# Optimizing the Marketing Authorization Process in Benin: Institutionalization and Development of Medicines Registration Standard Operating Procedures

March 2018


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SIAPS
Systems for Improved Access to Pharmaceuticals and Services

# Optimizing the Marketing Authorization Process in Benin: Institutionalization and Development of Medicines Registration Standard Operating Procedures

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March 2018

USAID FROM THE AMERICAN PEOPLE SIAPS

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



Kikule K, Nfor E, Saleeb S. 2018. *Optimizing the Marketing Authorization Process in Benin: Institutionalization and Development of Medicines Registration Standard Operating Procedures.* 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

medicines, medicines registration, medicines regulation, pharmaceutical, standard operating procedures

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## CONTENTS

## ACRONYMS

| | |
|---|---|
| DPMED | Department of Pharmacy, Medicines, and Diagnostics (Direction de la Pharmacie, du Médicament et des Explorations Diagnostiques) |
| MA | marketing authorization |
| MOH | Ministry of Health |
| MSH | Management Sciences for Health |
| SIAPS | Systems for Improved Access to Pharmaceuticals and Services |
| SIGIP-ARP | Integrated System of Computerized Management of Regulatory Process in a Drug Regulatory Authority |
| SOP | standard operating procedure |
| WAEMU | West African Economic and Monetary Union |
| USAID | US Agency for International Development |
| WHO | World Health Organization |

## ACKNOWLEDGEMENT

The USAID-funded SIAPS Program is grateful to the USAID Benin office for funding this activity and for the support and guidance provided, especially from SIAPS Activity Manager/Commodities & Logistics Specialist Benin/USAID, Mr. Riccardo Missihoun.

We would like to extend our appreciation to the management of DPMED (*Direction de la Pharmacie, du Médicament et des Explorations Diagnostiques)* for their collaboration to establish better systems for enhanced pharmaceutical regulation. Specifically, we would like to express our thanks to the Director, DPMED, Professor Fernand Gbaguidi; the Deputy Director, Mr. Nicolas Sodabi; and the Head of Legislation, Regulation, and Pharmaceutical Governance, Dr. Benoit Hounkpevi. Special gratitude goes to Dr. Jocelyn Satchivi, who worked to draft the procedures in French amid competing priorities. The whole DPMED team is appreciated for the work done, despite the inherent constraints at the time.

Finally, we are thankful for the leadership and guidance provided by SIAPS Program management and the regulatory systems strengthening team.

# INTRODUCTION

The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is a five-year cooperative agreement funded by the US Agency for International Development (USAID) and implemented by Management Sciences for Health (MSH). The goal of SIAPS is to improve the availability of quality pharmaceutical products and effective pharmaceutical services by strengthening pharmaceutical systems.

Pharmaceutical regulation is an essential component of pharmaceutical management systems that are required to ensure access to quality assured medicines. In Benin, the government has fair amount of control over the distribution of pharmaceuticals, however, regulatory systems in place currently are not adequate to ensure that all medicines sold are of assured quality. Medicine regulation is carried out by the DPMED, a technical department within the Ministry of Health (MOH). The national pharmaceutical policy revised in 2015 coordinated and managed by DPMED specifies that medicine regulation should be undertaken in the country. Regulation of the pharmaceutical sector is covered in various laws and decrees creating a legal framework for controlling medicine safety and quality on the market.

DPMED is responsible for registration of medicines prior to importation by licensed importers and their use by health providers and consumers. However, the department is hindered in execution of its mandate because of several challenges. The extent of illegal and unregistered medicines in circulation is not uncommon, like in other developing countries where an estimated 10.5% of medicines circulating on the market are deemed to be substandard or falsified according to the recently published WHO report.[1] DPMED is constrained by its capacity to effectively regulate the pharmaceutical sector with consequent inefficiencies in key processes, such as medicine registration, leading to delayed access to life-saving medicines.

For these reasons, the Benin MOH sought assistance from USAID to help strengthen the medicine registration system for effective performance to hasten access to quality assured medicines.

The SIAPS Program conducted a rapid assessment of the medicine registration system in November 2016, and in August 2017, conducted a detailed assessment of the medicine registration system at DPMED.

Based on the findings from the two assessments conducted by the SIAPS Program, several recommendations were made. One of the recommendations was to optimize the medicine registration process by establishing a consistent way of handling registration dossiers to promote an efficient process. Standard operating procedures (SOPs) were developed so that the registration department could operate more efficiently. In addition, the SOPs served as a prerequisite for establishing an effective and sustainable electronic medicine registration system.

The electronic system for registration of medicines and other health products known as SIGIP-ARP (Integrated System of Computerized Management of Regulatory Process in a

[1] WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products. Geneva: World Health Organization; 2017
http://www.who.int/medicines/regulation/ssffc/publications/GSMS_Report.pdf?ua=1

Drug Regulatory Authority) was installed in 2016 by DPMED, however, it was not performing effectively. SIAPS worked with DPMED to improve the functionality of SIGIP-ARP and to develop SOPs for medicine registration based on the legal framework and international best practices.

Regional procedures for registration of medicines for human use are well specified in Annexes I, II, and III of Regulation No. 06/2010/CM/WAEMU. However, these have not been transformed into a context that works for Benin.

## PURPOSE

The main purpose was to provide technical assistance to optimize the medicine registration system so that DPMED can effectively regulate medicines.

### Specific Objectives

- Determine the procedures used by DPMED for granting marketing authorization (MA) for medicines

- Identify key stages critical in ensuring delivery of efficiency in the medicine registration process

- Develop key SOPs used in the medicine registration process on the basis of international best practices and the legal provisions currently in force

## METHODOLOGY

Key documents related to the medicine registration process at DPMED were initially reviewed. These included, but were not limited to, the national and regional legislation, the quality manual, and previous assessment reports for DPMED.

Preliminary versions of SOPs were developed by the SIAPS team and given to the DPMED staff to transform into templates that conform to the legal, regulatory, and managerial context currently in place. Because of the limited time available for SIAPS to support DPMED, it was jointly resolved that the team embark on developing three basic SOPs on:

- Receipt and screening of dossier applications for MAs of medicines
- Evaluation and registration of medicines
- Archiving and storage of dossier applications and samples

SIAPS and DPMED staff reviewed the documents for completeness and accuracy. The draft templates were then sent to the DPMED focal person for updating and translation into French on the basis of legal and regulatory requirements. Thereafter, the procedures were checked by the head of Legislation, Regulation, and Pharmaceutical Governance prior to review by DPMED's deputy director.

SIAPS' plan was to orient DPMED staff on the medicine registration procedures before their final approval for implementation. However, because of time constraints, the planned orientation did not take place.

## RESULTS

Establishing SOPs for the medicines registration process is key to ensuring consistency, orderly processing of applications, and effective execution of all registration activities within the organization. Regulations required that DPMED establish procedures for receiving and evaluating application dossiers. Procedures are required for the following stages of the medicines registration process[2]:

1) Receiving application dossiers for MA of medicines

2) Screening application dossiers

3) Evaluating and registering medicines

4) Completing post-registration activities, including variations, renewals, suspensions, withdraws, and cancellations of registered medicines

Three out of four SOPs were developed and are available in English (annexes A, B, and C) and French (annexes D, E, and F).

- SOP for Receipt and Screening of Dossier Applications for Marketing Authorization

- SOP for Evaluation and Registration of Medicines

- SOP for Archiving and Storage of Dossier Applications and Samples

These SOPs await review by DPMED's deputy director prior to registration and staff orientation. Thereafter, the procedures will be approved by the director of DPMED before implementation.

[2] World Health Organization Global Benchmarking Tool (version V 2017); http://www.who.int/medicines/regulation/benchmarking_tool/en/

## RECOMMENDATIONS AND WAY FORWARD

With the support and technical assistance from the USAID-funded SIAPS Program, the three basic SOPs were developed and should be reviewed and discussed with the registration staff before approval by the director for use by DPMED. There was insufficient time to complete the whole process of documenting procedures in all areas and steps of the medicine registration process.

The following recommendations and way forward are given for consideration by DPMED:

- Complete the review of the three SOPs (by the specified responsible officers at DPMED)

- Arrange orientation and training of medicine registration staff on the SOPs before finalization for approval by the director

- Prepare guidelines on the medicine registration process for applicants so they can understand what happens before and during the assessment of medicines

- Develop and implement other guidelines, SOPs, and forms to strengthen the registration process at the national level based on provisions in national and regional regulations and international best practices. The following should be established at the national level:

    - Guidelines for:

        - Submission of documentation to register pharmaceutical products
        - Notifications and variations for a registered pharmaceutical product
        - Submission of documentation to register pharmaceutical products prequalified by WHO and approved by member states of the International Council on Harmonization

    - SOPS for post-registration activities, including variations, renewals, suspensions, withdraws, and cancellations of registered medicines as well as an appeal procedure

It is recommended that an overall quality management system be implemented within DPMED to facilitate effective documentation control as well as communication and information exchange internally and externally with the public and other stakeholders.

## CONCLUSION

Establishing a process for development of medicine registration SOPs has enabled DPMED to institutionalize the process of documenting key procedures in medicine regulation. This approach may be applied to other regulatory activities and processes.

Establishment of well-documented SOPs is a prerequisite not only for attaining consistency with the medicine regulatory authority but a necessary activity before establishing an effective and sustainable electronic medicine registration system.

Because of the limited time and other internal constraints, it was not possible to complete the development process. However, the preliminary work done will serve as an impetus for creating an overall quality management system within DPMED.

# ANNEX A. SOP FOR RECEIPT AND SCREENING OF DOSSIER APPLICATIONS FOR MARKETING AUTHORIZATION



## CONTENTS



| Prepared by: | Checked by: | Reviewed by: | Authorized by: |
|---|---|---|---|
| **Name:** Dr. Jocelyn Satchivi | Dr. Benoit Hounkpevi | Dr. Nicholas Sodabi | Prof. Fernand Gbaguidi |
| **Job title:** Registration Officer | Head of Registration Division | Deputy Director | Director |
| **Signature:** | | | |
| **Date:** | | | |

## 1.0 Policy and Legal Requirements

- Rules of WAEMU n ° 06/2010/CMIUEMOA 2010-10-01 relating to the procedures for registration of pharmaceuticals for human use in the member states of WAEMU
- Law 97-020 of 17 June 1997 on exercise of practices by private medical and paramedical professionals
- Law 97-025 of 18 July 1997 on control of drugs and precursors
- Decree 97-632 of 31 December 1997 on registration of medicines for human use
- Inter-ministerial order No. 005/MICPE/MSP/MFE/DC/DCCI of 18 February 2002 on the composition, responsibilities, and operation of the tariff commission for drugs and pharmaceutical specialties in the Republic of Benin (RB)
- Interministerial order No. 006/MICPE/MSP/MFE/DC/DCCI of 18 February 2002 establishing the means of setting prices in private pharmacies, prices of drugs, products, and pharmaceutical specialties in the RB
- Interministerial order No. 11063/MS/SMSACFA/DC/SGM/DTC/DPM/SA of 26 October 2006 establishing the means of setting prices of generic essential drugs and medical consumables in public, private, faith-based, and associated health services
- Interministerial order no. 249/MS/DC/SGM/DTC/DPMED/DA/SA of 26 June 2014 that describes the creation, powers, composition, and functioning of the Committee of Experts responsible for the approval of drugs for human use in RB

## 2.0 Purpose

The purpose of this SOP is to guide DPMED staff on the receipt and screening of CTD-based dossier applications submitted for the registration of medicinal products and processed through SIGIP-ARP.

## 3.0 Scope

This procedure is applicable to DPMED staff involved in the process of receipt and screening of medicine registration applications for granting of marketing authorization.

## 4.0 Responsibilities

It is the responsibility of the Director General of DPMED to ensure that this procedure is adhered to by all DPMED staff. It is the responsibility of the Head of the Registration Division to ensure that the procedure is applied by all relevant staff.

## 5.0 Resources

- Computer with internet connectivity to access web-based SIGIP-ARP software
- Printer to print documents from SIGIP-ARP
- Network attached storage system for secure shared folders

## 6.0 Roles

Keep the names and contact information of DPMED staff and officials involved in the drug registration receipt process up to date.

| | Name | Email address |
|---|---|---|
| **Receiver** | | |
| **SIGIP-ARP administrator** | | |
| **Screeners** | 1.<br>2. | |

Notify the administrator immediately of any changes in roles, responsibilities, and email addresses.

| User | User role (menu and items) | Remarks/notes |
|---|---|---|
| Receiver | Receives documents and CDs from applicants and provides them to the medicine registration administrator | Does not use the SIGIP-ARP system |

| User | User role (menu and items) | Remarks/notes |
|---|---|---|
| SIGIP-ARP administrator | • User registration<br>• Applicant registration<br>• Manage applicants<br>• Registered product (view only)<br>• Suspended product (view only)<br>• Revoked product (view only)<br>• Submitted applications (view only)<br>• Saved applications (view only)<br>• Administrator menu | No application-level permission except view with permission. |
| Screener | • Screen applications based on product registration checklist<br>• Registered applicants (view only)<br>• Registered product (view only)<br>• Suspended product (view only)<br>• Revoked product (view only) | Only the pending list is shown in the shared screen |

## 7.0 Procedures

### 7.1 Receiving Applications and CTD-Based Dossiers at the DPMED Office

1) The applicant should physically submit the following to their assigned receiver in the DPMED office:

   a) Completed application form (annex 1) for marketing authorization of a medicine
   b) Payment receipt for product registration
   c) Two CDs containing the CTD-based dossier and paper dossier
   d) Each CD should be labeled with:

      - Applicant's name
      - Name of the product-original copy
      - Product application reference number
      - Date of submission

2) After logging in the CDs and documents, the receiver provides them to the medicine registration administrator

### 7.2 Responsibilities of the Medicine Registration Administrator

1) Creates a profile for the applicant in SIGIP-ARP and registers the pharmaceutical company as the "applicant" once the form has been received

2) Downloads the CTD-based dossiers onto a secured shared folder

3) Uploads the files into the shared folder by creating a subfolder with the name of the applicant, including the date and application reference number, for example, using the first three letters of the company name, name of product, and product application reference number

4) After downloading all the files on the CD into the shared folder, the CD and other documents, together with the medicine samples, are sent to the screener

5) Administrator then notifies the relevant screener by email that a new application and dossier have been submitted

### 7.3 Role of the Screener

1) After getting a notification from the administrator, the screener ensures the completeness of the dossier assigned to him/her.

2) The screener logs into SIGIP-ARP with their user name and password to start screening the dossier using the template in SIGIP-ARP.

3) The screener proceeds with the verification and screening of the application and CTD-based dossier for completeness; if there are deficiencies (missing modules, subsections of modules, documents, etc.), the application is put on hold until all missing items are submitted.

   a) A deficiency letter with a list of the missing information is automatically generated and sent to the applicant requesting submission of the missing items.
   b) Once the applicant has gathered all the missing documents, data, and responses, the applicant should send the material to the screener on a CD labeled Amendment CD-1.
   c) When the screener receives the information, and if the dossier is now complete, the application is filed for evaluation.

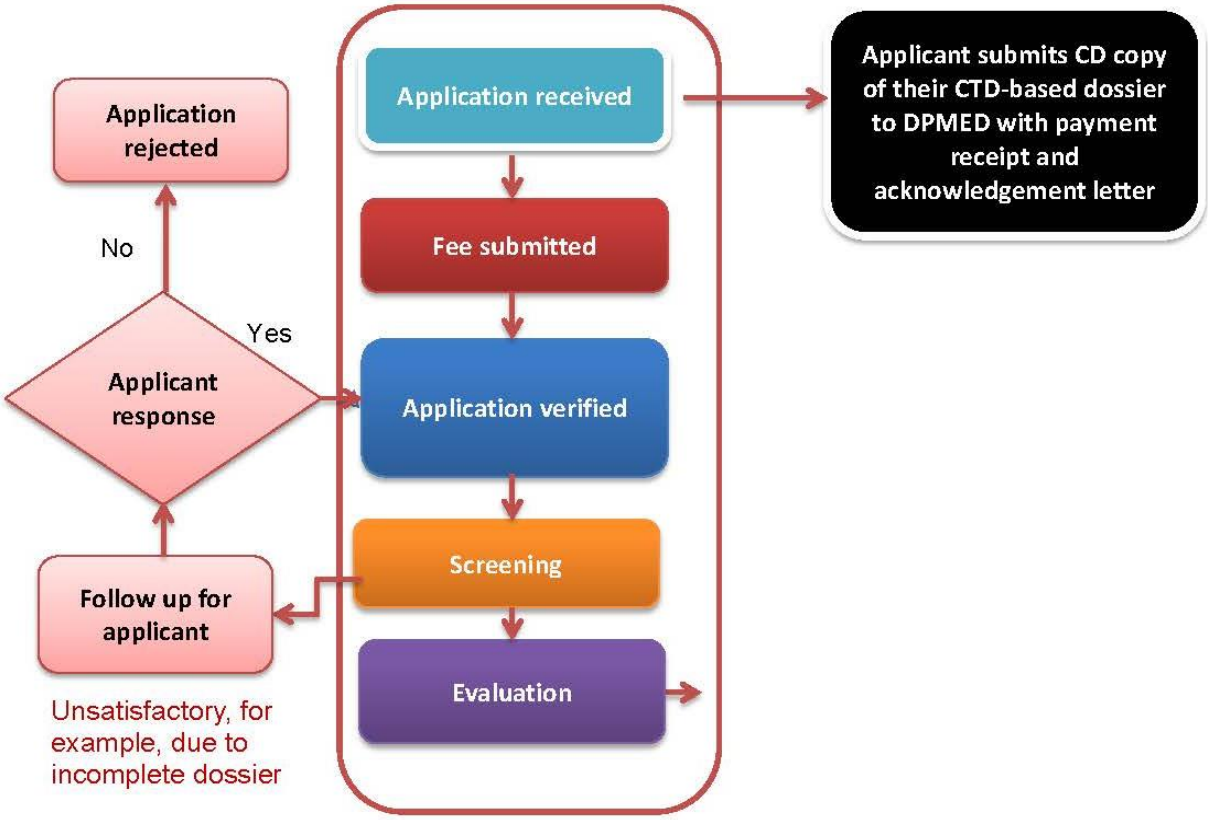
4) If there are no deficiencies, an acceptance letter is generated stating that the application has been accepted for evaluation; SIGIP-ARP will generate an estimated date for completion of dossier evaluation.

5) The screener sends a medicine sample test request to LNS comprising the medicine sample and completed sample test request form.

6) When the sample analysis is completed, the results are communicated to the screener.

7) Once screening of the application is complete, it is prepared for submission to the Technical Experts Committee.

### 7.4 Schematic Overview of Application Receipt and Screening Process



## 8.0 Revision History

| Revision | Date | Modified by | Reason for Change |
|---|---|---|---|
| 00 | | | |
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## 9.0 Addendum

Annex 1: Application Cover Letter

Annex 2: Acknowledgement Letter

Annex 3: Screening Checklist

Annex 4: Sample Analysis Request Form

# ANNEX B. SOP FOR EVALUATION AND REGISTRATION OF MEDICINES



## CONTENTS



| Prepared by: | Checked by: | Reviewed by: | Authorized by: |
|---|---|---|---|
| **Name:** Dr. Jocelyn Satchivi | Dr. Benoit Hounkpevi | Dr. Nicholas Sodabi | Prof. Fernand Gbaguidi |
| **Job title:** Registration Officer | Head of Registration Division | Deputy Director | Director |
| **Signature:** | | | |
| **Date:** | | | |

## 1.0 Policy and Legal Requirements

- Rules of WAEMU n ° 06/2010/CMIUEMOA 2010-10-01 relating to the procedures for registration of pharmaceuticals for human use in the member states of WAEMU
- Law 97-020 of 17 June 1997 on exercise of practices by private medical and paramedical professionals
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- Interministerial order No. 005/MICPE/MSP/MFE/DC/DCCI of 18 February 2002 on the composition, responsibilities, and operation of the tariff commission for drugs and pharmaceutical specialties in the Republic of Benin (RB)
- Interministerial order No. 006/MICPE/MSP/MFE/DC/DCCI of 18 February 2002 establishing the means of setting prices in private pharmacies, prices of drugs, products and pharmaceutical specialties in the RB
- Interministerial order No. 11063/MS/SMSACFA/DC/SGM/DTC/DPM/SA of 26 October 2006 establishing the means of setting prices of generic essential drugs and medical consumables in public, private, faith-based, or associated health services
- Interministerial order no. 249/MS/DC/SGM/DTC/DPMED/DA/SA of 26 June 2014 that describes the creation, powers, composition, and functioning of the Committee of Experts responsible for the approval of drugs for human use in RB

## 2.0 Purpose

The purpose of this SOP is to guide DPMED staff on the technical evaluation and review of CTD-based dossier applications for the registration of medicinal products processed through SIGIP-ARP before a regulatory decision is made to register the medicine for use.

## 3.0 Scope

This procedure is applicable to DPMED staff involved in the process of technical evaluation, review, and decision making of medicine registration applications for granting marketing authorization.

## 4.0 Responsibilities

It is the responsibility of the Director General of DPMED to ensure that this procedure is adhered to by all DPMED staff. It is the responsibility of the Head of the Registration Division to ensure that the procedure is applied by all relevant staff.

## 5.0 Resources

- Computer with internet connectivity to access web based SIGIP-ARP software
- Printer to print documents from SIGIP-ARP
- Network attached storage system for secure shared folders

## 6.0 Roles

Keep the names and contact information of DPMED staff and officials involved in the dossier evaluation process up to date.

| | Name | Email address |
|---|---|---|
| **Moderator (Head of Registration Division)** | **1.** | |
| | **2.** | |
| **Evaluators (Committee of Experts)** | **1.** | |
| | **2.** | |
| | **3.** | |
| | **4.** | |
| | **5.** | |
| | **6.** | |
| | **7.** | |
| | **8.** | |
| | **9.** | |
| **Reviewers (NMC)** | **1.** | |
| | **2.** | |

| | Name | Email address |
|---|---|---|
| | 3. | |
| | 4. | |
| | 5. | |
| | 6. | |
| | 7. | |
| | 8. | |
| **Director, DPMED** | | |

NMC, National Medicine Commission

Notify the administrator immediately of any changes in roles, responsibilities, and email addresses.

| User | User Role (Menu and Items) | Remarks/notes |
|---|---|---|
| **Moderator** | • Processes product applications assigned by screener<br>• Registered applicants (view only)<br>• Registered product (view only)<br>• Suspended product (view only)<br>• Revoked product (view only) | Only the pending list is shown in the shared screen. |
| **Evaluator** | • Evaluates applications assigned by moderator<br>• Views evaluator's reports (under "application processing" menu) and response<br>• Registered applicants (view only)<br>• Registered product (view only)<br>• Suspended product (view only)<br>• Revoked product (view only) | |
| **Reviewer** | • Reviews applications assigned by moderator<br>• Views reviewer's reports (under "application processing" menu) and responds<br>• Registered applicants (view only)<br>• Registered product (view only)<br>• Suspended product (view only)<br>• Revoked product (view only) | Only the pending list is shown in the shared screen. |
| **Head of Registration Division** | • Processes product application for review of full application cycle<br>• Makes comments in "executive summary" under "Assessment" to complete the application<br>• Registered applicants (view only)<br>• Registered product (view only)<br>• Suspended product (view only)<br>• Revoked product (view only) | Dashboard can be added more value to track/ progress at a glance. |

## 7.0 Procedures

The moderator is responsible for the following steps.

### 7.1 Processing the Results of Sample Analysis

1) Logs into SIGIP-ARP with their user name and password and quickly checks the screened application

2) Confirms results of the sample analysis

    a) If the sample passes the analysis, the product is considered for technical evaluation
    b) If the sample fails the analysis, the applicant of the product is notified in writing and requested to submit an explanation. The dossier application is not forwarded for technical evaluation until a favorable sample report is obtained

### 7.2 Preparing Dossier Applications for Technical Evaluation

1) Develops a list of dossier applications to be submitted for technical evaluation by the Committee of Experts
2) Prepares draft letters of invitation for the Committee of Experts

3) Submits the draft letters of invitation to the director of DPMED through the secretariat for consideration and signature

4) After receipt of the signed letters of invitation, prepares files for evaluation, together with all relevant documents, and communicates to the Committee of Experts that their participation in a technical evaluation session on a specified date and time is required

### 7.3 Technical Evaluation of Dossier Applications

1) The Committee of Experts evaluates the technical file. They—

    a) Study the administrative part of the file
    b) Evaluate the technical file
    c) Study samples as well as records provided

2) The committee proposes a technical opinion, which is documented in a word file, for the NMC.

### 7.4 Preparation of Reports for Submission to the NMC

1) Prepares all the information and documents required by the members of the commission (table comparing the list of products, table of the results of the quality control analysis, and the evaluation summary by the Committee of Experts)

2) Prepares samples to be distributed to members of the NMC

3) Ensures the availability of the attendance list

4) Prepares draft letters of invitation for the NMC members for approval by the minister of health through the office of the DPMED director

5) Informs members of the NMC about the date of the meeting

### 7.5 Review of Technical Evaluation Reports by the NMC

1) Members of the NMC

   a) Sign conflict of interest and confidentiality forms
   b) Evaluate the opinion of the Committee of Technical Experts
   c) Provide their opinions on the registration of the submitted products

2) The moderator then prepares the minutes and report to be submitted to the minister of health for consideration

### 7.6 Preparation of the Report by NMC for Submission to the Minister of Health

1) The moderator transmits a copy of the minutes and report of the deliberations by the NMC through the office of the DPMED director

2) The director sends the same copy of the minutes and the report to the minister through the secretariat for information and decision

3) The moderator also follows up on implementation of recommendations and the decision to grant marketing authorization of the submitted products by the minister of health.

### 7.7 Communication of Decision to the Applicant by the Director, DPMED

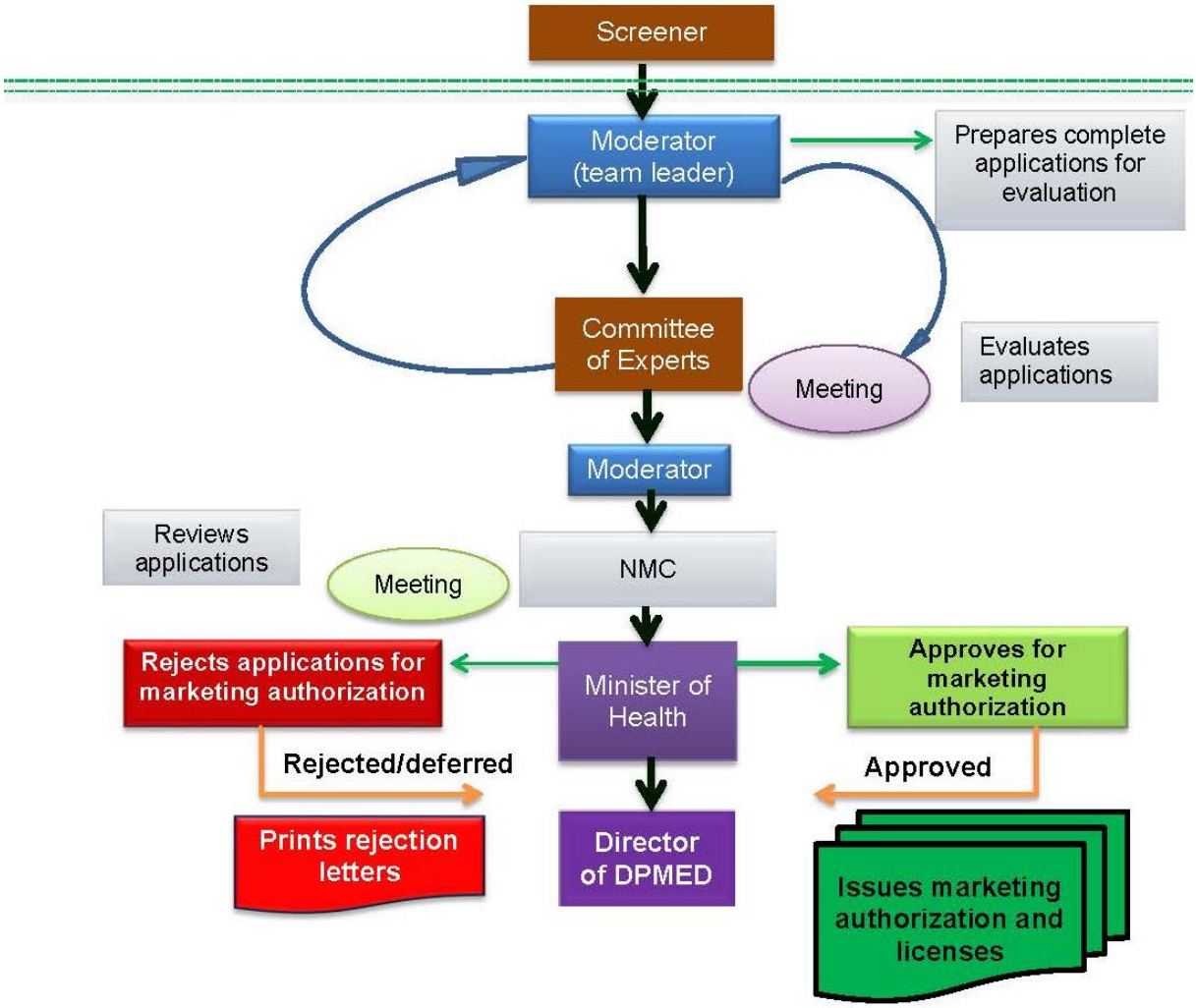
The moderator prepares draft notifications for products approved for marketing authorization, those rejected, and those deferred with reasons

The moderator submits the draft notifications for signature to the DPMED director

The director endorses the notifications in accordance with the decision of the minister of health

The director notifies the applicants of the marketing authorization decision, together with the registration certificate, if applicable.

## 7.8 Schematic Overview of Evaluation and Registration Process



## 8.0 Revision History

| Revision | Date | Modified by | Reason for Change |
|---|---|---|---|
| 00 | | | |
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## 9.0 Addendum

Annex 1: Technical Evaluation Checklist

Annex 2: Report Template for NMC

Annex 3: Template for Letter to Minister of Health

Annex 4: Registration Certificate Template

# ANNEX C. SOP FOR ARCHIVING AND STORAGE OF DOSSIER APPLICATIONS AND SAMPLES



## CONTENTS



| Prepared by: | Checked by: | Reviewed by: | Authorized by: |
|---|---|---|---|
| **Name:** Dr. Jocelyn Satchivi | Dr. Benoit Hounkpevi | Dr. Nicholas Sodabi | Prof. Fernand Gbaguidi |
| **Job title:** Registration Officer | Head of Registration Division | Deputy Director | Director |
| **Signature:** | | | |
| **Date:** | | | |

## 1.0 Policy and Legal Requirements

- Rules of WAEMU n ° 06/2010/CMIUEMOA 2010-10-01 relating to the procedures for registration of pharmaceuticals for human use in the member states of WAEMU
- Law 97-020 of 17 June 1997 on exercise of practices by private medical and paramedical professionals
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- Interministerial order No. 006/MICPE/MSP/MFE/DC/DCCI of 18 February 2002 establishing the means of setting prices in private pharmacies, prices of drugs, products and pharmaceutical specialties in the RB.
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- Interministerial order no. 249/MS/DC/SGM/DTC/DPMED/DA/SA of 26 June 2014 that describes the creation, powers, composition, and functioning of the Committee of Experts responsible for the approval of drugs for human use in RB

## 2.0 Purpose

The purpose of this SOP is to guide DPMED staff to efficiently and systematically file, retrieve, and store CTD-based dossier application files and samples for registration of medical products.

## 3.0 Scope

This procedure is applicable to DPMED staff involved in the process of filing, retrieving, and storing medicine registration applications for granting of marketing authorization.

## 4.0 Responsibilities

It is the responsibility of the director general of DPMED to ensure that this procedure is adhered to by all DPMED staff. It is the responsibility of the head of the Registration Division to ensure the procedure is applied by all relevant staff.

## 5.0 Resources

- Storage cabinets
- Premises for storing dossier application files and samples

## 6.0 Roles

Keep the names and contact information of DPMED staff and officials involved in the archiving process up to date.

| | Name | Email address |
|---|---|---|
| **Stores administrator** | | |
| | | |
| | | |

Notify the administrator immediately of any changes in roles, responsibilities, and email addresses.

| User | User role (menu and items) | Remarks/notes |
|---|---|---|
| **Store administrator** | • Application registration<br>• Registered product (view only)<br>• Suspended product (view only)<br>• Revoked product (view only)<br>• Submitted applications (view only)<br>• Saved applications (view only)<br>• Administrator menu | No application-level permission except view with permission. |

## 7.0 Procedures

### 7.1 Filing/Storage of CTD-Based Dossier Application Files and Samples at DPMED

1) The store administrator confirms that:

   a) The dossier application to be filed and corresponding samples to be stored have been received as per SOP XXX regarding receipt of application dossiers.
   b) The dossier application to be filed has been recorded as per SOP XXX regarding SIGIP-ARP data entry.

2) The dossier application should then be filed in alpha-numerical order in the relevant section, i.e., human, veterinary, food supplement, or herbal medicine applications, of the DPMED store. The coding system for the shelf location is provided (for illustration) as follows:

   - Alphabetical number for location of shelf, e.g., A, B, C….
   - Levels on a particular shelf, e.g., L1, L2, L3, L4....
   - Serial number for the specific location, e.g., 01, 02, 03….

   A specified dossier would be assigned a location number, e.g., BL201

3) The corresponding samples should be stored likewise in the DPMED sample store.

### 7.2 Retrieval of Dossier Application Files and Samples

- All requests from DPMED staff to retrieve dossier application files and/or stored samples should be sent to the store administrator in charge of filing applications and/or storage of samples.

- Before a file is retrieved from the DPMED store or a sample from the sample store, an entry must be made in the register of medicine registration application files/sample retrievals and restorations (see annex 1).

- All retrievals of files and/or samples must be supervised by the registration officer in charge of dossier application file/sample retrievals or the Head of the Registration Division.

## 7.3 Restoration of Dossier Application Files and Samples

a) All requests for the restoration of retrieved dossier application files or samples should be sent in writing to the designated officer in charge of filing files/storing samples.

b) All restorations should be to the original storage location and be performed only by the store administrator.

c) After a dossier application file or sample has been restored correctly to the DPMED store or sample store, the appropriate entry is made in the register of medicine registration application files/sample retrievals and restorations (see annex 1).

## 8.0 Revision History

| Revision | Date | Modified by | Reason for Change |
|---|---|---|---|
| 00 | | | |
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## 9.0 Addendum

Annex 1: Format for Register of Medicine Registration Application Files/Sample Retrievals and Restorations

## ANNEX C1. ADDENDUM TO ANNEX C: FORMAT FOR REGISTER OF MEDICINE REGISTRATION APPLICATION FILES/SAMPLE RETRIEVALS AND RETURNS

### Addendum to Annex C: Format for Register of Medicine Registration Application Files/Sample Retrievals and Returns

| Date of retrieval | F/S | No. | Dossier application file/ sample name | Requested by (name) | Returned by (sign) | Date of return |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |

**Note:**
Column F/S: enter appropriate letter to indicate whether a file (F) or sample (S) is being retrieved

1/1