA users due to the rapid increase in volume of regulatory work and various types of regulatory applications caused by the growth of relevant industries, such as food, cosmetics, and pharmaceuticals.

Additionally, serious restrictions in performing regulatory work have resulted due to inefficient methods of managing regulatory data and accessibility to the data. The quality of regulatory data has not been well maintained due to the lack of manpower and the unclear designation of responsible staff.

Legal Framework

Current laws and regulations do not define or limit the use of electronically issued official certificates or letters from automated systems. The PFDA's legal department is responsible for issuing legal documents, including official certificates and letters. The legal interpretation and feasibility to adopt an electronic approval system requires further examination.

Current Processes of Regulatory Functions

Processes of each regulatory function are well defined. However, due to the lack of manpower, officers often have to work to fill others' responsibilities without sufficient knowledge of the respective SOPs.

PFDA staff is well aware of their roles in each step and have the computer skills to perform their routine work using PFDA IT tools. Although the current IT system does not provide online electronic submission for product registration, applicants are supposed to submit electronic copies via portable devices, such as a USB. Reviewers also review application dossiers electronically, instead of by printed hard copies.

However, due to the lack of technical staff and the increase in applications for regulatory approvals, there has been a significant backlog of applications for marketing authorizations and variations. There are approximately 11,000 backlogged product registration applications (medicine only), including renewal and variation applications. Only 56 technical staff (with the

support of 33 non-technical staff) are in charge of reviewing and approving 6,000 regulatory applications per year.

According to the interviewees of the PFDA, the number of backlog has been decreasing through improving registration processes and the use of IT document tracking tools. However, the access to relevant regulatory data still remains as challenges for staff as they spend extra time searching for information via email communication and waiting for scanned copies to be delivered from the central database.

Medicine Registration

The Public Assistance Information and Receiving (PAIR) unit of the PFDA is responsible for screening and receiving applications directly from clients for product variation and renewal applications, applications for licensing establishments, and any other type of inquiry. PAIR uses an IT tool to schedule appointments semi-automatically once they receive requests from applicants (applicants can send an email directly from an application form once they complete the application form). A letter including document tracking number is automatically generated by the system and is sent to applicants by a PAIR staff.

PAIR unit also screens the completeness of dossiers by referring to the checklist using a pop-up window in the system. Once application is received, a document tracking number is created automatically through the system and both applicants and reviewers can track the record using the document tracking number. The unit is also responsible for scheduling appointments with applicants by utilizing an automated IT system. The system is effective enough for PAIR staff to perform their routine work. However, the system is not comprehensive enough for reviewers to monitor the progress of each application or to review dossiers electronically. Reviewers must track data by using the document tracking number in order to find dossiers, which are saved in a designated folder of the central database.

Current document tracking and the FDA Inventory System provide ample information to new applicants, but are neither user friendly nor efficient enough to search and retrieve data such as the history of variations, history of inspection results, and history of PMS data in relation to registered products. Therefore, technical staff must spend their time requesting and searching data in order to perform routine regulatory work. Technical staff often request data via email or telephone because electronic copies or data search functions are not readily available.

Dossiers are submitted electronically. The current IT system used by PFDA is not a complete electronic submission of the Association of Southeast Asian Nations (ASEAN) Common Technical Document (CTD). PFDA adopted the ASEAN CTD Guidelines in 2013 and currently receives application dossiers based on the ASEAN CTD Drug Registration Requirements. However, there is lack of detailed guidance for applicants on how to prepare application dossiers, including naming of files.

Licensing of Premises

The PFDA is planning to roll-out an online-based application system called E-LTO (License to Operate), which will include the applications for establishments such as importers, traders, distributors, manufacturers, pharmacies, detail outlets, Clinical Research Organizations, and GMP facilities. The PFDA Already been launched the E-LTO last July 2016 and tested with selected applicants. Considering the large number of applications per year (e.g., 5,093 applications up to July, 2016 for 12 technical staff), the new system is expected to expedite the application and review process.

Inspections

Scheduling and managing inspections is done manually, with the data stored accordingly in the PFDA's inspection IT system. However, access to the history of inspection result data is limited, especially for officers who work at regional offices. A comprehensive data management system is necessary to better monitor the progress of scheduled inspections and take regulatory actions after inspections.

Clinical Trial Approvals

The Clinical Trials Unit is responsible for reviewing and maintaining the data from clinical trial applications and the registry of approved clinical trials. Communication with external reviewers is done through postal mails. The Clinical Trials unit has been preparing an online-based clinical trial application IT tool in collaboration with the Western Pacific Regional Office of the World Health Organization. If the new IT system is launched, it will help the unit monitor the progress of application review and approval process in real time online.

Post-Marketing Surveillance

The Post-Marketing Surveillance (PMS) Unit is responsible for monitoring the quality and safety of registered products in the market. Because there is limitation in conducting tests of samples prior to product marketing authorization by the PFDA, the unit has a high volume of workload to collect samples and testing to check the quality of products circulated in the market. The unit collaborates closely with Regional Field Offices by receiving samples and sharing test results. However, the main method of communication is through postal mail. Therefore, access to PMS data is limited, especially for officers who work at field offices.

Pharmacovigilance

The Pharmacovigilance (PV) Unit is responsible for collecting, reporting, and analyzing adverse event (AE) reports and other safety reports related to medicine use. The PV unit receives AE reports via various means of communication, including email, the PFDA website, phone, fax,

and PAIR. The unit reports AE cases to the Uppsala center by using Vigiflow. The PV unit analyzes safety data as necessary and collects Periodic Safety Update Reports. However, PV unit staff have difficulty accessing regulatory data necessary to conduct their analyses. Although access to registration dossier data of recently registered products is easier, access to the history of variations and the most updated labeling data is more challenging. If necessary, PV staff will tell companies to update labels regarding safety issues. However, communication between the PV and Registration units is not well coordinated and not well documented for follow-up due to the lack of a platform for sharing the regulatory status of changes on registered products.

National Quality Laboratory

The NQL Unit is responsible for conducting tests of samples including medicines, food, cosmetics, and other health products, which are requested from different departments. Due to the lack of technical staff (analysts), there have always been backlog issues. A mere 10 analysts are responsible for 3,000 sample tests per year. Coding and managing data related to test requests and test results are completed by administrative staff. The NQL unit has its own database that includes test results. However, analysts can encounter difficulties accessing the regulatory information of registered products while verifying test methods and specifications due to problems accessing the medicine registration database.

Current Regulatory Data Management System

The Information, Communication, Technology, Management Division (ICTMD) of the PFDA is responsible for providing IT support to PFDA staff. ICTMD manages multiple regulatory databases as well as develops IT solutions to be used for key regulatory functions. ICTMD has provided staff with IT tools to help expedite routine work. Different IT tools are provided to track applications, document inspection results, and record official certificates and letters. Separate JAVA-based IT solutions became available in July 2016 for the licensing of premises, from submitting applications to approvals. Many other IT tools are under development or planned for other regulatory functions under the strong leadership of the PFDA.

However, the efficiency of the tools has often been diminished due to a fragmented data management system and difficulty navigating the data in order to perform routine regulatory work. Collaboration between the IT and technical teams has not been effective enough to improve IT tools due to lack of manpower and unclear roles and responsibilities in improving and maintaining regulatory data.

Users' Experience

PFDA users of IT tools are well trained to use current tools to perform their routine work. Although most tools are not necessarily user friendly in terms of their ease of use, users learned how to navigate the system to obtain necessary information using a document tracking number with a combination of different pathways, such as phone calls or emails. Overall, users agree that

the current IT tools and data management system are not user friendly and that it is difficult to obtain necessary regulatory data, particularly data that is older and not available in an electronic format.

Serious restrictions in performing regulatory work have been identified due to inefficient methods of managing regulatory data and accessibility to that data. The quality of regulatory data has not been well retained due to the lack of manpower and the unclear designation of responsible staff. Currently, the IT department is responsible for updating and cleaning the list of registered pharmaceutical products. However, the list has not been well monitored by regulatory officers who can provide technical review and feedback to improve the quality of the data. As a result, the current repository of registered pharmaceutical products does not contain comprehensive data, such as quantity of active ingredients. In many cases, the history of changes to registered products has not been reflected in the list. For example, sometimes the legal name of the license holding company has been changed through the variation process, but this name change is not reflected in the list.

RECOMMENDATIONS

In order to meet the increasing demands on the PFDA to perform regulatory work, a major upgrade of the current regulatory data management system is highly recommended.

- 1) **Improving the quality of regulatory data:** Databases of registered medicines, health products, licensed premises, and other regulatory information should be improved in order to build a strong regulatory data management system. The availability of usable and searchable data will improve the accessibility of necessary regulatory data to assist regulators in performing their work in a more effective and efficient way. Current databases contain a large amount of scanned images of documents, which does not allow regulators to search information in an efficient manner.
 - a) Registration data: Searchable data should include the name of products (both generic and brand names), active ingredients, quantity of active ingredients, name of manufacturers, name of license holders, name of premise representatives (manufacturer or importer), pharmaceutical or/and therapeutic classifications, indications, etc. Other regulatory information should also be searchable using product registration numbers or registered product names.
 - b) History of variations: History of variations should be readily available to check the compliance and latest regulatory information for registered products. The most updated information should also be made readily available in order to check the current status of registered products. Building the database on the history of variations can be challenging when digitalized data is not available. Therefore, PFDA can consider hiring additional human resources to build database. Then, PFDA can verify the data by requesting product marketing stakeholders to provide the information during their regular inspections or requesting to submit the relevant data as a requirement for new variation applications.
 - c) Labeling information: Most updated labeling information should be linked to a registered product database so that regulators can easily check labeling compliance and take any necessary regulatory actions on time. Consumers would also have easier access to correct information and could contact manufacturers for any safety concerns, if necessary.
- 2) **Strengthening the protection of confidential information:** The PFDA needs to prepare for electronic submission of dossiers through eCTD, which will require higher security protection of confidential information. Currently, the PFDA receives files through USB portable devices without providing clear instructions for naming or formatting files. Submitting files through USB portable devices can be used for until eCTD submission becomes available. However, PFDA can expedite the process of uploading files in an organized structure of dossiers so that reviewers can find necessary information in a more efficient way.

- 3) **Human resource development:** The PFDA needs to designate full-time staff to manage regulatory data in order to build regulatory databases, starting with registered medicines. Staff should work closely with the IT department to select the data fields to transform unusable data to searchable data. Each department or regulatory unit can designate staff to engage in the project since each department has their own unique needs to access to specific regulatory data. Once building the database is completed, the designated staff can reduce their involvement in time and efforts. Maintenance can be done by the center or IT staff to upgrade the database depending on the changes of needs from different departments.
- 4) **Online-based medicine registration system:** Currently, the PFDA receives applications when applicants visit the PFDA office to submit files of dossiers in order to file regulatory applications such as product registration applications. The PFDA can prepare for electronic submission of dossiers through eCTD via an online-based medicine registration system. In this way, the PFDA can easily build databases of registered products.
- 5) **IT tools for other regulatory functions:** Once the PFDA strengthens the database of registered medicines, it can develop integrated IT tools for other regulatory functions, as these subsequent tools can have an access to a core database to search for necessary information.

Implementation Strategy

A short-term, mid-term, and long-term improvement plan also need to be developed, as well as a long-term strategic plan, in order to strengthen the regulatory data management system. Following a comprehensive assessment of the current system, a roadmap with a detailed implementation plan must be developed (see figure 1). All functions are interrelated; therefore, a comprehensive regulatory database management tool must be developed based on users' needs across all regulatory functions.

Depending on the availability of resources (including budget, staff, technical assistance, and experienced IT developers), the PFDA should develop a strategic plan including short-term, mid-term, and long-term implementation plan. The time to be needed for implementation will vary depending on the availability of resources. Without having a clear strategic plan, it can be challenging to mobilize proper resources and to improve regulatory processes as well as to implement comprehensive regulatory data management system.

Without streamlining current regulatory processes, implementing comprehensive regulatory data management system will be challenging. Therefore, each regulatory function (responsible department) needs to be involved in creating and improving the quality of its regulatory database together with improving the process.

However, implementing a comprehensive regulatory data management system is not likely solve the problems of current backlog issues. Factors which contribute the long list of backlog need to

be identified in order to solve problems. Factors may include issues with inadequate human resources compared to the volume of registration applications or inefficient review process. Once the root causes are identified, the PFDA can solve the issues related to backlog together with implementing a comprehensive regulatory data management system which allow the PFDA to improve their efficiency in several ways.

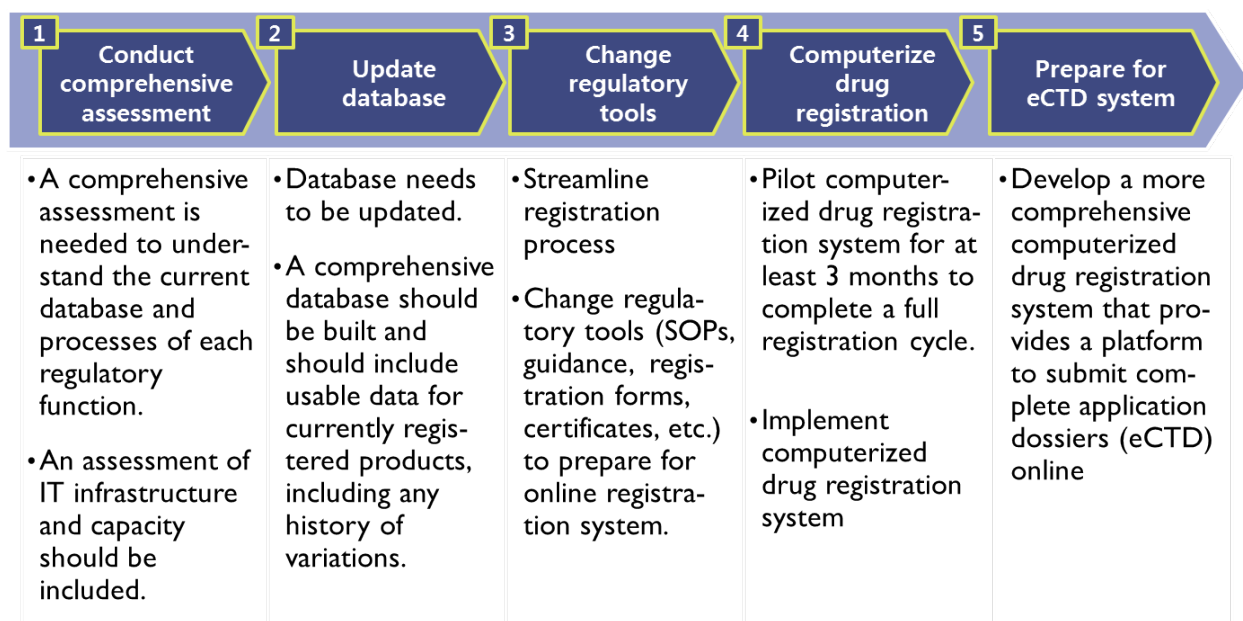


Figure 1. Roadmap to improve the medicine registration process

Short-Term Plan (3 to 6 Months)

The short-term plan should include quality improvement of regulatory data, such as the list of registered products, licensed premises, clinical trials applications, inspection data, and other regulatory information. The quality of the data should be based on the accessibility of necessary information that allows users to search in a more effective way. Scanned copies of old documents need to be reviewed and transformed into usable and searchable data.

- Step 1: Based on the assessment results, the PFDA needs to form a team to develop long-term strategies and implementation plans to improve the regulatory data management system. A study tour is one effective way of learning about the advanced regulatory data management systems of other NMRAs before the PFDA designs and launches its own new IT tools.
- Step 2: Improving the regulatory database is the first step toward preparing for the introduction of more comprehensive IT solutions to regulatory data management. Technical staff should be involved in identifying categories to transform non-searchable data into searchable data using scanned copies of medicine registration information.

Mid-Term Plan (6 to 12 Months)

The mid-term plan should include the improvement of IT tools per regulatory function, such that they can meet the demands and expectations of users, through close collaboration between technical staff and IT developers. Important data should be shareable between different IT tools. Interchangeability of IT tools for sharing data should also be considered when developing and improving these tools. Core data should be maintained at the central level and should be shareable between departments, regardless of their IT tools.

- Step 1: A task force must be organized to take the lead in regulatory data management improvement initiatives. The task force should include representatives from each regulatory function, as well as IT specialists. The task force should conduct a detailed assessment to identify areas for improvement, including the needs for accessing regulatory data, types of searchable medicine registration information, and challenges with existing IT tools.
- Step 2: The newly developed regulatory database needs to be incorporated into new regulatory function IT tools, including an online medicine registration submission tool. Users can provide feedback to further improve the system.

Long-Term Plan (12 to 24 Months)

The long-term plan should include the integration of the existing regulatory data management system, which includes the completed eCTD for medicine registration. Currently, the PFDA accepts electronic files and reviews electronic dossiers. With the completed eCTD submission, reviewers can reduce the time needed to manage data related to medicine registration. With the launch of eCTD submission, a new integrated regulatory data management system can be incorporated to maximize the availability of a high volume of usable data. Security to protect confidential information should also be considered to ensure data protection. The country's IT infrastructure, including internet speed and transmission of a high volume of data, is one of the critical factors to be considered before launching eCTD for medicine registration.

ANNEX A. LIST OF INTERVIEWEES

| Name | Title | Organization/Affiliation |
|---------------------------|---------------------------------------------------------------------|---------------------------------|
| Maria Lourdes C. Santiago | Officer-in-Charge (OIC), Director General | PFDA, Ministry of Health |
| Melody M Zamudio | OIC, Center for Drug Regulation & Research | PFDA, Ministry of Health |
| Abdel Raouf Qawwas | Key Expert/Drug Regulations Pharmaceuticals and Essential Medicines | EPOS Health Management |
| Lanette Lee Querubin | OIC, Product Research and Standards Development Division (PRSDD) | PFDA |
| Grace Medina | OIC, Product Research and Standards Development Division PLRD | PFDA |
| Estrellita Pastolero | OIC, PAIR | PFDA |
| Ryan Glenn de Guma | OIC, ITCMD | PFDA |
| Dr. Tito King | Medical Specialist | PFDA |
| Jade Mae Biyo | Food and Drug Regulation Officer | PFDA |
| Pia Angelique Priagola | Food and Drug Regulation Officer | PFDA |
| Khristie Michelle Ventura | Food and Drug Regulation Officer | PFDA |
| Manuel Dulzo, Jr. | Food and Drug Regulation Officer | PFDA |
| Francis Angelo Deal | Administrative Assistant | PFDA |
| Justin Jerome De Jesus | Food and Drug Regulation Officer | PFDA |
| Maria Glezila Soriano | Food and Drug Regulation Officer | PFDA |
| Joanna Feliza Tayag | Food and Drug Regulation Officer | PFDA |
| Juan Paolo Tonolet | Food and Drug Regulation Officer | PFDA |
| Alyssa Uy | Food and Drug Regulation Officer | PFDA |
| Mark Ryann Lirasan | Food and Drug Regulation Officer | PFDA |
| Kira Nicole Po | Food and Drug Regulation Officer | PFDA |
| Willison John DeLuna | Food and Drug Regulation Officer | PFDA |
| Mary Joie Jardinero | Food and Drug Regulation Officer | PFDA |
| Joel Ubalde | Information Officer | PFDA |
| Rogelio Manapat | Food and Drug Regulation Officer | PFDA |
| Michael Galang | Food and Drug Regulation Officer | PFDA |
| Michael Castillo | Food and Drug Regulation Officer | PFDA |
| Joanne Elaine Villaneuva | Food and Drug Regulation Officer | PFDA |
| Camille Rosario Castaneda | Food and Drug Regulation Officer | PFDA |
| Leslee Ann Lorna De Jesus | Food and Drug Regulation Officer | PFDA |
| Czarina Fortuno | Food and Drug Regulation Officer | PFDA |