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Final Report

Consultancy for Scoping of a Continental Regulatory Information Management System Solution and Information Sharing Platform for the Member States in the African Union

To:
Senior Operations Officer,
The World Bank Group,
Washington DC.

Submitted by:

BEWSYS
Better World Systems

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The Technical Working Group which consisted of:

Name	Organisation & Role
1. Yvonne Nkrumah	The World Bank Group, *Task Team Leader (TTL)*
2. Apollo Muhairwe	The World Bank Group
3. Yvette M. Atkins	The World Bank Group
4. Margareth Sigonda	NEPAD
5. Nancy Ngum	NEPAD
6. Abayomi Tosin Akinyemi	NAFDAC (Nigeria)/*Chairman, C-IMS TC*
7. Anthony Toroitich	IGAD MRH Secretariat
8. Fatuma Adan	IGAD MRH Secretariat
9. Sakhile Dube	SADC MRH Secretariat/MCAZ (Zimbabwe)
10. Sybil Nana Ama Ossei-Agyeman-Yeboah	ECOWAS MRH
11. Jane Mashingia	EAC MRH Secretariat
12. Andrew C.S. Kajeguka	EAC IT Secretariat
13. Aime Djitafo Fah	ECCAS MRH Project
14. Meba Theophile	CEMAC MRH Secretariat
15. Olufemi Balogun	NAFDAC (Nigeria)
16. Gedion Murimi	PPB (Kenya)
17. Emmanuel Owusu	FDA (Ghana)
18. Tich Nyovhi	MCAZ (Zimbabwe)
19. Athanas Mseki	TMDA (Tanzania)
20. Teboho Ramosangoana	SAHPRA (South Africa)
21. Fasil Hailemaiam	EFMCA (Ethiopia)

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Abbreviations and Acronyms

Abbreviation	Full Name
ADR	Adverse Drug Reactions
AIRP	Ivorian Pharmaceutical Regulatory Authority
AMA	Africa Medicines Agency
AMRH	African Medicines Regulatory Harmonization
AMU	Arab Maghreb Union
ANAMEV	The National Agency for Medicines and Health Evacuations
ANPP	The National Agency for Pharmaceutical Products
API	Active Pharmaceutical Ingredient
AU	African Union
AUDA	African Union Development Agency
BMGF	Bill and Melinda Gates Foundation
BOMRA	Botswana Medicines Regulatory Authority
CAPA	Central Administration for Pharmaceutical Affairs
CEN-SAD	Community of Sahel–Saharan States
COMESA	Common Market for Eastern and Southern Africa
CTD	Common Technical Document for Registration of Pharmaceuticals for Human Use
DFID	UK Department for International Development
DGPES	General Directorate of Pharmacy and Health Equipment (Country)
DPMED	Department of Pharmacy and Diagnostic Exploration
DPML	Department of Pharmacy, Medicine and Laboratory
EAC	East African Community
ECCAS	Economic Community of Central African States
ECOWAS	Economic Community of West African States
EDA	Egyptian Drug Authority
EFMHACA	Ethiopian Food, Medicine and Healthcare Administration and Control Authority
ERIS	Independent Health Regulatory Entity
FAQs	Frequently Asked Questions
FGM	Female Genital Mutilation
GCP	Good Clinical Practices
GDP	Good Distribution Practices
GLB	Good Laboratory Practice
GMP	Good Manufacturing Practices
HIV/AIDS	Human Immuno-Deficiency Virus/Acquired Immuno-Deficiency Syndrome
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
IGAD	Intergovernmental Authority on Development
INN	International Non-proprietary Names
KPPB	Kenya Pharmacy and Poisons Board
L IMS	Laboratory Information Management System
LPL	Libyan Pharmaceutical List
MCA	Medicine Control Agency
MCAZ	Medicines Control Authority of Zimbabwe

Abbreviation	Full Name
MoH	Ministry of Health
MRH	Medicine Regulatory Harmonization
MSPRH	Ministry of Health, Population and Hospital Reform
NAFDAC	National Agency for Food and Drug Administration and Control
NDFRA	National Drug and Food Regulatory Authority
NEPAD	New Partnership for Africa's Development
NMFA	National Medicines and Food Administration
NMRA	National Medicine Regulatory Authority
NODCR	National Organization for Drug Control and Research
NORCB	National Organization for Research & Control of Biologicals
NPMEC	National Pharmaceutical and Medical Equipment Company
PMPA	Pharmaceutical Manufacturing Plan for Africa
R IMS	Regulatory Information Management System
R-IMS	Regional Information Management System
REC	Regional Economic Community
SADC	Southern Africa Development Community
SAPHRA	South Africa Pharmaceutical and Health Products Authority
SMF	Site Master File
TMDA	Tanzania Medicines and Medical Devises Authority
USD	United States Dollars
WB	The World Bank Group
WHO	World Health Organization
ZAMRA	Zambia Medicines Regulatory Authority
ZFDA	Zanzibar Food and Drug Agency

Executive Summary

Introduction

The African Union (AU), through its development agency AUDA-NEPAD, in collaboration with Development Partners (BMGF, WHO, DFID, World Bank, and others) are currently undertaking the initiative to increase access to safe and quality medicines through harmonization of medicines regulatory requirements across its member states. Progressively, the AMRH implementation has established the need to develop a continent-wide Regulatory Information Management System (R-IMS) to enable the exchange of regulatory information across the regions and the national medicine regulatory authorities (NMRAs) in Africa. As a critical first step in establishing a national, regional, and a continental-wide R-IMS, the World Bank contracted Bewsys Limited to conduct a systems requirements study to determine the technical considerations needed to develop the continental regulatory information management system and information sharing platform for member states in the African Union

Methodology

From April to September 2020, the project was carried out using a mixed research methods approach that comprised desk research, virtual interviews, and administering of questionnaires to NMRAs of all 55 AU Member states. The desk research extensively covered all 55 member states. The online survey had a response rate of 57% and 13 countries (represented by their NMRAs) participated in the country-specific virtual interviews. For reliability and validity, a Technical Working Group that had been established by the AMRH Steering Committee was mandated to provide expert advice as needed, guide the project, monitor progress, and provide quality assurance. AMRH REC Coordinators were also requested to act as the consultant's contact persons with the National Medicines Regulatory Authorities (NMRAs) and Regional Economic Communities (RECs). Based on the findings, this report provides detailed recommendations on the systems requirements, project work plan, and indicative costs of developing national, regional, and continental technical infrastructure for the continental regulatory information management system and information sharing platform for member states in the African Union.

Study Findings

Generally, Member States of the AU with functional NMRAs undertake seven (7) main functions in their respective jurisdictions. The functions were identified as marketing authorization, licensing of manufacturing establishments, imports and export control, inspection of manufacturing premises and distribution channels. Others include market surveillance (product quality monitoring, pharmacovigilance, control of drug promotion and advertising), quality control, and oversight of clinical trials on drugs. Currently, 36% of the NMRAs of the AU member states have a fully functional IMS, while 64% either have unequipped MoH/NMRA websites or rely on other countries for medicine regulation information. Some barriers that hinder the development or implementation of basic

medicines regulatory functions in some African states are financial, resistance to change, practical and technological barriers, legal and institutional barriers, political and cultural barriers, and, at times, unrealistic expectations.

Although not fully harmonized, there is a level of collaboration and information sharing among NMRAs with each other, within each REC and at continental level. Forty-four (44%) of NMRAs shared information about their regulatory functions and medicine regulation policies. Approximately half of the continents' NMRAs (42%) have integrated their systems with that of their RECs. Information shared among NMRAs typically covers registrations (products, manufacturers, and premises), medical product recalls, pharmacovigilance and safety. 54% of the NMRAs rely heavily on other NMRAs demonstrating the critical role of information sharing.

In developing a continental R-IMS solution, it is necessary to assess the current state of the infrastructure in order to determine the requirements to build and maintain the system. Currently, less than half of the NMRAs have the minimum infrastructure needed to support the development of R-IMS solution and, ultimately, the continental R-IMS solution. The research showed that 82% of the 32 countries stated that their NMRAs had functional software in the organization. 78% use the software frequently in their daily operations. 46% of the NMRAs systems are web-based systems that are accessible through a browser (Chrome, Mozilla, and Safari), while 36% are desktop-based systems that need to be downloaded on a device before use. 18% of the NMRAs use both web-based and desktop-based regulatory systems. With regards to supporting infrastructure to run their R-IMS solution efficiently, 64% of the NMRAs offices have a computer- to-employee ratio of 1:1. At the same time, the internet speed is fairly distributed from poor (<5Mbps) to good (above 40Mbps). The R-IMS solution currently being used in countries and regions across Africa are open-source platforms, mainly SIAMED, Vigiflow/Vigibase, Pharmadex, and MedNet. MedNet is a collaborative platform provided by the WHO for sharing and exchange of scientific information. Pharmadex is a web-based tool that helps streamline and track medicines registration for a national drug regulatory authority. Vigiflow is a WHO web-based Individual Case Safety Report (ICSR) Management System that can be used in safety reports management. SIAMED is a WHO model system for computer-assisted drug registration

Recommendations

1. All NMRAs should have a website to facilitate access to medicine regulatory information.

To develop the continental R-IMS solution, first, we propose the development of NMRA websites that will facilitate access to medicine regulatory information for countries that currently lack access to an autonomous R-IMS solution or MoH/NMRA website. The objective is to ensure that all member states have the basic technical infrastructure needed to share medicine regulatory information in their respective jurisdictions publicly. At a minimum, every NMRA in Africa should have a publicly accessible website that provides comprehensive information on the following regulatory functions: product registration/market authorization processes, adverse drug reaction reporting, document repository, contact information and an online searchable register of approved products. Also, clinical trials authorizations, GMP compliant manufacturers, authorized importers, and exporters and licensed

premises should also be published. To ensure that the website efficiently supports the functions and operations of the NMRAs, we propose that the website is developed as a WordPress template. The website should have a content management system, online register search and navigation, multi-lingual support, technical configuration of hosting server, dedicated hosting, shared hosting and security configurations as part of its minimum requirements.

2. Develop an autonomous R- IMS solution for all NMRAs to enable integration of the independent systems.

Subsequently, we also propose the development of an autonomous R-IMS solution for all NMRAs to enable the integration of the independent systems to develop the harmonized regional and continental R-IMS solution. The identified users of an R-IMS solution are manufacturers, importers, exporters, the general public, inspectors, assessors, finance, management, and laboratory technicians. The interactions of these users help attain the required regulatory standards of the pharmaceutical industry. In the proposed R-IMS solution, we have detailed twelve system modules (Premise Module, Product Module, GMP Module, Import, and Export Module, Inspection Module, Finance Module, Track, and Trace Module, Monitoring and Evaluation Module, Laboratory Module, Document Library Module, Report Module, User Administration) as the minimum functional modules required to enable the NMRAs to carry out their regulatory mandates. With these modules, the integrated systems solution will be used for information sharing on product registration, premises license, GMP certificates, import/export permit and licenses, adverse drug reactions, product recalls, and substandard/falsified medicines across Africa.

3. The IMS Technical Working Group should be coordinated at continental level and be expanded to include more representatives from NMRAs, domain experts and other stakeholders.

To establish an efficient continental R-IMS solution, we recommend that a technical group comprising representatives from the NMRAs, domain experts, and other stakeholders of the system is created. The system should be developed based on the user and technical requirements and the system specification documents that have been collected and approved by the stakeholders. A pilot of the R-IMS solution modules should be conducted on a small-scale (in 3 countries) to ensure that potential system challenges are identified, controlled, and addressed on time before the full-scale implementation. Knowledge transfer and training must also be prioritized, strategically designed and implemented to ensure that system administrators are adequately equipped to manage the system after deployment. To ensure continuity and sustainability of the continental R-IMS solution, we recommended that a Continental organization such as AUDA-NEPAD coordinates and manages the activities of the continental R-IMS.

4. A national R-IMS, and ultimately continental R-IMS solution with proposed modules, can be developed from scratch or built on an existing open source R-IMS solution.

Finally, to develop the national R-IMS solution and ultimately the continental R-IMS solution, the proposed modules can either be implemented from scratch or built on an existing (open-source) R-IMS, solution specifically Pharmadex. The development of the national R-IMS solution from scratch will take

a total of 23 months, including pilot and scale-up. To reduce the software development time of the national R-IMS solution (not including deployment and piloting) from 19 months to 4 months, the system can be developed based on an existing open-source solution, specifically Pharmadex. Both approaches to establishing the R-IMS solution provide unique time, cost, and usability trade-offs that should be factored in the decision-making process. The estimated cost for the complete project which includes websites for the NMRAs, a National R-IMS solution, and a Regional and Continental R-IMS solution for information sharing and collaboration is in the range of USD 1,108,000. The estimated cost of developing the national R-IMS solution from scratch is USD 496,000, while the cost of developing the national R-IMS solution based on Pharmadex is approximated at about USD 260,000.

Chapter 1: Project Background

The right to health is an international human right as stipulated in Article 25 of the Universal Declaration of Human Rights and Article 12 of the International Covenant on Economic, Social and Cultural Rights. This right is also affirmed in Article 16 of the African Charter on Human and Peoples Rights. States Parties are obligated to protect the health of their population and it is the duty of the State to improve access to good quality medicines for better treatment outcomes. Regulation of medical products assures medicine quality, safety and efficacy and contributes to the promotion and protection of public health and results in better health outcomes. The African Union Assembly Decision {Assembly/AU/Dec.55(IV)} taken during the Abuja Summit in January 2005 requested the AU Commission to develop a Pharmaceutical Manufacturing Plan for Africa (PMPA) within the framework of the then New Partnership for Africa's Development (NEPAD). The Africa Medicines Regulatory Harmonization Multi-Donor Trust Fund (AMRH) was established in 2011 to help support regional harmonization efforts to remove barriers that hinder access to quality medicines. Managed by the World Bank, its primary objective is "to promote the harmonization of medicines regulation, to increase access to essential and quality medicines, by strengthening governance and regulatory systems of the pharmaceutical sector in Africa.

In 2012, the 19th African Union Assembly Decision {Assembly AU/Dec.442(XIX)} on the AU Roadmap for Shared Responsibility and Global Solidarity for the AIDS, TB and Malaria response in Africa was adopted. Among other things, the Roadmap emphasizes the need to accelerate and strengthen regional medicines regulatory harmonization initiatives and lay the foundation for the African Medicines Regulatory Agency (AMA). Since 2012, AMRH has been active in East, West and Southern Africa and the Horn of Africa and assisting in their regional consensus building efforts to harmonize requirements across countries, increase collaboration, strengthen regulatory capacity, and accelerate registration of quality medicines. In 2015 the Executive Council Decision {(EX.CL/Dec.857 (XXVI)} endorsed the milestones for the establishment of the AMA in Africa within the context of the African Medicines Regulatory Harmonization (AMRH) Initiative, which contributes to the PMPA and to the development of health human capital for the fulfilment of the African Union's human and social development enshrined in Agenda 2063.

The AMRH is also committed to the fulfilment of the vision of the African Medicines Agency (AMA). The goal of the AMA is to ensure the coordination and strengthening of continental initiatives to harmonize medical products regulation, provide guidance and technical support to improve access to quality, safe and efficacious medical products and health technologies on the continent. AMA will work within the existing continental architecture of Regional Economic Communities (RECs) and Regional Health Organizations (RHOs) to support AU Member States. In preparation for the establishment of the AMA, there is a need to begin connecting and linking the information management systems for medicines regulation on the continent. While some countries have strong IMS solution in place for medicines regulation, others have next to nothing. This is further compounded by very few RECs having functional regional IMS solution for ensuring that the less resourced countries are able to tap into regulatory data which is essential for ensuring the quality of medicines on their markets. This information gap

underscores that more work needs to be done to fully realize our collective goals towards a more harmonized future for medicines regulatory harmonization in Africa.

In order to facilitate decision making and information sharing amongst Member States and stakeholders, an integrated continental IMS will have to be developed for the continent, by connecting regional IMS solution where they exist, ensuring interoperability. In regions where there are no R- IMS, building/establishing systems for R-IMS solution will enable information sharing not only among countries in those regions, but also across countries on the continent. Information sharing will enhance the gains of medicines regulatory harmonization. Furthermore, the technical aspects of medicine regulation and decision making also need to be supported by robust R-IMS solution and continental IMS solution. Hence, an integrated continental Regulatory Information Management System at continental level connecting the regional economic communities (RECs) and National Medicines Regulatory Agencies (NMRAs) will be an important means of ensuring speedy access to medical products that are safe, efficacious and of assured quality, to the African population as well as information on the same.

A critical first step in establishing a regional and ultimately a continental R-IMS solution is to assess the current IMS solution in place at both national and regional level where they exist and recommend specifications/requirements for a solution as well as scope the activities needed to operationalize the solution. In March 2020, the World Bank contracted Bewsys Limited, an IT Consulting firm to scope the current IMS solution at national and regional levels and make policy and technical recommendations on potential solutions to facilitate the sharing of regulatory data and information on medicines among countries in Africa. The recommendations from the scoping should provide the basis for policy dialogue at the AU, including the envisaged AMA as a continental medicines regulatory agency. This report provides an assessment of medicine regulatory functions, the current IMS solutions and supporting infrastructure in operationalising the functions in African States and the proposed system requirements and roadmap to establish the continent-wide integrated IMS solution intended to provide online and real-time medicine regulation information and support workflow management in Africa.

Chapter 2: Project Scope

The objective of the project was to assess medicine regulatory policies, the current IMS solutions and supporting infrastructure to propose system and user requirements and a roadmap to establish the continent-wide integrated IMS solution for the AU Member States. The scope of the project was aimed at:

I. Assessing the existing Regulatory Information Management System (R-IMS) solutions and associated supporting infrastructure in all the Member States' National Medicines Regulatory Authorities (NMRAs);
II. Reviewing and conducting a situational analysis on existing continental e-governance initiatives and/or platforms in the health sector at the AU, AU organs and AU Member States including those planned or under development, to ensure that the requirements specifications for the continental IMS solution are aligned/ interoperable with existing continental platforms.
III. Reviewing of country policies and regulatory framework and propose policy considerations necessary for a regional and continental IMS solution.
IV. Conducting a comparative study of existing regional IMS solutions and Infrastructure (identified in (i)) and propose detailed and necessary recommendations and options for the establishment of a regional R-IMS solution in each REC, if none exists and an integrated IMS solution, with interoperability properties, for the continent;
V. Identifying the users of the proposed regional and continental R-IMS solution (NMRAs and stakeholders) and document their requirements;
VI. Producing a detailed roadmap for the proposed solution including indicative costs for the same, highlighting any obstacles or processes to be followed;
VII. Producing the Technical, User Requirements and Specifications report for the proposed Regulatory Information-sharing platform for medicine regulation that links the NMRAs in their respective RECs and also to the continent-wide R-MIS solution.

Based on the project objectives, Bewsys Limited, the consultancy firm was required to deliver the following:

1. An inception report to demonstrate the understanding of the assignment and outline the methodology to be utilized;
2. A feasibility study report on the assessment of the existing systems in the NMRAs, system requirements and scoping of the best approach to establishing an integrated IMS solution for medicines regulation in Africa for the AMRH project.
3. Technical, User Specification Requirements and Specification report for the proposed continental IMS solution platform for medicine regulation that links the NMRAs on the continent;
4. A technical and executive report, outlining:
    a. a brief overview of the existing IMS solution in AU Member States' NMRAs including challenges, obstacles and opportunities;
    b. a report on the status of e-governance initiatives/platforms in the Health sector at the AU, AU organs, and AU Member States, including policy considerations.

c. recommendations for customization of already existing workflow management systems that can be adapted and adopted by other NMRAs;
d. a detailed description of an appropriate approach, methodology and roadmap to developing and implementing an integrated IMS solution that will enhance decision making and information sharing within the context of the AMRH initiative and increase the transparency and ease of access to non-confidential medicine regulation information to all stakeholders.

Chapter 3: Methodology

3.1. Research Design

In order to obtain current and relevant information, a situational and comparative analysis of the existing medicine regulatory frameworks, R-IMS solutions, and supporting infrastructure available at national, regional, and continental levels was conducted. The descriptive research method was adopted for the purpose of the assignment. Data was collected through desk research, online survey, and interviews. The collected data was then thematically analyzed using statistical methods and also systems analysts and software engineers to inform the recommendations.

3.2. Data Collection

Desk Research

The desk research was conducted to identify and understand the existing software/systems being used by the NMRAs and understand the medicine regulatory functions of each country. At this stage, the research team gathered and analyzed publicly available data on medicine regulation and regulatory information systems available on NMRA websites, national ministry of health (MoH) websites, the WHO's report on Globally identified Websites of Medicines Regulatory Authorities (World Health Organization, 2012) and other relevant online publications on medicine regulation.

Online Survey

An online survey was designed in collaboration with the technical working group in English and French. The survey's questionnaire was categorized into six sections which required responses on the current regulatory functions of NMRAs, their information management systems (if any), their associated infrastructure and documentation standards, and the features NMRAs would require in the new system. The questionnaire was administered to at least three representatives of NMRAs (ICT Officer, Regulatory Officer, and Administration Officer) of the 56 member states via email on June 16, 2020. At the time of reporting, 32 countries had responded to the survey- accounting for a 57% response rate.

Interviews

Before the data analysis of the survey responses, virtual interviews were conducted with the objective of seeking further clarification on the survey responses. The NMRAs participated in virtual interviews which were facilitated by the consultant and conducted via Google Hangout, Skype, Zoom, WhatsApp, and phone calls. The interview questions were designed to gain the NMRAs assessment of the feasibility of the project and understand the unique system requirements of each NMRA. The interviews were conducted in French and English.

3.3. Research Variables

In identifying and scoping the user requirements for the integrated web-based Regulatory Information Management System (R-IMS) solution, the consulting team needed to understand the core functions

of NMRAs to ensure that all data collected and analyzed adequately captured their operations. Using the WHO's Global Benchmarking Tool (GBT) as a reference, the consulting team outlined the core NMRA functions to be considered in the data collection and data analysis. The WHOs Global Benchmarking Tool recognizes nine (9) overarching functions within National Regulatory Systems. The overarching functions within National Regulatory Systems were identified as:

1. National Regulatory Systems (RS)
2. Registration and Marketing Authorization (MA)
3. Vigilance (VL)
4. Market Surveillance and Control (MC)
5. Licensing Establishments (LI)
6. Regulatory Inspection (RI)
7. Laboratory Testing (LT)
8. Clinical Trials Oversight (CT)
9. NRA Lot Release (LR)

In addition, as stated in the terms of reference (TOR) of the assignment, the assessment of the existing R-IMS solutions, and the recommendations focused on the modules listed below:

1. Product Registration Module
2. Inspections Module for both GDP and GMP
3. Laboratory Information Management System
4. Pharmacovigilance Module
5. Clinical Trials Module
6. Post Marketing Surveillance Module
7. Import and Export Module
8. Licensure Module – Professionals and Premises
9. Track and Trace Module
10. Monitoring and Evaluation Module
11. Finance Module

Chapter 4: Situational Analysis of Existing IMS Solutions and Infrastructure in AU Member States and Enabling Policies and Regulatory Framework

4.1. Review of National Medicine Functions and Regulation in AU Member States

The regulatory functions undertaken by NMRAs in Africa include Registration and Marketing Authorization (MA), Regulatory Inspection (RI), Laboratory Testing (LT), Vigilance (VL), Market Surveillance and Control (MC), Licensing Establishments (LI), Import and Export (IE) and Clinical Trials Oversight (CT).

Across the five subregions of Africa, at least 28 countries have a form of regulatory function. The most prevalent functions in the subregions are on the Licensing Establishment, Import and Export Control, Registration and Market Authorisation and Regulatory Inspections functions. The least prevalent medicines regulatory functions in the AU Member States is Clinical Trials Oversight and Laboratory Testing. On average, eight countries across each of the five subregions lack a Laboratory Testing and Clinical Trial Oversight functions.

Overall, 37 out of the 55 AU Member States have publicly accessible information on the medicine regulatory functions of their NMRAs. The East African and West African regions have the most extensive medicine regulatory functions. Approximately 62% of the countries in West and East Africa have at least one medicine regulatory function. The region with the least extensive medicine regulatory functions is North Africa where more than 50% of the countries lack publicly accessible information on their medicine regulation functions.

Region[1]	Total Number of Countries	Number of Countries with Medicines Regulatory Functions on:							
		MA	RI	LT	VL	MC	LI	IE	CT
Central Africa[2]	9	6	5	3	3	3	6	6	3
East Africa[3]	14	10	10	11	11	11	10	11	9
North Africa[4]	7	3	1	2	2	2	2	2	2
South Africa[5]	10	7	9	4	8	6	8	7	6
West Africa[6]	15	10	11	11	11	11	11	11	8
Total	55	36	36	31	35	33	37	37	28

Table 1: Coverage of national medicines regulatory functions in Africa Union Member States

[1] The regional classifications below is based on AU subregions categories. This is because, some AU member states are members of more than one REC. To avoid duplication of data, AU subregions were used to present an overview of the medicines regulatory functions across AU member states. Section 4.4. focuses on specific initiatives in the RECs.
[2] Central Africa Countries: Burundi, Cameroon, Central African Republic, Chad, Republic of Congo, DR Congo, Equatorial Guinea, Gabon, Sao Tome and Principe.
[3] East Africa Countries: Comoros, Djibouti, Eritrea, Ethiopia, Kenya, Madagascar, Mauritius, Rwanda, Seychelles, Somalia, South Sudan, Sudan, Tanzania and Uganda.
[4] North Africa Countries: Algeria, Egypt, Libya, Mauritania, Morocco, Saharawi and Tunisia.
[5] South Africa Countries: Angola, Botswana, Eswatini, Lesotho, Malawi, Mozambique, Namibia, South Africa, Zambia, Zimbabwe.
[6] West Africa Countries: Benin, Burkina Faso, Cabo Verde, Cote d'Ivoire, Gambia, Ghana, Guinea, Guinea-Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone, and Togo.

Region	Total Number of Countries	Number of Countries Without[7] Medicines Regulatory Functions on:							
		MA	RI	LT	VL	MC	LI	IE	CT
Central Africa	9	1	2	3	3	3	1	1	4
East Africa	14	2	0	0	2	0	1	0	2
North Africa	7	0	2	1	1	1	1	1	1
South Africa	10	1	1	2	1	1	2	1	1
West Africa	15	2	1	3	1	1	1	1	4
Total	55	6	6	9	8	6	6	4	12

Table 2: Non-coverage of national medicines regulatory functions in Africa Union Members States

Central Africa: National Medicine Regulatory Functions

Medicine regulatory functions are fairly developed and publicly accessible in the Central African Region. The most regulated functions in the region are Registration and Marketing Authorisation, Licensing Establishments and Imports and Exports Control. The least regulated functions in the region are Laboratory Testing, Vigilance, Market Surveillance and Control, and Clinical Trials Oversight. Two out of the eight countries, specifically DR Congo and Equatorial Guinea lack publicly available information on medicine regulatory functions in their jurisdictions. Among the six countries that have publicly available information, Chad has the most extensive functional coverage while Central African Republic and Republic of Congo have the lowest functional coverage; with no Laboratory Testing (LT), Vigilance (VL), Market Surveillance and Control (MC) and Clinical Trials Oversight (CT) functions.

Country	MA	LI	RI	VL	CT	IE	MC	LT
1. Burundi								
2. Cameroon								
3. Central African Republic								
4. Chad								
5. Republic of Congo								
6. DR Congo	No data	No data	No data	No data	No data	No data	No data	No data
7. Equatorial Guinea	No data	No data	No data	No data	No data	No data	No data	No data
8. Gabon								
9. Sao Tome and Principe				No data			No data	No data

Key: Green = Available, Red = Not available

Table 3: Coverage of national medicine regulatory functions in Africa Union Member States in Central Africa

[7] The table excludes AU member states that do not have publicly available data on medicines regulatory functions.

East Africa: National Medicine Regulatory Functions

Overall, the medicine regulatory functions in this region are fairly developed. Although a significant proportion of the subregion has medicine regulatory functions, 43% of the countries lack publicly available information about the functions of their NMRAs. Excluding Djibouti, Eritrea, and South Sudan, which have no publicly available information on their NMRAs regulatory functions, all the other countries (i.e. 79%) in the region have at least one regulatory function. The most prevalent function in this region is the subregion are Import and Export Control, Laboratory Testing and Market Surveillance and Control. The least prevalent is the Registration and Marketing Authorization, the Clinical Trial, and Vigilance functions. 21% of the countries in the sub-region lack those functions. Ethiopia, Kenya, Mauritius, Rwanda, Sudan, Tanzania, and Uganda are among the 50% of the countries in the subregion that have an officially known NMRA that is aligned to all the medicines regulatory functions.

Country	MA	LI	RI	VL	CT	IE	MC	LT
1. Comoros								
2. Djibouti	No data	No data	No data	No data	No data	No data	No data	No data
3. Eritrea	No data	No data	No data	No data	No data	No data	No data	No data
4. Ethiopia								
5. Kenya								
6. Madagascar		No data	No data		No data	No data	No data	No data
7. Mauritius								
8. Rwanda								
9. Seychelles			No data					
10. Somalia	No data	No data	No data		No data	No data	No data	No data
11. South Sudan	No data	No data	No data	No data	No data	No data	No data	No data
12. Sudan								
13. Tanzania								
14. Uganda								

Key: Green = Available, Red = Not available

Table 4: Coverage of national medicine regulatory functions in Africa Union Member States in East Africa

North Africa: National Medicine Regulatory Functions

Information on the medicine regulatory functions in North African states are less publicly accessible. Three (3) out of the seven (7) countries in the subregion have publicly available information on their medicine regulatory functions. Libya, Mauritania, Saharawi, and Morocco do not have publicly available information on their medicine regulatory functions. Egypt and Tunisia have the most extensive medicine regulatory functions in the region addressing up to eight regulatory functions. While Tunisia lacks a Regulatory Inspections function, Algeria only has a Registration and Market Authorisation function.

Country	MA	LI	RI	VL	CT	IE	MC	LT
1. Algeria								
2. Egypt								
3. Libya	No data	No data	No data	No data	No data	No data	No data	No data
4. Mauritania	No data	No data	No data	No data	No data	No data	No data	No data
5. Morocco	No data	No data	No data	No data	No data	No data	No data	No data
6. Saharawi	No data	No data	No data	No data	No data	No data	No data	No data
7. Tunisia								

Key: Green = Available, Red = Not available

Table 5: Coverage of national medicine regulatory functions in Africa Union Member States in North Africa

South Africa: National Medicine Regulatory Functions

National medicine regulatory functions in the South Africa subregion has extensive coverage. Aside from Eswatini, all countries within the subregion had some publicly accessible information on medicine regulatory functions. South Africa, Zambia, and Zimbabwe had the most extensive and publicly accessible medicine regulatory functions; on all eight regulatory functions. The remaining countries in the region either lacked some regulatory functions or in some cases had no publicly available information on the regulatory functions. Angola only had Licensing Establishments and Regulatory Inspection functions. Lesotho, Mozambique, and Namibia on the other hand lacked publicly available information on some functions. Despite having Regulatory Inspections and Vigilance functions, Lesotho is one of the countries with the least publicly available information in the region.

Country	MA	LI	RI	VL	CT	IE	MC	LT
1. Angola								
2. Botswana								
3. Eswatini	No data	No data	No data	No data	No data	No data	No data	No data
4. Lesotho	No data	No data			No data	No data	No data	No data
5. Malawi								
6. Mozambique					No data		No data	No data
7. Namibia								No data
8. South Africa								
9. Zambia								
10. Zimbabwe								

Key: Green = Available, Red = Not available

Table 6: Coverage of national medicine regulatory functions in Africa Union Member States in South Africa

West Africa: National Medicine Regulatory Functions

Most of the countries in the West African subregion have extensive medicines regulatory functions. Three out of the 15 West African states do not have publicly available information on medicines regulation functions within their jurisdictions. The countries without publicly available information were Mali, Senegal, and Togo. Aside from Benin, all the 12 countries in the subregion with publicly available data undertake at least 5 out of the 8 regulatory functions. Clinical Trials and Laboratory Testing functions are least undertaken in the subregion. 47% of the countries within the subregion have extensive functions addressing all the eight medicine regulatory functions. Burkina Faso, Cote d'Ivoire, Ghana, Guinea, Liberia, Nigeria, and Sierra Leone have all 8 medicines regulatory functions.

Country	MA	LI	RI	VL	CT	IE	MC	LT
1. Benin								
2. Burkina Faso								
3. Cabo Verde								
4. Cote d'Ivoire								
5. Gambia								
6. Ghana								
7. Guinea								
8. Guinea-Bissau								
9. Liberia								
10. Mali	No data	No data	No data	No data	No data	No data	No data	No data
11. Niger								
12. Nigeria								
13. Senegal	No data	No data	No data	No data	No data	No data	No data	No data
14. Sierra Leone								
15. Togo	No data	No data	No data	No data	No data	No data	No data	No data

Key: Green = Available, Red = Not available

Table 7: Coverage of national medicine regulatory functions in Africa Union Member States in West Africa

4.2. Assessment of the Existing R-IMS Solutions in AU Member States

Overview of Existing R-IMS Solutions in African NMRAs

Twenty (20) of the African Union Member States have an existing IMS solution. They also have a website that covers the major processes represented in the IMS. 17 countries have websites with no IMS solution while 18 countries have neither a website nor an IMS. Out of the 32 countries that responded to the questionnaire sent out, 40% of the countries have their website/IMS solution linked to that of their respective RECs thus sharing information with their RECs. The NMRAs share information on the list of registered products, renewal, and variations, list of registered premises and status, list of pharmaceutical manufacturers, medical product recalls, pharmacovigilance and safety, list of banned products, and list of withdrawn products with their RECs. Collaboration and interaction among countries are mostly informal with 56% of the countries relying on other countries. Information is shared purposefully for reliance on the regulatory function activities conducted in other countries. Among themselves, these countries share information on statistics on registration (registered products, rejected products, products pending approval), similar for clinical trials and other regulatory functions, safety alert information, pricing of products, and request for experts. The regulatory functions that are most supported by R-IMS solutions include product registration/marketing authorizations, inspections, pharmacovigilance, clinical trials, post-marketing surveillance, quality control, and import and export. The least supported regulatory functions by R-IMS solution include monitoring and evaluation, track and trace, and finance.

Region	Total Number of Countries in Region	Number of Countries with R-IMS Functionality			
		Availability of R-IMS	Availability of NMRA/MoH Website	Information sharing with REC	Collaboration with other Countries
Central Africa	9	2	5	7	5
East Africa	14	6	12	4	3
North Africa	7	0	2	1	1
South Africa	10	6	8	7	6
West Africa	15	8	13	4	4
Total (Africa)	55	22	40	23	19

Table 8: Existing R-IMS Solution Coverage among NMRAs in the Africa Union

Coverage of R-IMS Solutions in Central Africa

Although the adoption of technologies – R-IMS solutions and websites are low among NMRAs in Central Africa, NMRAs actively collaborate and share information with their REC and other countries. Two countries (Burundi and Cameroon) of the eight states in the subregion has adopted the use of an R-IMS solution in medicine regulation at the NMRA. Five countries – Burundi, Cameroon, Congo Republic, DR Congo, and São Tomé & Principe have NMRA/MoH website to share medicine regulatory information with the public. Despite the low adoption of technology in the region, information sharing, and collaboration is significantly high. Apart from Equatorial Guinea and São Tomé & Principe, all countries in the region share medicine regulatory information with the REC. Similarly, apart from Equatorial Guinea, São Tomé & Principe, and Chad, all countries in the subregion, collaborate with other countries.

Country	Availability of R-IMS	Availability of NMRA/MoH Website	Information sharing with REC	Collaboration with other Countries
1. Burundi				
2. Cameroon				
3. Central African Republic				
4. Chad				
5. Congo Republic				
6. Democratic Republic of Congo				
7. Equatorial Guinea				
8. Gabon				
9. São Tomé & Principe				

Key: Green = Available, Red = Not available

Table 9: Existing R-IMS Solution Coverage among NMRAs in the Central Africa

Coverage of R-IMS Solutions in East Africa

More NMRAs in the East Africa subregion have NMRA/MoH websites compared to R-IMS software. Except for South Sudan and Sudan, all 12 states in the subregion have and use NMRA/MoH websites to share medicine regulatory information with the public. Forty-three percent (43%) of countries in the subregion have and utilize an R-IMS in their operations. Ethiopia, Kenya, Rwanda, Tanzania, Uganda, and Sudan have operationalised R-IMS solutions in their NMRAs. Comoros, Djibouti, Eritrea, Madagascar, Mauritius, Seychelles, Somalia, and South Sudan have not adopted R-IMS solutions in their NMRAs. There are exceptionally low collaboration and information sharing within the subregion. Only 4 out of the 14 states (Tanzania Ethiopia, Kenya, and Rwanda) actively share information with the REC and only three (3) of those countries (Ethiopia, Kenya, and Rwanda) collaborate with other countries in medicine regulation.

Country	Availability of R-IMS	Availability of NMRA/MoH Website	Information sharing with REC	Collaboration with other Countries
1. Comoros				
2. Djibouti				
3. Eritrea				
4. Ethiopia				
5. Kenya				
6. Madagascar				
7. Mauritius				
8. Rwanda				
9. Seychelles				
10. Somalia				
11. South Sudan				
12. Sudan				
13. Tanzania				
14. Uganda				

Key: Green = Available, Red = Not available

Table 10: Existing R-IMS Solution Coverage among NMRAs in East Africa

Coverage of R-IMS Solutions in North Africa

Technology adoption, information sharing, and collaboration in medicine regulation in North Africa are in a critical state. Only two countries have adopted a form of technology in medicine regulation in the subregion. Algeria and Mauritania have NMRA/MoH websites for public information on NMRA functions. No countyr in the greion has adopted an R-IMS solution in its regulatory functions. Tunisia is the only country within the region that shares medicine regulatory information with a REC and collaborates with other countries.

Country	Availability of R-IMS	Availability of NMRA/MoH Website	Information sharing with REC	Collaboration with other Countries
1. Algeria				
2. Egypt				
3. Libya				
4. Mauritania				
5. Morocco				
6. Saharawi				
7. Tunisia				

Key: Green = Available, Red = Not available

Table 11: Existing R-IMS Solution Coverage among NMRAs in the North Africa

Coverage of R-IMS Solutions in South Africa

The adoption of technologies to support medicine regulatory functions in South Africa outweighs the level of information sharing and collaboration among NMRAs in the Southern Africa subregion. All the countries have an MoH/NMRA website in the region except Angola and Lesotho. IMS availability is fairly distributed among the countries with 6 (60%) NMRAs having an R-IMS solution. NMRAs are more engaged in information sharing with RECs than collaborating with other. While 60% share regulatory information with the RECs only 40% collaborate with other countries in the region.

Country	Availability of R-IMS	Availability of NMRA/MoH Website	Information sharing with REC	Collaboration with other Countries
1. Angola				
2. Botswana				
3. Eswatini				
4. Lesotho				
5. Malawi				
6. Mozambique				
7. Namibia				
8. South Africa				
9. Zambia				
10. Zimbabwe				

Key: Green = Available, Red = Not available

Table 12: Existing R-IMS Solution Coverage among NMRAs in South Africa

Coverage of R-IMS Solutions in West Africa

The adoption of technologies to support medicine regulatory functions in West Africa outweighs the level of information sharing and collaboration among NMRAs in the subregion. Apart from Guinea and Guinea-Bissau, NMRAs and MoHs in the subregion have websites for public medicine regulatory information. Fifty-three percent (53%) of NMRAs in the subregion have operationalised an R-IMS solution in their regulatory functions. NMRAs in Benin, Cape Verde, Gambia, Guinea-Bissau, Liberia, Mali, and Niger do not use an R-IMS in their regulatory processes. However, Burkina Faso, Côte D'Ivoire, Ghana, Guinea, Nigeria, Sierra Leone, Senegal, and Togo have adopted R-IMS solutions in their processes. 43% of the countries in the region have also adopted both R-IMS solutions and websites. Information sharing and collaboration in medicine regulation are exceptionally low in West Africa. 47% of the countries in the region have also adopted both R-IMS solutions and websites in managing information at their NMRAs. Information sharing and collaboration in medicine regulation are exceptionally low in West Africa. Only four (4) of the sixteen (15) especially Burkina Faso, Guinea, Liberia, and Sierra Leone share information with the REC as well as collaborate with other countries in medicine regulation.

Country	Availability of R-IMS	Availability of NMRA/MoH Website	Information sharing with REC	Collaboration with other Countries
1. Benin				
2. Burkina Faso				
3. Cape Verde				
4. Côte D'Ivoire				
5. Gambia				
6. Ghana				
7. Guinea				
8. Guinea-Bissau				
9. Liberia				
10. Mali				
11. Niger				
12. Nigeria				
13. Sierra Leone				
14. Senegal				
15. Togo				

Key: Green = Available, Red = Not available

Table 13: Existing R-IMS Solution Coverage among NMRAs in West Africa

Adoption of Global R-IMS Solutions in NMRAs in Africa

Some R-IMS solutions that have been adopted across Africa include SIAMED, Vigiflow/Vigibase, Pharmadex, and MedNet. They are mainly used to manage medicine regulation activities as well as document repositories for the adopting countries. Some countries have customized systems or are in the process of acquiring customized systems while some use Microsoft Word and Excel to produce, manage, and store information.

The benefits of the adopted systems include the fact that they are major document repositories, help in capturing of technical and administrative details of dossiers in the various regulatory functions, act as a collaborative platform for information and document exchange, help in data analysis and tracking critical information for decision making.

However, some of the disadvantages of these systems include the fact that most of them are stand-alone and not integrated with other existing in-country systems for seamless information exchange, they are obsolete and outdated and the external ownership limits full exploration of the systems and slow decision making for improvement purposes.

Pharmadex

Pharmadex is a web-based tool that helps streamline and track medicines registration for a national drug regulatory authority by recording and organizing information on suppliers and products, tracking product applications in the registration process, analyzing and comparing suppliers and products, and tracking critical information for decision-making, such as costs, usage, and safety. Pharmadex supports product registration, marketing authorization, and pharmacovigilance. Pharmadex is currently being used by 12 countries in Africa namely, Burkina Faso, Cameroon, Côte d'Ivoire, Democratic Republic of Congo, Kenya, Rwanda, Uganda, Tanzania, Ethiopia, Mali, Mozambique and Senegal. According to one NMRA Pharmadex is good but it can be better if it has an integrated inspection activities data.

Benefits of Pharmadex: The benefits of Pharmadex includes enabling tracking of product registration process, analysing and comparing products and suppliers, enabling document exchange on the platform and providing a platform for communication among the countries that have adopted it.

SIAMED

The WHO developed the Model System for Computer-assisted Drug Registration (SIAMED) to improve the efficiency of drug regulatory authorities by enabling them to ensure that market authorizations are in line with the national drug policies. In general, the system is considered out of date and unfit for purpose.

The countries that have used and discontinued using SIAMED include Botswana, South Africa, Comoros, Côte d'Ivoire, and Gabon. Zambia and Tunisia are currently using it for marketing authorization and laboratory activities.

Benefits of SIAMED: The benefits of SIAMED include helping in report generation and management of laboratory activities

Challenges with SIAMED: The challenges of SIAMED include obsolescence, SIAMED is not user friendly, uploading information on the platform is challenging and communication with marketing authorization applicants is difficult.

MedNet

MedNet is a collaborative platform provided by the WHO for sharing and exchange of scientific information which can be accessed at a country level with authorization from WHO. The NMRA then issues the access to individuals according to their responsibilities. MedNet is mostly used by SADC countries including Zambia, Zimbabwe, Botswana, Namibia, South Africa, Mozambique, Malawi, Democratic Republic of Congo and Tanzania for product registration and document exchange and storage purposes.

Benefits of MedNet: MedNet functions as a document repository.

Challenges with MedNet: The following are the challenges faced while using MedNet:

1. MedNet does not provide any processing functions.
2. Difficulties in migrating documents from the system.
3. MedNet does not provide any other functions other than the storage of documents.
4. MedNet has session time-out thus it is difficult to continuously upload/download files.
5. Lack of confidentiality among the team members collaborating on the MedNet platform.
6. Lack of ownership and control makes confidentiality difficult.

Vigiflow and Vigibase

Vigiflow is a WHO web based E2B compatible Individual Case Safety Report (ICSR) Management System. It allows for data entry, assessment, storage, and retrieval of information and communication with other parties by national authorities and companies.

The system allows for communication with the WHO global database of ICSRs, VigiBase. The countries that are currently using Vigiflow include Cabo Verde, Sierra Leone, Niger, Zambia Botswana and Nigeria. They use the platform for creating adverse drug reaction reports, pharmacovigilance, alert systems and e-reporting.

Benefits of Vigiflow and Vigibase: Some of the benefits of using Vigiflow include helping in sharing safety reports and pharmacovigilance information, enabling each department to own a database for storing information, allowing communication with the WHO global database of ICSRs and providing real-time information on drug reactions happening across the world from other countries.

SIMFAR

SIMFAR is used by Cabo Verde. It helps with the codification of medicines registered. All the details of a medicine are entered into SIMFAR and the system generates and assigns a code to the medicine. SIMFAR was originally built to manage the regulation of medicines from the marketing authorization stage to the post market surveillance stage. However, due to technical challenges, SIMFAR is currently only used to assign codes to medicines and to regulate the prices of the medicines.

ASYCUDA World

The Zambian government implemented the ASYCUDA World, a computerized system developed by the United Nations Conference on Trade and Development (UNCTAD)which brings together all agencies that have a role in clearing of various goods that are being imported or exported out of the country. ZAMRA hopes to build an R-IMS that supports all medicine regulatory activities in the next year. This system will also be integrated with ASYCUDA to allow for a seamless flow of information.

The Government of Nigeria in conjunction with the Ministry of Finance have implemented a Single Window for Trade, which is an integrated information system for all government agencies involved in trade. The system is to make information sharing easier and to prevent users from sending the same information to different agencies. Through that system, NAFDAC issues import permits to its clients. This information is shared with Customs, the Central Bank of Nigeria, and the Tax office.

Adoption of Custom R-IMS Solutions in NMRAs in Africa

Botswana, Côte d'Ivoire, Comoros, Ghana, South Africa, Nigeria, Zambia and Zanzibar have adopted custom R-IMS solution for their NMRAs. The systems serve the following purposes in these countries: document management to store dossiers, finance and administration, management of the marketing authorizations that are issued in terms of archiving, monitoring and validity, all regulatory functions, generation of import licenses, adverse drug reaction reporting and management of laboratory activities.

Benefits of Custom R-IMS Solution:

1. Simplifies regulatory function operations processes.
2. Stores, manages, analyses and reports on information when needed.
3. Provides e-services for regulatory function activities like e-registration.

Challenges with Custom R-IMS Solution:

1. Most of the systems are stand-alone and not integrated with other necessary applications.
2. Comoros' system has problems with logistics and supplier misunderstandings.

Adoption of Microsoft Applications in R-IMS solutions in NMRAs in Africa

Botswana, Cape Verde, Gabon, South Africa and Sierra Leone have adopted Microsoft applications for their information management. They use Excel to store the list of all approved medicines and Microsoft Word, Excel, and Adobe to create licenses. They use these apps for document storage and communication via emails.

Benefits of Microsoft Applications: They are basic systems, easy to navigate and allow seamless interaction among users. They are not internally developed, thus cost effective.

Challenges with Microsoft Applications: Microsoft applications cannot process regulatory activities like registration, they have limited functionalities and some countries are not able to afford the subscription charges.

Challenges with Adopting R-IMS solutions in Africa

1. Obsolescence

Most of the systems adopted by African countries have run obsolete with time. This makes integration with current technology difficult. Current technology enables simplification of e-processes, are easy to navigate, provide advanced statistical analysis and e-reporting features. Unless a system is developed from scratch, it will be difficult to explore and enjoy the advanced technology that prevails.

2. Limited Functionalities

The systems listed above have extremely limited functionalities. They are therefore not able to process all the regulatory function activities. Besides product registration which most of them can support, they do not have features for pharmacovigilance, quality control, GDP/GMP inspection, licensing, post market surveillance and other necessary functions like monitoring and evaluation, finance, and project management. This has posed a huge challenge in using the systems.

3. Technical Problems

Users of SIAMED have complained of difficulties in uploading data to the system. MedNet has session time-outs thus it is difficult to continuously upload/download files. Comoros, on the other hand have misinformation of supplier information on their system.

Systems need close monitoring and maintenance. Therefore, countries should staff their Information Management and IT teams to maintain technical problems and troubleshoot any system problems that may occur.

4. External Ownership

Countries that have adopted the systems explained above have complained of challenges that comes with external ownership. First, full exploration of the system is limited. Updates of the system are slow, that is why some of them have run obsolete. Countries lack the rights to tailor the systems to fit their specific in-country regulatory activities.

5. Stand-alone Systems

Stand-alone systems are difficult to work with because the user cannot integrate other applications with it to enhance the performance. Their functionality is limited to what they were created for, thus as time goes by, they become very limiting.

6. Funding

Maintenance of systems needs funding, for both hardware and software infrastructure. Many countries lack the funds to maintain their systems and keep them up to date with the current technology. As a result, the systems run obsolete or experience many technical challenges.

4.3. Assessment of Supporting Infrastructure for R-IMS Solutions and Information Sharing Platform for African NMRAs

Overview of Supporting Infrastructure for R-IMS Solutions in NMRAs

To implement a regional and continental R-IMS solution and information sharing platform, there is the need to assess the availability of supporting infrastructure in the AU Member States. To function effectively, NMRAs need access to supporting infrastructure including regulatory software solutions with interoperable system specifications, reliable internet connectivity, computers, efficient communication channels, and existing collaborative relationships with other member states. To assess the availability of these supporting infrastructure, a questionnaire was administered to all NMRAs to enquire about their access to an R-IMS solution, the usage of the R-IMS solution in operations, access to the internet and computers, and communication, and collaboration procedures. Thirty-two (32) countries out of the 55 member states participated in the survey: accounting for a 57% response rate. This chapter provides detailed findings and implications of the available supporting infrastructure on the implementation of the regional and continental R-IMS solution and information sharing platform for the AU Member States.

R-IMS Solution Software Availability and Usage

In the survey, NMRAs were asked if they utilize regulatory software in their operations and the extent to which the software is institutionalized in the regulatory process. 82% of the 32 countries that responded to the questionnaire stated that they have access to regulatory software in their NMRA. 78% of the respondents also indicated that they use the software frequently in daily operations. Based on the survey responses, less than half of NRMA's (26 countries) in the AU have access to R-IMS solutions and less than half (24 countries) frequently use their R-IMS solution in their operations. This implies that to develop a regional and continental R-IMS and information sharing platform, there needs to be significant investment in providing NMRA's with R-IMS solutions. There also must be an enabling environment to ensure that the systems are frequently utilized in regulatory operations in the respective NMRA jurisdictions. Consequently, countries that have R-IMS solution software that is currently not in use also need support to fully operationalize their systems in their operations.

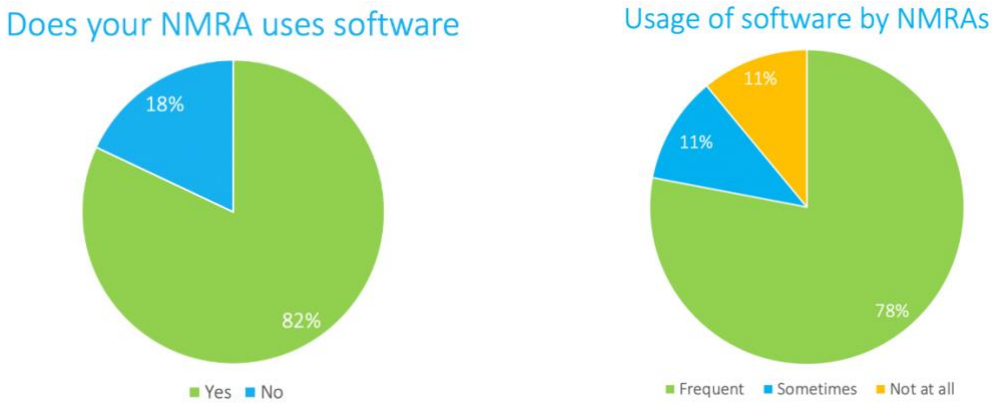

Figure 1: R-IMS Software Availability and Usage

Internet Connectivity and Access to Computers

In the survey, NMRAs were asked about internet connectivity and computer to employee ratios at their NMRA offices. To ensure that NMRAs have an enabling environment to operationalize R-IMS solution software in operations, internet connectivity and staff access to computers at NMRA offices are critical. From the survey responses (32 countries), the computer-to-employee ratio is mostly 1:1 (64%) while the internet speed is fairly distributed from poor(<5Mbps) to good (above 40Mbps).

With a fair distribution of internet connection, NMRAs have a favourable environment to operationalize R-IMS solution software in their operations. However, there should be consideration so as to ensure that R-IMS solution software solutions adopted in NMRAs have the capacity to function and synchronize data both offline and online and have efficient bandwidth optimization to cater to internet connectivity fluctuations. With 64% of the respondents having a 1:1 computer-to-employee at their offices, NMRAs potentially have the capacity to operationalize the R-MIS solution software frequently in their operations.

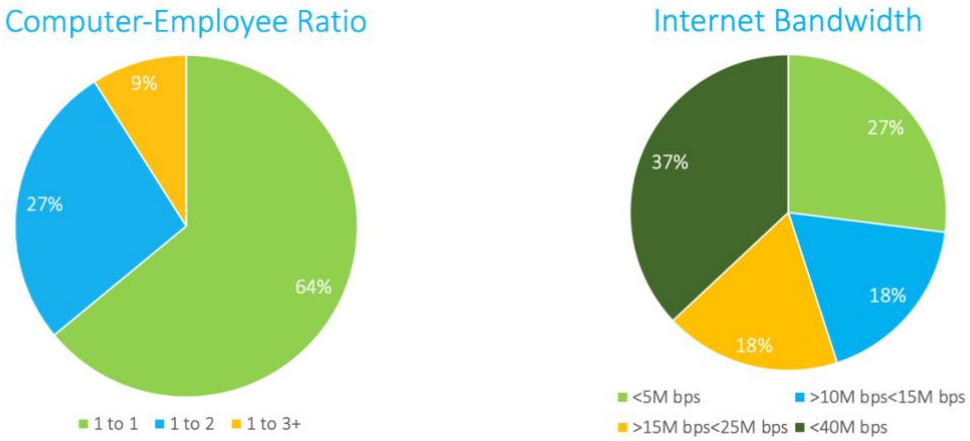

Figure 2: Internet Connectivity and Access to Computers

R-IMS Solution Specifications

In the survey, NMRAs were asked to provide information on system specifications (whether desktop-based or web-based), hosting (whether on-site or off-site) of their existing R-IMS software, and the desired user features for a future R-IMS solution software. Knowledge of the system specifications can ensure that future system design and development consider compatibility with the existing R-IMS solution software and desired user needs at NMRAs.

From the survey responses, 46% of the 26 NMRAs with a R-IMS solution have web-based R-IMS solution software that can be accessed through a web browser (Chrome, Mozilla, Safari). Web-based systems are convenient when devices have limited storage and facilitate the provision of real-time data and easy communication, and collaboration. However, the dependence on access to reliable internet connectivity can be a challenge in using web-based R-IMS software. From the survey responses, 36% of 26 NMRAs with an R-IMS solution have desktop-based R-IMS solution software that can be accessed after installation on a computer device. With desk-top based R-IMS, regulators can access the system irrespective of internet connectivity. However, due to its offline functionality, there can be significant challenges and limited capacity to collaborate and provide real-time data. While most have at least one

type of R-IMS solution software, 18% of the 26 NMRAs with an R-IMS solution have both web-based and desktop-based R-IMS solution software to complement each other.

With regards to system hosting, 46% of the 26 NMRAs with an R-IMS solution host their systems on-site, 9% host off-site (cloud hosting), and 45% have both on-site and off-site hosting. While on-site hosting provides control benefits, it also exposes NMRAs to significant cost and technical challenges in operating their systems including limited connectivity options, high tendency to run low-tier facilities, high costs of procuring and maintaining dedicated web server hardware, providing dedicated technical systems support, and exposure to systems security threats. The challenges associated with on-site hosting can be eliminated by off-site hosting through web-hosting service providers.

In addition, when asked the desired system features, the 32 responding NMRAs indicated the need for R-IMS systems that have the capacity to support:

1. Real-time assessment of dossier
2. Report Generation
3. Role assignment
4. Document management
5. Tracking
6. Audit trails
7. Automatic generation of Marketing Authorization Certificates
8. Automatic update of the Register for Market Authorization, Inspections, GMP, Clinical trials, and GDP
9. Billing and Revenue Module
10. All regulatory functions
11. User support needs

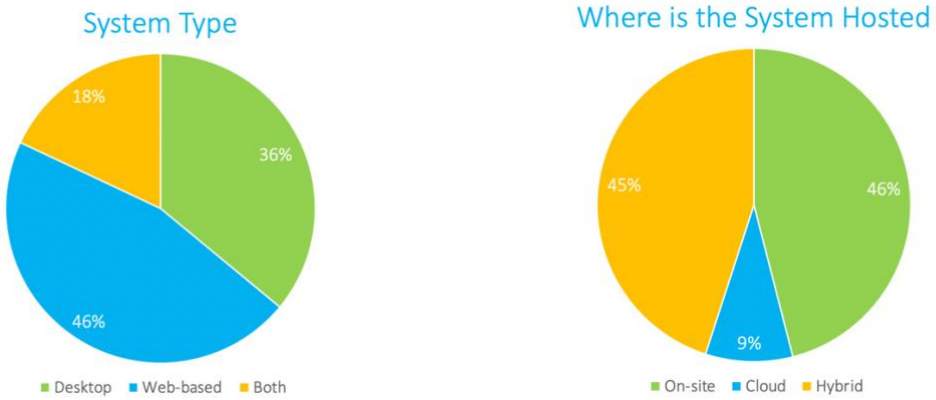

Figure 3: R-IMS System Specifications

Information Sharing

To support the information-sharing platform, there is a need to assess the existing communication and collaboration systems and processes among NMRAs. In the survey, information sharing among NMRAs was assessed. From the survey, more than (54%) of the responding NMRAs rely on other NMRAs for information on their regulatory functions. Nearly half (42%) of the NMRAs have integrated their regulatory systems with their RECs. From the survey, 44% of the 32 NMRAs widely share information about their regulatory functions and medicine regulation policies with other countries. The NMRAs usually share information on:

1. List of Registered Products, Renewal, and Variations
2. List of Registered Premises and Status
3. List of Pharmaceutical Manufacturers
4. Medical Products Recalls
5. Pharmacovigilance and Safety
6. List of Banned Products
7. List of Withdrawn Products

Information is shared using channels such as emails, physical meetings, virtual meeting platforms (WhatsApp, Zoom, Skype, Google Hangout), MoH/NMRA websites, and R-IMS solution. However, 18% of the responding NMRAs do not share their regulatory information with other NMRAs due to the sensitivity of regulatory information, lack of technical know-how on collaboration, lack of systems integration, and memorandum of understanding with countries and RECs to support collaboration and information sharing.

4.4. Assessment of Existing Regional E-Governance Initiatives in Africa's Medicines Regulatory Sector

East African Community (EAC)

EAC Regional e-Governance Initiatives in the Medicines Regulatory Sector

At the regional level, there is an on-going process of developing the EAC portal for joint processes and integrating it with the systems at the national level. All information on the joint evaluations will be stored on this one platform. The countries in the EAC will have one disaster recovery and backup, and each country will also be able to access all the medicine registers.

There are also on-going discussions about each country's integration points, the type of information that can be disclosed and how this information will be shared.

Economic Community West African States (ECOWAS)

ECOWAS Regional e-Governance Initiatives in the Medicines Regulatory Sector

ECOWAS uses a collaborative cloud-based platform hosted by the WAHO IT Team with support from the Secretariat to manage the medicine regulation activities across the countries in the region. Currently, the platform only conducts registration processes. The platform can only be accessed by the seven Expert Working Groups including the GMP group, IMS group, Quality Control, Registration and Dossier Group. The Registration and Dossier group which directly interacts with the platform consists of representatives from Nigeria, Ghana, Burkina Faso, Togo, Cote d'Ivoire, Sierra Leone, and Senegal. The other working groups submit dossiers and other documents relevant to dossier registration to the Registration Group to be uploaded to the cloud. NMRAs within ECOWAS have access to a web portal on the collaborative cloud platform where publications from the expert working groups can be accessed.

ECOWAS states also have access to OSPSIDA, a West Africa Regional HIV Pharmaceutical Management Information Dashboard developed by the USAID funded SIAPS (System for Improved Access to Pharmaceuticals and Services) Program. OSPSIDA was implemented in the sixteen focus West African countries to enhance the management of HIV & AIDS commodities. The goal of the dashboard is to capture, track, aggregate, and disseminate information about ARVs, RTKs, and other HIV/AIDS commodities to support evidence-based decision making in the subregion. The dashboard assists countries and organizations including USAID/WA, UNAIDS regional, WAHO, GFATM and other stakeholders in improving forecasting, supply planning and procurement to support the continuous availability of ARVs, RTKs, and other HIV/AIDS related commodities. The dashboard also offered regional partners a platform to easily share information on funding flows and stock out risks. The data available on this platform is used to inform decision-making and help identify solutions to mitigate risks in the short, medium and long terms.

ECOWAS mainly communicates with expert groups, who act as representatives to disseminate information in their respective countries. ECOWAS is informed about regulatory activities conducted by

the countries through reports from the expert groups. Communication is also done via virtual and physical meetings when need be. ECOWAS also supports inter-country mentoring in the region.

Benefits of the ECOWAS Regional Medicine R-IMS Solution Initiatives

Initiatives in the ECOWAS region have focused on sharing expert publications on specific subject areas. Targeted communication ensures that the relevant decision makers have access to technical reports.

Challenges Associated with the ECOWAS Regional Medicine R-IMS Solution Initiatives

Lack of System Control and Ownership: Since the platform was developed by the IT Team in WAHO, the other countries were not responsive enough despite being briefed on their activities on the platform.

Frequent Changes of Technical Group: The NMRAs within ECOWAS frequently change their technical representatives who have been trained to adopt the platform. This creates a gap in knowledge transfer and threatens the sustainability of initiatives.

Intergovernmental Authority on Development (IGAD)

IGAD Regional e-Governance Initiatives in the Medicines Regulatory Sector

IGAD uses a cloud-based database and MedNet to manage and coordinate medicine regulatory functions information in the IGAD member countries. The databases enable users to access and share information on registered medicines. However, it does not support any other regulatory function. Every NMRA in the community has access to the database. NMRAs upload their dossiers including a list of registered medicines on the platform to be accessed by IGAD and the member countries. IGAD communicates with its member countries through emails and physical meetings. The IGAD community has identified the need for system with project management capability to enable its officials to assign tasks, assess and evaluate the performance of the project, capture, and analyze data and automatically produce reports. Currently, IGAD is working towards increasing the scope of the Kenya's Pharmacy and Poisons Board (PPB) and Ethiopia's Food and Drug Authority (EFDA) NMRA systems to cover IGAD.

Benefits of the IGAD Regional Medicine R-IMS Solution Initiatives

IGAD's initiatives have supported some countries in the region to access and share information on registered medicines.

Challenges Associated with the IGAD Regional Medicine R-IMS Solution Initiatives

IGAD, which uses a cloud-based database and MedNet have challenges that need to be addressed to enhance regional medicine collaboration and information sharing. Some prevailing challenges with the cloud-based database are:

1. Lack of support for any regulatory function processes
2. Inability to automatically upload documents
3. Lack of interoperability: The database is a stand-alone database which is not connected to the NMRAs existing systems.
4. Poor data validation capacity: The platform is not well validated which allows duplication of data in the database.

Some prevailing challenges with MedNet in IGAD are:

1. User-friendliness: MedNet has session time-outs thus it is difficult to continuously upload/download files
2. Lack of confidentiality among the team members collaborating on the MedNet platform.
3. Ownership and Control: The WHO rather than IGAD has control and ownership over MedNet. This limits IGADs ability to manage user access, making system administration and confidentiality difficult.

Other barriers that have hindered the success and progress of IGAD's initiatives are the lack of a protocol for information sharing, sustainability of the system post-funding, maintenance of the system, staffing of technical human resource to manage the system and the lack of funds to sponsor the development of the system.

Southern African Development Community (SADC)

SADC Regional e-Governance Initiatives in the Medicines Regulatory Sector

ZaZiBoNa is a collaborative medicine registration (work-sharing) initiative in the SADC region. ZaZiBoNa process is a collaborative procedure of 14 Southern African Development Community (SADC) countries in which national regulatory authorities jointly assess medicines for registration purposes. Currently, there are nine (9) of the 14 member states actively participating in ZaZiBoNa namely Zambia, Zimbabwe, Botswana, Namibia, Tanzania, Democratic Republic of Congo, Malawi, Mozambique, and South Africa. The remaining six (6) of 14 member states do not actively participate in dossier assessment but are involved in training programs and information sharing on products approved through the collaborative procedure. In the long term, all SADC countries are expected to actively participate depending on their capacity.

Also, all the 16 member countries in the SADC region use the WHO database - MedNet to support registration functions. The WHO is responsible for providing countries within the REC access to MedNet. With reference to a signed MOU, countries in the SADC region can collaborate and share registration information. While some NMRAs are actively involved in the collaborative registration program, others only have access to the information derived from the process due to their limited capacity to conduct medicine registration in their jurisdictions. The countries that are actively involved in conducting the joint registration process include Zambia, Zimbabwe, Botswana, Namibia, South Africa, Mozambique, Malawi, Democratic Republic of Congo, and Tanzania. Although the collaborative registration program supports information sharing, NMRAs have the autonomy to review, accept, or reject any recommendations on registered products under the initiative. All information shared in the program is required to be covered by an MOU that provides security and maintains the confidentiality of information being shared. This enables countries under the program to have different bilateral agreements with other countries in the REC. While information flow is usually confidential, countries openly share statistics on registration (registered products, rejected products, products pending approval), similar for clinical trials and other regulatory functions, safety alert information, pricing of products, and request for experts.

Benefits of the SADC Regional Medicine R-IMS Solution Initiatives

The ZaZiBoNa process and the MedNET registration collaboration initiatives aimed at:

1. reducing time taken to grant marketing authorization in individual participating countries

2. utilizing efficiently, resources available within the regional national regulatory authorities through sharing
3. making available good quality medicines to all those who need them in the region

Challenges Associated with the SADC Regional Medicine R-IMS Solution Initiatives

In SADC, regional medicine regulation has faced some peculiar challenges related to the supporting regulatory policies and the R-IMS systems adopted. Every country in the SADC region has its own autonomous R-IMS processes and in some cases R-IMS system which forms integration barriers in collaborative initiatives. The SADC medicine regulatory harmonization program also faces significant participation challenges given that the program is not a legally or politically binding initiative rather a voluntary information-sharing initiative. Countries that joined the collaborative MedNet registration program also faced some technical system issues including lack of access to critical processing functions, lack of R-IMS software control and ownership of data, and document migration challenges.

World Health Organization (WHO)

WHO Regional e-Governance Initiatives in Africa's Medicines Regulatory Sector

The WHO provides participating countries in the WHOCRP program with a confidential restricted-access MedNet website on which the countries can upload and access information about pre-qualified Finished Pharmaceutical Products (FPPs).

4.5. Considerations for a Regional and Continental R-IMS Solution

Lessons from the Pan American Health Organization

The Pan American Health Organization (PAHO) is a specialised international health agency for the Americas. This organisation ensures that all people in the region have access to the quality healthcare. To achieve its mission, PAHO has undertaken various technological initiatives to improve access to medicines in the region. In 1999, the Pan American Drug Regulatory Harmonization (PANDRH) was initiated. The main objective of the PANDRH is to strengthen the regulatory functions and systems of NRAs in the region, by enhancing cooperation and information sharing. Also, PAHO has developed a Regional Platform on Access and Innovation for Health Technologies (PRIAS).

It is composed of a series of virtual tools designed to support and promote technological innovation, access, rational use, regulation and governance of health technologies from a public perspective. It serves as a platform for reliable information on the development of health products. The PRAIS platform is of two components; a website; providing public information regarding news updates, COVID-19 resources, among others and a database with information regarding medicine regulation, medical devices, blood and radiology health.

In 2020, PAHO launched an annotated medicine and device list portal called MedList. This portal provides evidence summaries based on context and answers questions on the clinical use of a drug. The portal is a sub-feature of PRIAS. The homepage of the MedList portal provides a summary of the number of medicines and medical devices that have been registered in the region and the number of evidence summaries. Users can filter the registered drugs by countries in PAHO. It also provides the WHO model list of essential medicines and the list of prequalified medicines. The PAHO strategic fund medicine and revolving fund lists is also present. The figure below shows the homepage of the MedList Portal.

One main feature the AU R-IMS could include from the systems used in PAHO is the ability to filter the medicine list by country. NMRAs would be able to compare their medicine lists with that of other NMRAs on the continent. It would help them identify where they could get certain medicines and understand how best to utilise them.

Furthermore, PAHO has developed various standardised proposals, guidelines, templates, among others, for the various NRAs to follow when sharing information. PAHO ensures that these standardised documents meet international standards and guidelines for the different countries to converge their regulatory functions. The AU R-IMS could adopt this process to enhance effective communication among nations as they converge through this initiative.

Chapter 5: Roadmap, Technical, User Requirements and Specifications for the Establishment of National, Regional and Continental R-IMS Solution and Information Sharing Platform

5.1. Technical specifications and user requirements for proposed National R-IMS Solution

Provision of Websites for National Medicine Regulatory Authorities in Africa

NMRA websites should provide information on its regulatory functions organized and presented in a way that visitors can quickly navigate to desired pages. The website should have a clean and intuitive navigation and architecture complying with the highest web standards, as well as relevant and visually appealing design elements for improved user experience. The website should have a load time less than 5 seconds and in addition,

1. Comprehensive information on regulatory functions. This information can be accessed using an "About" menu
2. Comprehensive information on product registration/market authorization should also be available. This should include fees and application process
3. An online searchable register for:
    a. Approved/registered products
    b. Clinical trials (ongoing or even completed ones)
    c. GMP compliant manufacturers
    d. Authorized importers and exporters
    e. Licensed premises
4. Safety Information including an online form for adverse drug reaction reporting
5. Contact Information – Address, Telephone, Map, Contact Form
6. Document repository for relevant legislation, publications, and regulatory documents
7. FAQs

Proposed Website Structure for National Medicine Regulatory Authorities in Africa

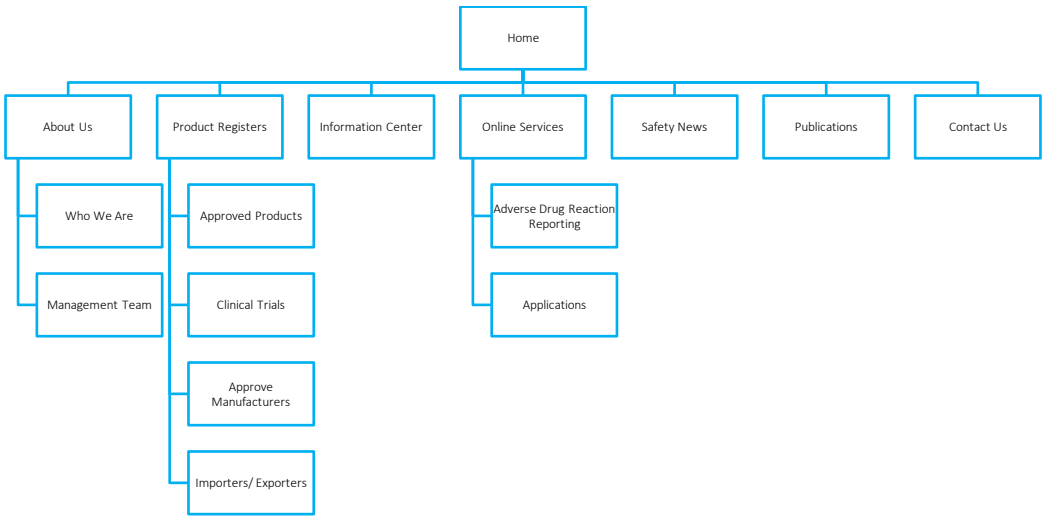

Figure 4: Website Structure for National Medicine Regulatory Authorities in Africa

Content Management System

WordPress is recommended for use as the content management system for NMRAs without a website. WordPress has an open-source content management system option that is easy to use and allows non-technical users to update website content. It is also a safe and secure platform and is built to be search engine optimization friendly. According to a recent study from Kinsta, WordPress dominates the CMS market share.

Online Register

The website should feature a searchable online register for products, clinical trials, premises/manufacturers and importers and exporters depending on the regulatory function of the NMRA. A plug-in for the content management system (CMS) should be developed. This plug-in should connect directly to the R-IMS solution via an API to pick information to be displayed in the register. This will ensure an up-to-date list on the website.

A manual update on the list on the website can result in outdated information in instances where the officer responsible forgets to upload new information. However, there should be an option to manually update the list on the website or overwrite information fetched from the R-IMS solution.

Templates

To reduce cost and make it easy to deploy websites for the NMRAs, creation of a customizable WordPress theme that has at least 3 layouts is recommended. The theme should allow the user to easily setup their website by choosing the layout that best suits their needs. The theme should have options that allows users to set the layout, responsiveness, colours, header, menu, logo, page title, footer and background for their website.

With these options available, the NMRAs can adjust the template to fit with the country's preferences in terms of look-and-feel. This template should have a predefined structure like what is proposed above with default content. This makes it easier for users to setup their website. The templates should be based on responsive, mobile-first templates. The template should be SEO friendly.

Search and Navigation

The website template should support simple and advanced searches including full text. WordPress comes with a search function which makes it easier to implement this functionality. The website template should have faceted searches for principal sections, provide bread crumb navigation, and a dynamic site map.

Multi-lingual Support

The website template should be multilingual and support English, French and Portuguese. These are the main languages used across the African countries, as identified from the survey findings.

Website Analytics (Google analytics)

Google analytics should be integrated into the website to keep track of visitors and record information such as their operating system, browser, location, and some demographic information where possible.

Number of users per timeframe (daily, weekly, monthly, and annual) is an example of a report that can be generated from Google analytics. Google Analytics is currently free to use.

Technical Configuration of Hosting Server

The website CMS and template should be set up and configured in such a way that it can be hosted by any company that provides commercial Linux hosting. The server should have industry standard security features and measures that protect it from unauthorized use, cyber-attacks, viruses, worms and other common Internet security threats. The NMRAs that are capable can host the website with the minimum requirements below.

Processor: 2.0 GHz+
RAM: 4 GB+
Disk Space: 50 GB+
PHP: Version 7.3 or greater
Web Server: Apache or Nginx
Database: MySQL or MariaDB/

Shared Hosting

The AU NEPAD secretariat should have a server with an open-source web panel such as Webmin or CentOS Web Panel installed. This will be a shared hosting environment. Shared hosting is a type of web hosting where a single physical server hosts multiple sites. Many users utilize the resources on a single server, which keeps the costs low. Users will not have access to each other's hosting account or control over their website.

Processor: 4 cores @ 3.0+ GHz
RAM: 32 GB+
Disk Space 2 x 240 GB SSD
PHP: Version 7.3 or greater
Web Server: Apache or Nginx
Database: MySQL or MariaDB

Security Configurations

Security configurations should be in place to protect the website from unauthorized use. This includes but not limited to:

1. Secure website pages using secure sockets layer (SSL).
2. Disallow unsafe file uploads by restricting file uploads to a few allowed file types.
3. Hide site errors from end-users.
4. Use of strong passwords
5. Set appropriate directory permissions
6. Disable directory listing

Provision of R-IMS Solution for National Medicine Regulatory Authorities in Africa

Overview

With only twenty (20) of the African Union Member States having an existing R-IMS solution at their NMRAs, it is critical that NMRAs are provided access to R-IMS solutions before extensive regional and continental medicine regulatory collaboration and information sharing can be feasible. Although, the required AU R-IMS solution is intended to have 11 modules supporting the medicine regulatory functions, NMRAs currently lacking R-IMS solution need four (4) primary modules and eight (8) supporting modules for feasible regional and continent collaboration. The minimal R-IMS solution that can be adopted by the NMRAs currently lacking an R-IMS solution should have the following primary modules:

1. Premise Licensing Module
2. Product Licensing Module
3. Import and Export Module
4. GMP Module

The primary modules however need to be supported by:

1. Finance Module
2. Document Library Module
3. Report Module
4. User Administration Module

With this R-IMS solution, the NMRAs can share information and have centralised oversight over managing regulatory workflow processes involving manufacturers, importers, exporters, the general public, inspectors, assessors, finance, management, and laboratory technicians.

Proposed Structure and Features of R-IMS for NMRAs in Africa

To inform the development of the proposed national R-IMS solution, an information flow and system requirements was developed considering the identified medicine regulatory functions of the NMRAs:

1. Marketing authorization (MA)
2. Licensing of manufacturing establishments
3. Imports and export control
4. Inspection of manufacturing premises and distribution channels
5. Market surveillance (product quality monitoring, pharmacovigilance, control of drug promotion and advertising)
6. Quality control
7. Oversight of clinical trials on drugs

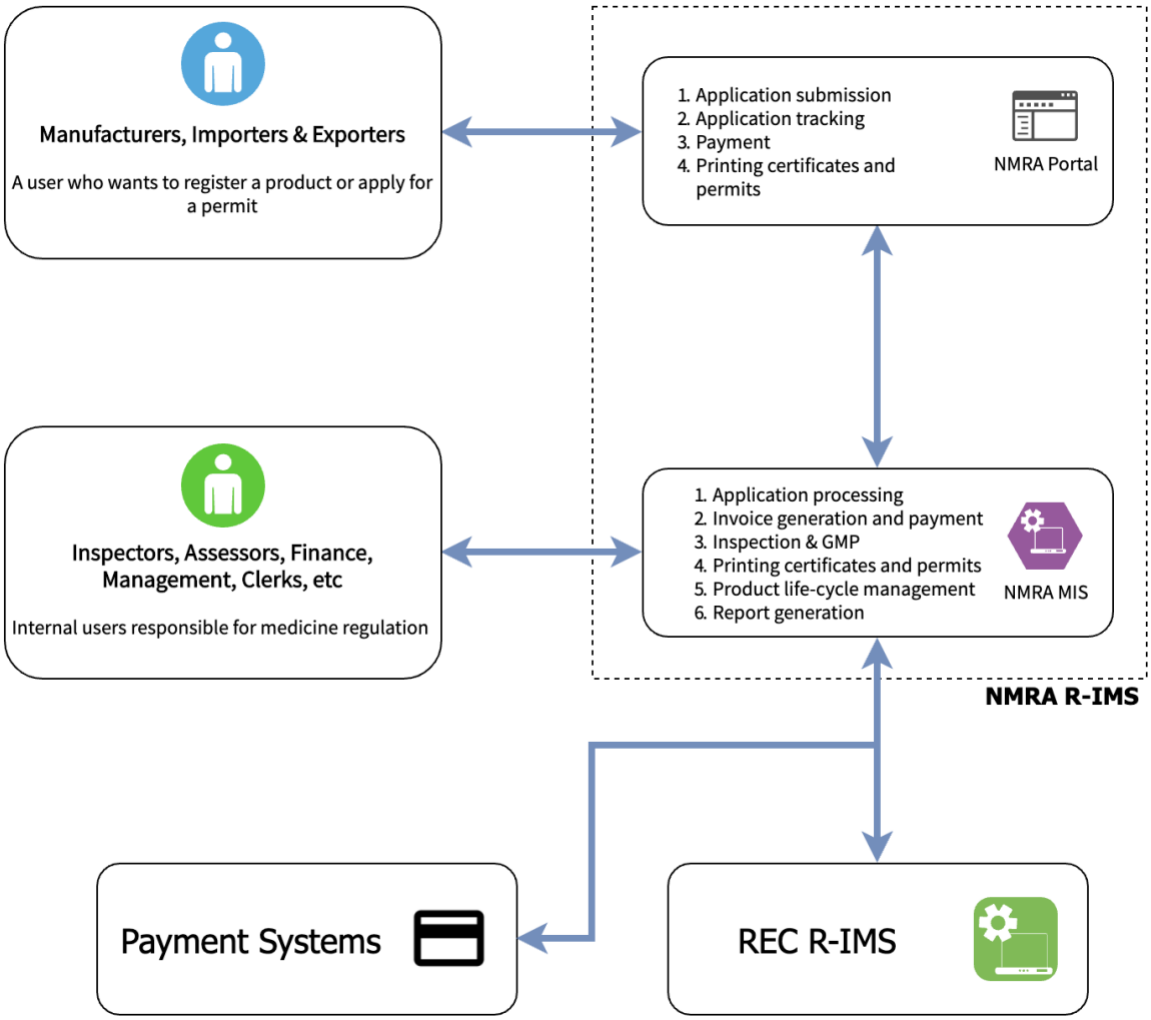

Figure 5: Information flow for R-IMS in National Medicine Regulatory Authorities in Africa

Premise Module

The Premise Module supports the management of processes involved in premise license registration, renewal, variation, and withdrawal. There will be five main types of premises which will be pre-configured. The premise types are: Manufacturer, Wholesaler, Retailer, Institution and Individual.

Id	Name	Description
1.	Premise License Application Submission	Application submission for registration, renewal, variation or withdrawal
2.	Premise Application	Receives applications for registration, renewal, variation and withdrawal.
3.	Premise Verification	Verifies application documents attached/ Pre –Technical Screening
4.	Premise Approval	Approves or rejects all applications
5.	Premise Admin	Configures setups and has full access to the application, verification and approval processes.
6.	Premise Price Setup	Premise registration, renewal and variation invoice generation

Id	Name	Description
7.	Premise Licensing Period Setup	Licensing Periods
8.	Premise Invoice Expiry Setup	Invoice Expiry

Table 14: Premise Module Requirements

Product Module

The term "Product" refers to either of the following, foods, drugs, medical devices, and cosmetics. The product module supports the management of processes related to product license registration, license retention, license alteration, license withdrawal, clinical trial, product promotion and product survey.

Id	Name	Description
1.	Product License Application Submission	Application submission for registration, retention, variation or withdrawal
2.	Pharmacovigilance Product Survey	Application Submission
3.	Product Promotion	Application Submission
4.	Product Clinical Trial	Application Submission
5.	Product Application	Receives applications for registration, retention, variation and withdrawal.
6.	Product Verification	Verifies application documents attached/ Pre –Technical Screening
7.	Product Technical Screening	Performs Technical Screening
8.	Product Evaluation Assignment	Assigns product for first or second evaluation
9.	Product Evaluation	Perform evaluation on a product
10.	Product Review Assignment	Schedule and assign product for review
11.	Product Ratification	Approves or rejects product application based on reviews and evaluation
12.	Product Admin	Configures setups and has full access to the application, verification, screening, evaluations and ratification processes.
13.	Product Price Setup	Product registration, retention, variation, promotion and clinical trials invoice generation
14.	Product Licensing Period Setup	Licensing Periods for (Registration, Promotion, Clinical Trial)
15.	Product Invoice Expiry Setup	Invoice for (Registration, Promotion, Clinical Trial)

Table 15: Product Module Requirements

Import and Export Module

The import and export module facilitates the processing of import permit, export permit, import license registration, import license renewal, export license registration and export license renewal.

Id	Name	Description
1.	Import/Export Permit Application	Application submission for import and export permit
2.	Import/Export License Application	Application submission for import/export license registration
3.	Import/Export License Renewal	Application submission for import/export license renewal
4.	Import/Export Application Verification	Verifies permit application documents
5.	Import/Export Permit Approval	Approves or rejects permit application
6.	Import/Export License Approval	Approves or rejects license applications
7.	Import/Export Admin	Configures setups and has full access to the application, verification, and approval processes.
8.	Product Price Setup	Import/Export permit, license registration and renewal invoice generation
9.	Import and Export Licensing Period Setup	Licensing Periods
10.	Import and Export Invoice Expiry Setup	Invoice Expiry

Table 16: Import and Export Module Requirements

GMP Module

The GMP Module manages the GMP License Registration and GMP License Renewal processes.

Id	Name	Description
1.	GMP License Application Submission	Receives applications for registration, retention, variation and withdrawal. Also performs data entry
2.	GMP Application Verification	Verifies application documents attached. Performs Pre – Technical Screening
3	GMP Technical Screening	Perform technical screening of GMP application
4	GMP Approval	Approves or rejects application after inspection

Table 17: GMP Module Requirements

Inspection Module

The Inspection Module manages premise inspection, POE inspection, GMP inspection and enforcement processes.

Id	Name	Description
1.	GMP Inspection Assignment	Schedules and assigns a GMP application for inspection
2.	GMP Inspection	Performs inspection and file report
3.	GMP Inspection Admin	Configures setup and has full access to GMP inspection features

Id	Name	Description
4.	Premise Inspection Assignment	Schedules and assigns premise application for inspection
5.	Premise Inspection	Performs inspection and files report for first or second evaluation
6.	Premise Inspection Approval	Approves or rejects application based on inspection report
7.	Premise Inspection Admin	Configures setup and full access to premise inspection features
8.	POE Inspection Application	Receives POE application and sample analysis report
9.	POE Inspection	Performs physical examination
10.	POE Inspection Approval	Provides sample analysis
11.	POE Inspection Admin	Configures setup and has full access to POE Inspection

Table 18: Inspection Module Requirements

Finance Module

The Finance Module enables payment submission, auto invoice generation, pricing set-up, currency set-up and exchange rate set-up. Payment submission is available in two forms; agency payment submission and integrated payment submission.

Id	Name	Description
1.	Finance Payment	Receives Payment
2.	Finance Admin	Configure setups and pricing

Table 19: Finance Module Requirements

Document Library Module

The Document Library Module enables the input of documents including Product dossier, Bank deposit slips and Building plans. The module also supports the generation of documents including Invoices, Licenses, Letters, Payment Receipts and Notices. Document storage is on the file system in pdf format.

Id	Name	Description
1.	Document Viewer	Search and View Documents
2.	Document Admin	Configures setup and can view documents

Table 20: Finance Module Requirements

Report Module

This module provides access to the report for different modules in the system.

Id	Name	Description
1.	Premise Report	Generate premise reports
2.	Product Report	Generates product reports
3.	GMP Report	Generates GMP reports
4.	Import Export Report	Generates import export reports
5.	Inspection Report	Generates inspection reports
6.	User Administration	Audit trail and user administration reports
7.	Report Admin	Generate all reports

Table 21: Report Module Requirements

User Administration

Id	Name	Description
1.	User Administration	Performs user setup and overall system setup, has full access to the system

Table 22: Report Module Requirements

Main Actors of the NMRA System

The following are the parties that will interact with the system.

1. NMRA Officers involved in the various regulatory functions
2. General public
3. Drug Manufacturers
4. World Health Organization and other technical partners

Main Use Cases Associated with the Actors

NMRA Officers can access:

a. List of products registered in other countries
b. List of premise licenses issued in other countries
c. List of GMPs issued by other countries
d. Import/Export permit and licenses in other countries
e. Adverse Drug Reactions, product withdrawals and counterfeit drugs reported in other countries

A medicine registration assessor can:

a. Retrieve and view medicine applications as well as their supporting documents sent for joint evaluation.
b. View a repository of medicine registration guidelines and procedures.
c. View all licenses, permits and certificates issued by the Ministry of Health.
d. Download and upload assessment reports.

A medicine registration inspector can:

a. Access and upload inspection reports.
b. Access product assessment reports.

The coordinators can:

a. View lists of submitted medicines by countries.
b. Filter common drugs to be submitted for joint evaluation.
c. Access assessment and inspection reports for drugs submitted for evaluation

A drug manufacturer can:

a. Apply for product registration
b. Receive notifications to approve a product being evaluated jointly.
c. View assessment reports and respond with additional information.

The public can:

a. Search for and view registered and licensed medicines for a country.
b. View medicine regulatory information.

Alternative Approaches to Provision of R-IMS Solution for National Medicine Regulatory Authorities in Africa

Two alternative approaches can be adopted in the development of national R-IMS solution for AU Member States that currently lack the systems. Based on the proposed modules and capacity assessment review, the two proposed approaches to developing the national R-IMS solution are:

1. Development of National R-IMS solution from scratch
2. Development of National R-IMS from an Open-Source R-IMS solution (Pharmadex)

Development of National R-IMS solution from Scratch

Development of the National R-IMS solution from scratch will take a total of 23 months including the pilot and scale up phases. Per the indicative workplan, it will take approximately 6 months to develop the first version of the national R-IMS solution from scratch. While building the R-MS solution from scratch is associated with higher costs and time there would be greater opportunity for system customisation to meet the capacity assessment needs and systems requirements of the NMRAs.

Development of National R-IMS solution from an Open-Source R-IMS solution (Pharmadex)

Development of the National R-IMS solution from open-source R-IMS solution will take approximately 4 months not including deployment and piloting. While providing time and cost savings, developing the R-IMS solution from an open-source has some limitations. Considering Pharmadex as the open-source R-IMS solution, there are some potential advantages:

1. Pharmadex is web based which is one of the requirements of the system to be developed.
2. Pharmadex handles medicine registration and has a medicine register which takes care of some of the modules required by the system.
3. Existing documentation on developing additional functionalities for Pharmadex exists.
4. Less time involved.
5. Reduced cost based on number of days required.

However, the limitations with Pharmadex are:

1. Poor user interface design and experience.
2. Pharmadex was developed using Java. After handover, it might be difficult for the NMRAs to maintain the R-IMS solution since there are limited Java developers compared to PHP developers.
3. Features of some modules might be limited based on the existing features.
4. Some products (medical, food and cosmetics) registration may not be supported.

5.2. Technical Specifications and User Requirements for Proposed Regional R-IMS Solution

The proposed website will be integrated with the regional website or IMS solution. The integrated system will be used for the information on product registration, premises license, GMP certificates, import/export permit and licenses, adverse drug reactions, product recalls and counterfeit drugs, since these are the most common regulatory functions used across many countries in Africa. This process has been illustrated in the figure below:

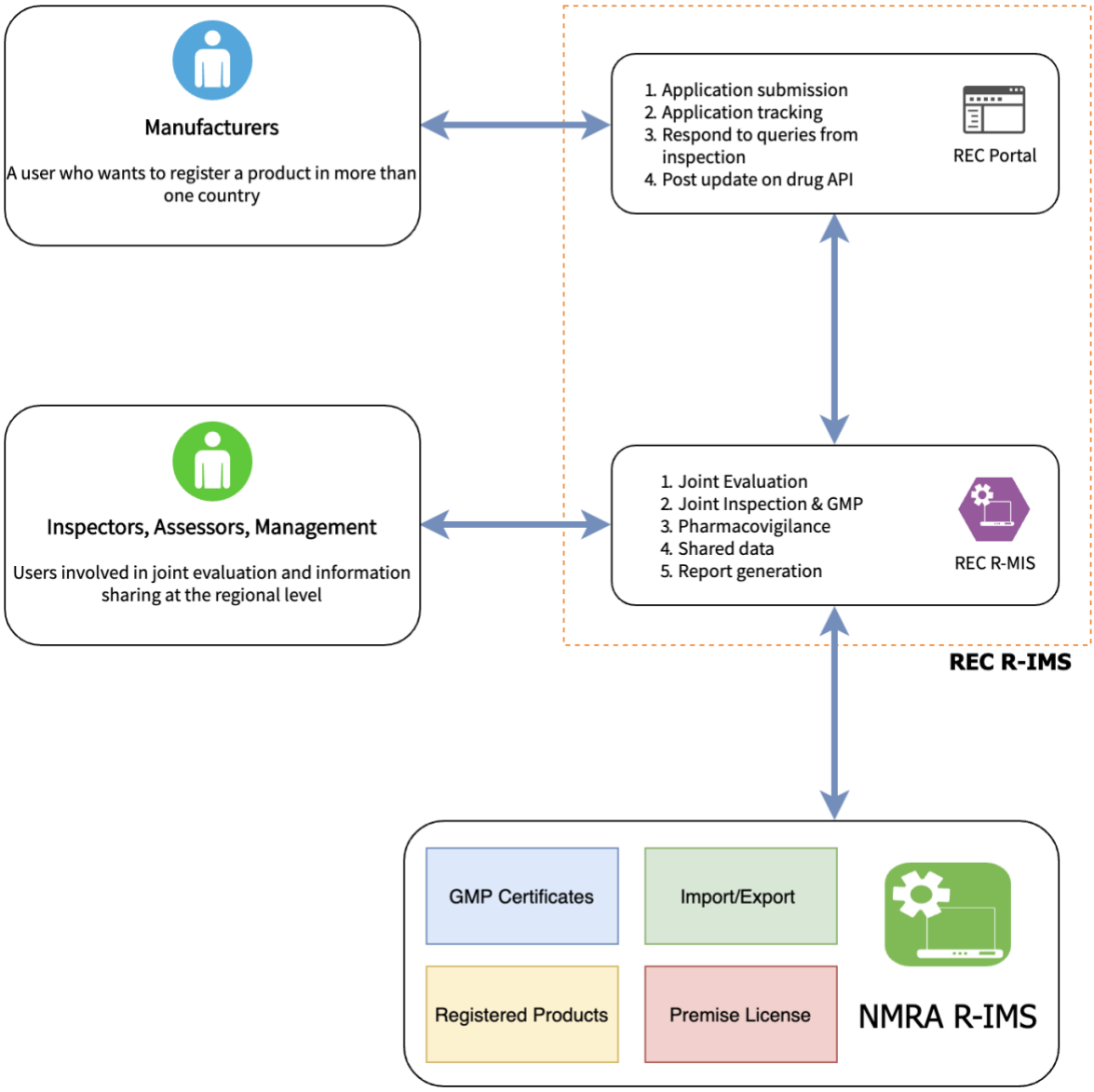

Figure 6: Information Flow for AU R-IMS Solution

Regional R-IMS Solution and Information-Sharing Platform

The African RECs need robust systems that will make joint product evaluation and sharing confidential information more convenient. The proposed solution is an integrated R-IMS solution that will provide real-time medicine regulatory information. This integrated R-IMS solution will have these modules:

1. Product Module
2. Assessment Module
3. Inspection Module
4. Questions & Answers Module
5. Pharmacovigilance Module
6. Events Module
7. User Module
8. Document Library Module
9. Forum Module
10. Administration module
11. Aggregated database of the following in other countries:
    a. Registered Products
    b. Premise License
    c. GMP Certificates
    d. Import/Export permit and Licenses

The system to be developed for the NMRAs and existing systems will connect to the REC R-IMS solution for information sharing via a secured internet connection.

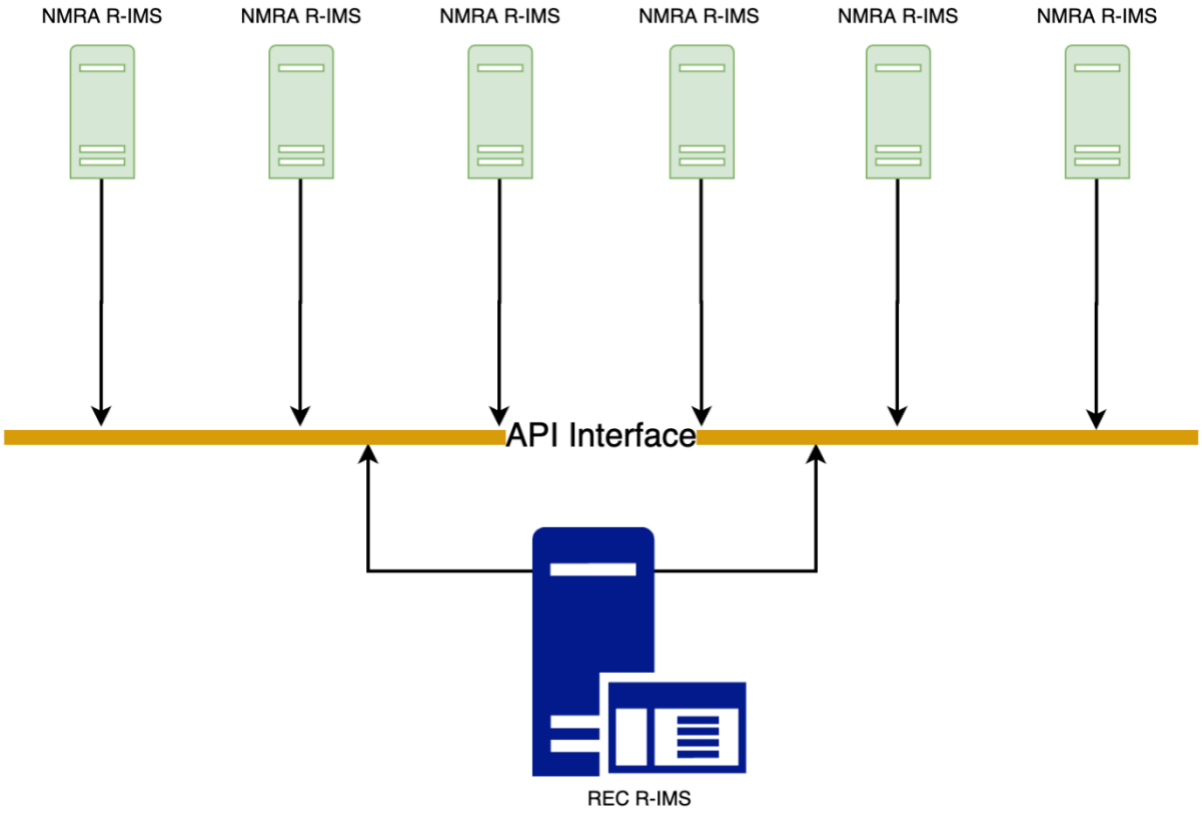

Figure 7: NMRA R-IMS solution Connecting via API to the R-IMS solution for information sharing

Requirements	Requirements Description	Notes
General System Requirements		
Accessible and user-friendly	The system shall be accessed outside an organization and on a public network via a secure protocol. The system interface should be accessible to users.	The system shall be accessed online via internet protocols and can be accessed by users anywhere. The system shall provide information in an understandable format. It shall also fulfil the appropriate accessibility guidelines.
Support Web services	The system should be able to support web services protocols	The system shall interact with appropriate web services using standard protocols
Have supporting information	Supporting information on the system shall be provided.	Information about the usage of the platform shall be provided. Concise information in manuals will make use of the system easier and more effective.
Question and Answer Module Requirements		
Allow asking and answering of questions	The system shall allow users to pose and answer questions.	The system shall allow users to type up and submit questions and reply to these messages. Recommended: Users can receive email alerts when there is a new question or if their questions have been answered.
Search question and answer posts	The system shall allow users to search for questions and their answers	The system shall employ search functionality to aid users easily identify previously asked questions and their answers.
Product Module Requirements		
View products lists	The appropriate users should be allowed to access lists of medicines pending registration in countries.	The system shall allow the user to view a list of medicines pending registration in two or more countries. The system should filter and group recurring products.
Upload product dossiers	The system should allow the upload of large product dossiers	The system shall allow the appropriate users to upload project dossiers.
View product recommendations	The users should be able to view products which are recommended for approval or rejected	The system shall display a list of products recommended for approval.
Assessment Module Requirements		
Manage assessment reports	The system should allow users to upload and modify assessment reports.	Assessors can upload and add comments to assessment reports.
Inspection Module Requirements		
Manage inspection reports	The system should allow the upload and modification of inspection reports.	Inspectors can upload and modify assessment reports.

Requirements	Requirements Description	Notes
General System Requirements		
Access consolidated assessment reports and list of questions	Inspectors shall be granted access to reports from the assessment phase.	The system shall grant users with inspector privileges access to assessment reports and other information.
User Module Requirements		
Account creation	Major stakeholders (drug manufacturers) of the system should be able to create accounts. Administrators should be able to add new user accounts.	The system shall allow the user to create accounts and see information that is relevant to them. The system shall also allow administrators to add, delete and alter user accounts.
Authentication	Users shall be identified and verified uniquely.	There shall be a consistent method of user authentication. For example, each user should have unique usernames and passwords.
Messaging	Individuals and groups should be able to send messages to each other.	The assessors and inspectors shall be able to send messages to each other and correspond with product manufacturers.
Information access	Users with privileges shall have access to the appropriate information	Users can be granted privileges and user roles. These privileges determine the kind of information that can be accessed by the user.
View list of users	The system shall have and display a repository of users.	The system shall provide information on the names, privileges, contact information, etc of users.
Pharmacovigilance Module Requirements		
Adverse drug reactions reporting	The system should allow the user to upload details of adverse drug reactions.	The system shall have a form that a user can fill and submit to file an adverse drug reaction report.
Access to pharmacovigilance information	Users of the system can view general pharmacovigilance information.	Based on their privileges, users can view timely pharmacovigilance information.
Events Module Requirements		
Display events	Events shall be displayed in a timely manner.	Events will be displayed in a chronological and timely order with the most recent or upcoming at the top.
Document Library Module Requirements		
Upload and download of information	Users can upload and download information on the system.	The system should allow uploading and downloading of documents based on their privileges
Document management	The system should enable documents to be managed.	The system should provide a means of identifying and tracking versions of key documents.

Requirements	Requirements Description	Notes
General System Requirements		
Add, delete and modify files	Users can add, modify and delete files.	The system should allow users to add files and alter or delete files they upload. It should also allow administrators to update information on procedures, rules and regulations.
Blog Module Requirements		
Share blog posts	Users can upload text posts, share web links and upload media	The system shall support the sharing of media and text files
Search blog posts	Users can search through blog posts.	A search functionality can be incorporated to aid users to sift through blog posts.
Administrator Module Requirements		
Assign user roles	The system shall allow user roles to be assigned to users.	The admin should be able to assign privileges and roles to users.
Enable reporting	The system should be able to generate reports	The system shall produce reports for management. Reports shall be printable. It shall be possible to export reports in interoperable formats.

Table 23: Design, Development and Implementation Requirements

5.3. Proposed Roadmap for Implementation of Continental Medicine R-IMS Solution in Africa

In developing the continental R-IMS solution, it is recommended that a technical working group is developed to manage the project and the system development is informed by the capacity assessment, user and technical requirements and developed in phases from pilot to scale up stage. This section outlines the priority areas in establishing the continental R-IMS solution.

Creation of A Technical Working Group

To effectively establish the regional R-IMS solution, a technical group must be created. The technical group will comprise of representatives from various NMRAs, domain experts and other stakeholders of the system who will contribute appropriate information to the development of the R-IMS. Actively engaging the actual system users through technical working groups in the development process will ensure that user system requirements are continually assessed and incorporated for a feasible and sustainable system design.

User-Centred System Development

The system will be developed based on the user and technical requirements and the system specification documents that have been collected and approved by the stakeholders. Through this, the system can be developed with a key consideration for the capacity assessment findings, and, user and systems requirements attained from this consultancy project.

Modular Systems Development

Considering the varied R-IMS solution and information capacities of the AU Member States, there is the need to utilise a modular systems development approach in implementing the AU R-IMS and information sharing platform. There is the need to ensure that all member states have the capacity to use R-IMS solution to track the same functions at their NMRAs to ensure that no country is left behind. To ensure this, the system development process must prioritise development and scaling of specific modules periodically. Based on the continental R-IMS solution capacity assessment, it is recommended that the initial (prioritized) modules should be piloted in at least countries that perform the related medicine regulatory function on a small scale to ensure that any system challenges identified are efficiently resolved. After a successful pilot and incorporation of recommended revisions, the system can then be rolled out to the other NMRAs.

Phased System Implementation

The systems must be implemented in phases with the priority of determining and addressing system issues before full adoption in the AU. The system must be tested at all levels of development to ensure a bug-free system and assess actual system feasibility and sustainability in the users' routine operations. A small-scale pilot of the modules in the system must also be prioritised. The pilot is an important stage which will help early identification and resolution of potential problems that would stifle the accomplishment the project goals before full implementation. Based on the continental R-IMS solution capacity assessment, it is recommended that the initial (prioritized) modules should be piloted in at least countries that perform the related medicine regulatory function on a small scale to ensure that

any system challenges identified are efficiently resolved. After a successful pilot and incorporation of recommended revisions, the system can then be rolled out to the other NMRAs.

Knowledge Transfer and Change Management

Knowledge transfer, training and change management must be prioritised in the system implementation process. Considering that technical competence and change are persistent barriers to R-IMS adoption and continuous usage in the NMRAs, there should be a well-designed change management strategy and training of systems users and administrators across the NMRAs and RECs. User manuals must also be provided to supplement the training given to the system users.

Effective Regional Coordination

To ensure continuity and sustainability of the continental R-IMS solution, a regional organization such as AUDA-NEPAD is recommended to manage and coordinate the activities of the proposed continental R-IMS. It is with this measure that the objective of sharing relevant information among NMRAs, the RECs and at continental level will be achieved.

5.4. Proposed Work Plan for the Continental R-IMS Solution and Information Sharing Platform for the Member States in the African Union

Proposed Work Plan for Development of National R-IMS Solution from Scratch

Detailed Activities	Months																												
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29+
Stage 1: Finalizing Requirements																													
1. Technical group formation																													
2. Finalize requirements and document them																													
Stage 2: Design, Development & Testing of First Version of National R-IMS Solution with Selected Modules																													
3. Wireframes and User Experience (UX) Design																													
4. Development of Prototype for review by Technical Group																													
5. Alpha testing																													
6. Incorporation of feedback from Technical Group to complete development of first version of the system																													
7. Beta testing																													
8. Development of user manual and training materials																													
9. Training																													
10. Server setup and deployment/roll out of first version for pilot																													
11. Pilot																													
12. Incorporation of feedback from the pilot																													
Stage 3: Design, Development & Testing of Second Version of National R-IMS Solution with Remaining Modules																													
13. Wireframes and User Experience (UX) Design																													
14. Development of Prototype for review by Technical Group																													
15. Alpha testing																													
16. Incorporation of feedback from Technical Group to complete development of first version of the system																													
17. Beta testing																													
18. Deployment/roll out of second version for pilot																													

Detailed Activities	Months																												
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29+
19. Update user manuals and training materials																													
20. Training																													
21. Pilot																													
22. Incorporation of feedback from the pilot																													
Stage 4: Deployment and full scale up of National R-IMS Solution																													
23. Finalize the system for deployment to other countries																													
24. Final testing																													
25. Training																													

Table 24: Proposed Work Plan for Development of National R-IMS Solution from Scratch

Proposed Work Plan for Development of National R-IMS Solution Using an Existing R-IMS Solution (Pharmadex)

Detailed Activities	Months																												
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29+
Stage 1: Finalizing Requirements																													
1. Technical group formation																													
2. Finalize requirements and document them																													
Stage 2: Design, Development & Testing of First Version of National R-IMS Solution with Selected Modules																													
3. User Experience (UX) Design and Update of Pharmadex																													
4. Testing																													
5. Development of user manual and training materials																													
6. Training																													
7. Server setup and deployment/roll out of first version for pilot																													
8. Pilot																													
9. Incorporation of feedback from the pilot																													

Detailed Activities	Months																												
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29+
Stage 3: Design, Development & Testing of Second Version of National R-IMS Solution with Remaining Modules																													
10. Wireframes and User Experience (UX) Design																													
11. Development of Prototype for review by Technical Group																													
12. Alpha testing																													
13. Incorporation of feedback from Technical Group to complete development of first version of the system																													
14. Beta testing																													
15. Deployment/roll out of second version for pilot																													
16. Update user manuals and training materials																													
17. Training																													
18. Pilot																													
19. Incorporation of feedback from the pilot																													
Stage 4: Deployment and full scale up of National R-IMS Solution																													
20. Finalize the system for deployment to other countries																													
21. Final testing																													
22. Training																													

Table 25: Proposed Work Plan for Development of National R-IMS Solution Using an Existing R-IMS Solution (Pharmadex)

Proposed Work Plan for the Complete Project

Detailed Activities	Months																												
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29+
Stage 1: Finalizing Requirements																													
1. Technical group formation																													
2. Finalize requirements and document them																													
Stage 2: Design, Development & Testing of Website																													
3. Website Structure, Concept and Design																													
4. Wireframes and User Experience (UX) Design																													
5. Review and feedback by Technical Group																													
6. Themes and Website Development																													
7. Review and feedback by Technical Group																													
8. Finalize theme based on feedback to create an installed WordPress theme																													
9. Server setup and registration of domain names																													
10. Deployment of website for NMRAs																													
11. Development of user manual and training materials																													
12. Training																													
Stage 3: Design, Development & Testing of First Version of National R-IMS Solution with Selected Modules																													
13. Wireframes and User Experience (UX) Design																													
14. Development of Prototype for review by Technical Group																													
15. Alpha testing																													
16. Incorporation of feedback from Technical Group to complete development of first version of the system																													
17. Beta testing																													
18. Development of user manual and training materials																													
19. Training																													
20. Server setup and deployment/roll out of first version for pilot																													
21. Pilot																													
22. Incorporation of feedback from the pilot																													

Detailed Activities	Months																												
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29+
Stage 4: Design, Development & Testing of Second Version of National R-IMS Solution with Remaining Modules																													
23. Wireframes and User Experience (UX) Design																													
24. Development of Prototype for review by Technical Group																													
25. Alpha testing																													
26. Incorporation of feedback from Technical Group to complete development of first version of the system																													
27. Beta testing																													
28. Deployment/roll out of second version for pilot																													
29. Update user manuals and training materials																													
30. Training																													
31. Pilot																													
32. Incorporation of feedback from the pilot																													
Stage 5: Deployment and full scale up of National R-IMS Solution																													
33. Finalize the system for deployment to other countries																													
34. Final testing																													
35. Training																													
Stage 6: Design, Development & Testing of Regional R-IMS Solution for Joint Evaluations																													
36. Wireframes and User Experience (UX) Design																													
37. Development of Prototype for review by Technical Group																													
38. Alpha testing																													
39. Incorporation of feedback from Technical Group to complete development of first version of the system																													
40. Beta testing																													
41. Server setup and deployment/roll out																													
42. Development of user manual and training materials																													
43. Training																													
44. Pilot of first version for joint evaluation																													

Detailed Activities	Months																												
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29+
45. Incorporation of feedback from the pilot																													
Stage 7: Design, Development & Testing of Regional R-IMS Solution for Information Sharing																													
46. Wireframes and User Experience (UX) Design																													
47. Development of Prototype for review by Technical Group																													
48. Alpha testing																													
49. Incorporation of feedback from Technical Group to complete development of first version of the system																													
50. Integration with other systems																													
51. Beta testing																													
52. Server setup and deployment/roll out																													
53. Development of user manual and training materials																													
54. Training																													
55. Final pilot																													
Stage 8: Deployment and full scale up																													
56. Finalize the system for full deployment																													
57. Final testing																													
Stage 9: Post Implementation Support																													
58. Application maintenance (bug fixes)																													
59. Support users																													

Table 26: Proposed Work Plan for the Complete Project

5.5. Indicative Costs for a Continental R-IMS Solution and Information Sharing Platform for the Member States in the African Union

Overview

The estimated cost for the complete project which includes websites for the NMRAs, a National R-IMS solution and a Regional and continental R-IMS solution for information sharing and collaboration is One Million, One Hundred and Eight Thousand United States Dollars (USD 1,108,000.00). The estimated cost of developing the National R-IMS solution from scratch is Four Hundred and Ninety-Six Thousand United States Dollars (USD 496,000.00). The cost of developing the National R-IMS solution based on Pharmadex is Two Hundred and Sixty Thousand United States Dollars (USD 260,000.00). All the estimated costs above are based on personnel costs only excluding, other costs such as travel, accommodation, etc.

Detailed Breakdown of Development Cost for National R-IMS Solution from Scratch

Detailed Activities	Number of Days	Number of Personnel	Daily Rate	Total (USD)
Stage 1: Design, Development & Testing of First Version of National R-IMS Solution with Selected Modules				
1. Wireframes and User Experience (UX) Design	20	1	400.00	8,000.00
2. Development of Prototype for review by Technical Group	60	3	400.00	72,000.00
3. Alpha testing	10	1	400.00	4,000.00
4. Incorporation of feedback from Technical Group to complete development of first version of the system	40	3	400.00	48,000.00
5. Beta testing	10	1	400.00	4,000.00
6. Development of user manual and training materials	20	2	400.00	16,000.00
7. Training	10	3	400.00	12,000.00
8. Server setup and deployment/roll out of first version for pilot	10	1	400.00	4,000.00
9. Incorporation of feedback from the pilot	40	3	400.00	48,000.00
Stage 2: Design, Development & Testing of Second Version of National R-IMS Solution with Remaining Modules				
10. Wireframes and User Experience (UX) Design	20	1	400.00	8,000.00
11. Development of Prototype for review by Technical Group	60	3	400.00	72,000.00
12. Alpha testing	10	1	400.00	4,000.00
13. Incorporation of feedback from Technical Group to complete development of first version of the system	40	3	400.00	48,000.00
14. Beta testing	10	1	400.00	4,000.00
15. Deployment/roll out of first second version for pilot	10	1	400.00	4,000.00
16. Update user manuals and training materials	20	2	400.00	16,000.00
17. Training	10	3	400.00	12,000.00

Detailed Activities	Number of Days	Number of Personnel	Daily Rate	Total (USD)
18. Incorporation of feedback from the pilot	40	3	400.00	48,000.00
Stage 3: Deployment and full scale up of National R-IMS Solution				
19. Finalize the system for deployment to other countries	40	3	400.00	48,000.00
20. Final testing	10	1	400.00	4,000.00
21. Training	10	3	400.00	12,000.00
Overall Total				**496,000.00**

Table 27: Detailed Breakdown of Development Cost for National R-IMS Solution from Scratch

Detailed Breakdown of Development Cost for National R-IMS Using an Existing R-IMS Solution (Pharmadex)

Detailed Activities	Number of Days	Number of Personnel	Daily Rate	Total (USD)
Stage 1: Finalizing Requirements				
1. Finalize requirements and document them	10	2	400.00	8,000.00
Stage 2: Design, Development & Testing of First Version of National R-IMS Solution with Selected Modules				
2. User Experience (UX) Design and Update of Pharmadex	20	2	400.00	16,000.00
3. Testing	10	1	400.00	4,000.00
4. Development of user manual and training materials	10	2	400.00	8,000.00
5. Training	10	3	400.00	12,000.00
6. Server setup and deployment/roll out of first version for pilot	10	1	400.00	4,000.00
7. Incorporation of feedback from the pilot	20	3	400.00	24,000.00
Stage 3: Design, Development & Testing of Second Version of National R-IMS Solution with Remaining Modules				
8. Wireframes and User Experience (UX) Design	20	1	400.00	8,000.00
9. Development of Prototype for review by Technical Group	40	3	400.00	48,000.00
10. Alpha testing	10	1	400.00	4,000.00
11. Incorporation of feedback from Technical Group to complete development of first version of the system	20	3	400.00	24,000.00
12. Beta testing	10	1	400.00	4,000.00
13. Deployment/roll out of second version for pilot	10	1	400.00	4,000.00
14. Update user manuals and training materials	20	2	400.00	16,000.00
15. Training	10	3	400.00	12,000.00
16. Incorporation of feedback from the pilot	20	3	400.00	24,000.00
Stage 4: Deployment and full scale up of National R-IMS Solution				
17. Finalize the system for deployment to other countries	20	3	400.00	24,000.00
18. Final testing	10	1	400.00	4,000.00
19. Training	10	3	400.00	12,000.00
Overall Total				260,000.00

Table 28: Detailed Breakdown of Development Cost for National R-IMS solution Using an Existing R-IMS solution (Pharmadex)

Detailed Breakdown of Development Cost for Complete Project

Detailed Activities	Number of Days	Number of Personnel	Daily Rate	Total (USD)
Stage 1: Finalizing Requirements				
1. Finalize requirements and document them	10	2	400.00	8,000.00
Stage 2: Design, Development & Testing of Website				
2. Website Structure, Concept and Design	40	1	400.00	16,000.00
3. Wireframes and User Experience (UX) Design	20	1	400.00	8,000.00
4. Review and feedback by Technical Group			400.00	
5. Themes and Website Development	40	2	400.00	32,000.00
6. Review and feedback by Technical Group			400.00	-
7. Finalize theme based on feedback to create an installed WordPress theme	20	2	400.00	16,000.00
8. Deployment of website for NMRAs	20	2	400.00	16,000.00
9. Development of user manual and training materials	20	1	400.00	8,000.00
10. Training	10	2	400.00	8,000.00
Stage 3: Design, Development & Testing of First Version of National R-IMS Solution with Selected Modules				
11. Wireframes and User Experience (UX) Design	20	1	400.00	8,000.00
12. Development of Prototype for review by Technical Group	60	3	400.00	72,000.00
13. Alpha testing	10	1	400.00	4,000.00
14. Incorporation of feedback from Technical Group to complete development of first version of the system	40	3	400.00	48,000.00
15. Beta testing	10	1	400.00	4,000.00
16. Development of user manual and training materials	20	2	400.00	16,000.00
17. Training	10	3	400.00	12,000.00
18. Server setup and deployment/roll out of first version for pilot	10	1	400.00	4,000.00
19. Incorporation of feedback from the pilot	40	3	400.00	48,000.00
Stage 4: Design, Development & Testing of Second Version of National R-IMS Solution with Remaining Modules				
20. Wireframes and User Experience (UX) Design	20	1	400.00	8,000.00
21. Development of Prototype for review by Technical Group	60	3	400.00	72,000.00
22. Alpha testing	10	1	400.00	4,000.00
23. Incorporation of feedback from Technical Group to complete development of first version of the system	40	3	400.00	48,000.00
24. Beta testing	10	1	400.00	4,000.00
25. Deployment/roll out of first second version for pilot	10	1	400.00	4,000.00
26. Update user manuals and training materials	20	2	400.00	16,000.00
27. Training	10	3	400.00	12,000.00
28. Incorporation of feedback from the pilot	40	3	400.00	48,000.00

Detailed Activities	Number of Days	Number of Personnel	Daily Rate	Total (USD)
Stage 5: Deployment and full scale up of National R-IMS Solution				
29. Finalize the system for deployment to other countries	40	3	400.00	48,000.00
30. Final testing	10	1	400.00	4,000.00
31. Training	10	3	400.00	12,000.00
Stage 6: Design, Development & Testing of Regional R-IMS Solution for Joint Evaluations				
32. Wireframes and User Experience (UX) Design	20	1	400.00	8,000.00
33. Development of Prototype for review by Technical Group	60	3	400.00	72,000.00
34. Alpha testing	10	1	400.00	4,000.00
35. Incorporation of feedback from Technical Group to complete development of first version of the system	20	3	400.00	24,000.00
36. Beta testing	10	1	400.00	4,000.00
37. Server setup and deployment/roll out	10	1	400.00	4,000.00
38. Development of user manual and training materials	20	2	400.00	16,000.00
39. Training	10	3	400.00	12,000.00
40. Incorporation of feedback from the pilot	40	3	400.00	48,000.00
Stage 7: Design, Development & Testing of Regional R-IMS Solution for Information Sharing				
41. Wireframes and User Experience (UX) Design	20	1	400.00	8,000.00
42. Development of Prototype for review by Technical Group	60	3	400.00	72,000.00
43. Alpha testing	10	1	400.00	4,000.00
44. Incorporation of feedback from Technical Group to complete development of first version of the system	20	3	400.00	24,000.00
45. Integration with other systems	40	2	400.00	32,000.00
46. Beta testing	10	1	400.00	4,000.00
47. Server setup and deployment/roll out	10	1	400.00	4,000.00
48. Development of user manual and training materials	20	2	400.00	16,000.00
49. Training	10	3	400.00	12,000.00
Stage 8: Deployment and full scale up				
50. Finalize the system for full deployment	40	2	400.00	32,000.00
51. Final testing	10	1	400.00	4,000.00
Stage 9: Post Implementation Support (1 year)				
52. Support users	120	2	400.00	96,000.00
Overall Total				**1,108,000.00**

Table 29: Detailed Breakdown of Development Cost for Complete Project

National R-IMS Solution Hosting Options

Below are the minimum server specifications to host the National R-IMS solution in the country.

Dedicated Server

This will be a single computer unit hosted at a data centre. This will be the preferred option if a country does not wish for its data to reside outside the country. The cost below is for the server unit and does not include other cost such as co-location charges and backups.
CPU: 4 cores @ 3.0 GHz
RAM: 16 GB
Storage: 2 x 1 TB GB SSD
Estimated cost (One-Time): $4,000.00

Virtual Private Server (VPS)

A virtual private server is a virtual machine sold as a service by an Internet hosting service such as Amazon Web Services (AWS).

CPU: 6 cores
RAM: 16 GB
Storage: 320 GB SSD
Block Storage: 1 TB
Estimated cost/Month: $300.00

Continental R-IMS Solution Hosting Options

Below are the minimum server specifications to host the National R-IMS in the country.

Dedicated Server

This will be a single computer unit hosted at a data centre. This will be the preferred option if a country does not wish for its data to reside outside the country. The cost below is for the server unit and does not include other cost such as co-location charges and backups.

CPU: 6 cores @ 3.0 GHz
RAM: 32 GB
Storage: 2 x 1 TB GB SSD
Estimated cost: $6,000.00

Virtual Private Server (VPS)

A virtual private server is a virtual machine sold as a service by an Internet hosting service such as Amazon Web Services (AWS).
CPU: 8 cores
RAM: 32 GB
Storage: 640 GB SSD
Block Storage: 2 TB
Estimated cost/Month: $600.00

5.6. Proposed R-IMS Solution Software Implementation

Vendor Selection

After accepting that developing a continental R-IMS solution is feasible, a vendor should be selected to develop the system. This process will involve:

1. The creation of Terms of Reference. The document will give an overview of the project and the proposed solution with our findings so far, the scope of the project, and the deliverables of the project. This will serve as a guide for the developers as they develop the R-IMS. The terms of reference will also determine which vendors are eligible to handle the project.
2. Development of request for proposal. If vendors are going to be selected objectively, there should be a request for proposal which contains the project's terms of reference. Vendors will be able to bid for the project and the best one can be picked based on their eligibility and cost.
3. Creation of evaluation team. A team comprising of the major stakeholders of the system can be assembled to assess the features, price and software criteria provided by each vendor. A representative from our consultancy will also be beneficial in this team.

Project Kick-Off

To commence the project after finding a suitable vendor, a team should be created that will ensure that there is accountability and for the project's success. This team will be made up of the continental R-IMS solution major stakeholders. This will include representatives from the NMRAs, RECs, from the World Bank and from NEPAD. The vendor will then meet with this team to discuss what is required of the vendor again.

Development of R-IMS Solution

At this stage, the vendor starts development of the R-IMS solution based on the requirements they have received. This stage will involve the following processes:

Requirements Gathering and Analysis

Based on the user requirements we have identified and any other requirements that the vendor discusses with the stakeholders, the vendor will analyze and collate all of these requirements into a product requirements document. At this phase, prototypes are developed. After analyzing the users' needs and requirements, the developers will create prototypes in the form of drawings to test if they have captured the all the users' requirements.

Software Design

The system and software design are created from the requirements stated in the requirement document. At this stage, the developer specifies the hardware and software requirements and defines the overall system architecture. At this phase, a Testing Plan is developed. The Testing Plan will guide the developers on how to test the system at each phase of the software development lifecycle to ensure that quality goals are met. The testers define what to test and how to test them.

Development & Implementation

The work is divided in the modules and the developers will start developing these units. They then incorporate the feedback they receive into the system they are creating.

Testing

At this stage, unit testing, system testing, acceptance testing, functional testing and other types of testing are conducted. The code of the system is tested against the requirements to ensure that it meets the needs of the users.

Deployment

After the development of the system to the satisfaction of the stakeholders and testing is successful, the system is handed to over to the users.

Training

Key stakeholders will be trained to manage and use the system optimally. Training manuals and documents have to be made available for reference and guidance.

Go live

At this stage, the system is ready to be used by the users. Random pieces of data should be checked to ensure that information and data has transitioned and is processing as it should.

Chapter 6: Conclusion

The report summarizes the existing systems that have been implemented in some of the NMRAs with their advantages and disadvantages. These systems do not allow for information sharing or support all the regulatory functions of the NMRAs that use them.

To adopt the IMS solution of an existing country or regional economic community (REC) for an R-IMS solution will be challenging unless this country or REC is willing to share the source code with a third-party to further develop to a state that can easily be adopted by the remaining NMRAs. Depending on how these systems are structured, it might be better to develop from scratch rather than building on an existing solution as these solutions are tailored towards the operations of the NMRA. The country or REC should also be willing to share the source code with other countries that want to develop their own custom systems. Adopting the source code of another system will also pose a lot of resource challenges.

To develop the National R-IMS solution, two approaches can be used. Based on the proposed modules and our research findings, the two proposed approaches are:

1. Development of National R-IMS solution from scratch
2. Build on an existing R-IMS solution (Pharmadex)

Development of the National R-IMS solution from scratch will take approximately 23 months including pilot and scale up.

To reduce the software development time of the National R-IMS solution not including deployment and piloting from 19 months to 4 months, the system has to be developed based on an existing solution and some products (medical, food and cosmetics) registration taken out. For this approach, we propose the use Pharmadex. Pharmadex is web based and open source software (OSS). Being open source means software development service provider can pick the code and modify it.

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Appendix

Country Profiles: National Medicine Policies and Regulatory Functions

Access Country Profiles using this Link AU Country Profiles National Medicine Regulatory Authority Policies.

Software Requirements Specification (SRS) Document for AU R-IMS

Access the SRS document using this link: AU R-IMS Software Requirements Specification.

Research Data Collection Tools

NMRA Questionnaire - English

https://docs.google.com/forms/d/e/1FAIpQLSdw_mCvL09DXlOvnYQavPQHKkk8d0JPVFxenypRECdOSYR_ig/viewform?vc=0&c=0&w=1

NMRA Questionnaire - French

https://docs.google.com/forms/d/e/1FAIpQLSc9HVO_tw28gxIFKu3WS7SwoHSD4SD36q6MGSiEQAMNDy_e4w/viewform?vc=0&c=0&w=1&usp=mail_form_link

NMRA Interview Guide

Introductions

- Full Name
- Country
- Position/Role
- Name of National Medicine Regulatory Authority (NMRA)
- Duration of time in the current position

A walk-through of the entire marketing authorization process, the various actors in that process and the software/systems, if any, that support the process. NB: Marketing authorization may or may not include registration & licensing depending on the infrastructure and resources of the NMRA. Ask about the reasons why certain regulatory functions are not performed and if there are current plans in progress to start functioning in those areas

Registration

- Types of product registration
- duration of each type,
- pre-requisites for registration,
- when marketing authorization is issued,
- how MA holders are regulated.
- What software is used to capture, store, manage this information?
- In which format are the applications received?

- If there is an online platform for registration, ask about the process by which online applications are reviewed and moved from one actor to another.

Inspection

- How are GDP and GMP inspections conducted?
- What are the prerequisites for inspection?
- In what cases do they waiver GDP and GMP inspections (especially for imported drugs)? Are there GDP/GMP certificates that are more recognized than others? Why? Are there harmonization initiatives that allow GDP and GMP inspections to be waived?
- How is inspection information collected, managed and stored?

Laboratory Services

- Is there a national lab that collaborates with the NMRA? If not? Do they collaborate with labs in other countries/ developmental agencies such as WHO?
- What sort of information does the laboratory communicate with the NMRA? Which medium is used in communicating?
- Is there a system/software that collects, manages and stores lab information? If yes, what are the details of this software? If not, how is lab information managed?

AU R-IMS Solution NMRA Questionnaire

A Project on a Regulatory Information Management System (R-IMS) for Medicines Regulatory Harmonization (MRH) across all countries in Africa - User Requirement Gathering Questionnaire

Section 1 Introduction

The African Union (AU) has been making certain decisions and initiatives to support the human right to health as stipulated in Article 25 of the Universal Declaration of Human Rights. To achieve this, an integrated continental Information Management System (IMS) will have to be developed for the continent, by connecting Regional IMS (Regional-MIS) where they exist, ensuring interoperability. This will be an important means of ensuring speedy access to medical products that are safe, efficacious, and of assured quality to the African population as well as information on the same. The proposed continent-wide integrated IMS should provide online and real-time availability of medicine regulation information and support workflow management, where possible.

Bewsys (the consultant firm) has been contracted by the World Bank in collaboration with African Union Development Agency (AUDA-NEPAD) to assess existing IMS Solutions for medicines regulation at national, regional, and continental levels and make technical recommendations and specifications for ideal R-IMS solutions at all levels to facilitate work and confidential sharing of regulatory data and information on medicines among countries in Africa. Kindly help us achieve this goal by answering this questionnaire accordingly. Your feedback will majorly impact the solutions for the continental Regulatory Information Management Systems (R-IMS).

For further inquiries about this questionnaire, please contact us on support@bewsys.com or call us via: +233 30 2506143

Section 2: Personal Information

Kindly let us know your full name, position/role and the NMRA you are representing in the spaces provided below:

Full name: FirstName, Surname

Position/Role: Select Position/Role

Name of National Medicine Regulatory Authority (NMRA)
Name of your NMRA
Country: Select your country

Email Address : Address

Phone Number Phone Number

Skype ID: Skype Identification

Kindly select your Regional Economic Community (REC)
☐ IGAD - Intergovernmental Authority on Development
☐ SADC - Southern Africa Development Community
☐ COMESA - Common Market for Eastern and Southern Africa
☐ ECOWAS - Economic Community of West African States
☐ EAC - East African Community
☐ ECCAS - Economic Community of Central African States
☐ AMU - Arab Maghreb Union

Kindly select the main language you use in your country
☐ English
☐ French
☐ Arabic
☐ Portuguese
☐ Amharic

Section 3: Regulatory Functions

In this section, we would like to know the various regulatory functions performed by your NMRA

Kindly select the regulatory function(s) available in your organization in the list below
☐ National Regulatory Systems (RS)
☐ Registration and Marketing Authorization (MA)
☐ Vigilance (VL)
☐ Market Surveillance and Control (MC)
☐ Licensing Establishments (LI)
☐ Regulatory Inspection (RI)
☐ Laboratory Testing (LT)
☐ Clinical Trials Oversight (CT)
☐ NRA Lot Release (LR)
☐ Other
Kindly state if you selected "Other"

Kindly describe, in short paragraphs, the operations of the regulatory function(s) you selected in the question above.
Description

Section 4: Information Management System

This section seeks for information on how your organization manages information both locally and other collaborating parties internationally.

Do you have computers that are used in the day-to-day regulatory operations in the organization?
☐ Yes
☐ No

What is the computer/tablet-employee ratio in your organization (exclude personal devices)?
Select the ratio
Kindly state if you selected “Other”

Does your National Medicine Regulatory Authority use software for its day to day regulatory operations?
☐ Yes
☐ No

If yes, what regulatory functions does your current software system support?
☐ National Regulatory Systems (RS)
☐ Registration and Marketing Authorization (MA)
☐ Vigilance (VL)
☐ Market Surveillance and Control (MC)
☐ Licensing Establishments (LI)
☐ Regulatory Inspection (RI)
☐ Laboratory Testing (LT)
☐ Clinical Trials Oversight (CT)
☐ NRA Lot Release (LR)
☐ Other
Kindly state if you selected “Other”

Kindly give a brief description, in short paragraphs, of how the software supports the regulatory functions you selected in the previous question.
Description

How satisfied are you with the software?
Select

What are some of the weaknesses that the software has in supporting the regulatory functions you selected above? Kindly describe.
Description

Kindly recommend ways in which the software can be improved.
Description

Is this software a web-based (accessed using a web browser like Firefox or Google Chrome) or a desktop application?
☐Web-based
☐Desktop
☐ Both Web-based and Desktop

Where is the software hosted?
☐The Cloud(online)
☐On-site (offline on physical servers)
☐ Hybrid (both onsite and on the cloud)

If you selected “The Cloud” kindly state, the type of cloud hosting used in your organization.
State

Was this software developed in house or was its development outsourced?
☐In-house
☐Outsourced
☐Partially in-house and Partially outsourced

Is the software supported internally or by a third-party?
☐Internally
☐ Third-party
☐Both internal and third party

Was your system development supported by any external parties (in terms of development funding)?
☐ Yes
☐ No

Kindly select the funding source for the development of the system.
☐ Private Donor
☐ International Development Agency
☐ Government
☐ Internally Generated Funds
☐ Other
State if you chose "Other"

Please select an option below that best describes your current usage of the software.
Select

If you are not satisfied with your current software, please state the areas the software needs improvement.
State
Please rate the internet speed in your organization.
Rate

What is your satisfaction level of your choice above? Kindly select (1 = Not at all Satisfied, 2 = Partly Satisfied, 3 = Satisfied, 4= More than Satisfied, 5 = Very Satisfied)
Choose an item.

Section 5: Information Sharing

In this section, we would like to know how you share information with other collaborators.
Is your National Medicine Regulatory Authority's system linked/integrated with your Regional Economic Community's (REC's) system?
☐ Yes
☐ No

If yes, kindly select the Regional Economic Community (REC) with which your system is linked.
☐ IGAD - Intergovernmental Authority on Development
☐ SADC - Southern Africa Development Community
☐ COMESA - Common Market for Eastern and Southern Africa
☐ ECOWAS - Economic Community of West African States
☐ EAC - East African Community
☐ ECCAS - Economic Community of Central African States
☐ AMU - Arab Maghreb Union

Does your National Medicine Regulatory Authority (NMRA) rely on information such as market authorization from other country's NMRAs for your regulatory functions?
☐ Yes
☐ No

If yes, kindly state the name of the NMRA and the regulatory function you rely on them for.
State

Does your National Medicine Regulatory Authority share pharmaceutical information with other countries?

☐ Yes
☐ No

If yes, kindly select the type of information your organization shares with other countries or REC if it appears in the list below:

☐ List of Registered Products, renewal, and variations through by each REC
☐ List of Registered Premises and status by each REC
☐ List of Pharmaceutical Manufacturers by each REC
☐ Medical Products Recalls by each REC
☐ Pharmacovigilance and Safety Alert by each REC
☐ List of Banned Products by each REC
☐ List of Withdrawn products by each REC

If yes, kindly state the country(s) with which you share information in the space provided below.
State

If yes, briefly describe your communication process and channels you use to share the above information with other countries in the region.
Brief Description

If no, briefly explain why
Brief Description

Does your National Medicine Regulatory Authority share pharmaceutical information with the Regional Economic Community (REC) you are part of?

☐ Yes
☐ No

If yes, kindly select the type of information your organization shares with the REC if it appears in the list below:

☐ List of Registered Products, renewal, and variations through by each REC
☐ List of Registered Premises and status by each REC
☐ List of Pharmaceutical Manufacturers by each REC
☐ Medical Products Recalls by each REC
☐ Pharmacovigilance and Safety Alert by each REC
☐ List of Banned Products by each REC
☐ List of Withdrawn products by each REC

Section 6: System Documentation Standards

In this section, we seek for information about the availability of the documentation about your system, including system architecture and user inputs and outputs from the system.

Does your organization have an available documentation of the architecture of your system?

☐Yes
☐No

If yes, what kind of system documents does your company have? Kindly select.

☐ Requirements Document
☐ System Architecture Design
☐ Source Code
☐ Validation Documents
☐ Verification and Testing Reports

☐ Maintenance or Help Guide

Does your NMRA keep system log files of the activities that happen on the system?
☐ Yes
☐ No

Section 7: System User Requirements

In this section, we would like to find out the requirement you would want to be included in a new and/or your existing system.

If a software that supports your workflows/functions was to be developed for your NMRA, please identify its key users in and outside your organization.
☐ Manufacturers
☐ Importers
☐ Exporters
☐ General Public
☐ Inspectors
☐ Assessors
☐ Finance Professionals
☐ Management
☐ Laboratory Technicians
☐ Other
State if you chose "Other"

What is/are the primary language(s) of the users identified in the question above? E.g. English, Portuguese, etc.
☐ English
☐ French
☐ Arabic
☐ Portuguese
☐ Amharic
☐ Spanish

How familiar are these users with computers and internet usage?
Choose an item.

Which additional business process and areas would you want the software to support?
☐ Project Management
☐ Revenue Collection
☐ Enforcement
☐ Other
Kindly state if you selected "Other"

Aside from interested parties in your organization, which other organizations will use information from the system?
☐ World Health Organization (WHO)
☐ Ministry of Health
☐ Local Pharmacies
☐ Manufacturers (both local and international)
☐ National Laboratories
☐ National Pharmaceutical Research Centers
☐ Other
Kindly state if you selected "Other"

What are the possible barriers to the implementation of a software that supports your workflows/functions in your country and across your region?

☐ Legal and institutional barriers
☐ Financial barriers
☐ Political and cultural barriers
☐ Practical and technological barriers
☐ Resistance to change
☐ Inadequate Sponsorship by top-management
☐ Unrealistic Expectations
☐ No Compelling Case for Change
☐ Other

Kindly state if you selected "Other"

If a software that supports your workflows/functions was to be developed for your NMRA, what would you want it to do? Please list all desirable features.
Brief Description

Have you seen/used the following software or other software you liked and would want this new software to look like?

☐SIAMED
What are the pros and cons that you identified in this system?
Pros
Cons

☐ VigiFlow/Vigibase
What are the pros and cons that you identified in this system?
Pros
Cons

☐ GASYNET
What are the pros and cons that you identified in this system?
Pros
Cons

☐ MedNet
What are the pros and cons that you identified in this system?
Pros
Cons

☐Other

If you selected "Other", please provide the name and a link to the software.
Name: State the Name here
Link: Enter the Link here

Also, describe what you liked, intrigued you or disliked about the software.
Pros
Cons

Section 8: System Sustainability

In this section, we would like to know your thoughts on the sustainability and scalability of your system.

How would you rate the sustainability of your system?
Rate

Kindly give a reason for your answer above
Give a Reason

Kindly estimate the number of people that your system serves.

Daily Select
Weekly Select
Monthly Select

Does your system ever experience traffic in certain seasons?

☐ Yes
☐ No

If yes, kindly state the seasons
State

Does your organization do a timely system maintenance check?

☐ Yes
☐ No

If yes, how often does your organization run the maintenance checks?
Select

Does your organization have an annual budget for System Maintenance?

☐ Yes
☐ No

How long does it normally take to run a complete system maintenance check on your system? Kindly State.
State

Do the system users in your organization receive refresher training on how to use the system?

☐ Yes
☐ No