Functional Comparison of Electronic Medicines Registration Systems

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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.

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Key Words

medicines registration, eHealth, process optimization, web-based, automation, transparency

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ACRONYMS AND ABBREVIATIONS

CTD	Common Technical Document
DPMED	Ministry of Health Pharmacy Department Benin
SIGIP-ARP	Integrated System of Computerized Management of Regulatory Process in a Drug Regulatory Authority
USAID	US Agency for International Development
WAEMU	West African Economic and Monetary Union

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SIAPS would like to acknowledge the management of the Ministry of Health Pharmacy Department Benin (DPMED) for their consistent and effective leadership in mobilizing technical experts from the organization's different directorates and its partners to review existing practices. We would also like to thank Mr. Ricardo Missihoun of USAID's Benin Mission for providing the required financial resources to the project and their close follow-up. The staff of DPMED is also appreciated for their commitment in reviewing the existing practices and providing feedback at different stages of the system development while still carrying on their day-to-day activities.

BACKGROUND

In Benin, a lot of effort has been put into changing from a manual medicines registration system to an electronic one. Initially, SIAMED was installed as a way to achieve this goal; however, due to the lack of support for the tool, the system was abandoned and the agency resorted to a Microsoft Excel-based solution. In early 2016, a medicine registration system called SIGIP-ARP was installed at DPMED, however, additional functionality is required to make it effective.

In November 2016, SIAPS offered technical assistance to DPMED to optimize the current medicine registration system, potentially by using the web-based medicine registration tool Pharmadex. After the assessment at DPMED in August 2017[1], SIAPS found that the SIGIP-ARP system in place was a software recommended for the regional West African Economic and Monetary Union (WAEMU) member states and was preferred by DPMED. Hence, it was jointly resolved to strengthen the system already in place.

A server room was setup and a rack server installed to hold the current and any other future systems for DPMED (e.g., inspection software). SIGIP-ARP was modified to improve its performance, which has enabled DPMED to do concurrent data entry of registration applications. DPMED is currently progressing on this task, and SIGIP-ARP can generate monitoring reports, which the director can use for management purposes. DPMED has yet to develop monitoring and evaluation indicators to track the data entry.

FUNCTIONAL COMPARISON

Features	Applications tested	
	SIGIP-ARP	**Pharmadex**
Price	Proprietary with development costs	Free and open source
Demo available	X	√
Current scale		
Countries	2: Burkina Faso and Democratic Republic of Congo	4: Bangladesh, Ethiopia, Mozambique, and Namibia
Registration module		
CTD format compliant	Not precisely, only the assessors reports and the decision of the commission are reflected	√
Web-based access and application submission by manufacturers, importers, and distributors	X	√
Optional public online availability of selected reports, e.g., list of approved medicines, manufacturers, etc.	X	√
Inspection module		
Captures inspection reports	X	X
Operational requirements		
User manual	√	√
Deployment manual	√	√
Local support availability	√	√
Source code available	√	√
User security access levels	√	√
Immediate availability for use	√	X
Easy to use and learn	√	√
Documentation quality	√	√
Training availability	√	√
System requirements		
CPU minimum	Intel i7	Intel Xeon, 2 core
Memory	12Gb	8Gb
Hard disk	100Gb	100Gb
Network/internet	LAN	LAN 10mbit/s
Operating system	Windows	Windows or Linux
Networked	√	√
Database	PostgreSQL	MySQL
Architecture	WinDev	Apache/Java
Desktop application	√	X
Web-based	X	√
Security levels	√	√
Score	12 out of 17	14 out of 17

Results

- The systems align quite well with only a few differences.
- The main benefit of SIGIP-ARP is that it is immediately available.
- The main benefit of changing to Pharmadex is that it is web-based, so applying for registration can be done by the applicants, which would save DPMED a lot of time.

SUSTAINABILITY PLAN

The current human resources at DPMED are sufficient to keep SIGIP-ARP running on the new server and to do some basic maintenance. A network technician has already been contracted and he is knowledgeable about the hardware and software configuration on the new server. An electrician is also available to maintain power circuits, lights, and the air conditioner in the server room.

If DPMED needs to expand the server or setup additional virtual machines to run other management information systems, they will need technical assistance from a contractor or a donor-funded project.

DATA MIGRATION PLAN

Should DPMED decide to benefit from Pharmadex, they would need to work with a software developer/database specialist to setup data migration between SIGIP-ARP and Pharmadex.

This can be automated, thereby integrating the two systems; or data from SIGIP-ARP can be migrated to Pharmadex, and then DPMED continues medicine registration in Pharmadex only.

SIGIP-ARP is the software recommended for the region (WAEMU countries), which means that integrating SIGIP-ARP and Pharmadex would probably be preferred.

The main benefit in switching to Pharmadex (a web-based system) would be that a large chunk of the workload could be transferred to the actual applicants who can do much of the data entry themselves instead of DPMED using its limited staff and resources for this purpose.

To consider whether to use SIGIP-ARP or Pharmadex in the future, DPMED needs to consider the advantages and disadvantages of both systems and assess whether the two can be integrated to benefit from both.

An effective electronic medicine registration system is required to achieve the following:

- Handle online applications for marketing authorization
- Allocate serial numbers to applications sequentially and automatically
- Capture details of product, applicant, and manufacturers
- Handle applications for variations and historical changes with the corresponding dates
- Indicate the validity of the marketing authorization and renewals
- Capture application processing steps with the corresponding dates, including major steps of the registration process using the CTD format
- Categorize products by using the ATC code and distinguish products with one or more active pharmaceutical ingredients
- Generate the marketing authorization/registration certificate and unique registration number
- Make SOPs, forms, and templates available
- Enable adequate storage and archiving of data on products and applicants
- Generate reports and registers that are available to the public and those for internal use only

- Link with other regulatory functions, e.g., inspection, import/export control, clinical trials, and laboratory

- Link with finance for invoicing, payroll, and payment of fees

- Enable use of a common language for ease of communication (English or other)

Based on the prevailing situation at DPMED, the observations made and the work already undertaken to improve the medicines registration system in Benin, it is recommended that DPMED continue operating with the current electronic system SIGIP-ARP.

However, given the factors listed earlier that are required to operate an effective electronic medicine registration system, DPMED should consider switching to or integrating with Pharmadex, given that one of its advantages is the fact that the burden of data entry into the system is borne by the applicant, especially in the present situation in which DPMED is short staffed.

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