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Assessment of the availabilty and accessibility of information on the websites of selected national medicines regulatory authorities

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ASSESSMENT OF THE AVAILABILITY AND ACCESSIBILITY OF INFORMATION ON THE WEBSITES OF SELECTED NATIONAL MEDICINES REGULATORY AUTHORITIES

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A research report submitted to the Faculty of Health Sciences University of the Witwatersrand, Johannesburg, in partial fulfillment of the requirements for the Degree: Masters in Pharmaceutical Affairs

University of Witwatersrand

DECLARATION

I, Hleliwe Ennie Mhaule declare that this Research Report is my own, unaided work. It is being submitted for the Degree of Masters in Pharmaceutical Affairs at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

_____

(Signature of candidate)

_____day of_____20_____in_____

ABSTRACT

Accessibility and availability of reliable and accurate information on medicines regulation is of necessity; especially where patients' treatment is concerned and informed decisions needs to be made. This information, which is now available on the internet is intensifying and originates from varied numerous sources. National Medicines Regulatory Authorities (NMRAs) can play an integral part by publishing accurate information and making it accessible and available to stakeholders.

Aim: To assess the availability, accessibility and adequacy of information published on the websites of selected MRAs.

Objectives: To evaluate the availability and accessibility of information on the websites of 9 African and 5 non-African who are also part of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S).To assess the navigability of the websites of the selected NMRAs and to further compare the functionality of the websites of the African NMRAs with those of PIC/S MRAs.

Method: A quantitative and qualitative desktop review of websites was conducted using a tool adapted from previous studies with 20 assessment criterions, which were divided into two categories, website design functionality and website content. These were set up as a score of either a Yes' or 'No' answer.

The websites of 14 Medicines regulatory authorities (MRAs), of which nine were from African countries i.e. South Africa, Zimbabwe, Zambia, Tanzania, Ghana, Kenya, Namibia, Botswana and Nigeria and nine from overseas countries; United Kingdom, Switzerland, Australia, Singapore and Canada were evaluated.

Results: Both the PIC/S and African MRA websites scored above 80% onwebsite userfriendliness. While the availability of information on pharmacovigilance and medicinal products, the PIC/S MRAs excelled by achieving a 100% and 92% respectively. The African MRAs websites scored 55% for pharmacovigilance publications on their websites and 13.4 % on availability of information on medicinal products. Notwithstanding that, no information was available regarding PILs and a list of non-propriety pharmaceutical drug names. Other significant findings in the African MRAs websites from the study were a lack of information on approved

pharmaceutical manufacturers and guidance for the pharmaceutical industry applicants. On average, the African MRAs achieved 37% and 71% respectively compared to the PIC/S MRA websites, who scored 60% and 100% respectively.

Conclusion: There is a lack of ongoing published information on medicines safety alerts and adverse drug reactions in African countries, despite the fact that procedures for reporting adverse drug reactions and events are available in thesewebsites. While PIC/S MRAs share information on practices around GMP, they also seem to share common best practices in regulatory medicines information dissemination.

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LIST OF ACRONYMS

ADRs:	Adverse Drug Reactions
AMRH:	African Medicines Regulatory Harmonization
API:	Active Pharmaceutical Ingredient
EMA:	European Medicines Agency
GMP	Good Manufacturing Practice
GCP	Good Clinical Practice
FDA	Food and Drug Administration (United States)
FDAG:	Food and Drug Authority Ghana
HSA:	Health Science Authority
ICT:	Information and Communication Technology
ITU:	International Telecommunication Union
MCAZ:	Medicines Control Authority of Zimbabwe
MCC:	Medicines Control Council
MHRA:	Medicines and Healthcare Products Regulatory Agency
MHB:	Ministry of Health Botswana
MRA:	Medicines regulatory authority
NDOH	National Department of Health
NMRA:	National Medicines Regulatory Authority
NMRC:	Namibia Medicines Regulatory Council
NAFDAC:	The National Agency for Food and Drug Administration and Control
PPB:	Pharmacy and Poison Board Kenya
PIC/S:	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PILs:	Patient Information Leaflets
PI:	Package Insert
SADC:	Southern African Development Community
SPC:	Summaries of Product Characteristics
TGA:	Therapeutics Goods Administration (Australia)
TFDA:	Tanzania Food and Drug Authority
UK:	United Kingdom
USA:	United States of America
UNESCO:	United Nations Educational, Scientific and Cultural Organization
WHO:	World Health Organization
ZAMRA:	Zambia Medicines Regulatory Authority

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CHAPTER 1

INTRODUCTION

1.1 STUDY OVERVIEW

Chapter 1 provides background information on the establishment of Medicines regulatory authorities (MRAs), their mandates and responsibility on regulatory information dissemination. It also introduces the type of information the MRA may publish for its stakeholders. Chapter 2 dwells on literature review. Literature was sought from similar studies, especially on non-African countries as limited research has been done in the African countries. Chapter 3 outlines the research methodology and data collection from the 14 selected MRA websites over a period of two months October 2015 to November 2015. Then the results are outlined and discussed in chapter 4. Finally, chapter 5 makes the conclusions and recommendations.

1.2 Background Information

Medicines regulation is a practice based on activities and functions aimed at ensuring the safety, efficacy and quality of medicines (1). Medicines regulatory systems originated in the early 1900s in reaction to malpractices in the pharmaceutical industry (2).The systems were later tightened in the 1960s in the wake of the thalidomide disaster. This led to the introduction of the first product proof of efficacy requirements by the regulatory authorities starting in the United States of America (USA) (3).

MRAs were established and mandated to conduct mutually reinforced activities all aimed at promoting and protecting public health (4). These activities include but are not limited to issuing of,

- Marketing authorization (also known as registration)
- Licenses to manufacturers
- Licenses to importers and exporters of medicines
- Continuous monitoring of the safety of medicines (pharmacovigilance)

In order for medicines to be registered for use by the public, the pharmaceutical industry would submit information to the MRA. This information details the quality control of the active pharmaceutical ingredient (API), excipients, animal and human

studies undertaken to establish its acute and chronic toxicity of the finished final product (3). Studies of pharmacological effects from clinical studies intended to demonstrate efficacy would also be included. This process is called a new drug application or medicines marketing authorization (registration).

Once the new drug has been approved by the MRA, the MRA is obliged to fulfill its public health mandate by publishing information pertaining to that medicine. This is to support the safe use or access of the medicine by both the general public and healthcare professionals (5). In the event that the MRA rejects the drug application, it should also disclose the reasons for the non-approval.

This is because publication of data relating to the safety and efficacy of a product that is not licensed in a specific country can be valuable to other populations in countries where the product is licensed (6).This includes data on unsuccessful clinical trials or product registration which may contain valuable information for further research. Unlicensed products in the same therapeutic class as the licensed products further provide significant information on the safety and pharmacology of the licensed products (6).

Globally, current developments in pharmacy practice and medicine are encouraging a proactive role of the pharmaceutical industry in empowering patients in healthcare decisions (7). Available sources of information have become numerous and varied, with the internet being at the forefront. Previous research (8, 9) has found that the internet has been a catalyst for the major shift in communication. It has also empowered patients to ask more questions and demanding more information regarding their treatment. The internet also has an impact on health care professionals on how they access information relevant to their work.

Due to potential conflicts of interest inherent in the private provision of information by other sources (6) and given their public health mandate, regulatory authorities represent an important source of information which is deemed independent and therefore credible and reliable.

Further, to enhance the transparency and work of MRAs, these authorities need to provide information in ways that are comprehensible to healthcare providers as well as the lay public. Information from MRAs would maintain the general public’s confidence in pharmaceutical products by ensuring the public is protected from ineffective and harmful medicines (10) through provision of information on the safety,

quality and efficacy of medicines. The information is also meant to be accessible, clear, relevant and credible so it can be distributed through various channels.

Most countries have an official communication channel (mostly in the form of an official government gazette) through which the NMRA can communicate with the public while others use their websites specifically to reach global audiences (10).

1.3 MRA stakeholders and their relevant type of information

Important stakeholders who access regulatory information from MRAs are the pharmaceutical industries, clinicians and other healthcare professionals, researchers, policymakers and the public. These stakeholders have different information needs and therefore the MRAs have to accommodate all of them.

The pharmaceutical industry needs information regarding guidelines on the registration of medicines, registration of ongoing and completed clinical trials etc. The public, which includes health care professionals and lay people, on the other hand need information on the safety and adverse drug reactions and reporting procedures. While the NMRAs, may need information for the purposes of sharing experiences and collaborations with one another.

Nevertheless, there are still significant barriers to access to information and these include data restrictions, infrastructure and low literacy. These are discussed in detail below.

1.4 Barriers to access to medicines regulatory information

1.4.1 Data restrictions

Confidential and restricted pharmaceutical industry data may influence how the regulators draft their medicines regulations policies (11). NMRAs cannot share certain proprietary information received from applicants, for example the control procedures for the starting materials used to synthesize the API. Despite continuous efforts by government to advance and implement legislation on pharmaceuticals; the pharmaceutical industry and the regulator are still bound by some clauses in the law that promote privacy and confidentiality (12)**.**

For example in Canada, the Access to information Act and Therapeutic Products Directorate makes provisions for such restrictions. While in South Africa data restriction is governed by the secrecy clause in terms of section 34 of the Medicines and Related substances Act, 1965 (Act 101 of 1965). However, such limitations have had a negative impact especially on the safety and efficacy information contained in unpublished clinical trials. These have been generally unavailable to researchers, physicians and patients (12) and can compromise patients' safety.

1.4.2 Non-disclosure policies by companies

Various controversies have highlighted how the pharmaceutical industry has concealed clinical safety data. The control has been justified as protecting their financial interests (2). Nevertheless, this is not the same in all countries. For example in the USA the Food and Drug Administration (FDA) publishes information from preclinical and clinical trials that is considered proprietary in Canada (13).

The notion here is, if scientific data submitted to regulatory agencies is never allowed to enter normal peer-review channels, neither these data nor the medicines regulators evaluations can become subject to scrutiny by independent scientists, health care professionals and consumers (12).

1.4.3 Infrastructure

Lack of infrastructure where the agencies are highly dependent on industry fees to keep up with operations may lead to the agency focusing on being a service provider rather than on medicines regulation (7, 14). The regulator may not have sufficient financial resources to sustain itself in order to strike a balance between fees covering the full cost of services and government support.

Internet is now an important portal of information however access to it can be restricted by the lack of Information and Communication Technology (ICT) infrastructure. Where there is limited access to the internet a significant body of health-related information may not reach users in developing and transitional countries (15).

As of November 2012 there were 46 MRAs out of the 53 countries in the African continent, of which the World Health Organization (WHO) identified one, had no MRA and only 35countries had a websites (16).

1.4.4 Poor governance

Conflict of interest among those who regulate medicines and their relationship with those they regulate may influence publishing biased product information or giving too little information on safety (17). For example there are still concerns about the influence of advisory committee's members' financial relationships on the US FDA's drug approval process (18).

1.4.5 Literacy

Literacy plays a key role in a patient's ability to use information and services. This can affect health outcomes(19).Low literacy levels in medicine user may impede access to information as the use of jargon and scientific terms excludes even the educated lay public from understanding fully the information accessed (20).

The lowest national literacy rates have been observed in sub-Saharan Africa and in South and West Asia. Youth literacy rates for the population aged 15 to 24 years are also generally higher than adult literacy rates. However youth literacy rates remains low across sub-Saharan Africa , South and West Asia (21).

1.5 Problem statement

Access to medicines regulatory information is important to support the effective and safe use of medicines by stakeholders. Gaps in information availability and credibility limit stakeholders' access to relevant and important information (10). Evidence does exist that there are concerns in this regard; and there is a need for transparency from NMRAs. Because of the increasing importance of the internet in sharing of regulatory information, MRAs have a responsibility to ensure that the information available on their websites is adequate, credible and easily accessible.

1.6 Study aim and objectives

The aim is to assess the availability, accessibility and adequacy of information published on the websites of selected MRAs. In addition, a comparison will be performed across the selected MRAs using these parameters.This will be done in order to understand global best practice on information dissemination in medicine regulation and to make recommendations to policymakers.

The objectives are as follows:

- To evaluate the availability and accessibility of information on the websites of 9 African and 5 non-African (PIC/S) NMRA
- To assess the navigability of the websites of the selected NMRAs
- To compare the functionality of the websites of the African NMRAs with those of PIC/S

CHAPTER 2

LITERATURE REVIEW

There is a global trend towards using the internet to provide both technical and non-technical regulatory information to appropriate stakeholder which has enhanced the means of acquiring and sharing useful information (22). This information being disseminated to a broad stakeholder mix should meet the minimum criteria in terms of accessibility, availability and reliability (5, 23, 24).

It is also the responsibility of the MRA's websites to provide evidence-based information that has been limited by parameters such as ease of use and navigation of the website by different audiences (25).

A study by Godlee et al. (26); found that the lack of access to information remained a major obstacle to knowledge-based health care in developing countries. In 1994 a meeting to review global access to health information concluded that the majority of healthcare professionals in developing countries had inadequate access to

information and that any information available to them was often unreliable or irrelevant (26). At that time, it was predicted that the majority of healthcare professionals in the developing world would be able to access information more easily by 2004.

In a study by the World Health Organization (WHO) in 2001 (23) only 53 NMRAs websites were identified globally and only fifty one were evaluated (including South Africa, Botswana, United Kingdom (UK) Australia and Canada). The method used was based on a set of key criteria (general and specific) on different types of medicines information i.e. information on how to ensure safe, efficacious use of medicines, list of registered medicines etc) and a scoring ranging from zero to two (zero= inadequate, one = intermediate, two= good) was utilized to credence each criterion. Five of these websites were only available in their national languages (Austria, Greece, Italy, China and Portugal).The study also found that 80% of the websites had inadequate sections on medicines pharmacovigilance and more than 50% did not give access to information on registered medicines (23). Only 13.7% of the websites scored ‘good’ on information on medicinal products.

A follow up study in 2009 using the same criteria on 116 WHO member states showed that criteria such as the frequency of information updates, pharmacovigilance information and regulatory guidance for applicants for medicines marketing authorization (registration) had improved substantially (24).The study also identified that NMRAs websites more than doubled from 27% in 2001 to 59 % in 2009. Patient information leaflets (PILs) and summaries of product characteristics (SPC) were only available in a third of the reviewed websites. The percentage of websites judged to be of user friendliness increased from 29% in 2001 to 43% in 2009 (24).

Another study which was more focused on African countries, assessed MRAs in 26 sub-Saharan African countries over a period of eight years from 2002 to 2009 (27). It showed that nine of the 26 NMRAs had set up a website. Five of these were in need of updating and one had links, which were not functioning correctly. MRA interaction with stakeholders only took place in the form of meetings with regulatory and professional associations. Little information was made public on decision-making and current information on approved medicines was not constantly publicly available.

Twenty-three of the NMRAs had no written declarations of interest and confidentiality agreements in place. These findings show a lack of transparency by the MRAs.

Another recent study, the Vitry et al.2008 (5), assessed the provision of regulatory information on regulatory authorities' websites of six countries (USA, Canada, UK, France, Australia and New Zealand) and at the European level (European Medicines Evaluation Agency) (5). The assessment included 16 criteria (set up as checklist of a 'yes' or 'no' answer) organized in three domains i.e. information on marketed medicines, information on assessment of medicines and information on medicines safety. The study found that all websites provided a list of authorized medicines in the country. SPCs and PILs were accessible in all except in Australia and the UK. Only the USA provided a searchable register of ongoing and completed clinical trials. While only the UK and the US websites, provided information on declined medicine registrations. Cancellation of medicine registrations was absent or incomplete in all countries except in the UK. All websites presented safety alerts and reporting procedures for adverse drug reactions. The results showed a great variability in the level of published information each country MRA deemed as important for publishing. This variability can also be due to lack of guidance on the required quality of information and the type of information that should be published on the websites.

While availability and adequacy of information on the websites is of importance, access to the internet is just as significant.

2.1 Internet connectivity in Africa and access to information

Internet penetration has grown from 17 million Internet users in 2005 to an estimated 172 million world-wide in 2014 (28). It cannot be measured only in terms of the number of connected individuals, but access to internet must be considered. It was estimated that by the end of 2014, one out of ten households (10%) would have internet access at home in Africa, contrary to an average of 31.2% in all developing countries (29). By 2015, globally 3.2 billion people were using the internet of which 2 billion are from developing countries (30).

Africa as a developing continent is experiencing an unprecedented increase in internet use and the number of cell phone users (31). Currently there are 330.9 million internet users in Africa in a population of 1.1 billion (32) . Most of these users

connect to the internet via mobile phones. For example escalation in mobile technology coverage in Zambia has made internet widely available, providing an opportunity for the patients and health professionals to use these media for evidence-based decision making (33).

Large variations exist across different African countries particularly, in Sub-Saharan Africa. Seychelles and South Africa rank the highest in internet penetration (with 50.4% and 48.9% of internet users, respectively); while the countries with the least internet penetration are Eritrea and Burundi (0.90% and 1.30%, respectively) (29). There are probably many reasons for this; chief among them would be poor internet connectivity, infrastructure and costs.

From this discussion, it can be understood that information sharing or dissemination is a two-way function. Thus, the MRA has to have the resources and means of putting out the information. For example, ICT infrastructure, trained personnel and access to broadband while the consumer of that information i.e. the general public, healthcare professionals and corporate should equally have the means of accessing that information in the form of computers or smart phones and affordable internet connection.

NMRAs can make effective use of internet first and foremost by having an accessible functional website which serves as a means of the organization to communicate with its stakeholders (34).

CHAPTER 3

RESEARCH METHODOLOGY

3.1 Study design

A quantitative and qualitative desktop review of websites was conducted using a tool adapted from previous studies with 20 assessment criteria for the evaluation of MRA websites (5, 23, 24). These were divided into two categories, website design including functionality and website content. Some criteria had sub-criteria that allowed for a more detailed assessment, for example pharmacovigilance, information for pharmaceutical applicants and user-friendliness criteria. The criteria were set up as a score of either a 'Yes' (information is available) or 'No' (information is not available) except for the 'Language' and 'Website downloading speed' criteria.In the assessment, the languages used and downloading speed in the website were rather recorded. Furthermore, in the case of a 'Yes' score a further commentary was made regarding the adequacy of the available information. Each criterion was defined in Appendix B. This design allowed for comparison among the websites for their functionality and content availability.

To test for functionality of interactive features and response to queries, communication was sent to randomly selected MRAs via their websites and the functionality was evaluated based on the response.

The websites of 14 MRAs were evaluated. The nine MRAs from African countries were Medicines Control Council (MCC) South Africa, Medicines Control Authority of Zimbabwe (MCAZ), and Zambia Medicines Regulatory Authority (ZAMRA) Zambia. The Tanzania Food and Drug Authority (TFDA) in Tanzania. Food and Drug Authority Ghana, Pharmacy and Poison Board (PPB)Kenya, Namibia Medicines Regulatory Council (NMRC)Namibia, Ministry of Health Botswana and the National Agency for Food and Drug administration and Control (NAFDAC)Nigeria.

The five from overseas PIC/S MRAs were; Medicines and Healthcare Products Regulatory Agency (MHRA) United Kingdom, Swissmedic Switzerland, Therapeutics Goods Administration (TGA) Australia, Health Science Authority (HSA)) Singapore and Health Canada were evaluated.

The selection of the African MRAs i.e. MCC South Africa, Ministry of Health Botswana, ZMRA, FDA Ghana, and PPB Kenya is mainly based on their involvement in regional harmonization efforts such as the African Medicines Regulatory Harmonization (AMRH) and Southern African Development Community (SADC). But they also have common challenges with regulatory infrastructure(35),access to essential medicines and insufficient capacity building in medicines regulations (36). These challenges are different to the other overseas selected countries i.e. Switzerland and UK, which are well resourced and have high capacity building initiatives to facilitate access to information. They also have high standards, consistent enforcement and are so called 'stringent' (35). Hence, it will be valuable to compare information dissemination among these countries. MCC South Africa is also the only African MRA member of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) together with Australia UK, Switzerland, Singapore and Canada. PIC/S provides an active and constructive co-operation in the field of Good manufacturing practice (GMP) (37). We wanted to compare the standard of uniformity of medicines regulatory information dissemination. This places the MCC (South Africa) in the centre of the selected MRAs as shown on Figure 3.1.

And also some of PIC/S NMRAs were also included in previous similar studies(5)as the current study i.e. (TGA)Australia, (MHRA)UK and Switzerland (Swissmedic)**.**The information gathered will be used to identify any changes or improvements since previous studies.

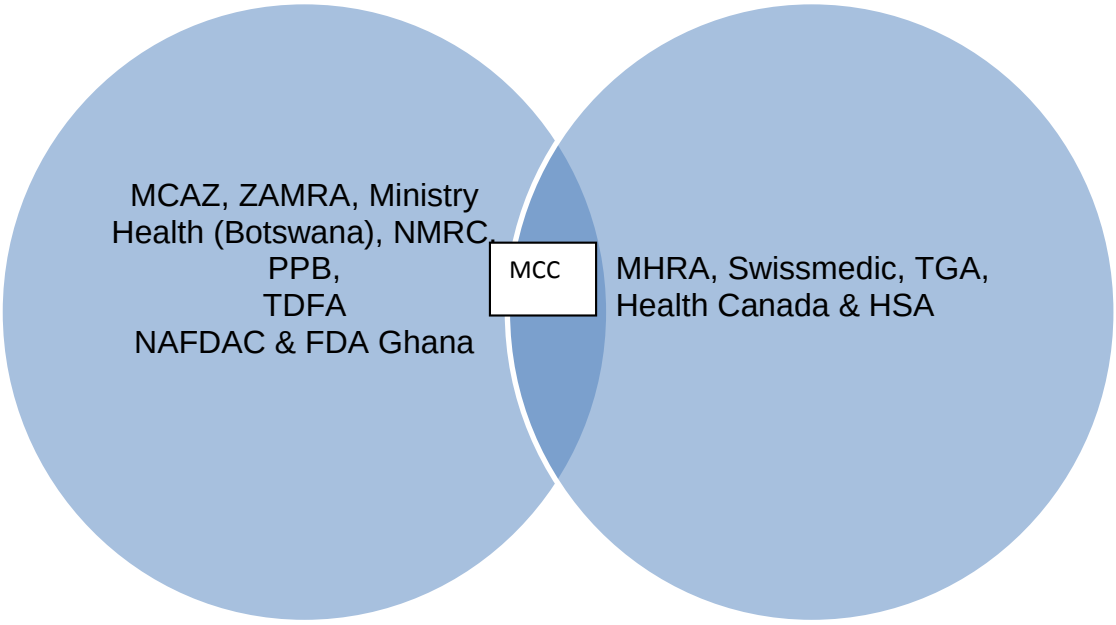


Figure 3.1 MRAs selected for this study

3.2 Data collection and analysis

Data was collected from 14 websites between October and November 2015 based on a data collection tool adapted from previous research (5, 23, 24) as outlined in Table 3.1 below. The Vitry et al. study (5) used a survey instrument which involved 16 criteria organized in 3 domains: information on marketed drugs, information on assessment of drugs and information on safety of drugs. While the tool of the first WHO 2001 (23) study used the method based on a set of key criteria (six general and 18 specific) on different types of medicines information i.e. information on how to ensure safe, efficacious use of medicines, list of registered medicines etc. A scoring ranging from zero to two (zero= inadequate, one = intermediate, two= good) was utilized to credence each criterion. A follow up study (24) used the same data collection tool with some modification of adding 'Language' as a separate criterion instead of being incorporated in the 'user friendliness' criterion. This was done to emphasize on the importance of the availability of information in both English and the national language. Other additional criterion included website downloading speed, organizational mission statement, interactive features and list of approved manufacturers, importers etc.

The current study used a data tool collection combination from both the above two studies and categorized it under two categories. First, the website design and functionality (9 criteria) which included user friendliness, navigability, relevant links contact details, information updates, services, downloading speed, search engine and site maps. Then the second category was based on the website contents(11 criterion) i.e. organization mission statement, organizational structure, news and meetings, pharmacovigilance, interactive features, regulatory guidance on legislation & regulations, guidance for pharmaceutical industry applicants, approved manufacturers , information on medicinal products (human/veterinary), medicine regulatory publications and the language used on the website. Each criterion had a sub criterion, which elaborates (define) the criteria. Refer to Appendix B.

Data were then captured on to Microsoft Excel™ and descriptive statistics were used to analyze the data.

Table 3.1 Assessment criteria used within two categories (listing done according to website user preference*)*

Website design and functionality	**Website content**
• User friendliness • Navigability • Downloading speed • Site map • Search engine • Website update/prevalence • Relevant Links • Services • Contact details	• Mission statement, • Organizational structure • News events and meetings • Pharmacovigilance reports • Interactive features • Regulatory guidance on legislation & regulations • Guidance for pharmaceutical industry applicants • Manufacturers • Information on medicinal products (human/veterinary) • Medicines regulations publications • Language

CHAPTER 4

RESULTS AND DISCUSSION

The website evaluation was conducted focusing on two categories i.e. website design including functionality and website content. Detailed information on how the evaluation was done is in section 3.2. Table 4.1 in Appendix A lists the results of the 20 criterion that were used for the five overseas countries on the adequacy of information and table 4.2 lists the results of the nine African countries.

4.1 Website design and functionality

This was evaluated using nine criteria, which are discussed in detail below.

4.1.1 User friendliness

This relates to the information being logically presented on the website and regardless of the user's education or experience they can find the information (23). Aesthetic effects are of importance i.e. graphics and videos, emotional appeal, spelling, grammar and usability (38).

Figure 4.1 illustrates the results that 4/5 (80%) of the selected PIC/S MRAs made use of aesthetic features with Swissmedic making no use of pictorials on their website. The African MRAs also scored 8/9 (88%). Botswana and Switzerland had no pictorials/images. The websites for the UK, Switzerland and Singapore, had options to change font size according to user requirements. This is valuable for readability purposes (39). Information was also presented logically and could be located in all (100%) of PIC/S MRAs websites. The African MRAs achieved 6/9 (67%).

Compared with the WHO 2001 study (23) 29 % of the 51 evaluated country MRAs had scored 'good' for user friendliness while in the 2009 study, 43% scored 'good'. Improvements from MRAs can be clearly seen that they are making an effort to enhance website user-friendliness.

In the current study spelling and grammar were correct on all (100%) oversees MRAs website and 89% for African MRAs. The Ministry of Health Botswana had at least two grammatical errors on the regulatory services home page. This creates an impression of carelessness and can affect the credibility and accuracy of the content on the website.

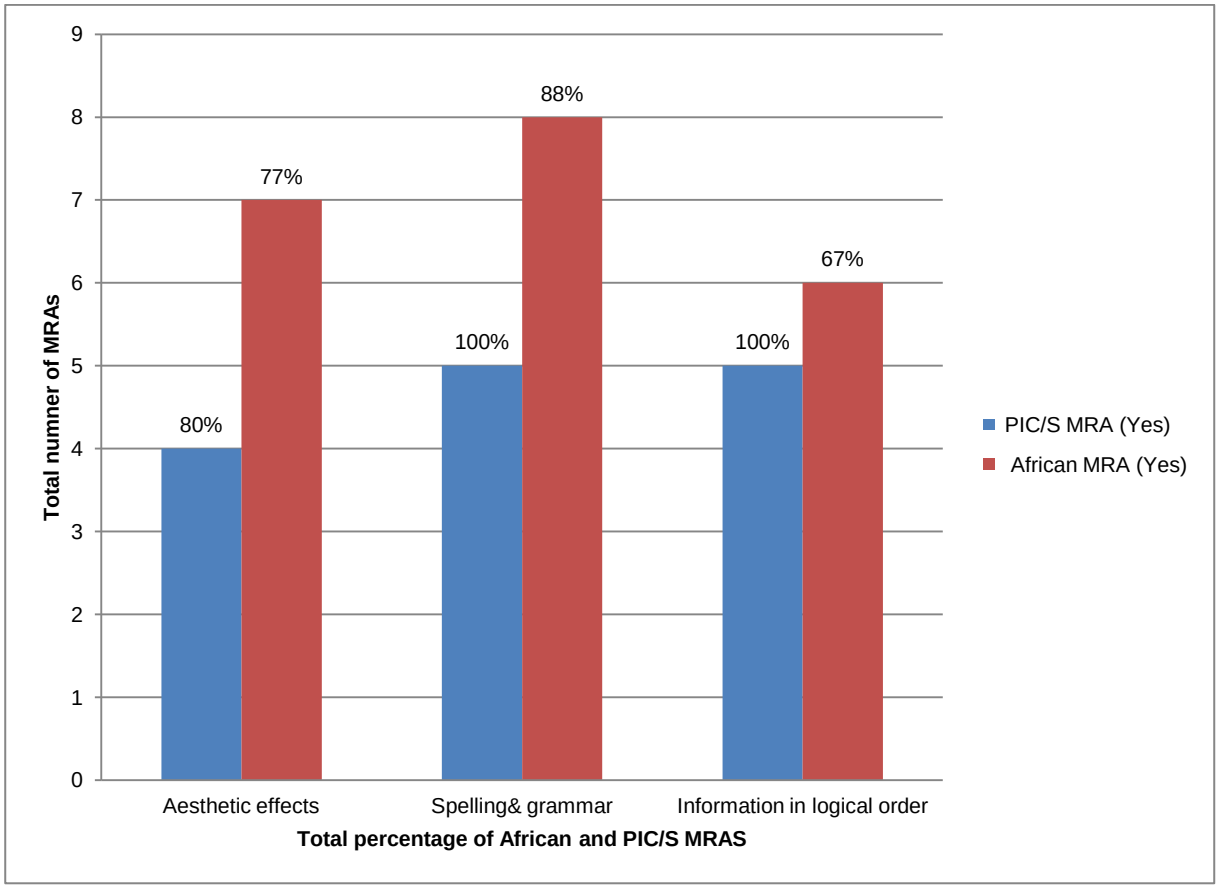


Figure 4.1 User friendliness website assessments of five PIC/S and nine African MRAs

4.1.2. Navigability

A functional website should be easy to operate and users should be able to find information within a reasonable time (39) and where there are large amounts of information on the site, a search function should be provided (23). In the 2001 WHO study (23) country MRAs scored 59% on navigability criterion and 35 % in the 2009 study (24) out of the 51 countries evaluated.

The current study found that information was found within three clicks in all websites. Navigation was achieved with a provision of a search function from page to page, link to link for, in 5/5 (100%)PIC/S MRAs websites. Navigation was found poor on the MCC (South Africa) website, the information was grouped together lacking common content or unrelated to the menu option thus making it difficult to find. Despite this finding navigability seemed to have improved since the WHO 2009 study on the selected MRAs.

4.1.3 .Downloading Speed

The home page and subsequent links (except those from web sites outside the control of the MRA) should be displayed less than 5 seconds using download speed at a connection rate of 56K per second. Google recommend the effect of site speed on user satisfaction to be included as one of the more than 200 factors that determine search rankings (40).

Table 4.3. Downloading speeds of selected MRAs at 56k/s connection rate

Country MRA	Downloading speed @ 56k/seconds
NAFDAC(Nigeria)	498.41
NMRC (Namibia)	422.08
PPB (Kenya)	283.22
FDA Ghana)	262.66
MHRA (UK)	254.76
Ministry of Health Botswana	227.99
MCAZ (Zimbabwe)	220.70
TFDA (Tanzania)	126.11
Health Canada	64.21
MCC (South Africa)	47.78
Swissmedic (Switzerland)	38.19
ZAMRA (Zambia)	7.35
TGA (Australia)	0.61
HSA (Singapore)	0.23

Table 4.3 shows the results of the downloading speed of each website using Website Optimization Tool; Web Page Analyzer 0.98. The HSA (Singapore) website had the fastest downloading speed while NAFDAC (Nigeria) had the slowest. The results could be biased as the ICT server of the user has the potential of affecting the downloading speed of the website. In addition, such an assessment is complicated because assessment should be done by accessing the websites at the same time using the same devices and internet connection on repeated occasions. Other factors are, some African countries have under developed ICT infrastructure (22). Surprisingly ZAMRA (Zambia) had the third fastest downloading speed out of the 14 MRAs. And although aesthetic features are desirable, large images and videos can slow down the website downloading speed reducing user satisfaction (38).

Studies have found that slow internet connection speed was one of the constraints to access and use of the internet (40). Other factors to be considered are the relationships between page loading time, the length of time the responsive user will stay on the website and user-website interaction (40).

4.1.4 Site map

A site map or navigation bar/menu is valuable in each website page to facilitate navigation of the website (41). Thus, the user is able to know the current page while also browsing from the navigation title. This shows how organized is the website.

The study found that all 5/5 (100%) of PIC/S MRAs website scored 'Yes' for the site map criterion, while African MRAs scored 67% (6/9).

4.1.5 .Services

This criterion relates to the relationship between the information provided on the website and products or services (23). The user is also able to identify what the functions of the service provider are through the information published on the website.

The services offered included core services such as marketing authorization (also known as registration), licensing of manufacturers, importers and exporters of medicines and continuous monitoring of the safety of medicines. Other services may include but not limited to publication of PILs, safety alerts, registered clinical trials etc.

All the African and PIC/S MRAs (100%) were found to comply with this criterion. It was also noted that these MRAs had published varied information on services they provide and thus quality of the information was not evaluated in this study.

4.1.6 *Related Links*

To help the user to reach the required information quickly and navigate easily within the website (41) links should work properly and take the user where they intend to go.

The study found that (4/5) 80% of PIC/S MRAs websites had clearly labeled links with Swissmedic being the exception. The African MRAs achieved (9/9) 100% on this criteria. Links were mostly to other government websites i.e. Department of Health, Education and WHO, which are relevant to MRA services and stakeholders.

4.1.7. Search engine

The importance of a website search engine is to enable the user to reach the required information quickly and navigate easily. These are also the elements of website usability.

In this study, (7/9) 78% of African MRAs website had their own search engine set up for searching either by key words or with an ‘A-Z’ index. MCC and ZAMRA had no search engine while the PIC/S MRAs achieved 100%. The results shows great improvement since only 14% of 51 country MRAs evaluated in 2009 (23) by the WHO, had a score result of ‘good'. The MCC website has a search function restricted only to the ‘Publications’ page and does not allow the user to fully search the entire website. This makes the website exploring experience tedious and users may end up abandoning the website.

4.1.8. Updates and relevance

A website with current, useful and relevant information adds value to its intended audience and the information fits to user’s need (41).

The study found that all MRAs included a date next to the latest uploaded communication. However, inclusion of a date does not necessarily mean real time data but can mean the date when the information was added unto the website. The latest information was highlighted by titles such as ‘Latest’ or ‘News’ for example on the homepage of MHRA (UK), TGA (Australia), and NAFDAC (Nigeria), MCC (South Africa) websites. The frequency of the website updates was no evaluated.

4.1.9. Contact details

A list of contact information also defines different functions or department of the MRA and identifying the prime lines of responsibility. (23). The existence of such communication channels for the audience with the organization, imparts confidence on the authenticity and functionality of the organization. This amplifies transparency of the MRA.

All (9/9) 100% of the African MRA websites, scored 'yes' for the inclusion of contact details. The only differences were the MCC included the specific official's names, telephone, fax numbers, and email addressing the MRA function. While the other eight MRA only listed non-person specific contact details. ZAMRA, MCAZ, TFDA, PPB, NMRC and MHB had a single point of contact. Ghana first listed the contact details of the chief executive officer followed by a one single point of contact for all other queries. The contact details of each region were also published. While the Nigeria, NAFDAC provided a single

point of contact for each Nigerian State with no person specific details. It should be noted that NAFDAC (Nigeria) have offices in all their states while most other MRAs are centralized.

The PIC/S MRAs also scored 100% 'yes'. The MHRA, Health Canada, HSA and TGA Australia had contact details of each MRA unit function but with no person specific details. The MHRA published its management board members names while Swissmedic published their Agency Council and management board members names.

4.2 Website content

4.2.1. Mission statement

A clear mission statement and organizational goals to guide the MRA is of necessity to fulfill their mission and objectives (4). In this study 5/5, (100%) of the PIC/S MRA websites outlined their mission statement and their objectives while the African MRAs scored 78 % (7/9). MCAZ (Zimbabwe) and MCC (South Africa) provided a mission statement but rather information on the MRA's history and its service units.

4.2.2. Organizational structure

Effective MRAs must have a clearly defined structural and functional linkages and a system of accountability should be operational (4).

The study showed that the organizational structure was published in 5/5 (100%) of the PIC/S MRA websites and 8/9 (89%) for the African MRAs. However, only Switzerland, Singapore, Australia had an organ gram to illustrate communication and responsibility lines while Zambia, Botswana, Kenya, Tanzania and Nigeria did not publish their organizational structure. The structures of UK, Zimbabwe, Tanzania Ghana and Namibia were narrated and it was difficult to understand from these the clear lines of accountability. In the WHO 2009 study (24) only 27 % of the 51 evaluated countries scored 'good' on this criterion. However, this is a vague finding as it does not provide the existence of the graphic organizational structures but rather complies with the definition of an organizational structure in the evaluated MRAs.

4.2.3. News, events, and meetings

The publication of news, events and meetings informs the user about the activities that the MRA engages in with its stakeholders and also shows that the MRA is transparent in its activities (23).

All 5/5 (100%)) PIC/S MRAs had information on the latest news, events, and planned meetings.HSA (Singapore) published a graphic calendar. The African MRA scored 8/9 (89%). MCAZ and PPB Kenya had an actual graphic calendar highlighting dates of their upcoming meetings or events.

4.2.4. Pharmacovigilance

Pharmacovigilance is defined as the detection, assessment, and prevention of adverse drug reactions (ADRs) after the medicine has been in use by the public (42). MRAs ideally should have a functional unit that publishes information on products for which new safety concerns have been raised and reported with allowance made for reporting procedures.

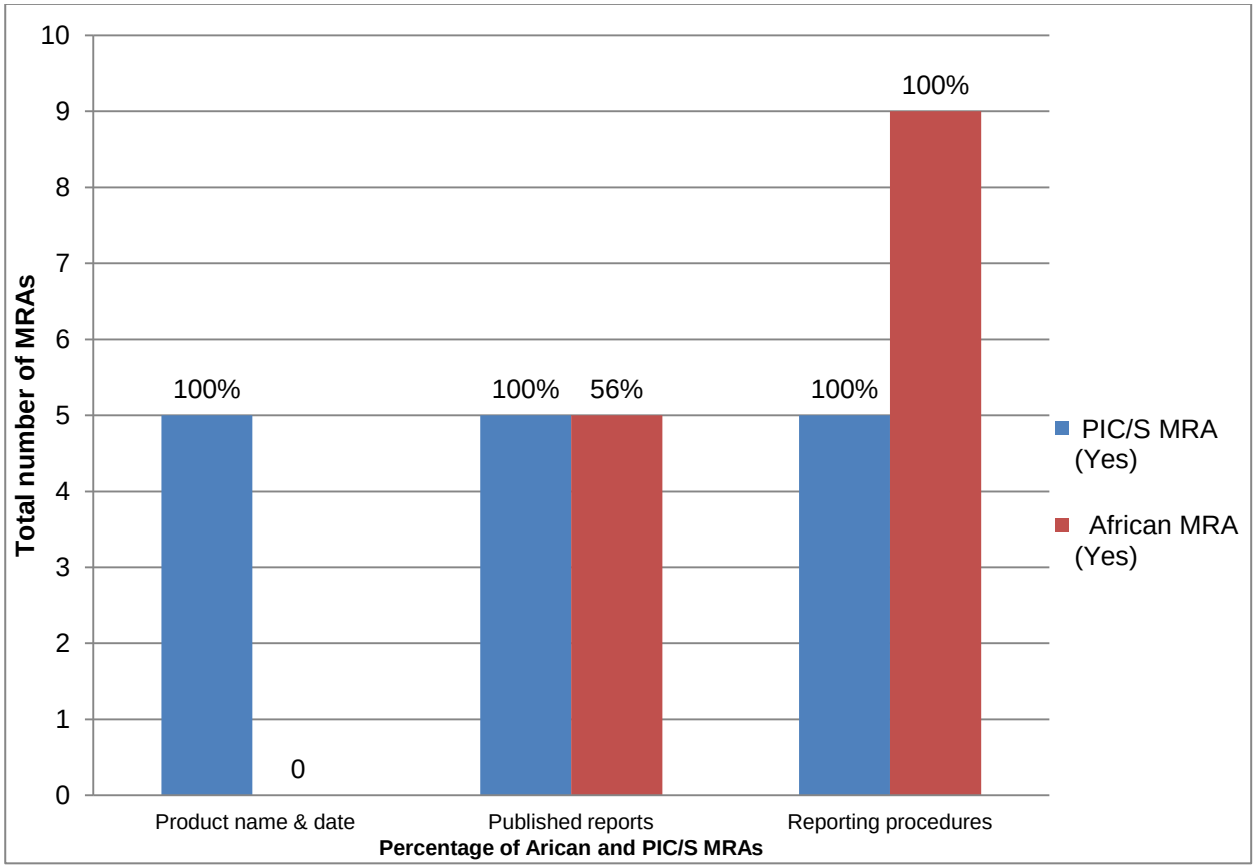


Figure 4.2 Availability of pharmacovigilance information on five PIC/S and nine African MRAs

Figure 4.1 depicts that all 5/5 (100%) PIC/S MRA websites provided pharmacovigilance information searchable by date and product name in the form of newsletters and warnings. They also provided procedures for reporting adverse drug reactions (ADR) and adverse drug events (ADE) and made the reports available. In particular, the MHRA further provided a guideline on reporting system for both the industry and consumers through the Yellow card scheme.

None of the African MRA published pharmacovigilance information searchable by date and product name. However, procedures for reporting adverse drug reactions and adverse drug events were published in all 9/9 (100%) MRA websites. In particular, FDA Ghana had a specific link for healthcare professionals that were accessible via password-protected login and then a Patient/General Public link. The latter appeared not to be functional when it was tested in the study.

PPB Kenya had two separate reporting forms. A pink form (reporting suspected poor quality medicinal product) and a yellow form (reporting a suspected adverse drug reaction) for their National Pharmacovigilance system. In addition, they had five downloadable tools such as, Desktop app and Mobile app for Android to support the pharmacovigilance reporting system.

Regarding the pharmacovigilance reports, 56% (5/9) MRAs i.e. MCC, PPB, NAFDAC, FDA Ghana and TDFA published them on their website. However, these reports were outdated. The MCC only had six archived reports dated between 2006 and 2012.On the Kenya (PPB) website, the latest report was dated November 2014; for FDA Ghana it was dated March 2015 and for NAFDAC the publication was just dated 2014. Nevertheless, NAFDAC had updated safety alerts on its homepage in the form of news flashes and warnings and not necessarily published in a formal newsletter or report. Tanzania published only two undated reports under the safety alert link.

ZMRA, MCAZ, NMRC and Botswana did not publish their pharmacovigilance reports while the NMRC (Namibia) had a sign posted link but it was not functional as the page was empty when the link was tested.

Overall for both PIC/S and African MRAs, South Africa (MCC), Canada (Health Canada), Zimbabwe (MCAZ) and Zambia (ZAMRA), pharmacovigilance information seemed more targeted to healthcare professionals than the general public.. This was reinforced by the fact that some websites had distinct links for patients and healthcare professionals.

These findings together with those from other previous similar studies show that there are still deficiencies in pharmacovigilance and reporting procedures systems. In the 2001 WHO study, 80% of the 51 assessed MRA were found to be inadequate while the 2009 study found only 18% to be 'inadequate' and 43% to be 'good' in this criterion. On the other hand the Vitry et al. 2008 study (5) found that all the six assessed MRA published safety alerts and ADR reporting procedures. However, none of these studies assessed the quality of information that should be available.

4.2.5. *Feedback form for informing the NMRA (Interactive features)*

Interactive features such as a help functions for the user, feedback forms and frequently asked questions with their answers, allows communication channels and feedback between the user and the website (43).

The study showed that 5/5 (100) of the PIC/S MRAs and (7/9) 78% of the African MRAs websites had interactive features such as an email, chat or online community and suggestion forms. NMRC Namibia and Ministry of Health Botswana did not have these features.

To test the functionality of the interactive features, websites of one of the African MRA MCC (South Africa) and one PIC/S (HSA Singapore) were selected. A feedback form from each website was completed with a question and sent to the respective MRA website. The findings were as follows; from the MCC (South Africa) website an immediate negative response from 'post master' with a statement of "a permanent mail delivery failure" was received. This meant the feedback form could not be mailed to the MCC thus users could no communicate with the organization through the website.

For Singapore (HSA) website, a question was sent regarding accelerated medicine registration and a response was received within 24 hours. The reply contained instructions on how to find the information in the website and this was verified by the information being identified by the researcher on the website. This exercise gave assurance that the user can actively communicate with the website; it also showed that the website is regularly monitored.

4.2.6. Regulatory guidance on legislation and medicines registration

A legislative framework is an important determining factor for effective medicines regulation. It should be sufficiently comprehensive and flexible to meet the objectives of drug regulation (4).

The study found that the laws, decrees and any legislative material related to pharmaceuticals were available on 5/5 (100 %) of the PIC/S MRAs and 7/9 (78%) of the African MRAs websites. Kenya only mentioned the legislation under which the MRA was established. While the Ministry of Health Botswana regulatory services did not mention any legislation regarding regulations of medicines.

4.2.7. Guidance for pharmaceutical industry applicants

When a pharmaceutical industry applicant needs to register medicines to be approved for use by the public, there are specific requirements from the MRA that must be adhered to in order to make the approval process efficient and within satisfactory periods. In order to create transparent communication lines, MRA should publish instructions, procedures and guidelines on medicines registration (4).These include but are not limited to preparation of registration of dossiers, accelerated or fast track registration procedures and guidelines. Variations (amendments), renewal, extension, transfer of marketing authorization. Application forms (that can be downloaded) and templates where required and information on (GMP) and Good Clinical Practice (GCP).

The study found that all of the PIC/S MRAs published all of the above procedures and guidelines.

While all the African countries published guidelines on the preparation of registration dossiers, however only 5/9 (56%) published information on accelerated (fast track/priority) registration guidelines and procedures. MCAZ, ZMRA, NMRC and NAFDAC did not do this. The MCC (South Africa) embedded this information in 'The General Information Guideline' document, which made it difficult to locate. The guidelines on the variations, renewal, extension, transfer of marketing authorization (medicines registration) were also found in 5/9 (56%) African MRA website. NAFDAC, ZMRA, Ministry of Health Botswana and NMRC did not publish this information.

To test for the response to queries, an email was sent to a randomly selected African MRA, TFDA Tanzania. A website response was received within 2 hours with instructions of

where to find the guideline on the website. The researcher then followed the instructions as given but the information still could not be found on the website. This showed poor navigability of the website and lack of reliability of the information published.

Application forms and required templates (that could be downloaded) were available in 8/9 (89%) of the assessed MRA websites. Nigeria (NAFDAC) had none.
Only 6/9 (67%) published guidance on GMP and GCP. The MRAs that did not comply were MCAZ, ZMRA, and NMRC. Kenya (PPB) only had guidelines on GCP available on their website.

4.2.8. *Medicinal products (human/veterinary medicines)*

Publication of information on medicinal products including human or veterinary, is one of the specific key criteria developed to assess MRA website (5, 24) as it is one of the functions of the MRA.
Publication of registered medicines by the MRA is important as it gives the public confidence that the medicines has been assessed and approved for safe use by the public. Medicines needs to be regulated are to avoid the use of ineffective, poor quality, harmful medicines which can result in therapeutic failure, morbidity and mortality (11).
Figure 4.3 shows that study found that all 5/5 (100%) PIC/S MRA websites made available a list of non-propriety pharmaceutical drug names, a list of registered medicines, patient information leaflets, and a search facility that permits the user to find items either by brand name or by holder of marketing authorization. The TGA (Australia) website is an excellent example of a searchable database for registered medicines as it included the product name, composition and use, product manufacturer and storage conditions.
However only 3/5 (60%) had a list of cancelled /withdrawn marketing authorizations. This information is important for users and prescribers to make health informed decisions and encourage further scrutiny by researchers where certain medication had been withdrawn. Only Health Canada, Swissmedic and HSA made this information available on their website.

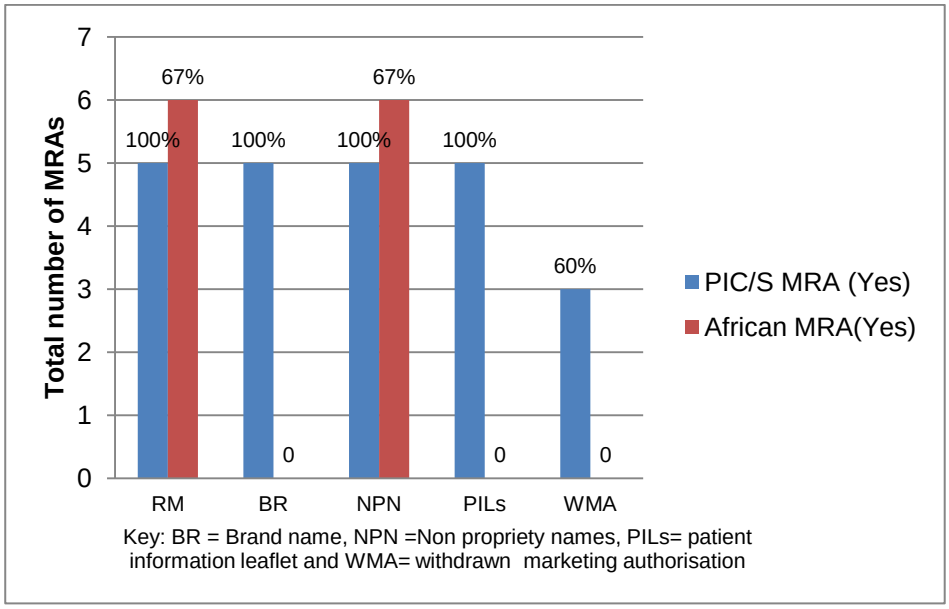


Figure 4.3: Availability of medicinal information on five PIC/S and nine African MRAs

As depicted in Figure 4.3, 6/9 (67%) of the African MRA websites made available a list of non-propriety pharmaceutical drug names and a list of registered medicines. Patient information leaflets, a search facility permitting the user to find items either by brand name with the holder of marketing authorization and a list of cancelled /withdrawn marketing authorizations were not available in all the African MRA websites.

Furthermore, in the PPB (Kenya) website, the link for the list of registered medicine is available but is not operational when it was tested.

The MCC (South Africa) only provided a database of registered medicines up to March 2015 with no search facility; MCAZ (Zimbabwe) had a database up to September 2015, NAFDAC (Nigeria) and TDFA (Tanzania) had a searchable database with no specific dates and the NMRC (Namibia) database was up to 2010. This showed lack of publishing up to date information, which could be frustrating to those who are prescribing and dispensing medicines to make informed decision on the safety, quality and efficacy of the medicine in question.

With regards to patient information leaflets (PILs),they have been developed for the purposes of informing patients about their medication regarding administration, precautions and potential side effects (44). However some previous research (45)have not been in complete favor of PILs due to low user literacy, usability, readability, patients'

emotional reactions and subsequent behavior towards them. Nevertheless, PILs still play a role in supporting medicines usage by patients regardless that none of the African MRAs published them on their websites.

Compared to the previous study, Vitry et al 2008 (5) the TGA (Australia) and MHRA (UK) still do not publish a list of cancelled or refused medicines registration. Perhaps the retention of such information is to protect data considered confidential by the pharmaceutical companies. However, such lack of information may be valuable to other MRAs and consumers, including globally identifying unregistered and counterfeits medicines. On the contrary, Health Canada published both withdrawn/cancelled post marketed and pre-marketing registration. The study also recognized a great improvement on availability of PILs from both of these MRAs that were previously not available in the Vitry et al 2008 study.

4.2.9. Approved manufacturers, Importers and exporters

The importance of this criterion is based on the MRAs fulfilling their mission of protecting and promoting public health by ensuring the medicines are manufactured in compliance with GMP. Lack of quality medicines is also exacerbated by the growth in pharmaceutical e-trade, which is unregulated and uncontrolled. This is where counterfeit, poor quality and harmful medicines can be available through exportation and importation channels (11).

Only 3/5 (60%) of the PIC/S MRAs made a list of approved manufacturers (name, addresses, and contacts) available on their websites. While 5/5 (100%) provided guidance for importers and exporters. The UK and Health Canada listed the approved medicine distributors and medicine wholesalers.

For the African MRAs, 3/9 (33%) made a list of approved manufacturers (name, addresses, and contacts) available on their websites. The MCAZ (Zimbabwe) incorporated this list within their registered medicine list. For PPB (Kenya) MRA the link for approved manufacturers is present but was not functional. Only 6/9 (67%) provided guidance for importers and exporters. while none published a list of the approved medicine distributors. Only the MCC made a list of approved medicine wholesalers available on the website.

4.2.10. Publications

This criterion is based on publication written and issued by the service provider (23), for example annual reports, quarterly reports, public assessment reports which explains the MRAs decision making on the safety of registered medicines.

Again, in this way the MRAs can be transparent about their human and financial resources. Especially those MRAs that are fully or partially funded by the pharmaceutical companies i.e. TGA (Australia), MHRA (UK) and Swissmedic (Switzerland) where bias may exist in medicines registration decision making (13, 46).

Our study found that all PIC/S MRAs published their annual reports, public assessment reports and newsletter articles or journals. The TGA (Australia), Health Canada and MHRA (UK) published public assessment reports or a summary basis of decision as it is called in Health Canada. Health Canada also published a 'drug submission performance report', which provides detailed information about the timeliness of pre-registration medicines review process against the performance service standards by the MRA. Furthermore, HSA (Singapore) published relevant scientific research articles on their websites. On the other hand, Swissmedic published a monthly journal on medicines regulatory matters.

For the African MRAs, 5/9 (56%) i.e. MCAZ, PPB, TDFA, NAFDAC and FDA Ghana published their annual reports on their website. None made the assessment reports available and at least 5/9 (56%) had newsletters or journals publications on theirwebsites. The MCC (South Africa) website publication consisted of forms, guidelines and policies. While the NMRC (Namibia), TFDA (Tanzania) and NAFDAC (Nigeria) published newsletters to which users could subscribe. The main topics covered in these newsletters were information on counterfeit products and pharmacovigilance alerts.

4.2.11. Language

The study found that all websites presented their information in English language and others had an alternative that is their national language. Most exceptionally is the Health Canada website, which made options for the user to switch between two official languages, English and French. While Swissmedic included options for user to translate the website content to either the German, French or Italian languages. Notwithstanding that, some of its website pages had section written in both English and German.

The TGA (Australia) website had an additional tool to translate from English language to at least 27 other languages such as Thai, Korean, Albanian , Hebrew and Hindi to name a few. It also provides a Google translator tool for other languages not included in their tool. TFDA (Tanzania) had their announcement of news & events in their national language, Kiswahili and the rest of the website content is in English.

The language used to publish the information on the website is of importance, as it needs to meet the needs of the user regardless of their country. Information should be available in different languages as part of the content quality dimension of a website (24, 41).This would especially be applicable to MRAs who have global stakeholders and who participate in information sharing initiatives. These may include harmonization initiatives such as the African Medicines Regulatory Harmonization Program (AMRH). The AMRH involves harmonization of technical evaluation of medicine registrations (36). Others initiatives are the International Generic Drugs Regulators Pilot (IGDRP) which aims at regulatory convergence cooperation to facilitate timely authorization and availability of safe, effective and quality generic medicines (47), also PIC/S which aims at standardization of GMP guidelines in countries such as South Africa, UK, Singapore and Switzerland (37). All these countries communicate with each regularly. The language of communication irrespective of which country the website accessed should not be a barrier to the user or to those who seek information.

CHAPTER 5

5.1 GENERAL DISCUSSION AND CONCLUSION

Overall the PIC/S and African MRA websites scored high onthe user-friendliness criteria. This is one of the important indicators in website evaluating models. An organization that makes an effort to design its website in an attractive and innovative way, can mean that potential readers may find significant information they want and not become uninterested to the site (48).

Concerning the availability of information on pharmacovigilance and medicinal products the PIC/S MRAs achieved 100% and 92% respectively. The African MRAs websites' scored 55% for pharmacovigilance publications on their websites. While 13.4 % had

information on medicinal products, with no availability of information regarding PILs and a list of non-propriety pharmaceutical drug names. This may be an indication of a lack of post -medicine registration surveillance and awareness by healthcare professionals to take the initiative to report pharmacovigilance events to the specific centers or the MRA (49).

Nevertheless, PILs as previously mentioned, are designed to support medicines users and healthcare professions, as only medicines information approved during registration process can be included in the PIL. In South Africa, most medicines are dispensed without PILs especially if medications are not dispensed in their original packaging material (pre-packed) i.e. in state hospital and primary health care settings. While Package Information leaflets (PIs) are mainly meant for health care professionals (50). Perhaps factors such as lack of resources by the MRA to ensure all dispensed and pre-packed medicines to include PILs contribute to this deficiency. Other factors may include patients not insisting on PILs due to lack of knowledge and access of to the PILs and trusting their healthcare professionals to provide them with all information (50). However, one of the findings was that they would actually prefer the PIL and its format for their medicines information. Another study in Australia (51) also identified health care professionals are still the preferred source of information for patients although patients desired PILs compared to electronic information. Thus, PILs are still a great source of medicine information whether electronically or not. The accessibility of PILs needs to be addressed by the MRA.

The current study also identified a lack of ongoing published information on medicines safety alerts and adverse drug reactions in African countries, despite the fact that procedures for reporting adverse drug reactions and adverse drug events are available in these websites. These reports are of importance as they are evidence of continuous monitoring of the safety and benefits of medicines already on the market. It also helps in development of new treatment strategies of these medicines (49).Key medicines regulatory matters such as publication of PILs, consistent and current pharmacovigilance reports still need major construction in the African countries.

Other significant findings from the study were a lack of information on approved pharmaceutical manufacturers and guidance for the pharmaceutical industry applicants in African MRAs websites. On average, they achieved 37% and 71% respectively. Compared to the PIC/S MRA websites that scored 60% and 100% respectively.

In conclusion, there is a lack of ongoing published information on medicines safety alerts and adverse drug reactions in African countries. Published pharmacovigilance reports were also scarce in these MRAs. While PIC/S MRAs share information on practices around GMP, they also seem to share common best practices in regulatory medicines information dissemination. In general, there is a poor focus on pharmacovigilance in most African countries, which would have important implications on patient safety.

5.2 Recommendations

A global set of standards on the quality of information to be accessible from MRAs needs to be established and implemented to avoid bias and inaccuracy on published information. The standard should set guidelines for minimum criteria for MRA website design, content as well as functionality.

Development and implementation of low literacy educational materials i.e. the use of pictorials, audio visuals can improve access to information on MRA websites. Financial and human resource support from stakeholders can benefit the MRA by refurbishing ICT infrastructures for the MRA to fulfill their public health mandate of ensuring the availability of information on the safety, efficacy and quality of medicines.

The recommendation is that African MRAs should prioritize adequate information dissemination via their websites to improve access by the general public, industry and health care workers.

APPENDIX A

Table 4.1 RESULTS FROM PIC/S overseas MRAs

Yes or No answer

Name of NMRA	***MHRA (UK)***	***TGA Australia***	***Health Canada***	***HSA Singapore***	***Swissmedic Switzerland***
Independent Website	*www.mhra.gov.uk*	www.tga.gov.au	www.hc-sc.gc.ca	www.hsa.gov.sg	www.swissmedic.ch

USER-FRIENDLINESS					
Most pages are designed attractively making use of aesthetic effect.	*YES*	*YES*	*YES*	*YES*	*NO*
Spelling and grammar are correct.	*YES*	*YES*	*YES*	*YES*	*YES*
Information is presented logically and can be located	*YES*	*YES*	*YES*	*YES*	*YES*
NAVIGABILITY					
Users can get the information they need within a reasonable number of clicks (preferably three or fewer)	*YES, 2 clicks*	*YES, 1 click*	*YES, 3 clicks*	*YES, 2 clicks*	*YES, 3 clicks*
Users can move from page to page, link to link	*YES*	*YES*	*YES*	*YES*	*YES*

DOWNLOADING SPEED					
Home page and subsequent links are displayed in up to 4 to 5 seconds.	254.76s	*0.61s*	64.21s	0.23	*38.19*
SITE MAP					
Site map shows logical lines and organization of the site.	*YES*	*YES*	*YES*	*YES*	*YES*
It shows clearly how to navigate through all pages.	*YES*	*YES*	*YES*	*YES*	*YES*
Users can easily find out where to go and how to get there.	*YES*	*YES*	*YES*	*YES*	*YES*
SERVICES					
Site offers information related to the NMRA	*YES*	*YES*	*YES*	*YES*	*YES*

Name of NMRA	***MHRA UK***	***TGA(Australia)***	***Health Canada***	***HSA(Singapore)***	***Swissmedic(Switzerland)***
RELEVANT LINKS					
Links to sites that are worthwhile and appropriate for the intended audience.	*YES*	*YES*	*YES*	*YES*	*NO*
Clearly labeled and identified purpose.	*YES*	*YES*	*YES*	*YES*	*NO*
Grouped in some type of logical order	YES	YES	YES	YES	NO
Current/unexpired and should operate efficiently	*YES*	*YES*	*YES*	*YES*	*NO*
SEARCH ENGINE *The site has its own search engine set up for searching either by key words or with an 'A-Z' index. It also permits searches for other sites.*	*YES*	*YES*	*YES*	*YES*	*YES*
UPDATES AND PREVALENCE					
Up-to-date information	*YES*	*YES*	*YES*	*YES*	*YES*
CONTACT INFORMATION					
Contact persons with names, telephone, fax numbers, and email for each MRA function	*YES, but not person specific*	*YES, but not person specific*	*YES but not person specific*	*YES but not person specific*	*YES, only single point of contact*

Name of NMRA	***MHRA UK***	***TGA Australia***	***Health Canada***	***HSA Singapore***	***Swissmedic Switzerland***
WEBSITE CONTENT					
MISSION STATEMENT					
Mission statement and purposes of the NMRA are clearly stated and easily accessible	*YES*	*YES*	*YES*	*YES*	*YES*
ORGANISATIONAL STRUCTURE					
The structure of the NMRA is available (.	*YES, but no organ gram*	*YES*	*YES*	*YES*	*YES*
An organ gram is available and complete	*YES*	*YES*	*YES*	*YES*	*YES*
NEWS ,EVENTS & MEETINGS					
NMRAs news, events, and meetings planned	*YES*	*YES*	*YES*	*YES*	*YES*
The calendar is available and updated.	*NO*	*NO*	*NO*	*YES*	*NO*
PHARMACOVIGILANCE					
Patient and health professionals can access by date and product name	*YES*	*YES*	*YES*	*YES*	*YES*
Procedures for reporting adverse drug reactions and adverse drug events	*YES*	*YES*	*YES*	*YES*	*YES*

Pharmacovigilance reports	*YES*	*YES*	*YES*	*YES*	*YES*
INTERACTIVE FEATURES					
Facility enabling any user to contact the authority	*YES*	*YES*	*YES*	*YES*	*YES*

Name of NMRA	***MHRA(UK)***	***TGA(Australia)***	***Health Canada***	***HSA(Singapore)***	***Swissmedic (Switzerland)***
REGULATORY GUIDANCE ONLEGISLATION AND MEDICINE REGULATIONS					
Laws, decrees, orders, and any legislative and regulatory material related to pharmaceuticals	*YES*	*YES*	*YES*	*YES*	*YES*
GUIDANCE FOR PHARMACEUTICAL INDUSTRY APPLICANTS					
Preparation of registration of dossiers	*YES*	*YES*	*YES*	*YES*	*YES*
Variations (amendments), renewal, extension, transfer of marketing authorization.	*YES*	*YES*	*YES*	*YES*	*YES*
Accelerated or Fast track registration procedures and guidelines.	*YES*	*YES*	*YES*	*YES*	*YES*
Application forms (that can be downloaded) and templates where required.	*YES*	*YES*	*YES*	*YES*	*YES*
Information on GMP and GCP	*YES*	*YES*	*YES*	*YES*	*YES*
MEDICINAL PRODUCTS (human/veterinary medicines)					
List of non propriety pharmaceutical drug names	*YES*	*YES*	*YES*	*YES*	*YES*
List of registered medicines & formulations	*YES*	*YES*	*YES*	*YES*	*YES*
Patient information leaflets	*YES*	*YES*	*YES*	*YES*	*YES*

Search facility that permits the user to find items either by brand name, holder of marketing authorization	*YES*	*YES*	*YES*	*YES*	*YES*
list of cancelled /withdrawn marketing authorizations	*NO*	*NO*	*YES*	*YES*	*YES*
MANUFACTURES, EXPORTERS , IMPORTERS, Distributors AND WHOLESALERS					
A list of approved manufacturers (name, addresses, and contacts)	*YES*	*NO*	*YES*	*NO*	*YES*
Importers & exporters :Guidance for importers, exporters	*YES*	*YES*	*YES*	*YES*	*YES*
Approved medicine wholesalers	*YES*	*NO*	*Yes*	*NO*	*NO*
Approved medicine distributors	*YES*	*NO*	*Yes*	*NO*	*NO*
PUBLICATIONS					
Annual rep	*YES*	*YES*	*YES*	*YES*	*YES*
Public assessment report	*YES*	*YES*	*YES*	*YES*	*YES*
Newsletter articles or journal	*YES*	*YES*	*YES*	*YES*	*YES*
***LANGUANGE**: A site should be presented in its national language and English*	*English*	*English*	*English*	*English*	*German and English*

Table 4.2. RESULTS FROM MRAs IN AFRICAN COUNTRIES

Name of NMRA	***MCC South Africa***	***MCAZ Zimbabwe***	***ZAMRA Zambia***	***MHB (Botswana)***	***NMRC Namibia***	***PPB Kenya***	***TFDA Tanzania***	***NAFDAC Nigeria***	***FDA Ghana Ghana***
Independent Website	www.mcczа.com	*www.mcaz.co.zw*	www.zamra.com	*none*	www.nmrc.com.na	www.ppbadvisory.com	www.tfda.or.tz	www.nafdac.gov.ng	www.fdaghana.gov.gh
WEBSITE QUALITY DESIGN									
USER FRIENDLINESS									
Pages are designed attractively making use of aesthetic effect.	*YES*	*YES*	*YES*	*NO*	*YES*	*YES*	*NO*	*YES*	*YES*
Spelling and grammar are correct.	*YES*	*YES*	*YES*	*NO*	*YES*	*YES*	*YES*	*YES*	*YES*
Information is presented logically and can be located	*NO*	*YES*	*YES*	*NO*	*YES*	*NO*	*YES*	*YES*	*YES*

Name of NMRA	***MCC South Africa***	***MCAZ Zimbabwe***	***ZAMRA Zambia***	***MHB (Botswana)***	***NMRC Namibia***	***PPB Kenya***	***TFDA Tanzania***	***NAFDAC Nigeria***	***FDA Ghana Ghana***
NAVIGABILITY									
Users can get the information they need within a reasonable number of clicks (preferably three or fewer)	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*
Users can move from page to page, link to link	*NO*	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*
DOWNLOADING SPEED									
Home page and subsequent links are displayed in up to 4 to 5 seconds.	*47.78s*	*220.7s*	*7.35s*	*227.99s*	*422.08s*	*283.22*	*126.11*	*498.41s*	*262.66s*
SITE MAP									
Site map shows logical lines and organization of the site.	*NO*	*YES*	*YES*	*YES*	*NO*	*NO*	*YES*	*YES*	*NO*
It shows clearly how to navigate through all pages.	*NO*	*YES*	*YES*	*YES*	*NO*	*NO*	*YES*	*YES*	*NO*
Users can easily find out where to go and how to get there.	*NO*	*YES*	*YES*	*YES*	*NO*	*NO*	*YES*	*YES*	*NO*

SERVICES									
Site offers information related to the NMRA	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*

RELEVANT LINKS									
Links to sites that are worthwhile and appropriate for the intended audience.	YES	NO	YES	YES	YES	YES	YES	NO	YES
Clearly labeled and defined purpose.	YES	NO	YES	YES	YES	YES	YES	NO	YES
Grouped in some type of logical order	YES	NO	YES	YES	YES	YES	YES	NO	YES
Current/unexpired and should operate efficiently	YES	NO	YES	YES	YES	YES	YES	NO	YES
***SEARCH ENGINE**:*									
The site has its own search engine set up for searching either by key words or with an 'A-Z' index.	NO	YES	NO	YES	YES	YES	YES	YES	YES

UPDATES & RELEVANCE									
Up-to-date information	YES	NO	NO	YES	YES	YES	YES	YES	YES
CONTACT INFORMATION									
Contact persons with names, telephone, fax numbers, and email for each MRA function	*YES, person specific for each unit*	*YES, Single point of contact*	*YES, single point of contact*	*YES, single point of contact*	*YES, single point of contact*	*YES, telephone numbers& email address for different queries.*	*YES, but not person specific. Details of the MRA headquarters and for each zone.*	*YES, only individual Nigerian states contact single point of contact.*	*YES, single point of contact for each MRA region and details of the Chief Executive Officer*

Name of NMRA	***MCC South Africa***	***MCAZ Zimbabwe***	***ZAMRA Zambia***	***MHB Botswana***	***NMRC Namibia***	***PPB Kenya***	***TFDA Tanzania***	***NAFDAC Nigeria***	***FDA Ghana***
WEBSITE CONTENT									
MISSION STATEMENT									
Mission statement and purposes of the NMRA are clearly stated and easily accessible.	*NO*	*NO*	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*
ORGANISATIONAL STRUCTURE									
The structure of the NMRA is available	*YES*	*YES*	*YES*	*NO*	*YES*	*YES*	*YES*	*YES*	*YES*
An organ gram is available and complete	*NO*	*YES*	*YES*	*NO*	*YES*	*YES*	*YES*	*YES*	*YES*
NEWS, EVENTS & MEETINGS									
NMRAs news, events, and meetings planned	*YES*	*YES*	*YES*	*NO*	*YES*	*YES*	*YES*	*YES*	*YES*
The calendar is available and updated.	*NO*	*YES*	*NO*	*NO*	*NO*	*YES*	*NO*	*NO*	*NO*

Name of NMRA	***MCC South Africa***	***MCAZ Zimbabwe***	***ZAMRA Zambia***	***MHB Botswana***	***NMRC Namibia***	***PPB Kenya***	***TFDA Tanzania***	***NAFDAC Nigeria***	***FDA Ghana***
PHARMACOVIGILANCE									
Patient and health professionals can access by date and product name (Safety& alerts)	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*
Procedures for reporting adverse drug reactions and adverse drug events	*YES, only for industry*	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*
Pharmacovigilance reports	*YES, archived between 2010 & 2012*	*NO*	*NO*	*NO*	*NO*	*YES, dated Novembe r 2014*	*YES, only 2 reports. Not dated.*	*YES*	*YES, dated March 2015*
INTERACTIVE FEATURES									
Facility enabling any user to contact the authority	*YES.*	*YES*	*NO*	*NO*	*YES*	*YES*	*YES*	*YES*	*YES*

Name of NMRA	***MCC South Africa***	***MCAZ Zimbabwe***	***ZAMRA Zambia***	***MHB Botswana***	***NMRC Namibia***	***PPB Kenya***	***TFDA Tanzania***	***NAFDAC Nigeria***	***FDA Ghana***
REGULATORY GUIDANCE ON LEGISLATION AND MEDICINE REGULATIONS									
Laws, decrees, orders, and any legislative and regulatory material related to pharmaceuticals	*YES*	*YES*	*YES*	*NO*	*YES*	*NO*	*YES*	*YES*	*YES*
GUIDANCE FOR PHARMACEUTICAL INUSTRY APPLICANTS									
Preparation of registration of dossiers	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*
Variations (amendments), renewal, extension, transfer of marketing authorization.	*YES*	*NO*	*NO*	*YES*	*NO*	*YES*	*YES*	*NO*	*YES*
Accelerated or Fast track registration procedures and guidelines.	*YES*	*NO*	*NO*	*NO*	*YES*	*YES*	*YES*	*NO*	*YES*
Forms (that can be downloaded) and templates where required.	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*	*YES*	*NO*	*YES*
Information on GMP and GCP	*YES*	*NO*	*NO*	*YES*	*NO*	*YES*	*YES*	*YES*	*YES*

Name of NMRA	***MCC South Africa***	***MCAZ Zimbabwe***	***ZAMRA Zambia***	***MHB Botswana***	***NMRC Namibia***	***PPB Kenya***	***TFDA Tanzania***	***NAFDAC Nigeria***	***FDA Ghana***
INFORMATION ON MEDICINAL PRODUCTS									
List of non propriety pharmaceutical drug names	*NO*	*YES*	*YES*	*NO*	*NO*	*YES*	*YES*	*YES*	*YES*
List of registered medicines & formulations	*YES, database up to March 2015*	*YES, database up to September 2015*	*NO*	*NO*	*YES, database up to 2010*	*NO*	*YES, no date specification on database*	*YES, no date specification on database*	*YES, no date specification on database*
Patient information leaflets	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*
search facility that permits the user to find items either by brand name, holder of marketing authorization	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*
List of cancelled /withdrawn marketing authorizations	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*
MANUFACTURERS, IMPORTERS , EXPORTERS , DISTRIBUTORS & WHOLESALERS									
A list of approved manufacturers *(name, addresses, and contacts)*	*YES*	*YES*	*NO*	*NO*	*YES*	*NO*	*NO*	*NO*	*NO*

Guidance for importers& exporters	*YES*	*YES*	*YES*	*NO*	*NO*	*NO*	*YES*	*YES*	*YES*
Approved medicine wholesaler	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*
Approved medicine distributors	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*
PUBLICATIONS									
Annual reports	*NO*	*YES*	*NO*	*NO*	*NO*	*YES*	*YES*	*YES*	*YES*
Public assessment report	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*	*NO*
Newsletter articles or journal	*NO*	*YES*	*NO*	*NO*	*NO*	*YES*	*YES*	*YES*	*YES*
LANGUANGE*: A site should be presented in its national language and English*	*English*	*English*	*English*	*English*	*English*	*English*	*Kiswahili & English*	*English*	*English*

Appendix B

Table 4.3. Definition of each criterion

Criteria	*Operational definition*
User friendliness	*Information is presented logically and clearly enough to be successfully manipulated by the intended user and is easy to find.*
Navigability	*This permits a site to be used effectively and enables the user to get to the important information. Accessibility, logical organization, and internal search engines are essential.*
Speed	*The home page and most subsequent links (except those from web sites outside the control of the NMRA) are displayed in up to 4 to 5 seconds. (Website Optimization Tool; Web Page Analyzer 0.98, will be used to assess this)*
Site map	*Adequate website map or navigation bar/menu*
Search engine	*The site has its own search engine, set up for searching either by key words or with an 'A-Z' index*
Updates	*Up to date information on the website*
Mission statement	*The mission statement and purposes of the NMRA*

Contact information	*Contact persons with names, addresses, phone and fax numbers, and email of the agency*
Organizational structure	*The structure of the NMRA(organogram) and unit responsibilities*
Services offered	*The site offers information related to the agencies objectives and products*
News, event &meeting	*The site mentions and describes news, events, and meetings planned*
Safety alerts and adverse drug reactions(Pharmacovigilance)	*Information on products for which new safety concerns have been raised, how to report adverse drug reaction the NMRA*
Feedback form for informing the NMRA (Interactive features)	*Feedback between user and website (email, online community or suggested forms)*
Regulatory guidance on legislation and regulations	*Regulatory guidance such as laws, decrees, orders, and any legislative and regulatory material related to pharmaceuticals, promotion and advertising, and e-trade should be available.*
Instructions for applicants	*Information for pharmaceutical industry applicants for registration of products*

Medicinal products (human/veterinary medicines)	*Information on authorized products in the country*
Approved manufactures	*Information or statistics on manufacturers in the country*
Imports and exports	*A list of approved wholesalers, distributors, and pharmacies*
	Guidance for importers, exporters
Links	*Links provided to other pages and sites*
Publications	*Downloadable NMRA or relevant medicine's regulator publications. The publication page can contain, for example, the NMRA's bulletin, annual report, quarterly report, cumulative list of recalls, safety alerts (and other decisions that restrict use of medicinal products), guidance materials, latest list of approved products, latest list of approved manufacturers, wholesalers, importers, distributors, medical journals, newsletters, and periodicals, etc*
Language	*National language and/or English*

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