GALVmed

Protecting Livestock – Improving Human Lives

A policy scoping study on harmonization of registration requirements for veterinary products for mutual recognition among East African community partner states

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List of acronyms

ABREMA	Burundi Medicines Regulatory Authority
AIDS	acquired immunodeficiency syndrome
AMR	antimicrobial resistance
AMRH	African Medicines Regulatory Harmonisation
ATPS	African Technology Policy Studies Network
AUCHM	AU Conference of Health Ministers
AU-IBAR	African Union Interafrican Bureau for Animal Resource
AU-PANVAC	African Union Pan African Veterinary Vaccine Centre
CC	concerned country
CGMR	Coordination Group for Mutual Recognition
DFCA	Drugs and Food Control Authority (South Sudan)
DPML	Department of Pharmacy, Medicines and Laboratories (Burundi)
EAC	East African Community
EAC-MRH	East African Community Medicines Regulatory Harmonization
FAO	Food and Agriculture Organization
GALVmed	Global Alliance for Livestock Veterinary Medicines
GDP	gross domestic product
GMP	good manufacturing practice
ICH	International Conference on Harmonisation
IVP	immunological veterinary product
KVA	Kenya Veterinary Association
MA	marketing authorization
MRF	mutual recognition framework
MRP	mutual recognition procedure
NDA	National Drug Authority (Uganda)
NEPAD	New Partnership for Africa's Development
NGO	non-governmental organization
NRA	National Regulatory Authority
OIE	World Organisation for Animal Health
PMPA	Pharmaceutical Manufacturing Plan for Africa
PPB	Pharmacy and Poisons Board (Kenya)
RC	reference country
REC	Regional Economic Community
RFMA	Rwanda Food and Medicines Authority
RPMPA	Regional Pharmaceutical Manufacturing Plan of Action
RVF	Rift Valley fever
SDGs	Sustainable Development Goals
SPC	Summary of Product Characteristics
SPS	sanitary and phytosanitary
TFDA	Tanzania Food and Drugs Authority
TWG	Technical Working Group
VICH	Veterinary International Conference on Harmonization
VMD	Veterinary Medicines Directorate (Kenya)
WHO	World Health Organization

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Executive Summary

Rationale and objectives

The East African Community (EAC) is a Regional Economic Community (REC) established by the EAC Treaty of 2000 and is made up six Partner States: Burundi, Kenya, Rwanda, South Sudan, Tanzania and Uganda. The main objective of the EAC is to foster integration and cooperation among its Partner States. In this regard the EAC, through the support of the Global Alliance for Livestock Veterinary Medicines (GALVmed), has been engaged in activities to harmonize technical requirements for veterinary vaccines registration in East Africa. These activities are expected to have an impact on agriculture and livestock production and, consequently, to contribute to food security, and to enhance trade integration and growth of the East African economy.

Harmonization of regulations in animal health and specifically in the requirements for registration of veterinary vaccine products is of utmost importance for the development of the livestock industry within the East African region. Regulatory harmonization in the veterinary sector will contribute to increased access to safe, high-quality and efficacious veterinary medical products, leading to increased livestock production and reduction in the negative effects on human health arising from zoonotic diseases. The harmonization process has led to the development of a mutual recognition procedure (MRP) in the registration of veterinary medicines, aimed at addressing the lack of a common regulatory mechanism for the control and registration of veterinary medicines within countries in the EAC. It is hoped that the harmonization of the technical requirements and use of MRPs within the EAC will improve efficiency and predictability in veterinary medicine registration systems and lead to increased access to safe, high-quality and efficacious veterinary medicines. The principle of the proposed MRP is the acceptance of an authorization for a medicinal product issued by one of the countries in a group of countries, such as the EAC Partner States, by the other countries in that group. The work on harmonization of technical requirements for veterinary medicine registration and the MRP draws its mandate from the EAC Council of Ministers' decision (*EAC/CM30/DECISION 34*) that adopted the decisions and directives of the 7th Meeting of the Sectoral Council on Agriculture and Food Security, which set up an EAC Technical Working Group (TWG) to spearhead the harmonization process in veterinary medicine registration.

GALVmed has been working with RECs in Africa since 2011 to harmonize the registration of veterinary products towards a MRP. Following the establishment of the TWG, a lot of work has been done on the technical aspects of veterinary vaccine registration. GALVmed wishes to build on its technical work by reviewing the policy requirements for the implementation of MRPs and, at the recommendation of the TWG, GALVmed supported this policy landscaping study to increase understanding of what needs to be done on the policy and legal front to enable the implementation of MRPs in EAC Partner States. The results of this study will inform GALVmed's product development, policy and advocacy, and global access strategies. It also had the goal of providing an avenue for policy dialogue with the critical actors to identify means of fostering acceleration of the adoption of the regulatory harmonization process for mutual recognition among EAC Partner States.

The policy scoping study had three main objectives:

1. To review EAC laws/regulations on regulatory harmonization insofar as they are applicable to the implementation of MRPs.
2. To review the laws and regulations in EAC Partner States to determine gaps and where alignment is needed in order to implement MRPs at the national level.
3. To identify mechanisms and strategies that will facilitate and enhance national level ratification, domestication and actual implementation of MRPs.

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Study area and methodology

The policy landscape analysis covered the six EAC Partner States: Burundi, Kenya, Rwanda, South Sudan, Tanzania and Uganda. The study involved extensive desk studies to review and analyse key policy and legal documents. The sample of respondents involved in the study included representatives drawn from the government and public sector through the members of the National Regulatory Authorities (NRAs) who are in the TWG and the Coordination Group for Mutual Recognition (CGMR), the Directors of Veterinary Services in the EAC Partner States, and legal officers from livestock departments. EAC representatives also formed part of the sample frame, as well as national and local manufacturers, practitioners, importers and distributors of veterinary medicines.
The study employed both primary data and secondary data collection methods. Data from the study were analysed using mainly descriptive statistics, depending on the specific objectives being addressed.

Summary of findings

The EAC

1. The EAC Treaty of 2000 – which established the EAC – is a legally binding document among the EAC Partner States, with the mandate to foster integration and cooperation in the EAC region.
2. *Article 108* of the EAC Treaty is a significant provision that forms the basis for harmonization of regulations for veterinary medicines registration and sets out the nature of cooperation in plant and animal diseases control within the EAC Partner States.
3. The MRP is legally binding on Partner States as anchored on the Council of Ministers' decision with reference to the functions and the effects of the Council of Ministers' decision as spelt out in Chapter 5 of the EAC Treaty.

EAC Partner States

1. All the Partner States' laws on veterinary medicine registration address and emphasize the important aspects of safety, quality and efficacy.
2. The NRAs are mandated under the line Ministries of Health dealing with human and not animal health, while the veterinary sector is largely governed by the Ministries of Agriculture.
3. The NRAs execute their mandates as laid out in the Acts. This is done through subsidiary legislation, regulations, guidelines and procedures.

Mechanisms and strategies for MRP implementation

1. A majority of stakeholders are not conversant with EAC legal provisions that support the implementation of the Council of Ministers' decision.
2. There is low or inadequate publicity and dissemination of information by the TWG on ongoing MRP activities.
3. The results show that MRP implementation has either not begun or is moderately integrated in the NRAs. Therefore, the proposed actions by the TWG on implementing MRPs have not been fully actualized.
4. The respondents involved in the study believe there is a need for more intensive sensitization among key stakeholders.
5. The respondents largely hold the view that that there is change required to align national legislation and regulations on veterinary medicine registration with the MRP. This could be attributed to a lack of understanding of the MRP concept or process.
6. Financial and technical capacities as well as stakeholder engagement were listed as major barriers to implementation of MRPs.
7. The respondents highlighted the need for stronger involvement of the EAC Secretariat in the mutual recognition initiative to support and accelerate the adoption of MRPs.

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Conclusions

The EAC

1. The harmonization of technical requirements for veterinary vaccine registration and subsequent MRPs in the EAC derives its mandate from the EAC Council of Ministers' decision (EAC/CM30/DECISION 34).
2. The MRP seeks to advance the agenda on harmonization of regulations on veterinary medicine registration within the EAC.
3. The supportive provisions of the EAC are focused on the growth and development of the agriculture and livestock sectors, which will be greatly improved by the implementation of MRPs.
4. MRPs will enhance cooperation in the control of animal diseases in the EAC.

EAC Partner States

1. The NRAs in the EAC are the main authorities mandated to undertake veterinary medicine registration.
2. The MRP is not a replacement of the national registration procedures but works in parallel with the existing national regulations on veterinary vaccine registration. An applicant may still opt to apply for market authorization in one country of the EAC, where they will only be required to use the normal registration procedures for that particular country.
3. Lack of or weak policy frameworks and legislation guiding the veterinary vaccine sector has exacerbated the problem of access to and control of veterinary medicines leading to enforcement challenges by the NRAs.
4. Effective implementation of MRPs requires the commitment of Partner States' NRAs.

Mechanisms and strategies for MRP implementation

1. Given the role played by livestock production in the continent, availability and access to safe and effective veterinary products is imperative. The use of veterinary medicines requires regulation and legislation as in all other sectors.
2. Resources are required to undertake sensitization, capacity building, and to hold TWG and CGMR activities.
3. The respondents are willing to adopt MRPs provided there is necessary capacity building, sensitization and financial and technical support towards actualizing the MRP.
4. The majority of the stakeholders are in support of the harmonization process and MRPs.

Policy recommendations

The EAC

1. The EAC Secretariat should sensitize the TWG on the processes necessary for the approximation of laws that may be carried out in order to enhance MRPs. This is in line with the general provisions of the EAC Common Market Protocol Part I, Article 47 (1), which states that the Partner States undertake to approximate their national laws and to harmonize their policies and systems, for the purposes of implementing the Common Market Protocol.
2. The EAC Secretariat should strengthen policy advocacy and stakeholder sensitization on the legal provisions that give mandate to the harmonization process and MRPs.
3. There should be targeted efforts by the EAC Secretariat and the TWG aimed at inclusivity of key players in veterinary medicine registration including representatives of veterinary services, NRAs, veterinary councils and private sector actors (applicants).
4. There is a need for active dissemination of information on MRPs through the EAC website and other relevant EAC stakeholder forums by the EAC Secretariat, the TWG and GALVmed.

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EAC Partner States

1. The NRAs should engage in disseminating the information about MRPs by publishing the harmonized technical documents on their website and communicating the availability of the MRP for applicants in the EAC.
2. GALVmed should facilitate further sensitization meetings with relevant stakeholders to create awareness of MRPs among Partner States of the EAC.
3. There is a need for clarification from the Pharmacy and Poisons Board and/or the Veterinary Medicines Directorate (VMD) on the transitional arrangements involved and its implications on the adoption of MRP in the Kenyan regulatory framework.
4. The TWG members should lead efforts in advocacy and sensitization of the MRP as an EAC-led initiative supported by GALVmed to get buy-in and ownership within their NRAs.
5. The EAC Secretariat should formally communicate to the NRAs on the EAC roadmap for implementing MRPs. The TWG should also put in place measures for the translation of the MRP harmonized documents into French to allow for smooth adoption into French-speaking countries in the EAC.
6. Capacity building on MRPs is needed across the EAC NRAs, which can be done by the respective TWG members involved in their particular NRA.
7. There is a need for GALVmed, in partnership with the NRAs, to undertake pilot programmes and activities to test the practicability of the MRP in the EAC Partner States and enable review and revisions in accordance with the regulatory frameworks in the EAC.

Mechanisms and strategies for MRP implementation

1. Intense sensitization of the private sector, who is the applicant for MAs, to ensure ownership and buy in as well as feedback on how to make the process more efficient.
2. Policy dialogue and advocacy by the EAC and GALVmed on the MRP initiative for internalization and implementation in the EAC should be undertaken at both national and regional levels.
3. Strengthening the linkages between the Partner States' NRAs and the veterinary sector players through advocacy and joint capacity building activities should be facilitated by GALVmed.
4. The TWG should develop a clear roadmap and implementation plan with clear timelines for the roll-out of MRPs in the EAC Partner States. The EAC Secretariat should put in place effective communicative channels to the NRAs so that information from the EAC MRP initiative activities is disseminated to the relevant parties in the NRAs with decision-making capacity.
5. Implementation of MRPs is highly dependent on Partner States' representatives involved in these efforts pushing the agenda within their respective departments in their home countries to create buy-in and ownership in the NRA. This would help to promote trust and confidence in adoption of these MRPs.
6. There is a need to strengthen the collaboration between private and public sector entities to ensure effective implementation of MRPs.
7. Sensitization of the private sector and NRAs to also ensure the MRP is piloted properly, NRAs learn from each other, build trust and are comfortable with accepting the judgements made by their counterparts.

1 Introduction and rationale

The East African Community (EAC) is a regional intergovernmental organization made up of six Partner States: Burundi, Kenya, Rwanda, South Sudan, Tanzania and Uganda. Established by the EAC Treaty of 2000, the EAC seeks to widen and deepen economic, political and socio-cultural integration and cooperation among Partner States in various key strategic areas for their mutual benefit. With a combined gross domestic product (GDP) of US$110 billion and an estimated population of over 143.5 million people in 2014, the EAC's goal is to improve the quality of life of the people of East Africa through increased competitiveness, value added production, trade and investments (EAC, 2014).

Trade integration is a major pillar in the success of Regional Economic Communities (RECs) in Africa, as noted by the Abuja Treaty of 1991, which stipulated the following targets for African countries with regard to trade integration:

(a) By 2007 – stabilization of tariff and non-tariff barriers, customs duties and internal taxes in each REC; schedules for the removal of such barriers; harmonization of customs duties; strengthening of sector integration and coordination and harmonization of the activities of the RECs.

(b) By 2017 – establishment of a free trade area and customs union in each REC. Indeed, the Africa Union has more recently agreed to establish an African Continental Free Trade Area by 2017 (United Nations Economic and Social Council, 2015).

Agriculture, and particularly livestock production, is a major contributor to food security and the economy of the EAC. A large proportion of the population in East African Partner States, like other countries in sub-Saharan Africa, rely on agriculture both as a subsistence and income-generating activity. Livestock production largely contributes to meeting nutritional needs and sustainable agricultural development; given that agriculture is the primary source of food for a majority of households in East Africa. According to the latest EAC statistics (EAC, 2015a), the livestock population in East Africa has been on a steady increase and the data as provided by the EAC Partner States for the different types of livestock population is shown in Table 1.1.

Table 1.1 **Livestock population by type, '000 head**

Livestock	Partner States	YEAR									
		2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Cattle	Burundi	396	43	479	472	554	596	645	609	646	689
	Tanzania	18,398	18,755	19,100	19,798	19,210	19,210	21,257	21,125	24,300	
	Uganda				11,409	11,751	12,104	12,467	12,840	13,020	13,623
	Kenya					17,500	17,500	17,500	17,500	17,500	17,500
	Rwanda	1,077	1,122	1,147	1,194	1,219	1,335	1,143	1,135	1,132	
	EAC	19,871	20,311	20,726	31,873	50,234	50,745	53,012	53,209	56,598	
Sheep	Burundi	242	266	292	282	292	296	308	440	488	426
	Tanzania	3,536	3,556	3,600	3,562	3,600	3,600	6,397	5,715	8,100	
	Uganda										
	Kenya					17,100	17,100	17,100	17,100	17,100	17,100
	Rwanda	464	695	704	718	743	799	828	2,673	2,703	
	EAC	4,242	4,517	4,596	7,974	25,251	25,416	28,363	29,769	32,328	
Goats	Burundi	1,194	1,438	1,402	1,617	2,698	2,163	2,480	2,489	2,514	2,348
	Tanzania	13,050	13,330	13,600	13,052	13,701	13,701	15,244	15,085	16,300	
	Uganda				12,450	12,823	13,208	13,604	14,012	14,614	14,011
	Kenya					27,700	27,700	27,700	27,700	27,700	27,700
	Rwanda	1,340	1,331	1,368	2,519	2,735	2,971	2,970	807	799	
	EAC	1,584	16,099	16,370	2,638	59,657	59,743	61,998	60,094	61,927	
Pigs	Burundi	169	178	189	167	203	245	272	404	444	540
	Tanzania	1,200	100	1,200	1,600	1,869	1,869	1,900	1,581	2,400	
	Uganda				3,184	3,280	3,378	3,496	3,583	3,673	3,584
	Kenya					335	335	335	335	335	335
	Rwanda	347	527	570	586	602	684	706	989	1,011	
	EAC	1,716	1,905	1,959	5,537	6,289	6,511	6,693	6,893	7,863	
Poultry	Burundi	945	1,142	1,315	1,524	1,591	1,719	1,857	2,449	2,571	2,953
	Tanzania	5000	53,000	53,000	5000	58,000	58,000	42,667	42,667	66,000	
	Uganda				37,404	38,557	39,714	40,904	42,131	43,395	44,698
	Kenya					31,800	31,800	31,800	31,800	31,800	31,800
	Rwanda	2,109	1,776	1,867	2,217	2,848	4,081	4,421	4,688	4,803	
	EAC	5,054	55,918	56,182	97,145	132,796	135,314	121,649	123,735	148,569	

Source: EAC (2015)

Introduction and Rationale

1.1 Animal health and animal diseases

The livestock sector continues to face a number of challenges despite the clear dependence on livestock production by EAC Partner States for nutritional and economic reasons. Livestock keeping, practiced largely by pastoralists as well as mixed farmers, forms a significant proportion of the agricultural GDP and the national GDP of EAC Partner States. As shown in Table 1.2, livestock production contributed close to 20% of the agricultural GDP of Uganda and up to 52% in Kenya in 2008 with a contribution of 8% to 17% of the respective national GDPs (Gerber, 2010).

Table 1.2 **Livestock contribution to GDPs in the EAC**

Country	Share of agricultural GDP in total GDP (%)	Share of livestock GDP in Ag GDP (%)	Share of livestock GDP in total GDP (%)
Kenya	19.9	52.4	10.4
Tanzania	45.0	27.9	12.6
Uganda	42.5	19.8	8.1

Source: (Gerber, 2010)

The threat posed by animal diseases to animal production, and the indirect effects on human health, are a major global concern. In their systematic review of Rift Valley fever (RVF) epidemiology, Nanyingi et al. (2015) found that RVF epizootics and epidemics in livestock and humans have occurred periodically and recurrent epidemics have been reported for the last 60 years in sub-Saharan African countries, including countries in East Africa. Between 2006 and 2007, Sudan, Kenya, Somalia and Tanzania suffered outbreaks that led to substantial losses of livestock and over 900 human deaths. In response to the threat posed by livestock diseases like RVF in the EAC, there is a need for health management and control of animal health diseases involving the use of veterinary medicines and vaccines.

According to the World Organisation for Animal Health (OIE), more than 90% of the diseases recorded occur in Africa, the treatment and control of which invariably involves, in part, the administration of veterinary medicines (OIE, 2008). The use of these veterinary medicines for the control and management of animal diseases within the EAC region is, however, constrained by issues relating to veterinary drug misuse and the presence of substandard and counterfeit veterinary drugs in the market. According to the Kenya Veterinary Association (KVA, 2014), arid and semi-arid lands in Kenya, home to a significant proportion of the country's livestock, suffer from veterinary drug misuse that affects the health and well-being of animals and hurts the livestock trade both in local and international markets. The persistent occurrence of antimicrobial resistance (AMR) and food safety concerns in livestock production are also major problems that affect the administration of veterinary medicines (KVA, 2014). The issue of AMR is a growing global concern that threatens the achievement of Sustainable Development Goals (SDGs) and requires a global response, as evidenced by the high-level commitment by world leaders at the 71st session of the UN General Assembly who pledged to address the root causes of AMR across multiple sectors, especially human health, animal health and agriculture, in order to curb the spread of infections that are resistant to antimicrobial medicines. Countries reaffirmed their commitments to develop national action plans on AMR, based on the Global Action Plan on Antimicrobial Resistance – the blueprint for tackling AMR developed in 2015 by the World Health Organization (WHO) in coordination with the Food and Agriculture Organization of the United Nations (FAO) and the World Organisation for Animal Health (OIE) (UN General Assembly, 2016).

The significance attached to livestock production has led to the increased use of veterinary medicines and vaccines targeted at reducing the problems of infectious diseases that significantly reduce yields and benefits associated with livestock farming. The increased use of veterinary medicines and vaccines in the region greatly reduces the persistent threat of livestock diseases and is driven by the increased demand by livestock keepers to maximize on the potential benefits of livestock keeping. In this respect, it is hoped that accelerated access to quality, safe and efficacious veterinary medicines and vaccines will curb livestock diseases and consequently bolster livestock production as well as being an avenue to alleviate poverty and create wealth among livestock farmers.

The growth and development of the veterinary medicines and vaccines market due to increased local production and imports of veterinary medicines and vaccines within the East Africa region suggests the need for more stringent, effective and efficient regulation and control of veterinary medicine products. Thus, procedures now exist for the registration, distribution and control of these products in Kenya, Uganda and Tanzania while Burundi, Rwanda and South Sudan are working towards developing regulations to ensure the quality, safety and efficacy of the veterinary medicines and vaccines within their borders. The existing legislative and policy frameworks of the EAC Partner States provide a foundation for setting up regulatory authorities to enforce the regulations on all aspects of veterinary practice, including veterinary medicine registration.

1.2 Harmonization of regulations

(a) Global perspective

Harmonization of regulations involves the creation of common standards across internal markets among RECs and trade blocks. The International Conference on Harmonisation (ICH) has, over recent decades, been involved in ongoing efforts to harmonize regulations in the control of human medicines.

Globally, the control of drug quality and trade has become highly sophisticated because of the emerging regulatory needs of the pharmaceutical sector and, therefore, the need for regulatory harmonization in drug evaluation (Handoo *et al*., 2012).

The increased globalization in the development, manufacture, marketing and distribution of medical products and technologies in recent years has led to growth of the supply and demand chains in veterinary medicines and vaccines. This has seen similar regulatory harmonization activities in the veterinary sector, aimed at harmonizing veterinary medicine and vaccine testing and standards through the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The VICH is a trilateral (EU/Japan/USA) programme aimed at harmonizing technical requirements for veterinary product registration. It was officially launched in April 1996 and its primary mandate is targeted at establishing and maintaining quality, safety and efficacy standards in registration of veterinary medicines through harmonized technical requirements and at the same time to minimize the use of test animals and costs of product development (VICH, 2016).

According to Chapter 3.4 of the World Organisation for Animal Health (OIE) Terrestrial Code, good veterinary governance is a recognized global public good which is of crucial importance for the member countries of the OIE and, therefore, the harmonization of regulations is a key element in achieving good governance. There exist frameworks and guidance on how countries can achieve sound veterinary drug management with respect to the responsibilities of national governments, veterinary services, manufacturers, retailers and users of veterinary medicines and vaccines.

Introduction and Rationale

(b) African perspective

The African Union Commission has been engaged in human medical products regulatory harmonization efforts under the African Medicines Regulatory Harmonisation (AMRH) initiative in the domain of human health. The initiative is implemented in collaboration with the New Partnership for Africa's Development (NEPAD) Agency and Pan-African Parliament. This is in line with the Pharmaceutical Manufacturing Plan for Africa (PMPA) developed as a result of the adoption of the African Union (AU) Assembly Decision 55 (Assembly/AU/Dec.55 (IV)) by the AU Conference of Health Ministers (AUCHM) in April 2007. The decision was taken during the Abuja Summit in January 2005 and mandated the African Union Commission (AUC) to develop the PMPA within the framework of the NEPAD (AU, 2016). This programme has led to the development of the AU Model Law for Medical Products Regulation and Harmonization in response to challenges related to weak, outdated or non-coherent legislative frameworks, slow medicine registration processes and subsequent delayed approval decisions, inefficiency and limited technical capacity.

It is hoped that this model will address these challenges and contribute to increased access to safe, quality and efficacious medical products and technologies in the continent. The work of AMRH is guided by three focus areas: policy alignment, regional integration and harmonization, and human and institutional capacity development (NEPAD, 2016).

The African Union, through the Interafrican Bureau for Animal Resource (AU-IBAR), is also leading in the harmonization of veterinary laws and regulations across various RECs in Africa. AU-IBAR is currently working to strengthen veterinary governance through the harmonization of veterinary legislation for better regulation of veterinary medicines, in collaboration with FAO, OIE and African RECs including the EAC.

(c) EAC perspective

EAC Partner States embarked on a programme for Medicines Regulatory Harmonization (EAC-MRH) programme with the objective of improving access to safe, efficacious and good quality medicines. The EAC-MRH programme, which deals with human medicine, was launched in Tanzania in March 2012 and seeks to harmonize medicines regulation systems and procedures in accordance with national and international policies and standards. It is meant to improve the process of registering new drugs in the EAC market in order to increase availability of essential medicines in the region and enhance free movement of medicines within the region.

The EAC-MRH programme was mandated under the EAC Treaty: Chapter 21, Article 118 on Regional Cooperation on Health where one of the key policy priorities is the harmonization of medicines registration and regulation (EAC MRH, 2015). The long-term goal of the EAC-MRH programme is to harmonize Partner States' medicines policies and laws and develop a mutual recognition framework (MRF) and an information sharing policy for regulatory decisions. The EAC-MRH programme implementation was started following the approval of harmonized medicines registration guidelines, requirements and procedures by the 29th meeting of the EAC Council of Ministers in September 2014 and subsequent commencement on the use and domestication by EAC Partner States from 1st January 2015 (EAC MRH, 2014). One of the specific objectives of the EAC-MRH programme is the establishment of a framework for joint assessment and approval of medicinal product applications for registration and inspections of medicine manufacturing sites, and to ensure that these assessments are integrated into national regulatory decision-making.

On the veterinary front, the EAC with support from GALVmed has also led the process of the harmonization of technical requirements for the registration of veterinary vaccines in the region.

Harmonization of regulations in animal health and specifically in the registration of veterinary medicines is of utmost importance for the development of the livestock industry within the East Africa region and beyond. Regulatory harmonization in the veterinary sector will contribute to increased access to safe, quality and efficacious veterinary medical products, leading to increased livestock production and reduction in the negative effects to human health arising from zoonotic diseases. It is a unique approach to bringing together the regulatory authorities and stakeholders in the veterinary industry in the region to deal with issues of scientific and technical aspects of veterinary drug and vaccine registration (New Vision, 2013). The development and improvement of regional collaboration in the registration of veterinary medicines offers an opportunity to effectively support institutions and maintain mechanisms that promise the safe circulation and distribution of registered veterinary medicines within the EAC.

The EAC-MRH initiative for registration of human medicine differs from the EAC-MRP initiative for veterinary medicine registration in that in the EAC-MRH programme there is provision for joint inspections which may pose logistical challenges to coordinate. The MRP provides for Partner States to recognize each other's inspection and assessment, which is far more practical and efficient.

1.3 EAC mutual recognition procedures (MRPs)

(a) Background and rationale

The concept of mutual recognition is based on the principle of agreement of two or more countries to recognize one another's processes or actions. Under the frameworks of mutual arrangements, Partner States within economic communities are able to exchange information and work towards the adoption of best practices on standards and qualifications (World Customs Organization, 2011). It is, therefore, necessary that legislation and policies of Partner States within a REC be aligned with the mutual recognition arrangements to facilitate implementation.

GALVmed, enlisting the support of the EAC Secretariat, has been engaged in activities towards the harmonization of technical requirements and the development of a MRP within EAC Partner States. This is in a bid to curb problems related to inefficiencies and unpredictability in the systems for registering veterinary medicines which result in insufficient supply of quality veterinary medicines. It is hoped that the harmonization of the technical requirements and use of MRPs within the EAC will improve efficiency and predictability in the veterinary medicine registration systems and lead to increased access to quality, safe and efficacious veterinary medicines. The expected long-term impact of these efforts in harmonization of veterinary medicine registration is reduced livestock morbidity and mortality.

Under the MRP in East Africa, Partner States will recognize the dossier assessment, inspection and registration of one country **(the reference country[1])** to be equivalent to that of a Partner State **(concerned countries[2])** of the EAC (Cowan, 2015). The MRP provides a general scientific framework including basic methodology, technical requirements, ethical principles as well as regulatory aspects for the registration of veterinary medicines in EAC Partner States.

The proposed MRP is aimed at addressing the lack of a common regulatory mechanism for the control and registration of veterinary medicines within countries in the EAC. It provides for harmonized technical requirements for the registration of veterinary medicine across the EAC Partner States. It is important to note that the proposed MRP has been developed with veterinary vaccines in mind, but it will also be useful in the registration of veterinary pharmaceuticals.

1 The reference country (RC) is the country that the applicant for a market authorization decides to use to submit the dossier and samples for testing.

2 The concerned country (CC) is any or all the other countries among the EAC Partner States that the applicant wishes to have their product registered in.

Introduction and Rationale

(b) EAC mandate in the development of MRPs

The EAC Council of Ministers adopted the MRP in the EAC in order to harmonize the registration procedures of veterinary medicines in the Community. This was pursuant to the decision and directives of the East Africa Sectoral Council on Agriculture and Food Security that adopted the following documents on 5th September 2014 in Kigali, Rwanda:

1. The Terms of Reference of the Technical Working Group (TWG) and Coordination Group for Mutual Recognition (CGMR).
2. Proposed Mutual Recognition Procedure (MRP).
3. Summary Table of Steps for Mutual Recognition Procedures.
4. Proposed Guidelines for Technical Documentation required for a Registration Dossier of an Immunological Veterinary Product (veterinary vaccines).
5. Structure for a Registration Dossier for veterinary vaccines.

The EAC Sectoral Council on Agriculture and Food Security further directed the EAC Secretariat to constitute the Technical Working Group (TWG) and the Coordination Group for Mutual Recognition (CGMR).

The Secretariat, with technical and financial support from GALVmed, convened a meeting in March 2015, in Arusha, Tanzania, to constitute the TWG and the CGMR. In the Arusha meeting, it was agreed that a number of Standard Operating Procedures (SOPs) be developed to facilitate the operationalization of the EAC-MRP initiative.

The decision of the Sectoral Council on Agriculture and Food Security was adopted by the EAC Council of Ministers on 28th November 2014 in Nairobi, resulting in decision number EAC/CM30/DECISION 34.

(c) Application process under MRPs

The MRP is a process that enables applicants to seek marketing authorizations (MAs) simultaneously from EAC Partner States by submitting a single application instead of submitting several separate applications to the NRAs of the different EAC Partner States. The control and regulation of veterinary product registration and the prerogative to grant MAs is still vested in the NRAs of Partner States after satisfaction by the authorities that the submitted application is in compliance with their harmonized national registration requirements.

To facilitate efficient and effective implementation, the TWG has harmonized technical requirements that will see identical requirements in EAC Partner States for applicants, allowing the NRAs to keep up with the timelines as envisioned in the MRPs.

The MRP application process makes submission of applications easier, simpler and cost-effective, resulting in faster veterinary medicine registration.

Mutual recognition may either be followed for extensions to other Partner States of an existing licence[3] or for a new veterinary medical product[4]. The MRP will rely heavily on the output documents of the TWG that are harmonized and standardized in agreement with representatives of NRAs from the EAC Partner States. Harmonized guidelines to be followed by applicants developing vaccines and compiling dossiers have already been produced by the TWG. These Guidelines, together with other harmonized technical documents, namely: the Dossier Structure, an Application Form and templates for a Summary of Product Characteristics (SPC) and container labelling, were all developed by the TWG. They are controlled documents which will be coded then entered into the NRA's and EAC's document management system where they will be maintained and revised as necessary (Cowan, 2015).

3 Where one or more countries have issued a licence for the product and the applicant wishes to register it in other countries.

4 Where a new product has not yet been registered and the applicant wants to register it in several countries at the same time.

The operational process for application under a MRP is as described in the text box below.

Figure 1.1 **Application process under the MRP**

Description of the MRP process

- Whenever an Applicant contacts a Reference Country asking for a veterinary medicine dossier to be assessed through the MRP, the CGMR member in that Regulatory Authority is to be notified.
- The CGMR member notifies the MRP Coordinator who allocates a MRP reference number to the application for tracking purposes and advises all the CGMR members of the name of the product, the MRP reference number, the countries to which the application is being made (CCs) and the country that is acting as the Reference Country (RC). Such communications can be made by secure e-mail.
- When the dossier is ready for submission the Applicant sends identical, complete dossiers to the RC and all the CCs. The CGMR members notify the MRP Coordinator (MR-C) when they have received the complete application and fees.
- The RC appoints an assessor who reviews the dossier and prepares an Assessment Report (AR). If the application is for a new product, the RC may ask the Applicant to respond to any questions arising during the preparation of the report. If the Applicant has provided new information to the RC, this new information must also be sent to the CCs.
- The RC assessor sends their Assessment Report to the MR-C who ensures that it is forwarded and safely received by the CGMR members in each of the CCs for forwarding to the appropriate assessor.
- Assessors in the CCs do not need to re-assess the dossier; however, they or an expert in their country may review the dossier if they have a special interest in the product. If they wish to review and make comments on the dossier they must do this within the agreed timelines for MRP (e.g. within 30 days of receiving the dossier).
- If questions are raised by day 120 they are collated and forwarded to the Applicant by the RC and copied to the MR-C who forwards them to the CCs via the CGMR members.
- If no questions are raised the MRP moves directly to point 5. The MRP clock can stop at this stage and national MAs are issued within the agreed timeframe, i.e. 30 days.

- **= 150 days from clock start to approval/mutual recognition stage.**

If questions are raised by day 120 the Applicant responds to them as soon as possible and not later than day 180. The CCs receive copies of the responses via the MR-C and their assessors have an opportunity to discuss them with the RC. This process must be completed and agreement reached within 30 days. If the CCs are satisfied with the responses, they notify the MR-C who informs the Applicant, who may be asked to revise the draft SPC and packaging text that was submitted in the application dossier then forward these to the RC and CCs for approval. This process should be completed within 20 days. National MAs should then be issued within the agreed timeframe, e.g. 30 days.

Figure continued on page 18 ›››

Figure 1.1 **Application process under the MRP** *(continued)*

- **≤ 230 days from clock start to approval/mutual recognition stage**

Most communications between the MR-C and CGMR can be made by e-mail or conference calls. On rare occasions, if the RC and CCs cannot reach an agreement by day 180 on one or more issues a further 20 days are added to try to resolve the outstanding issues. If there is still no agreement after this time, it should be possible for the Applicant to request an appeal. This could take the form of a presentation to the TWG and their experts of the Applicant's justifications for their responses to certain questions. They may present additional information to support their case. If they do this, the additional information must be provided to TWG members and their experts prior to day 210 to enable a useful discussion to take place at the appeal meeting. The TWG members may ask the Applicant to leave the room during their deliberations. The decision of the TWG should be binding and respected by the RC and CCs.

Thus, MRP ends at point 6; however, the duration of the MRP depends on the following factors:

- If no questions are raised the clock can stop at day 120 = true mutual recognition
- If questions are raised and responses accepted the clock stops at or before day 200
- If questions are raised and agreement is not reached by day 200, the appeal delays the clock stop until day 260.

The process is summarized in the flow chart on pages 19 and 20.

Source: (Technical Working Group, 2017)

Mutual Recognition Procedure for Veterinary Vaccines in the EAC

Short and Medium Processing Times (150 – 230 days)

GALVmed
Protecting Livestock – Improving Human Lives

Application process begins here

Applicant selects Reference Country (RC). Sends them dossier and list of Concerned Countries (CCs)

RC checks dossier. During pre-submission meeting RC advises Applicant if product is eligible for Mutual Recognition Procedure (MRP) and if Good Manufacturing Practice (GMP) inspection is necessary

When dossier compliant, Applicant sends identical Application & Dossier to CCs

CCs screen application then advise Mutual Recognition Coordinator (MR-C) that dossier has been received

DAY 0: **CLOCK STARTS** → RC starts to prepare Assessment Report ↔ (RC and Applicant discuss and resolve any issues)

DAY 90:
RC sends Assessment Report to CCs to review (Takes up to 30 days)

DAY 120:
Two scenarios

SCENARIO 1
CCs inform RC they have no objections and confirm approval

CLOCK STOPS

DAY 150:
Marketing Authorisations issued by RC and CCs

SCENARIO 2
CCs send their own questions to RC

DAY 150: Applicant sends responses to questions to RC and CCs

DAY 180:
RC and CCs review and accept responses

Applicant sends final SPC and labelling to RC and CCs

DAY 200:
RC and CCs confirm approval
CLOCK STOPS

DAY 230:
Marketing Authorisations issued by RC and CCs

Number of days to process scenario 1	
7 days	
90 days	
30 days	
30 days	
150 days to complete scenario 1	

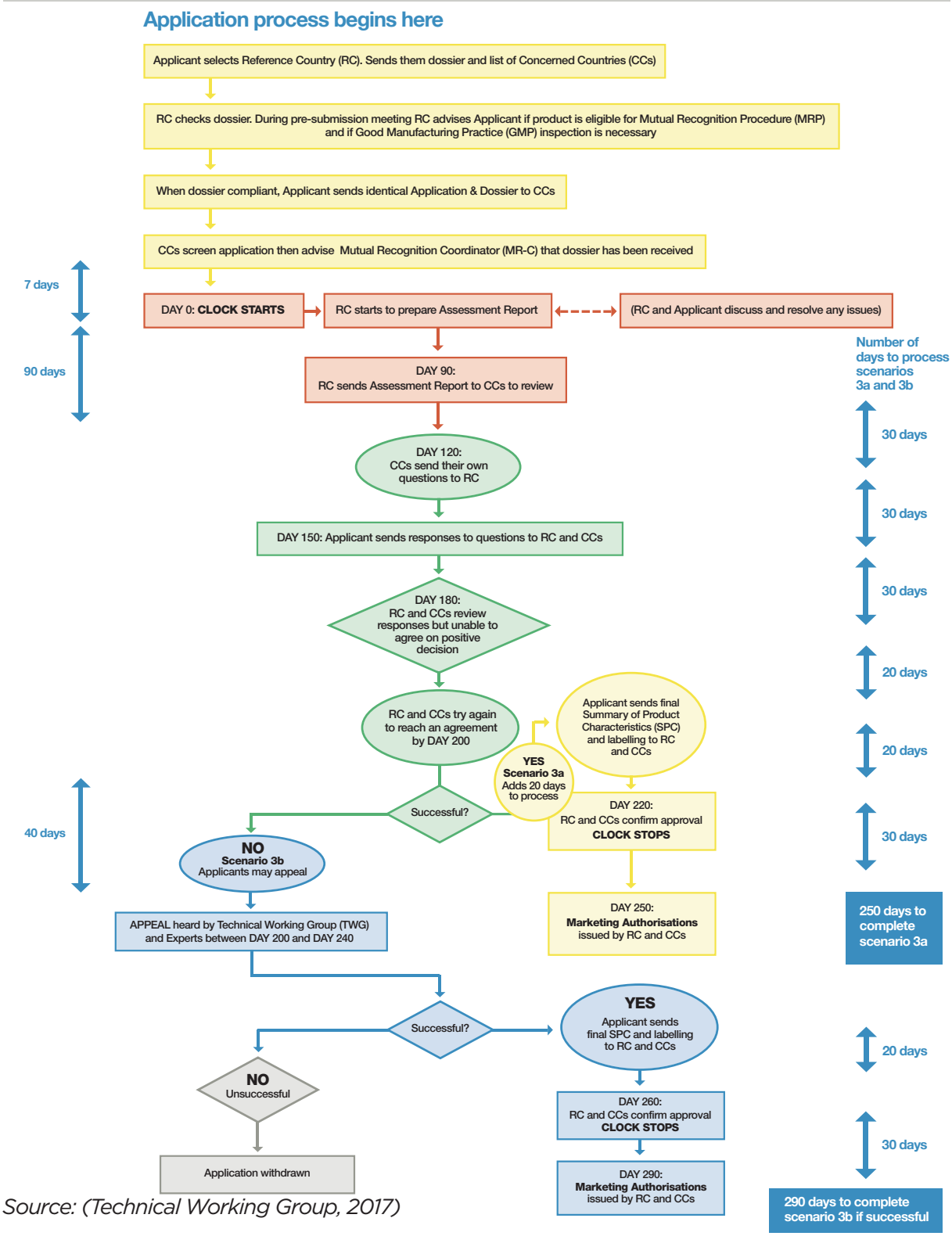
Number of days to process scenario 2	
30 days	
30 days	
30 days	
20 days	
30 days	
230 days to complete scenario 2	

Source: (Technical Working Group, 2017)

Introduction and Rationale

Mutual Recognition Procedure for Veterinary Vaccines in the EAC

Extended Processing Times (250 – 290 days)



Source: (Technical Working Group, 2017)

2 Purpose and objectives

Since 2011, GALVmed has been working with RECs to harmonize the registration of veterinary vaccines towards the use of MRPs. In the EAC, progress has been made on technical aspects, notably: standardization of key documents, and building the capacity of dossier assessors and GMP inspectors in national drug authorities. GALVmed wishes to build on its technical work by reviewing the policy requirements for the implementation of MRPs. During the 8th meeting of the TWG held in March 2016, it was recommended that GALVmed support a landscaping study to increase understanding of what needs to be done on the policy/legal front to enable the implementation of MRPs in EAC Partner States.

The results of this study will inform GALVmed's product development, policy and advocacy and global access strategies. It also had the goal of providing an avenue for policy dialogue with the critical actors to identify means of fostering acceleration of the adoption of the regulatory harmonization process for mutual recognition among EAC Partner States.

The policy scoping study had three main objectives:

1. To review EAC laws/regulations on regulatory harmonization insofar as they are applicable for the implementation of MRP.
2. To review the laws and regulations in EAC Partner States to determine gaps and where alignment is needed in order to implement MRP at the national level.
3. Identify mechanisms and strategies that will facilitate and enhance national level ratification, domestication and actual implementation of MRP.

See ANNEX 1 for the specific objectives and research questions for the study.

3 Methodology

3.1 Study location

The policy landscape analysis covered the six EAC Partner States: Burundi, Kenya, Rwanda, South Sudan, Tanzania and Uganda. The study involved extensive desk studies to review and analyse key policy and legal documents relating to policies for the harmonization of registration of veterinary products for MRPs in the EAC.

3.2 Sampling procedure

The sample of respondents involved in the study included representatives drawn from the government and public sector through the National Regulatory Authority (NRA) members in the Technical Working Group (TWG) and the Coordination Group for Mutual Recognition (CGMR), Directors of Veterinary Services in the EAC Partner States, and legal officers from livestock departments. The EAC representatives also formed part of the sample frame as well as national and local manufacturers, practitioners, importers and distributors of veterinary medicines. The sample size consisted of 56 respondents from the six EAC Partner States, of which only 15 responses were obtained. These were: 3 in Kenya, 7 in Uganda, 3 in Tanzania, 2 in Burundi. Of those interviewed, the TWG representation was as follows: 1 from Kenya, 1 from Uganda, and 1 from Burundi.

See ANNEXES 2, 3 and 4 for the sampled respondents, list of respondents, and TWG and CGMR members, respectively.

3.3 Data collection

A semi-structured interview schedule was developed by the ATPS and validated by GALVmed to ensure that the key objectives of the study were agreed on before the fieldwork commenced. Specifically, in Kenya, Tanzania and Uganda, both primary data and secondary data collection methods were employed.

Interviews with key informants were undertaken in Kenya, Uganda and Tanzania while the semi-structured interview schedules were sent out to respondents in all six Partner States as primary data sources. On the other hand, in Rwanda, Burundi and South Sudan, desk studies to review relevant policy documents and literature were conducted. These differentials in approach in the different countries were based on the fact that the earlier countries listed are in more advanced stages of being capable of implementation of the harmonization decision than the latter countries. During the course of the study, information was gathered through attendance at TWG meetings on mutual recognition and the EAC seminar on regional harmonization of legislation on regulation of veterinary medicines and biologicals. These two forums involved the major stakeholders in veterinary medicine registration and served the purpose of focus group discussions. These focus group discussions and respondent interviews were a measure to triangulate the data obtained from extensive desk studies carried out on the subject.

Secondary data sources were obtained from:

- national laws
- national regulations
- national guidelines
- national policy documents
- EAC legal provisions
- EAC policy documents
- international directives and reports
- relevant publications, journals and papers on veterinary medicine registration.

The study also explored international initiatives and trends, particularly those under the auspices of the World Organisation for Animal Health (OIE), the African Union Interafrican Bureau for Animal Resource (AU-IBAR) and other relevant organizations and how they relate to the initiative of the EAC Partner States on MRPs.

The documents analysed and reviewed as secondary data sources included the EAC-MRH, having been adopted and in the process of implementation among EAC Partner States. This was done for comparison with the proposed MRPs for veterinary medicines against the existing MRH for human medicines.

Primary data sources included:

- Interviews with key informants were undertaken in Kenya, Uganda and Tanzania.
- Semi-structured interview schedules were sent out to respondents in the EAC Partner States.

This was done in order to identify suitable mechanisms and strategies that will facilitate and enhance national-level ratification, domestication and actual implementation of MRPs in the region, and a five-point Likert-type scale was used to obtain data from the respondents. In each case, a mean cut-off point of ≥3.0 was set to identify statements that were significant. Any statement with mean score of 3.0 and above is considered significant and an effective strategy/mechanism while any statement with a mean score of <3.0 is considered not significant and hence not an effective strategy/mechanism.

See ANNEX 5 for the Questionnaire.

3.4 Data analysis

Data from the study was analysed using mainly descriptive statistics depending on the specific objectives being addressed.

Note: Work packages and terms of reference for the study are available in ANNEXES 6 and 7, respectively.

Photo credit: GALVmed/Karel Prinsloo

4 Analysis, results and discussion

This section presents the analysis, findings, discussions and policy recommendations in three sections as per the three study objectives.

4.1 Review of EAC laws and policies

The MRP initiative is an EAC-driven process that is facilitated by the EAC Secretariat and is founded in the EAC policies that aim at enhancing mutual cooperation among EAC Partner States. This is in line with the EAC integration agenda on social, economic and political goals. The EAC draws its mandate from the EAC Treaty, which established the EAC.

The institution of the EAC is governed by policies and legal statutes that are anchored on the EAC Treaty to help in advancing its goals and objectives. The focus of the analysis was on the EAC Treaty together with the policies in the EAC that support harmonization processes for mutual cooperation in the veterinary sector.

Table 4.1 shows the laws and policies in the EAC as an institution that support harmonization of technical requirements in veterinary medicine registration and MRP adoption in EAC Partner States.

Table 4.1 **List of legislation and policies in the EAC that influence the MRP**

S/No.	EAC legislation and policy	Section supporting harmonization	Year of enactment/review
1	East African Community Treaty	Chapter 1, Article 4 Chapter 1, Article 5 Chapter 1, Article 6 (f) Chapter 5, Article 14 Chapter 5, Article 16 Chapter 18, Article 108 Chapter 21, Article 118 (d)	2000
2	East African Common Market Protocol	Chapter 2, Article 4 Chapter 2, Article 5 Chapter 8, Article 45 Article 47 (1) and (2)	2009
3	4th EAC Development Strategy 2011/2012 to 2015/2016	Chapter 4	2011
4	EAC Vision 2050	Chapter 3.2	2016
5	The EAC Regional Pharmaceutical Manufacturing Plan of Action (RPMPA)	Objective of the RPMPA	2012–2016
6	EAC Strategic Interventions	› Agriculture and Rural Development Strategy › EAC strategy on control and prevention of transboundary animal and zoonotic diseases	2016
7	Report of 30th Meeting of the Council of Ministers	Part 4.1.1, Agriculture and food security	2014

Table 4.1 gives a summary of the different legislation and policies of the EAC Partner States that may influence MRP adoption and implementation. The proposed EAC-MRP is anchored on the statutes of the EAC Treaty of 2000 and the subsequent EAC protocols, plans, strategies and directives from EAC policy organs that are all legally mandated under the EAC Treaty. The legislative and policy environment of the EAC provides for mutual recognition under the following policy and legal documents.

4.1.1 The EAC Treaty

The EAC Treaty, which was ratified by Partner States of the EAC and came into force on 7th July 2000, is a binding document among these Partner States.

Chapter 1, Article 5 of the Treaty lists its objectives, where *Objective 1* gives impetus to the integration process. It states that: "The objectives of the Community shall be to develop policies and programmes aimed at widening and deepening cooperation among the Partner States in political, economic, social and cultural fields, research and technology, defence, security and legal and judicial affairs, for their mutual benefit" (EAC Treaty, 2000).

The subsequent provisions under the objectives, including the establishment of a customs union and a common market, pave the way for further integration of Partner States and provide a robust justification for the harmonization processes in various sectors including the agriculture and food security sector of the EAC. In *Article 6 (f),* cooperation for mutual benefit is listed as a fundamental principle of the EAC Treaty and this gives weight to the efforts into harmonization of technical requirements and MRPs for veterinary medicines registration.

The Council of Ministers is a policy organ of the EAC and its functions are spelt out under *Chapter 5, Article 14*. The decision adopted by the Council of Ministers as regards the MRP is based on *Function 3(d)* that gives them mandate to make regulations, issue directives, take decisions, make recommendations and give opinions in accordance with the provisions of the EAC Treaty; and *Function 5* that states: "The Council shall cause all regulations and directives made or given by it under this Treaty to be published in the Gazette and such regulations or directives shall come into force on the date of publication unless otherwise provided therein" (EAC Treaty, 2000).

Chapter 5, Article 16 gives the Effects of Regulations, Directives, Decisions and Recommendations of the Council of Ministers on Partner States and all other relevant institutions as subject to the Treaty. It states that: "Subject to the provisions of this Treaty, the regulations, directives and decisions of the Council taken or given in pursuance of the provisions of this Treaty, shall be binding on the Partner States, on all organs and institutions of the Community other than the Summit, the Court and the Assembly within their jurisdictions, and on those to whom they may, under this Treaty, be addressed" (EAC Treaty, 2000).

The MRP, therefore, is legally binding on EAC Partner States as anchored on the Council of Ministers' decision with reference to the functions and the effects of the Council of Ministers' decision as spelt out in *Chapter 5* of the EAC Treaty.

Chapter 18, Article 108 of the EAC Treaty on agriculture and food security sets out the nature of cooperation in plant and animal diseases control within the Partner States. *Article 108* of the EAC Treaty is a significant provision that forms the basis for harmonization of regulations for veterinary medicines registration with respect to the growth and sustainability of the agricultural sector in the EAC. The roles and functions of the Partner States in *Article 108* are listed as:

(a) Harmonize policies, legislation and regulations for enforcement of pests and disease control.

(b) Harmonize and strengthen regulatory institutions.

(c) Harmonize and strengthen zoosanitary and phytosanitary services inspection and certification.

(d) Establish regional zoosanitary and phytosanitary laboratories to deal with diagnosis and identification of pests and diseases.

(e) Adopt common mechanism to ensure safety, efficacy and potency of agricultural inputs including chemicals, drugs and vaccines.

(f) Cooperate in surveillance, diagnosis and control strategies of transboundary pests and animal disease.

The cross-border control of animal diseases through harmonized and strengthened institutions, policies and regulations is expected to lead to improved outcomes in livestock production and consequently contribute to agriculture and food security in the EAC.

Chapter 21, Article 118 (d) of the EAC Treaty on health, social and cultural activities touches on harmonization of drug registration procedures so as to achieve good control of pharmaceutical standards without impeding or obstructing the movement of pharmaceutical products within the Community. This serves to safeguard the human health aspect that is affected by animal diseases.

The adoption of the MRP, with respect to *Articles 108* and *118*, will serve to ensure safety, efficacy and quality in veterinary medicine registration in the EAC and hence safeguard both animal and human health.

4.1.2 EAC Common Market Protocol

The establishment of the EAC Common Market Protocol is pursuant to provisions of *Articles 76* and *104* of the EAC Treaty. *Chapter 2, Article 4* of the Common Market Protocol sets out the objectives of the EAC Common Market and *Objective 3* specifically speaks to efforts in harmonization. It states that: "In order to realize and attain the objectives provided for in this Article, the Partner States shall co-operate in, integrate and harmonize their policies in areas provided for in this Protocol and in such other areas as the Council may determine in order to achieve the objectives of the Common Market." There is also support for agricultural sustainability in *Chapter 2, Article 5* on the scope of cooperation, paragraph *3 (m)*; sustainably develop and promote agriculture and ensure food security in the Community. *Chapter 8, Article 45*, on cooperation in agriculture and food security, states that the Partner States shall undertake to *3 (g)* cooperate in the control of plant and animal pests, vectors and diseases.

Under *Part 1* of the general provisions of the EAC Common Market Protocol, *Article 47 (1)* states that the Partner States undertake to approximate their national laws and to harmonize their policies and systems, for purposes of implementing this Protocol and *47(2)*; the Council shall issue directives for purposes of implementing this Article.

The EAC Common Market Protocol came into force in July 2010 following ratification by all five EAC Partner States. With the implementation of the Common Market Protocol, a number of trade barriers between the EAC Partner States have been eliminated which would render cross-border supply of medicines between EAC Partner States much more convenient. It could also facilitate greater harmonization of laws and policies among EAC Partner States.

4.1.3 4th EAC Development Strategy 2011/12–2015/16

The EAC Development Strategy 2011/12–2015/16 outlines broad strategic goals of the EAC as well as the specific targets to be achieved during the period as stipulated. *Chapter 4* sets out the regional development priority areas where development objective (b) of full implementation of the common market and (f) of development and strengthening of the regional productive sectors, support the efforts in harmonization of regulations within the agriculture and livestock sector. The implementation of the EAC Development Strategy would, therefore, promote the adoption and domestication of the MRP as a measure to prevent and control animal diseases and consequently increase livestock production and trade in livestock among the EAC Partner States as aligned with the Development Strategy.

4.1.4 EAC Vision 2050

The EAC Vision 2050 lays out a broad perspective in which the region optimizes the utilization of its resources to accelerate productivity and the social well-being of its people. It portrays a future East Africa with rising personal prosperity in cohesive societies, competitive economies, and strong inter-regional interaction (EAC, 2015b).

The EAC Vision 2050, in *Chapter 3.2* in its Agriculture, Food Security and Rural Development pillar, outlines the livestock development sector emphasizing the need for Partner States to be committed to investing in improvement of the livestock sector in order to contribute to the reduction of poverty and enhance income generation in rural areas. Through the implementation of MRPs in veterinary drug regulation, the EAC Partner States can show their commitment towards improving the livestock sector and poverty alleviation.

4.1.5 The EAC Regional Pharmaceutical Manufacturing Plan of Action (RPMPA)

The EAC Regional Pharmaceutical Manufacturing Plan of Action 2012–2016 (RPMPA) supports the development of local veterinary medicine manufacturing capacity in order to provide a sustainable source of affordable quality medicines in the EAC. This regional Strategic Plan is designed to achieve the objectives of the Community as set out in *Article 118 (g)* of the EAC Treaty in which the Partner States agreed to cooperate in the development of specialized health training, health research, the pharmaceutical products and preventive medicines and is in line with the African Union Pharmaceutical Manufacturing Plan of Action (PMPA).

The implementation of this Strategic Plan will complement the ongoing EAC regional initiatives on developing a common regional medicines policy, which will include harmonization of drug registration procedures as stipulated in *Article 118 (d)* of the EAC Treaty.

The objective of the RPMPA is put down as the development of a regional roadmap to guide the EAC towards evolving an efficient and effective regional pharmaceutical manufacturing industry that can supply national, regional and international markets with efficacious and quality medicines. This is aligned with the objectives of the MRP of ensuring access to safe, quality and efficacious veterinary medicines.

4.1.6 EAC strategic interventions[5]

The Agriculture and Rural Development Strategy outlines the strategic interventions identified for the acceleration of agricultural sector development in the EAC Partner States. The primary focus areas of the strategy, which influence MRP implementation, are on improving food security and increasing intra- and inter-regional trade and commerce (EAC, 2015c. The EAC offers strategic intervention through the following mechanisms: improving food security by improving the performance and increasing agricultural productivity and returns to farmers, and increasing intra and inter-regional trade and commerce by increasing productivity, trade and cooperation.

The EAC strategy on the control and prevention of transboundary animal and zoonotic diseases also gives weight to the implementation of the MRP which will allow access to veterinary medicines for the control of transboundary animal diseases within the EAC.

5 The EAC strategic interventions are available online on the EAC website.

4.1.7 EAC Council of Ministers' decision

The EAC Council of Ministers' decision; *EAC/CM30/DECISION 34* on the harmonization of technical requirements for mutual recognition is found in the Report of the 30th Meeting of the Council of Ministers[6], Part 4 of the Report on Productive and Social Sectors under *4.1.1* of Agriculture and food security. It states that:
The Council took note of the decisions of the 7th Meeting of the Sectoral Council on Agriculture and Food Security (*EAC/CM 30/Decision 34*). This decision by the Council of Ministers is based on the decisions and directives made by the Sectoral Council as contained in a report *Ref: EAC/SR/170A/2014.*

The institutions of the EAC are structured as the executive, legislative and judicial organs along with a permanent secretariat. The executive arm of the EAC is comprised of the Summit of Heads of State of EAC Partner States, the Council of Ministers from each Partner State responsible for EAC affairs, and the Coordination Committee of Permanent Secretaries from each Partner State. The East African Legislative Assembly (EALA) is the legislative branch of the EAC and The East African Court of Justice (EACJ) serves as the judicial branch (EAC,2015c). For the purposes of harmonization of law and policy among EAC Partner States, the executive and legislative branches of the EAC are most relevant.

In this respect, the Council of Ministers' decision carries a lot of weight, given that the Council acts as the policy organ of the EAC and meets at least twice a year. The Council is responsible for taking major policy decisions, introducing bills in the EALA, gives directions to the Partner States and all subordinate organs and institutions of the EAC except the Summit, EALA and EACJ. It can also make regulations, issue directives, take decisions, make recommendations and give opinions in accordance with the Treaty. It can also establish Sectoral Council of Ministers on specific matters under the Treaty as well as Sectoral Coordination Committees. Thus, on specific subjects like health, education, etc., the Council can establish Sectoral Council of Ministers responsible for these departments in the Partner States, as well as Sectoral Coordination Committees of secretaries from these departments in the Partner States.
The regulations, directives and decisions of the Council are binding on the Partner States and all organs and institutions of the EAC except the Summit, EALA and EACJ.

4.1.8 Summary of findings on EAC laws and policies

1. The EAC Treaty of 2000 that established the EAC is a legally binding document among the EAC Partner States with the mandate to foster integration and cooperation in the EAC region. Therefore, the EAC Partner States are expected to participate in activities that advance the integration processes across the economic, social and political pillars of the EAC. Consequently, as per the provisions of the EAC Treaty, the Partner States are expected to adopt and ratify the EAC resolutions and decisions.
2. There are EAC regional legal and policy documents that are anchored on the provisions of the EAC Treaty which enhance cooperation and integration through laid out plans and strategies. These legal documents include the EAC Common Market Protocol and the Customs Union Protocol.
3. The MRP is legally binding on Partner States as anchored on the Council of Ministers' decision with reference to the functions and the effects of the Council of Ministers' decision as spelt out in Chapter 5 of the EAC Treaty. The EAC Council of Ministers' decision is legally mandated based on the functions and roles as prescribed in the EAC Treaty and Common Market Protocol.

6 The EAC Council of Ministers met in Nairobi on the 2014 where they took note of the agriculture and food security sectoral council report.

4 The harmonization of technical requirements for veterinary medicine registration is supported by the Common Market Protocol. The objectives of the Common Market Protocol set out the areas of cooperation and integration and take special cognisance of the powers of the Council of Ministers to issue directives and decisions.

5 The growth and sustainability of the agricultural sector in the EAC will be impacted positively by the adoption of MRP by Partner States. *Article 108* of the EAC Treaty is a significant provision that forms the basis for the harmonization of regulations for veterinary medicines registration and sets out the nature of cooperation in plant and animal diseases control within the EAC Partner States.

6 The EAC has a four-year development strategy (2012 to 2016) that has a focus on strengthening the agriculture and livestock productive sectors. The implementation of the MRP would help towards achieving this goal in the EAC through the prevention and control of animal diseases, leading to increase in livestock production and trade in livestock among the EAC Partner States as aligned with the Development Strategy. The EAC Community Vision 2050 also emphasizes the need for Partner States to be committed to investing in the improvement of the livestock sector in order to contribute to the reduction of poverty and enhance income generation in rural areas. This will be bolstered by the implementation of MRP.

7 The human health aspect will also be influenced through veterinary medicine registration under MRP and, therefore, *Chapter 21, Article 118 (d)* of the EAC Treaty that touches on harmonization of drug registration procedures aimed at achieving good control of pharmaceutical standards, is applicable in the implementation of the MRP. This is because the MRP seeks to ensure the safety and quality of veterinary medicines and, by extension, limit the negative effects of animal diseases to human health.

8 There exists an EAC Regional Pharmaceutical Manufacturing Plan of Action 2012–16 (RPMPA) that supports the development of local veterinary medicine manufacturing capacity in order to provide a sustainable source of affordable quality medicines in the EAC. This will complement the veterinary aspect of veterinary medicine registration through MRP.

9 The EAC has an Agriculture and Rural Development Strategy that outlines the strategic interventions identified for the acceleration of agricultural sector development in the EAC Partner States. The primary focus areas of the strategy that influence MRP implementation is on improving food security and increasing intra- and inter-regional trade and commerce (EAC, 2015c).

10 The EAC strategy on the control and prevention of transboundary animal and zoonotic diseases also gives weight to the implementation of the MRP which will allow access to veterinary medicines for the control of transboundary animal diseases within the EAC.

4.1.9 Alignment of EAC provisions with the MRP

1 The harmonization of technical requirements of veterinary medicine registration and subsequent MRP in EAC derives its mandate from the EAC Council of Ministers' decision (*EAC/CM30/DECISION 34*). This decision, based on the analysis, is anchored on a sound legal foundation aligned with the provisions of the EAC Treaty and Common Market Protocol.

2 The MRPs seek to advance the agenda on the harmonization of regulations on veterinary medicine registration within the EAC. This is in line with the EAC provisions as stipulated in the EAC Treaty and Common Market Protocol which aim to foster integration and cooperation among the Partner States. These harmonization efforts are aligned with the overall integration agenda of the EAC. The MRP is hoped to enhance trade in livestock and livestock products among the EAC Partner States.

3 The supportive provisions of the EAC are focused on the growth and development of the agriculture and livestock sectors, which will be greatly improved by implementation of the MRP. Therefore, these productive sectoral targets are aligned with the MRP's objective of providing access to safe, quality and efficacious veterinary medicines that will lower livestock mortality and morbidity and enhance livestock production. There will also be enhanced cooperation in the agriculture and livestock sector among Partner States.

4 The EAC strategy on the control and prevention of transboundary animal and zoonotic diseases also gives weight to the implementation of the MRP which will allow access to veterinary medicines for the control of transboundary animal diseases within the EAC.

5 The need to regulate and control veterinary products in circulation within the EAC in terms of quality, safety and efficacy is also aligned to the MRP which seeks to make the process of veterinary medicine registration more efficient and cost-effective and to reduce unnecessary duplication of work.

4.1.10 Policy recommendations

1 The EAC Secretariat should sensitize the TWG on the processes necessary for the approximation of laws that may be carried out in order to enhance MRPs. This is in line with the general provisions of the EAC Common Market Protocol *Part 1, Article 47 (1)* which states that the Partner States undertake to approximate their national laws and to harmonize their policies and systems, for purposes of implementing the Common Market Protocol.

2 The EAC Secretariat should strengthen policy advocacy and stakeholder sensitization on the legal provisions that give mandate to the harmonization process and MRP.

3 There should be targeted efforts by the EAC Secretariat and the TWG aimed at inclusivity of key players in veterinary medicine registration including representatives of veterinary services, NRAs, veterinary councils and private sector actors (applicants).

4 There is need for active dissemination of information on MRP through the EAC website and other relevant EAC stakeholder forums, by the EAC Secretariat, TWG and GALVmed.

5 NRAs in the EAC should be encouraged and supported to access and adopt best practices from already established trade blocks like the EU in the implementation of mutual recognition in veterinary medicine registration.

4.2 EAC Partner States' national laws and regulations

The EAC Partner States' veterinary sectors are governed by a number of laws and policies. Veterinary medicine registration is regulated under the national laws on drugs that cater for both human and animal medicine. In the analysis of the laws that may influence the implementation of MRP in EAC Partner States, the various veterinary laws and policies were reviewed for relevance in the adoption and implementation of the MRP. The national drug laws and regulations of Partner States were analysed for areas of alignment or conflict with respect to the key aspects of MRP. The national drug laws and regulations are the fundamental statutes that are applicable in veterinary medicine registration and consequently were regarded, for the purposes of this study, as the standard document to be analysed with respect to MRP.

4.2.1 Kenya

The veterinary and livestock sector in Kenya is governed by a number of laws, policies and regulations as listed in ANNEX 6.

Veterinary medicine registration is explicitly covered under the mandate of the Pharmacy and Poisons Act. The majority of the other laws and policies that govern the livestock and veterinary sector in Kenya do not directly address veterinary medicine registration. However, there are other laws and policies in this sector that cover veterinary medicine regulation and, by extension, address certain aspects of veterinary registration.

The Animal Disease Act Rules, for instance, in *Article 9 (I)*, states that: "The Minister may make rules for the better carrying out of this Act, and in particular, but without prejudice to the generality of the foregoing power, such rules may provide for prescribing standards for locally manufactured biological and chemical products used for the control of animal disease and prohibiting the manufacture of any such product."

The *Article 16 (1)* of the Animal Disease Act gives the Minister power to prohibit the use of a vaccine or drug for the treatment of animal disease in Kenya. The provisions of this Act are aimed at establishing regulations for veterinary medicine but do not directly influence the process of veterinary medicine registration which is the focus of MRP.

The law on drug regulation that is involved in veterinary medicine registration is analysed and discussed below in the context of its applicability to the implementation of the MRP in Kenya.

Alignment of the Pharmacy and Poisons Act and MRP requirements

In Kenya, the registration of veterinary medicines is currently under the mandate of the Pharmacy and Poisons Board (PPB) under the line Ministry of Health. PPB derives its power from the Pharmacy and Poisons Act, CAP 244, Laws of Kenya. This parliamentary Act gives PPB the mandate to enforce regulations over both human and veterinary medicines.

The Pharmacy and Poisons Act does not directly influence the operationalization of the MRP because it is the primary law which only gives guidance on the regulatory set up in veterinary medicine registration. The MRP, on the other hand, is a process that is involved with the technical requirements for veterinary medicine registration.

The Pharmacy and Poisons Act under *Article 35A* speaks to the licensing for manufacture of medicinal products. Specifically, in sub-articles (1), (3) and (4) it states that:

a. "No person shall manufacture any medicinal substance unless he has been granted a manufacturing licence by the Board."

b. "No person shall manufacture any medicinal substance for sale unless he has applied for and obtained a licence from the Board in respect of each substance intended to be manufactured" and in sub-article

c. "Any person who intends to manufacture a medicinal substance shall make an application in the prescribed form for the licensing of the premises and the application shall be accompanied by the prescribed fee."

Under *Article 35B*, the Pharmacy and Poisons Act deals with compliance to good manufacturing practice (GMP) and it states the following: "Every person who is granted a manufacturing licence under section 35A shall comply with the good manufacturing practices prescribed by the Board."

These two, *Articles 35A* and *35B*, are the ones that touch on the MRP aspects of dossier submission and assessment when applying for MAs and the aspect of inspection of premises. These provisions of the Pharmacy and Poisons Act give authority to the board to exercise the mandate as stipulated in the Articles mentioned. Therefore, the MRP needs only to comply with the guidelines and regulations in use by the PPB in order for it to be aligned with the Pharmacy and Poisons Act as the primary law governing veterinary medicine registration.

Analysis, results and discussion

In this regard, the PPB has in place subsidiary legislation to guide its operations when executing its mandate. These regulations are referred to as the Pharmacy and Poisons Rules anchored under Article 44 of the Pharmacy and Poisons Act which gives the Minister the power to make rules, after consultation with the Board, with respect to the functions stipulated in the Act. The Rules have specific provisions for control of drugs and for registration of drugs. The following is an analysis of the alignment of MRP requirements with the Pharmacy and Poisons Registration of Drugs Rules:

a) Dossier assessment

The Pharmacy and Poisons Registration of drugs Rules under *Rule 3* is involved in the control of manufacture of drugs and states that: "No person shall import, manufacture for sale or sell any drug in Kenya unless that drug has been registered in accordance with the provisions of these Rules."

Application for registration of drugs is found in *Rule 4* and in its *subsections 1 and 2* states that:

(1) "An application for registration of a drug shall be in Form 1 in the Schedule."

(2) "In addition to the information required to be furnished in the prescribed form the applicant shall furnish such further information and material as may be required by the Board for the proper evaluation of the drug in respect of which the application is made."

The provisions of *Rules* 3 and 4 are aligned with requirements under MRP which proposes a simultaneous application and submission of dossiers to the reference country (RC) and concerned country (CC). Therefore, if Kenya is either the RC or in the list of CCs, the application and dossier will be in accordance with *Rule 3* and will allow the PPB the opportunity for assessment of the dossier as the NRA of Kenya.

Subsection 1 of Rule 4 prescribes the use of Form 1 in making applications while the MRP has harmonized documents developed by the TWG. It is, therefore, necessary to have the required harmonized documents reflected in the Rules for submitting applications.

b) Inspections of premises

MRP does not provide for the joint inspection of premises and, therefore, the CCs are dependent on the inspection report of the RC. *Rule 10* of the Pharmacy and Poisons Registration of drugs Rules states that: "The Board may, before issuing a certificate of registration under these Rules, cause the premises in which the manufacturing of the drug is proposed to be conducted to be inspected by inspectors appointed for that purpose, and the inspectors shall have powers to enter the premises and inspect the plant and the process of manufacture intended to be employed in the manufacturing of the drug and make a report to the Board." Based on this rule, the members of the CGMR appointed to represent PPB in the MRP process should be able to present the inspection report of the RC to the Board without contravening any guideline.

c) Appeals may be heard by the TWG and experts

Rule 6 subsection 3 states that: "If the Board is not satisfied as to the safety, efficacy, quality or economic value of the drug, it may, after providing an opportunity to the applicant to be heard, reject the application for the registration of the drug and inform the applicant the reasons for rejection in writing."

This Rule allows for appeal by the applicant and is not specific on the composition of the appeal panel. Since it specifically references the PPB, and the TWG are drawn from the different Partner States' NRAs, it, therefore, would be within the Rule if the TWG form part of the appeal panel. The MRP is aligned to this subsection in terms of who can hear appeals made by the applicant.

d) Safety and efficacy trials

Rule 9 that touches on the conditions for registration of a new drug states that:

(1) "The Board shall, before registering a new drug for which the research work has been conducted in another country and its efficacy, safety, and quality established in that country, require an investigation on the pharmaceutical, pharmacological and other aspects of the drug to be conducted and clinical trials to be made which are necessary to establish its quality and where applicable the biological availability and its safety and efficacy to be established under local conditions."

(2) "Notwithstanding paragraph (1), the Board may register a new drug and require the investigations and clinical trials specified in paragraph (1) to be conducted after its registration."

Subsection 1 of Rule 9 provides for clinical trials to be conducted even if the research work has been conducted in another country so as to establish its efficacy under local conditions. The MRP envisions a regulatory system that would allow trial reports from clinical trials conducted in other countries with similar conditions so that there are fewer clinical trials during registration. *Subsection 1* of this Rule is, therefore, not aligned with the MRP and it is necessary for the TWG to draw up harmonized guidelines on clinical trials to guide the safety and efficacy tests under MRP.

Subsection 2 that allows for clinical trials to be conducted after the registration gives room for the MRP process to keep to its proposed timelines. Therefore, the MRP can be used to register a veterinary medicine and have the clinical trials conducted after the registration allowing for both the safety and efficacy of the veterinary medicine to be tested while also reducing delay in registration.

(e) Fees

Rule 5 outlines the prescribed application fees and these are applicable to the MRP process irrespective of whether Kenya is the RC or the CC. The MRP does not propose any fees but is dependent on the fee guidelines as set out in the respective NRA. Therefore, the MRP is aligned to the provisions for application fees and its operationalization will not touch on the existing fee guidelines.

(f) Issuance of certificate of registration

Rule 6 on the issuance of certificate of registration states that:

(1) "The Board shall consider the application made under rule 4, and, if it is satisfied of the safety, efficacy, quality, and economic value of the drug, shall register the drug and issue a certificate of registration which shall be in Form 2 in the Schedule."

(2) "The Board may, while considering a drug for registration under paragraph (1), approve the details as supplied by the applicant or approve it with such amendments as it may deem appropriate in respect of the following particulars:

(a) The name under which the drug may be sold;

(b) The labelling;

(c) The statement of the representations to be made for the promotion of the drug in respect of:

i. the claim to be made for the drug;

ii. the route of administration;

iii. the dosage;

iv. the contra-indications, side effects and precautions, if any; and

v. the package size."

The requirements for the issuance of a certificate of registration are aligned to those of the MRP in considering the safety, efficacy and quality of the veterinary medicine. However, it is necessary for the harmonized documents that detail the Summary of Product Characteristics (SPC) developed by the TWG to be adopted as part of the Rules. This will enhance clarity for the applicant during the application process.

Conclusion on alignment of the Pharmacy and Poisons Act and MRP requirements

Based on the analysis of the MRP alignment with the PPB Act, it is clear that there is no direct contravention of the laws and regulations on veterinary medicine registration when registration is done under MRP. Given that the MRP is not a substitute for existing regulations but complementary to the laid down rules and guidelines, the right course of action would be to publish the MRP as guidelines alongside the existing ones. The MRP ought to be anchored on the PPB Act that gives the mandate for drug regulation in Kenya. In this regard, the TWG members representing the PPB should be able to give guidance on the laid-out procedures for publishing and adoption of new guidelines within their NRA.

The timelines set under MRP may pose a challenge in terms of adherence, considering that there are no exact timelines for the PPB operations during registration.

Status of implementation of MRP in Kenya

According to the minutes of the latest TWG meeting (2016), the Republic of Kenya is on course in domesticating the MRP guidelines and adopting the documents. Thereafter, PPB has planned to sensitize the stakeholders on the EAC MRP process on harmonization of registration of veterinary medicines.

Kenya is currently in a state of transition in terms of the impending shift of the veterinary medicine regulation from the PPB under the Pharmacy and Poisons Act to the newly created Veterinary Medicines Directorate (VMD) mandated under the Veterinary Surgeons and Veterinary Para-Professionals Act, 2011. The VMD Regulations, made under section 6 (2) (f) of the Veterinary Surgeons and Veterinary Para-professionals Act, 2011, establish the VMD and regulate the manufacture, importation, exportation, registration, distribution, prescription and dispensing of veterinary medicines (including veterinary pesticides) and the practice of veterinary pharmacy in Kenya.

The VMD Regulations spell out the functions of the VMD as, among other things: "To formulate and enforce quality assurance standards in the manufacture, distribution and use of veterinary medicines to safeguard human and animal health and the environment; in consultation with the Director of Veterinary Services, to regulate the use of veterinary medicine for the treatment of animals under the Animal Diseases Act; and to consider applications for approval for market authorization of veterinary medicines." The Directorate shall also appoint veterinary medicine inspectors.

The Veterinary Surgeons and Veterinary Para-Professionals Act (The Veterinary Medicines Directorate) Regulations were gazetted on 9th October 2015. The VMD is still in the process of being set up and is expected to take over but there was no clear information on the exact timelines.

Policy recommendations for alignment of the Pharmacy and Poisons Act and MRP requirements

1. The PPB should enhance efforts to disseminate information about MRP and effectively communicate to applicants in the private sector on the availability of the MRP for use. The PPB should hold further sensitization meetings with relevant stakeholders to create awareness on MRP.
2. There is need for policy dialogue among the legal officers in the PPB and the TWG members for sensitization on the legal ramifications of the MRP process.
3. There is need for clarification from the PPB and/or VMD on the transitional arrangements involved and its implications for the adoption of MRP in the Kenya regulatory framework.

4.2.2 Tanzania

A list of the laws and policies in the veterinary and livestock sector in Tanzania are as shown in ANNEX 7.

The laws and policies in the veterinary sector are not explicit on technical requirements for veterinary medicine registration and thus do not directly influence the technical aspects of veterinary medicine registration under MRP. However, some of the laws and policies have some peripheral regulatory mandate that may indirectly influence the uptake of MRP within the national regulatory framework of veterinary medicine regulation and registration in Tanzania as is the case for the Animal Diseases Act.

The Animal Diseases Act makes provision for the surveillance, control and prevention of animal diseases and assurance of safety and quality of livestock products. It prescribes measures to be undertaken in the event of a disease outbreak, regulation of movement of animals and their products including trade, as well as public health measures to prevent spread of diseases from animals to humans. Under *Chapter 8* on general provisions on control of animal diseases of this act, section 54 deals with restrictions to importation of animal products and empowers the director to issue licences under certain conditions as set out in the secondary regulations. Pesticides are also regulated under the Animal Diseases Act (2003); this covers not only use but also registration of products and dealers. The MRP, as a process, is aligned with the umbrella provisions of this Act regarding veterinary medicine regulation. The technical requirements for veterinary medicine registration in ensuring safety, efficacy and quality will serve the overall purpose of the Act of controlling animal diseases.

The law on drug regulation that is involved in veterinary medicine registration is analysed and discussed below in the context of its applicability to the implementation of the MRP in Tanzania:

Alignment of the Tanzania Food, Drugs and Cosmetic Act and MRP requirements

The Tanzania Food and Drugs Authority (TFDA) is responsible for ensuring that all medicines, cosmetics and medical devices are correctly evaluated for quality, safety and effectiveness before being approved for use. The Authority is mandated through the Tanzania Food, Drugs and Cosmetic Act, 2003. The responsibility for inspection and enforcement of medicines, cosmetics and medical devices is also under their mandate as well as the control of clinical trials. The TFDA handles both veterinary and human medicine regulation and enforcement.

The MRP, as proposed, is a process that seeks to enhance efficiency in the registration of veterinary medicines and not to subvert the existing regulations. The provisions regarding drugs are dealt with in *Part 4* of the Tanzania Food, Drugs and Cosmetic Act. Under *Part 4 (b)* on Registration of Drugs, Medical Devices or Herbal Drugs, there are specific provisions on the conditions for registration as contained in *Article 51* which states that: "The Authority shall approve the registration of a drug, medical device or herbal drug if it considers that the availability of that drug is in the public interest and it is safe, efficacious and of acceptable quality; and in the case of a veterinary drug in relation to its effect on the health of animals, consumers of food of animal origin, the environment and users."

This is in alignment with the MRP that also seeks to speed up the process of veterinary medicines registration while ensuring that the veterinary medicines are safe, of required quality and efficacious.

The following is an analysis of the alignment of the MRP requirements with these specific provisions in Part 4 of the Tanzania Food, Drugs and Cosmetic Act:

a) Dossier assessment

Article 52 of the Tanzania Food, Drugs and Cosmetic Act deals with the applications for registration of drugs, medical devices or herbal drugs. It states under subsection 1 and 2 that:

(1) "Every application for the registration of a drug or medical device or herbal drug shall be submitted to the Director General in the prescribed manner and shall be accompanied by application fees, samples and such other particulars as are prescribed in the application guidelines issued by the Authority, and any other information as the Authority may require from time to time."

(2) "As soon as possible after receiving an application in terms of subsection (1), the Director General shall notify the applicant that the application has been received."

Under *Subsection 1* of *Article 52*, the TFDA may require the applicant, when submitting the application, to provide information from time to time concerning their application. The MRP allows for the CC, during the application process, to raise specific queries on the application which are channelled through the MRP coordinator and to the CGMR for the CC. This would apply when the application is not the RC.

The provisions of this section are aligned to the MRP based on the MRP requirements that all documents submitted by the applicant to the RC are to be shared with the CCs for their assessment. The CGMR will act on behalf of the TFDA to notify the applicants in the case of Tanzania not being the RC. The TFDA will also be able to assess the submitted dossiers and application to ensure they meet the requirements of their NRA.

b) Inspections of premises

The inspection of premises is addressed under *Part 4 (b)* in *Article 51 (c)* that states: "The Authority shall approve the registration of a drug, medical device or herbal drug if it considers that the premises and manufacturing operation complies with the current Good Manufacturing Practices requirements as provided in the regulations."

The provisions on the related costs of conducting a GMP inspection are found in *Article 52 subsection 3* that states: "The Authority may charge any applicant such costs as it may incur for the Purposes of carrying out Good Manufacturing Practice inspection or laboratory investigations prior to registration of any drug product."

These provisions on GMP inspection as articulated in this Part 4b of registration are aligned with the MRP requirements for GMP compliance by the applicants and the MRP leaves the responsibility of controlling costs to the NRAs. The MRP requirements need the applicant to comply with GMP and this can be done through the provision of a GMP certificate and not necessarily through physical inspection of the premises.

c) Approval for registration of veterinary medicines

Article 53 subsection 1 states that: "The Authority may, on application made and after conducting such investigation which it may consider necessary and if it is satisfied that the drug, medical device or herbal drug in question is suitable for the Purpose for which it is intended, and if it complies with the prescribed requirements it shall approve the registration of that drug or medical device or herbal drug subject to such conditions as it may impose." The MRP also requires that an applicant only be granted a MA once they comply with the set requirements as prescribed in the harmonized documents prepared by the TWG in which the TFDA is represented. Therefore, the requirements for registration under the TFDA are captured in the harmonized technical documents.

d) Appeals may be heard by the TWG and experts

Article 53 subsections 2 and 3 deals with the appeals process for applicants not satisfied with the decision of the Authority to decline their application for registration of drugs. These *subsections 2 and 3* of *Article 53* state that:

(2) "Where the Authority refuses to approve the registration of a drug, a medical device or a herbal drug; or approves registration of a drug subject to conditions fixed in terms of subsection (1), the Director General shall inform the applicant in writing of such decision and the reasons thereof."

(3) "Without the Prejudice of subsection (1), if the applicant is not so satisfied with the decision of the Authority he may, within sixty days after the date of the notification furnish the Director General with his representations; and if after consideration of any comments so submitted the Authority is satisfied with the representations, it may approve the registration of such drug, medical device or herbal drug or if it is still not satisfied it shall reject the application."

The appeal process under MRP requires the submission for appeal within 40 days whereas the requirements of the TFDA sets it at within 60 days. This allows for the MRP process to align with this particular regulation because the time limits in MRP are within the time limits recommended by the TFDA and the fewer days under MRP help to speed up the process.

The *subsections 2 and 3* do not stop appeals from being heard by other parties, therefore appeals could be heard by TWG.

e) Safety and efficacy trials

The Tanzania Food, Drugs and Cosmetic Act under *Part 4 (c)* has specific provisions for clinical trials of drugs, medical devices or herbal drugs. In *Article 63 (1)* the provisions for application to conduct clinical trials are stated as: "Any person wishing to conduct a clinical trial of a drug, medical device or herbal drug shall submit to the Authority an application in the prescribed form, signed by him and accompanied with a prescribed fee, an Ethical Clearance Certificate issued by any approved institute for medical research and any relevant information as provided under the guidelines for registration of drugs for clinical trial."

Article 64 (1) on the authority to cause investigation to be conducted states that: "Upon the receipt of an application in terms of *subsection (1) of Section 63*, the Authority shall cause to be conducted such investigations to authentify the safety, efficacy and quality of a drug, medical device or herbal drug and if it is satisfied that the drug, medical device or herbal drug is reasonably safe, efficacious and of acceptable quality, the Authority shall register the product for the purposes of clinical trials."

The primary purpose of the clinical trials is to ensure safety and efficacy. Therefore, the MRP requirements for safety and efficacy are aligned to the TFDA regulations. There are no explicit provisions that prohibit clinical trials under the registration process of the MRP.

Status of implementation of MRP in Tanzania

According to the TWG minutes of 2016, the MRP guidelines have been forwarded to the Veterinary Technical Committee of the TFDA which directed that they be shared with stakeholders. The stakeholders' meetings were conducted on 22nd September 2015. The stakeholders gave their observations and recommendations and TFDA is working on the recommendations and will communicate to the stakeholders before considering for approval.

Conclusion on alignment of the Tanzania Food, Drugs and Cosmetic Act and MRP requirements

The Tanzania Food, Drugs and Cosmetic Act does not have specific provisions that would hinder the implementation of the MRP based on the analysis of the MRP requirements against the Act.

Policy recommendation on alignment of the Tanzania Food, Drugs and Cosmetic Act and MRP requirements

1. The TFDA should hold further sensitization meetings with relevant stakeholders to create awareness on MRP. The ecommendations of the stakeholders from the sensitization meetings previously conducted by the TFDA should be shared with the other EAC Partner States.
2. The TFDA should publish the MRP guidelines on their website as a way to disseminate information and create awareness on MRP.
3. There is need for policy dialogue among the legal officers in the TFDA and the TWG members for sensitization on the legal ramifications of the MRP process.
4. The TWG members from TFDA should lead advocacy and sensitization of the MRP as an EAC led initiative supported by GALVmed to get buy-in and ownership within their Authority.
5. The EAC Secretariat should formally communicate to the TFDA on the roadmap for implementing the MRP.

4.2.3 Uganda

In Uganda, the livestock and veterinary sector has several laws and policies as listed in ANNEX 8.

The veterinary medicines registration process in Uganda is mandated by the National Drug Policy and Authority Act. Most of the other laws and policies in existence in the veterinary and livestock sector in Uganda do not directly govern veterinary medicines registration. However, there are other laws and policies in this sector that cover veterinary medicines regulation and by extension address certain aspects of registration like the Animal Diseases Act.

The law on drug regulation that is involved in veterinary medicine registration is analysed and discussed below in the context of its applicability to the implementation of the MRP in Uganda:

Alignment of the National Drug Policy and Authority Act and MRP requirements

In Uganda, the National Drug Authority (NDA) is responsible for human and animal medicines regulation. It is mandated by the National Drug Policy and Authority Act Cap 206, 2000 of the Laws of Uganda. Its functions are to regulate the quality, safety and efficacy of drugs. The registration of veterinary medicines is provided for under the National Drug Policy and Authority Act, 2000 which is under the ministry of health.

The MRP as a process takes into account the issue of ascertaining efficacy, safety and quality in the registration of veterinary medicines. Thus, when registering veterinary medicines under MRP, the conditions as stipulated in the Article on Drug regulation should be met for it to align with the National Drug Policy and Authority Act.

The National Drug Policy and Authority Act in *Article 35* subsections 1 and 3 of Drug regulation and registration of specialities states that:

(1) "The drug authority may scientifically examine any drug for the purposes of ascertaining efficacy, safety and quality of that drug and shall institute a system for the approval of drugs or drug combinations not included in the national list of essential drugs."

(2) "The drug authority shall keep a register of specialities in the prescribed form."

(3) "If, on application made in the prescribed manner and on payment of the prescribed fee, the authority is satisfied that the drug or preparation in respect of which the application is made has not previously been registered and that the use of the drug or preparation is likely to prove beneficial, the authority shall register the name and description of that drug or preparation."

In comparing the requirements under MRP and the set conditions under this Act, there is alignment and they both speak to ensuring safety, efficacy and quality.

The NDA is an autonomous body with fiscal independence and the funding of the NDA is addressed by *Article 55 (1)* of the National Drug Policy and Authority Act, which states that: "The funds of the drug authority shall consist of grants from the Government, grants and loans from anybody, organisation or person, interest on savings made by the drug authority, money that may accrue to the drug authority in the discharge of its functions; and money from any other source as may be approved by the Minister." Therefore, based on this provision NDA may seek funding from the sources listed to implement aspects of the MRP that could require additional financing above the set operational budgets of the Authority.

In discharge of its mandate, the NDA has in place regulations governing drug registration anchored on *Article 64 (1)* of the National Drug Policy and Authority Act that states: "The Minister may, on the advice of the drug authority, by statutory instrument, make regulations generally for better carrying into effect the provisions of this Act."

The following is an analysis of the alignment of MRP requirements with the NDA Regulations:

a) Dossier assessment

The MRP aspects of submission of applications and dossiers for assessment are addressed under *Part 2* of the National Drug Policy and Authority regulations on registration of products.

Regulation 4 concerning registration of drugs, preparations, vaccines and other immunological products states that: "All products shall be registered in Uganda before sale or distribution and a person who intends to manufacture, import or export a product shall, prior to the manufacture, importation or exportation of the product, apply to the Authority for registration of the product."

The MRP allows for the simultaneous process of registration where the registration occurs across the EAC Partner States within the same period of time. Therefore, the MRP will comply with Uganda regulations that require all products to be registered in Uganda whether it is the RC or a CC.

Regulation 6 deals with the application for registration which states: "An application for registration of a product shall be made to the Authority in the prescribed Form 1 of Schedule 2 to these Regulations for human or veterinary drugs and preparations and Form 2 of Schedule 2 for vaccines and other immunological products." This regulation is very supportive of the MRP process being that it clearly distinguishes between human and veterinary medicines.

This provision is aligned to the MRP which also requires submission of dossiers to all the Partner States in the prescribed format of the harmonized documents.

b) Inspection of premises

The MRP aspect dealing with inspection is addressed under *Regulation 25* on Compliance with Good Manufacturing Practice Guidelines of the Certificate of Suitability of Premises Regulations. The regulation states that: "The premises shall comply with the internationally accepted Good Manufacturing Practice Guidelines approved by the Authority."

The issue of inspection of premises is further mentioned in *Regulation 19* under the licensing regulations of the National Drug Policy and Authority for Good Manufacturing Practice Guidelines which states that:

(1) "The Authority shall, for the purposes of assessing the manufacturing practices of the manufacturer, adopt with the necessary modifications, internationally accepted Good Manufacturing Practice Guidelines."

(2) "A manufacturer who manufactures drugs in Uganda or outside Uganda for importation into Uganda shall comply with the Good Manufacturing Practice Guidelines adopted by the Authority."

(3) "The manufacturer shall, prior to manufacturing drugs or importation of drugs, as the case may be, make an application to the Authority for assessment of the facility to be used for manufacturing drugs, for compliance with Good Manufacturing Practice Guidelines."

(4) "An application for assessment for compliance with Good Manufacturing Practice Guidelines shall be made using Form 20 in the Schedule to these Regulations."

(5) "Where a manufacturer complies with the Good Manufacturing Practice Guidelines, the Authority shall issue to the manufacturer a certificate of compliance with Good Manufacturing Practice Guidelines in Form 21 in the Schedule to these Regulations."

There is alignment of these provisions on GMP and the MRP requirements although the regulations prescribe the use of specific forms which may not be possible when implementing MRP in other CCs.

c) Appeal may be heard by the TWG and experts

The National Drug Policy and Authority Regulations on registration under *Regulation 41 (1)* outline the provisions that may lead to refusal to issue certificate of registration by the NDA and in *Regulation 41 (2)* provides for appeal by the applicant. It states that: "Where the Authority refuses to issue, amend or alter the registration of a drug or preparation, vaccine or other immunological products or surgical instrument, as the case may be, the Authority shall notify the applicant in writing of the reasons for the refusal and give the applicant an opportunity to be heard."

The MRP requirements provide for appeals to be heard by the TWG and the provisions of this regulation are not specific to the composition of the appeal panel. Therefore, it is possible that the appeals may be heard by the TWG bearing in mind that the NDA forms part of the TWG membership and thus the Uganda NRA will be represented.

d) Safety and efficacy trials

The National Drug Policy and Authority Act has provisions for clinical trials under *Article 40* which states that: "The authority may issue a certificate to any person for the purpose of carrying out clinical trials in respect of a drug that may be specified in the certificate and no person may carry out any clinical trial in respect of any drug unless he or she is in possession of a certificate issued under subsection (1)."

In the National Drug Policy and Authority regulations on the conduct of clinical trials, *Regulation 3* for requirement for authorization of clinical trials states that:

(1) "A person shall not start or cause to be started a clinical trial or conduct a clinical trial without the authorisation of the Authority."

(2) "Authorisation for clinical trial shall be granted for drugs registered under the Act and for drugs that are not registered under the Act."

Regulation 4 which deals with the application for authorization to conduct clinical trials states that:

(1) "A person who wishes to conduct a clinical trial shall make an application to the Authority using Form 29 in Schedule 1 to these Regulations."

The provisions for conducting clinical trials in both the primary legislation; the National Drug Policy and Authority Act and subsidiary regulations, do not limit the registration of veterinary medicines under MRP. The MRP harmonized documents ought to be published so that they can be used alongside the prescribed forms because currently the NDA uses only its own form 29 for clinical trials.

e) Certificate of Registration

Regulation 14 of the National Drug Policy and Authority Regulations on registration deals with the conditions for issuance of a Certificate of Registration. It states that:

(1) "The Authority shall issue a certificate of registration of a product registered under these Regulations, in the prescribed Form 3 of Schedule 3 to these Regulations."

(2) The Authority shall issue a Certificate of Registration where the Authority is satisfied that:

(a) The product dossier is submitted with evidence of:

(i) the safety, efficacy and quality of the product;

(ii) the stability of the data regarding the product; and

(iii) two samples of the drug or preparation;

(b) The applicant has complied with internationally accepted Good Manufacturing Practices, adopted by the Authority.

The provisions thus require the applicant to comply with GMP which are also provided for in the MRP.

Status of implementation of MRP in Uganda

According to the report of the TWG meeting in 2016, the Republic of Uganda has, since adoption, taken the following measures:

1. Domesticated all the MRP guidelines;
2. Received over 50 applications based on the guidelines;
3. Initiated a close working relationship with the African Union Pan African Veterinary Vaccine Centre (AU-PANVAC) – such that all vaccines for importation into Uganda must have AU-PANVAC quality assurance certificate;
4. Have intensified inspection on handling of vaccines along the vaccine value chain, especially downstream.

Conclusion on alignment of the National Drug Policy and Authority Act and MRP requirements

1. Registration period and timelines are not specified in law or regulations.
2. MRP may bring in more funds being that the NRA relies on funding that is generated internally in the corporate institution in the form of fees for the services rendered.
3. The process of adoption of MRP in Uganda is more efficient because of the comprehensive regulatory framework in the country that provides for subsidiary regulations that govern all aspects of drug regulation. This helps to remove ambiguity in the application of laws.

Policy recommendations

1. There is a need for official communication from the EAC Secretariat to the NDA to provide a legal mandate for the implementation of the MRP in Uganda.
2. There is need for sensitization of the other NRAs to adopt best practices from Uganda on MRP implementation.
3. GALVmed should further facilitate stakeholder sensitization in Uganda to create awareness of the availability for use of the MRP in veterinary registration by applicants.

Photo credit:GALVmed/Karel Prinsloo

4.2.4 Rwanda

The current laws used in veterinary medicine registration in Rwanda are listed in ANNEX 9.

In Rwanda, an act of parliament (No. 74/2013 of 11/09/2013) was passed in 2013 establishing the Rwanda Food and Medicines Authority (RFMA) and stipulating its mission, organization and functioning. The law is yet to be fully implemented and to take effect although it was drafted in 2013. Currently, all matters pertaining to the control of pharmaceuticals including drugs, devices and diagnostics are handled by the Pharmacy Task Force (PTF) under the Ministry of Health of Rwanda. Veterinary drug registration is governed by Ministerial Order N°008/11.30 of 18/11/2010 determining the organization of veterinary pharmacy practice. The old law, Law N°12/99 of 1999, relating to pharmaceutical practice has since been repealed and is, therefore, not applicable to the current developments with respect to the harmonization of registration of veterinary medicines.

In the RFMA law, the sections that would affect the MRP implementation are contained in *Article 4 (2)* under the mission dealing with importation, manufacture, labelling, marking, storage, promotion, distribution and sale of food and pharmaceutical products, herbal medicines, cosmetics, poisons and other medical devices or substances used in the manufacture of products provided under this law. The proposed legal framework under the law of 2013 takes cognizance of the international standards and, therefore, provides an opportunity for harmonization with the other EAC Partner States.

The law is yet to become operational and thus there are no guidelines and regulations published for its operations and the Authority is also yet to be constituted.

Status of implementation of MRP in Rwanda

The TWG report of 2016 outlines the following with regard to status of implementation:

- The Republic of Rwanda has fully adopted the MRP guidelines.
- Already the sensitization of stakeholders on MRP has been budgeted for in the current financial year (2016).

Conclusion on alignment of MRP requirements to the regulatory framework of Rwanda

The current law of 2010 empowers the Minister to enact regulations and issue licences relating to veterinary products importation and manufactures in *Chapter 2, Article 12* and *Chapter 3, Article 15*. The current law that governs veterinary medicine regulation is based on a Ministerial Order which does not need legislative amendments to adopt the MRP. A Ministerial Directive is adequate to address any issue with the MRP not aligning with the regulations enacted under the Ministerial Order.

Policy recommendations

1. There is need for policy advocacy and adequate stakeholder sensitization in Rwanda by GALVmed in readiness for the implementation of the RFMA law where the MRP could be absorbed as guidelines and would be taken into consideration when drafting other regulations and guidelines and, therefore, avoid conflicting provisions.
2. The TWG should also put in place measures for the translation of the MRP harmonized documents into French to allow for smooth adoption into the French-speaking countries in the EAC.

4.2.5 Burundi

The livestock and veterinary laws and policies in Burundi are as listed in ANNEX 10.

The registration of veterinary medicines in Burundi falls under the mandate of the Department of Pharmacy, Medicines and Laboratories (DPML) in the Ministry of Public Health and Fight against AIDS, which regulates medicines, medical devices and diagnostics both for human and animal health. However, there are advanced institutional arrangements towards the establishment of the proposed Burundi Medicines Regulatory Authority (ABREMA) once a draft law (Draft Decree N° 100/ of 2016) is approved and enacted by the Senate of Burundi. The draft law seeks to establish the authority for the regulation of medicines and food in Burundi. The Authority will be domiciled in the Ministry of Public Health and Fight against AIDS.

The primary objective of ABREMA is to protect the health of the public by ensuring the quality and safety of medicinal products. This is laid out in *Chapter 1, Article 3 and Article 4* dealing with objectives and functions of the authority.

The Burundi legislative framework, being as yet not fully developed and functional, provides a good opportunity for the adoption and integration of the MRP within the regulatory framework for drugs and vaccine registration. In developing subsidiary legislation and regulations from the primary legal document, Burundi has the opportunity to adopt internationally recommended standards in veterinary vaccine regulation and this makes it easier to align with the MRP as well as to harmonize the regulations with the other EAC Partner States. It is also an opportunity to gain best practices from the already implementing Partner States like Uganda and, therefore, avoid any teething problems when they are finally able to adopt and use the MRP.

Status of implementation of MRP in Burundi

Members of the TWG and the CGMR have initiated talks with senior executives in the office of the Ministry of Agriculture and Livestock on the elaboration of a ministerial order establishing an authority of regulation of veterinary medicines in Burundi.

Conclusion on alignment of MRP requirements to Burundi proposed law

The major obstacle to implementing the MRP in Burundi is a lack of technical capacity to implement the MRP requirements. As a member state of the EAC, Burundi can benefit a great deal from the EAC integration agenda, which will give it the necessary impetus to harmonize its regulations to meet international standards as well as be in tandem with the other EAC countries.

Policy recommendations

1. The operationalization of the draft law will require drawing of rules, regulations and guidelines and, therefore, there is need for intensive sensitization and awareness among the relevant stakeholders who will be part of the process to ensure the technical regulations do not impede the functioning of the MRP.
2. There is need to facilitate policy dialogue and advocacy by GALVmed and other partners majoring on the need for MRP and expected benefits in Burundi.
3. There is need for capacity building of the stakeholders in veterinary medicine registration and regulation in Burundi to enhance quality in the drafting of the regulations on veterinary medicine.

4.2.6 South Sudan

The primary legislation that regulates all aspects of drug administration and control in the republic of South Sudan is the Drug and Food Control Authority Act, 2012 act no. 37 that came into force on 28th February 2012. The purpose of this Act is to provide for the establishment of an independent Drug and Food Control Authority in South Sudan and to provide an appropriate and effective independent regulatory mechanism to control and regulate the manufacture, supply, promotion, marketing, advertising, distribution and use of drugs, poisons, chemicals, cosmetics, medical devices and food for human or animal use.

In *Chapter 6* of the registration of regulated products and MA, *Article 35* gives the conditions for application for MA. In its *Subsections 1 and 2* it states that:

(1) "An application for Marketing Authorisation shall be submitted to the Secretary-General in the prescribed form and shall be accompanied by the prescribed fee."

(2) "The Authority may request additional information, take samples or request for samples from the applicant within a specified period of time in order to complete the dossier or to clarify issues related to the drug, poison, chemical, cosmetic, medical device or food. Where such a request has been made it shall be the duty of the applicant to avail the information to the satisfaction of the Authority, that safety, quality and efficacy are assured."

Subsection 6 of Article 35 further states that:

(6) "In determining whether or not to grant a product Marketing Authorisation license, the Board shall consult relevant authorities including health professionals, and may take into account regulatory information from other countries as well as pronouncements by international organizations."

Article 36 on Evaluation and Issuance of Marketing Authorization states that:

(1) "The Board shall make an order after considering product quality, safety and efficacy, as to whether a Provisionally Authorised or Registered drug, poison, chemical, cosmetic, medical device or food or a product which is not listed in the Inventory but in respect of which an application for its manufacture, import, export or sale in South Sudan has been filed after the Appointed Date, shall be granted a Marketing Authorisation license."

(2) "The Authority may at any time call upon any manufacturer, importer or exporter to furnish such information as is required in order to enable a Provisionally Authorised or Registered drug, poison, chemical, cosmetic, medical device or food or a regulated product sought to be manufactured, imported or exported after the Appointed Date to be evaluated and assessed."

(3) "If, in the opinion of the Board, a drug, poison, chemical, cosmetic, medical device or food shall be registered only if it is promoted, distributed or advertised in a particular manner or distributed subject to certain safeguards, it shall, in approving the registration of that medicine, fix such conditions as it considers necessary or desirable."

Articles 35 and 36 give provisions as relates to the MRP aspect of submission of applications and dossiers to the RC and CCs. There is alignment in these provisions and MRP requirements for dossier assessment by the RC and the CC. The provisions of the MRP allow for further assessment and queries by the CC on the submitted applications and, therefore, the South Sudan NRA may ask for clarification and additional information on the application submitted.

There is also room for consideration of regulatory information from other countries, which allows for MRP requirements that depend on Partner States' assessments and reports in certain aspects like inspection of premises.

Article 59 concerns the Conduct of Clinical Trials and states that: "No person shall conduct a Clinical Trial of any Medicine without the prior written authorisation of the Authority granted with approval of the Minister." *Article 60* provides the conditions for application for Conduct of Clinical Trials. It states that:

(1) "Any person who desires to conduct a Clinical Trial with respect to a Regulated Product shall submit to the Secretary General an application in the prescribed form, signed by him or her and accompanied by such fees as may be prescribed."

(2) "In case of a Regulated Product used for the treatment of animals, the application shall specify the kinds of animals that will take part in the Clinical Trial, and the names and addresses of the owners of such animals."

The provisions under *Articles 59 and 60* are addressed in the MRP requirements that allow for the conducting of safety and efficacy trials and sharing the reports of previously conducted trials under similar conditions with the NRA.

Article 77 has provisions on issuing Regulations: "The Minister shall issue regulations, orders and procedures for implementation of provisions of this Act." The MRP, therefore, could be adopted in the South Sudan's Drug and Food Control Authority as procedures for the implementation of the Act and do not necessarily require parliamentary amendments of legislation.

Conclusion on alignment of MRP requirements to South Sudan's Drug and Food Control Authority Act

South Sudan's Drug and Food Control Authority Act is still a relatively new law in comparison with the other EAC Partner States laws on veterinary medicine registration. Therefore, there is opportunity in the South Sudan NRA to implement MRP as guidelines to complement the regulations needed for the operations of the Authority in exercising its mandate.

Policy recommendations

1. There is need for the EAC to incorporate the South Sudan NRA into the TWG as a Partner State of the EAC.
2. Stakeholder engagement and sensitization is needed in South Sudan to create awareness on MRP and its processes.
3. There is need for capacity building on MRP of the South Sudan's NRA by GALVmed and the EAC.

Photo credit: GALVmed/Karel Prinsloo

4.2.7 Summary of findings on national laws on veterinary medicines registration in EAC Partner States

1. All the Partner States' laws on veterinary medicine registration address and emphasize the important aspects of safety, quality and efficacy. The MRP is aligned with these requirements of safety, quality and efficacy.
2. There are no definitive timelines for the registration process in the laws that govern veterinary medicine registration. The MRP has a clear pathway with specific timelines, which includes a cap of 210 days from the beginning of the registration process to the granting of a MA. This may pose a challenge during implementation in the individual NRAs.
3. The EAC countries are at different levels of implementation of MRP. Rwanda, Burundi and South Sudan are still in the formative stages of establishing NRAs and, therefore, are not actively engaged in the process of domesticating the MRP guidelines. Kenya, Tanzania and Uganda have functional NRAs but are at different stages of implementation. Uganda is leading in implementation, and as at the last TWG meeting, the NRA was only awaiting official communication from EAC to NDA to fully adopt the MRP guidelines. Tanzania is willing to adopt the MRP guidelines but feels there is need for further stakeholder engagement, sensitization and advocacy. Kenya is also willing but the issues relating to the push and pull between the existing NRA and proposed NRA for veterinary medicine is constraining the process.
4. There is no clear distinction between the human and veterinary aspects in the laws and regulations dealing with the registration of drugs. The legal documents are not specific on veterinary aspects of drug regulation and mostly the same procedures are used for both human and animal medicine registration.
5. The NRAs are mandated under the line Ministries of Health dealing with human and not animal health while the veterinary sector is largely governed by the Ministries of Agriculture. Kenya has proposed to set up a NRA to deal specifically with veterinary medicine.
6. The funding for the three functional regulatory authorities is mainly from fees collection. Therefore, the MRP would be able to sustain itself depending on the applications received through it.
7. The NRAs execute their mandates as laid out in the acts through subsidiary legislation, regulations, guidelines and procedures. These are drawn through ministerial directives in line with the functions and objectives stipulated in the Acts and do not necessarily need amendments of the primary legislation.
8. There are other laws within the livestock and agriculture sector that are peripherally involved in drug and vaccine regulation. These are mainly the animal diseases acts in Kenya, Uganda and Tanzania, which are engaged in activities of transboundary disease control and management and control of animal epidemics. Therefore, they are given some mandate to regulate veterinary medicine mostly to do with importation during certain circumstances.
9. The NRAs are the main veterinary medicine regulators that are involved veterinary medicines registration. Therefore, veterinary involvement may not be as robust as it should be.

4.2.8 Policy recommendations for national laws on veterinary medicines registration

1. The NRAs should engage in disseminating the information about MRP through publishing the harmonized technical documents on their websites and communicating on the availability of the MRP for applicants in the EAC.
2. GALVmed and other partners should facilitate further sensitization meetings with relevant stakeholders to create awareness on MRP sensitization on MRP among Partner States of the EAC.
3. There is need for policy dialogue among the legal officers in the NRA and the TWG members for sensitization on the legal ramifications of the MRP process in their respective NRAs.
4. There is need for clarification from the PPB and/or VMD on the transitional arrangements involved and the implications thereof to the adoption of MRP in the Kenya regulatory framework.

5 Recommendations from previous sensitization activities by NRAs should be shared in the TWG meetings to enhance the understanding of the issues in implementing MRP in each of the Partner States and act on them. There is also need for sensitization of the other NRAs to adopt best practices from Uganda on MRP implementation.

6 There is need for policy dialogue and sensitization on the differences in regulations in individual Partner States in order to enhance harmonization and approximation of laws and policies in EAC.

7 The TWG members should lead efforts in advocacy and sensitization of the MRP as an EAC-led initiative supported by GALVmed to get buy-in and ownership within their Authority.

8 The EAC Secretariat should formally communicate to the NRAs on the EAC roadmap for implementing the MRP. The TWG should also put in place measures for the translation of the MRP harmonized documents into French to allow for smooth adoption into the French-speaking countries in the EAC.

9 There is need for the EAC to incorporate the South Sudan NRA into the TWG as a Partner State of the EAC.

10 There is need to facilitate policy dialogue and advocacy by GALVmed and other partners focusing on the need for MRP and expected benefits in the EAC Partner States.

11 Capacity building on MRP is needed across the EAC NRAs which can be done by the respective TWG members involved in their particular NRA.

12 NRAs should incorporate the activities of the TWG in their respective work plans and there is need for adequate dissemination of information from the TWG on the status of their activities.

13 There is need for GALVmed in partnership with the NRAs to undertake pilot programmes and activities to test the practicability of MRP in the EAC Partner States and enable review and revisions in accordance with the regulatory frame.

14 There is need to strengthen collaboration and partnership among the Partner States' NRAs and EAC through stakeholder sensitization meetings and joint capacity building activities by EAC on the laws on veterinary medicine registration in Partner States.

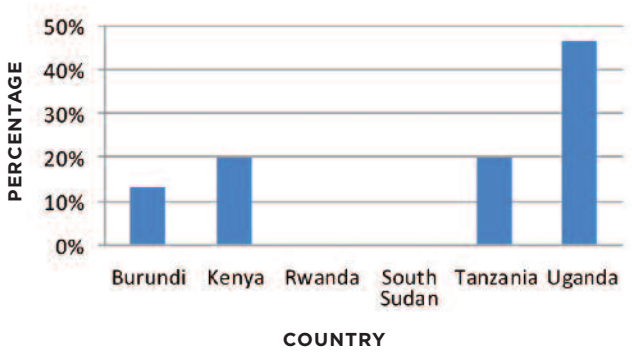
4.3 Opinions of respondents on MRP implementation

This section presents the opinions of the respondents on the adoption and implementation of the MRP. The respondents were made up of stakeholders in the veterinary sector and national veterinary medicine regulation authorities.

4.3.1 Response rate by country and sector

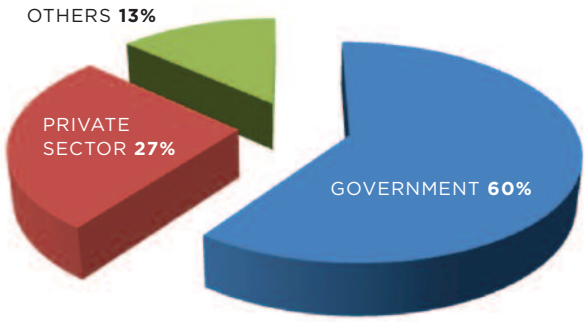
Figure 4.1 shows the responses from the individual EAC Partner States.

Figure 4.1 **Response rate by country**



In the countries' response rates, Rwanda and South Sudan were not represented while Uganda had the highest representation with 47%, followed by Tanzania and Kenya both at 20% and Burundi at 13%. Uganda had the highest response rate because it had the highest representation of the private sector that showed interest in being part of the study. South Sudan's lack of representation may be due to the lack of robust linkages with the EAC having just joined the EAC recently but also due to political instability. Figure 4.2 shows the responses by sector.

Figure 4.2 **Representation of respondents by sector**



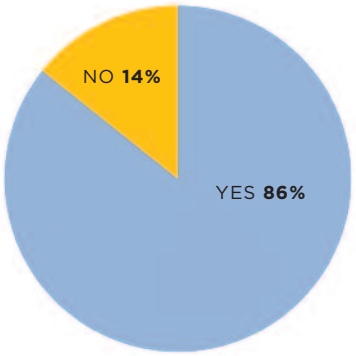
About 60% of the respondents interviewed represent the respective governments of the EAC Partner States under the relevant ministries of agriculture and livestock that deliver veterinary services. This also comprises NRAs who are involved in the registration of veterinary medicines. A total of 27% of the respondents were representatives of the private sector who are prospective applicants for MAs while 13% were in the category of 'others' who included representatives of the OIE.

The government or public sector had the majority representation because of the involvement of multiple sub-sectors dealing in veterinary medicines registration. The respondents under the public sector had representation from NRAs, veterinary councils and directors of veterinary services.

4.3.2 Level of awareness of the EAC Council of Ministers' decision

Figure 4.3 shows the respondents' level of awareness of the EAC Council of Ministers' decision (*EAC/CM 30/Decision 34*) that gives mandate on harmonization of technical requirements and MRPs. The majority (86%) of the respondents were aware of this Decision compared to 14% who were not aware.

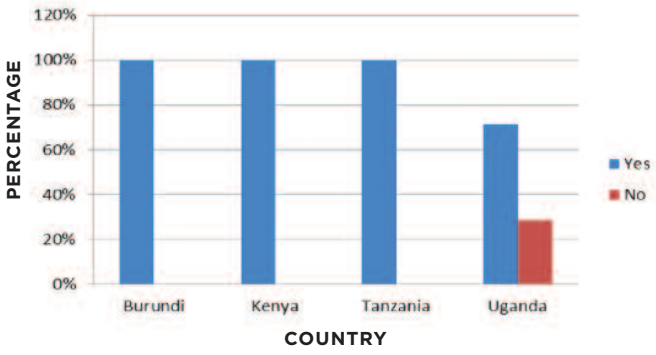
Figure 4.3 **Level of awareness of the EAC Council of Minister's decision**



The general higher level of awareness of the EAC Council of Ministers' decision by the respondents in the EAC could be due to the dissemination of information through the TWG members to their respective NRAs. The EAC Secretariat has also been instrumental in information sharing among the relevant stakeholders through EAC meetings and forums.

Figure 4.4 shows the disaggregated information on the level of awareness of the EAC Council of Ministers' decision among the individual EAC Partner States.

Figure 4.4 **Awareness of the EAC Council of Minister's decision among EAC Partner States**



The respondents from Burundi, Kenya and Tanzania were all aware of the EAC Council of Ministers' decision (100%). In Uganda, about 71% of the respondents were aware of the decision. The responses from Government show 100% awareness while 50% of the private sectors were aware of the EAC Council of Ministers' decision.

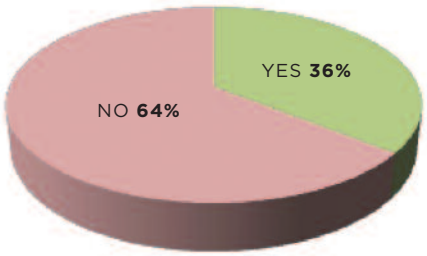
The responses from Uganda had both private sector and Government representations while the other EAC Partner States did not have private sector representation in their responses. This could explain why Uganda had only 71% awareness of the decision as compared to the other Partner States' respondents. The private sector has not been very much involved in the harmonization efforts towards mutual recognition especially with respect to the EAC mandate. Therefore, it is necessary to bring more private sector players on board in the EAC MRP activities. Based on the low level of awareness among the private sector representatives, there is need for more intensive stakeholder engagement through increased sensitization and awareness creation on the EAC Council of Ministers' decision within the private sector actors, not only in Uganda but also in the other EAC Partner States.

On the other hand, the high level of awareness among government stakeholders gives the implementation of the MRPs within the EAC a boost because the Government stakeholders involved in veterinary medicines registration are knowledgeable on the EAC Council of Ministers' decision that gives mandate to the harmonization process and subsequent MRP.

a) Legal provisions of the EAC that support MRP

The respondent's knowledge on the legal provisions that support MRP is shown in Figure 4.5.

Figure 4.5 **Legal provisions of the EAC that support the MRP**

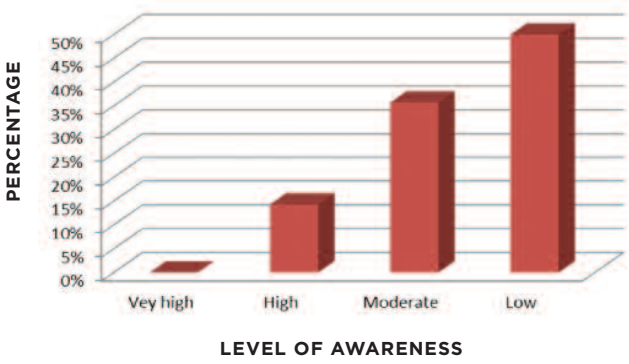


From the results in Figure 4.5, the majority (64%) of respondents were not conversant with the EAC legal provisions that support MRP. This, therefore, implies that while the respondents may be aware of the MRP, they do not know the legislative framework that gives them the mandate and this could pose a challenge during implementation when there is a perceived grey area on the legitimacy of the MRP process. There is, therefore, a need to undertake intensive sensitization by the EAC Secretariat and Partner States on the EAC legal provisions upon which the MRP derives its mandate.

4.3.3 Awareness of GALVmed-supported EAC activities on the MRP across the EAC

The level of awareness on GALVmed-supported EAC activities on MRP across the EAC is shown in Figure 4.6.

Figure 4.6 **Awareness of GALVmed-supported EAC activities on the MRP**



About 50% of the respondents believe that there is low awareness of GALVmed-supported EAC activities on MRP among the relevant stakeholders in the EAC. This low awareness can be attributed to the marketing and branding approaches/strategies being deployed by GALVmed in their work in the region, which may not be creating enough visibility of their work. There is, therefore, a need for GALVmed to engage in programmes/activities that will increase their visibility among relevant stakeholders in the region.

Figure 4.7 **Awareness of GALVmed-supported EAC activities on the MRP among EAC Partner States**

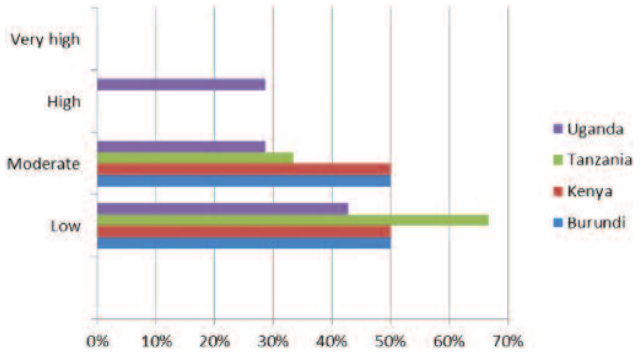


Figure 4.7 shows the level of awareness of GALVmed supported EAC activities on MRP among EAC Partner States. Uganda recorded the highest level of awareness (29%) while Tanzania had the lowest level of awareness (67% not aware) of GALVmed supported EAC activities. The Uganda NRA has made significant strides towards the implementation of MRP and this could be why the respondents in Uganda have higher awareness levels. Tanzania has also taken steps towards MRP adoption but it has focused on publicising the MRP as an EAC initiative and hence the Tanzania stakeholders' low awareness level of GALVmed's activities in the country.

Figure 4.8 **Awareness of GALVmed-supported EAC activities on the MRP by sector**

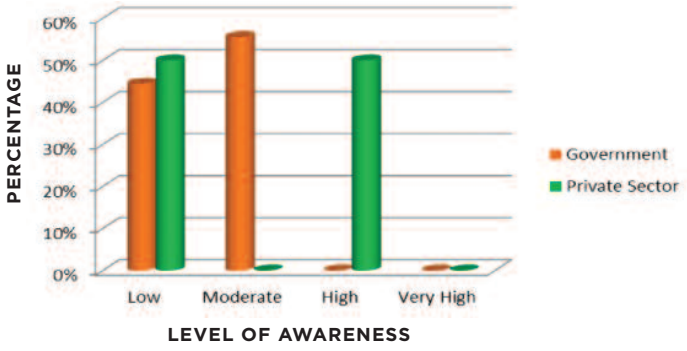


Figure 4.8 shows the perception by the respondents on awareness of GALVmed-supported EAC activities on MRPs between the public and private sector. The results show that the level of awareness among the public sector is perceived largely as moderate with 55% and the private sector as represented with 47% believing awareness is low. This could be attributed to the lack of dissemination of information among the private sector actors as regards the GALVmed-supported EAC activities on MRP. There is, therefore, a need for the involvement of private sector players in these efforts through sensitization and awareness creation. There is also the need to disseminate this information further among the private sector players.

4.3.4 MRP alignment with EAC integration agenda

In ranking the mean scores on the EAC involvement in MRP within the context of the EAC integration agenda as shown in Table 4.2, the respondents agreed that the EAC had put in place strategies for veterinary harmonization (4.0) and that Partner States are willing to adopt the EAC Council of Ministers' decision (4.0) while the respondents also agreed that the EAC has the legislative mandate to support implementation of MRP (3.69).

Table 4.2 **Mean scores on the EAC Secretariat's involvement in the MRP**

S/No.	Statement	Mean	SD
1.	EAC Secretariat strategies for veterinary harmonization of registration requirements	4.0	0.6
2.	Willingness by Partner States to adopt the EAC Council of Ministers' decision	4.0	0.7
3.	Legislative mandate of the EAC to support implementation of the MRP	3.69	1.25

Ranking scale: 1 = strongly disagrees; 2 = disagree; 3 = neutral; 4 = agree; 5 = strongly agree. Cut-off point = 3.0.

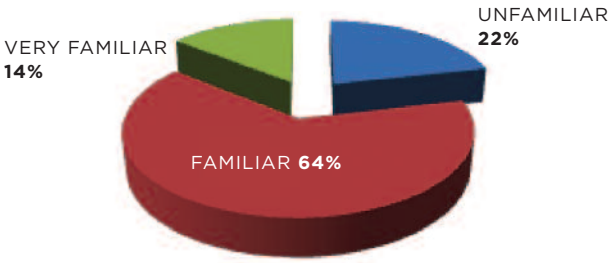
The factors listed in the table are key pillars necessary for the adoption and implementation of the EAC MRP and the favourable ranking as shown by the responses is a result of the goodwill and ownership of the process by the relevant stakeholders within the EAC.

Based on these results, there is a need for further strengthening of the EAC Secretariat strategies for adoption of MRPs, advocacy through providing a robust rationale for the need of Partner States to adopt the MRP and building a strong case for expected benefits. It is also important for the EAC to provide clarity on the legal mandate of the EAC-MRP and give direction on the legal processes required for ratification.

4.3.5 Familiarity with the EAC MRP

The results on familiarity with the EAC MRP are as shown in Figure 4.9.

Figure 4.9 **Familiarity with the EAC MRP**



A majority of the respondents (64%) are familiar with the EAC proposed MRP. This may be due to the already undertaken stakeholder sensitization meetings by the TWG members on MRPs in their respective Partner States. The sensitization done by the EAC Secretariat and GALVmed in various veterinary forums in the EAC could also explain the familiarity with MRPs by the majority of respondents.

Figure 4.10 **Familiarity with the EAC MRP among EAC Partner States**

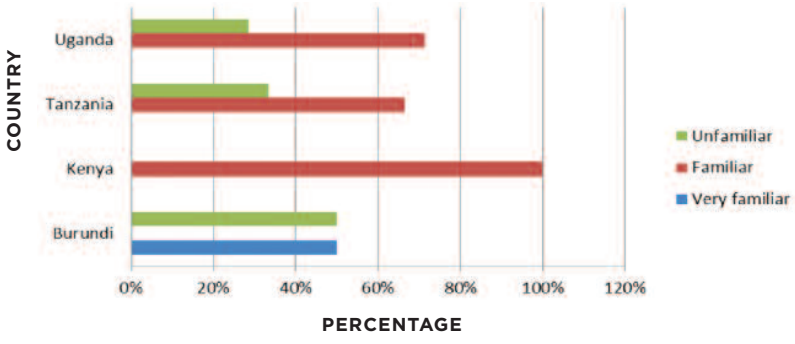
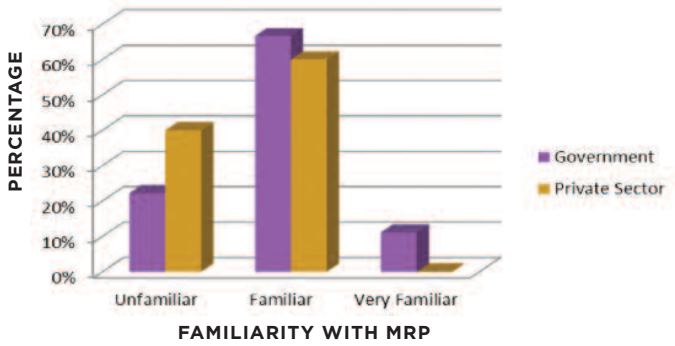


Figure 4.10 shows the familiarity with the MRP among the individual Partner States of the EAC. All the respondents from Kenya expressed familiarity with the MRP (100%) while respondents from Burundi were split at 50% for those very familiar and those unfamiliar with the MRP. The results may have been greatly influenced by the lack of private sector representation in the Kenya responses. Familiarity with MRP in the Partner States shows the dissemination of information and sensitization that has been done and whether it is necessary to continue with the same strategies.

Figure 4.11 **Familiarity with the EAC MRP by sector**

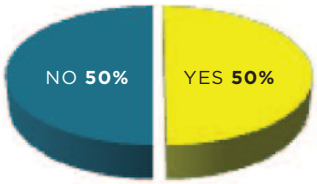


Familiarity with the MRP between the private and public sector is as shown in Figure 4.11. Only 10% of respondents from the public sector were very familiar with MRP while close to 67% were familiar and about 62% of the private sector were familiar. The majority of private sector representatives involved in the study were drawn from Uganda and, therefore, it would imply that they are more familiar with MRP because the Uganda NRA has made significant progress in MRP adoption. There are also close to 38% who are unfamiliar and, therefore, there still needs to be more awareness and sensitization on MRP among the private sector stakeholders.

4.3.6 MRP alignment with the veterinary medicines registration requirements in EAC Partner States

The question on perceptions of the alignment of MRP with the veterinary medicines registration requirements was thought to be an important factor in uptake of MRP and the results on the respondent's opinions are as shown in Figure 4.12.

Figure 4.12 **MRP alignment to veterinary medicines registration requirements**



According to Figure 4.12, half of the respondents believe the MRP is aligned to the registration requirements for veterinary products registration while the other 50% do not. The perception on MRP alignment is a consequence of the lack of clarity on the technical requirements for veterinary medicines registration and how they fit in with the existing requirements in Partner States' NRAs. Enhanced understanding of the MRP in the EAC would bring more clarity on the issue of alignment.

Figure 4.13 **MRP alignment to registration requirements for veterinary products registration among EAC Partner States**

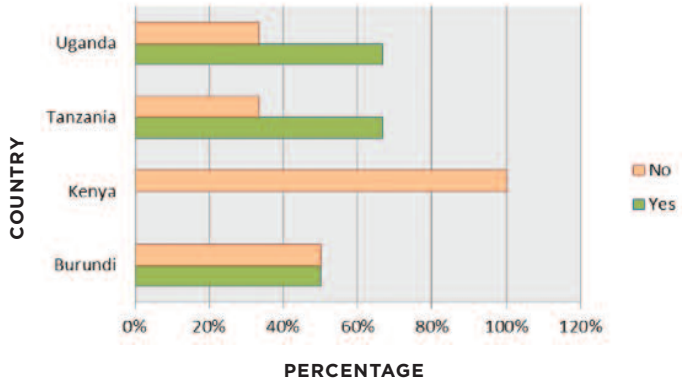
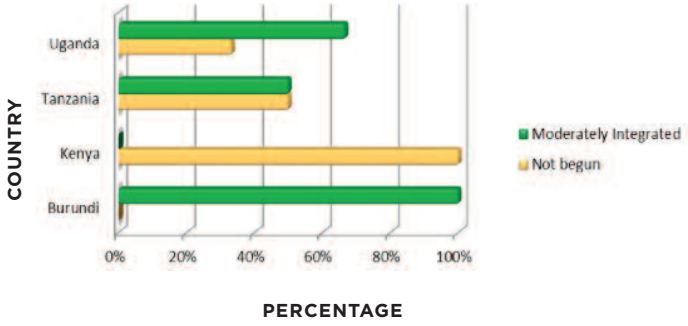


Figure 4.13 shows the respondents' views on the MRP alignment to their veterinary medicines registration requirements. Respondents from Uganda believe the MRP is 67% aligned to their national registration requirements and 33% believe they are not. Respondents from Tanzania also expressed similar views with 67% and 33% answering Yes and No, respectively, to the question on alignment with national registration requirements. Responses from Burundi were 50% Yes and 50% No while the respondents from Kenya believed the MRP was not at all aligned (100%) to their national registration requirements.

This opinion on alignment is largely influenced by the level of the respondents' familiarity with the MRP and the requirements for veterinary medicines registration under MRP. Based on these results, the issue of capacity building on the use of the MRP including training and further sensitization among all relevant stakeholders on the harmonized technical requirements vis-a-vis their national regulations is imperative. The undertaking of pilot activities would greatly increase the knowledge on practical applicability of MRP.

4.3.7 Current status of MRP implementation

Figure 4.14 **Current status of implementation among individual EAC Partner States**



The current status of implementation among the individual EAC Partner States is as shown in Figure 4.14. About 67% of the respondents from Uganda believe that the Council of Ministers' decision on harmonization is moderately integrated into their national regulatory framework while 33% opined that it has not yet begun. In Tanzania 50% believe it has not begun and the other 50% believe it is moderately integrated. The response from Kenya indicated the current status of implementation as not begun (100%), while in Burundi the respondents view the current status of implementation in their country as moderately integrated.

The disparity in the view of the status of implementation could be because of the different sectors involved in the processes as well as the lack of sensitization on the MRP leading to a lack of awareness. A plan for dissemination of information to the relevant stakeholders should be developed alongside the implementation plan to create ownership of the process which allows for accelerated adoption of the MRP.

Table 4.3 **Status of implementation of regulatory harmonization in EAC Partner States**

Country	Has a functioning NRA	Has adopted the harmonized guidelines	Has published the guidelines	Has alerted applicants to new harmonized requirements through stakeholder meetings	Has agreed to start the MRP
Kenya	Currently PPB, VMD will take over following completion of legal process	Yes	Yes, April 2016	Planned to be done by September 2016	Yes
Tanzania	TFDA	Yes, but wants changes made	Agreed to them in 2012 but has not published them yet	Yes, in September 2015	Committed to implement the MRP; waiting for procedures to be put in place
Uganda	NDA	Yes	Yes	September 2015	Yes, waiting for instruction from the EAC to NDA Board before starting
Rwanda	Ministry of Livestock will take responsibility for registration	Yes	Published in the Regulations for Rwanda Agricultural Board and veterinary services	Importers and pharmacies were alerted to new EAC requirements in May 2016	
Burundi	Commission has been created to draft pharmaceutical law and draft decree for creation of food and drugs regulatory authority	Waiting for implementation of regulatory authority	Waiting for implementation of regulatory authority	Was scheduled for August 2016 but hasn't happened	Waiting for implementation of regulatory authority
South Sudan	Drugs and Food Control Authority (DFCA)	Yes	No	No	N/A

Source: TWG, 2016

Table 4.3 is from TWG reports where the TWG members from the different NRAs gave the current status of implementation of the MRP in their respective NRA.

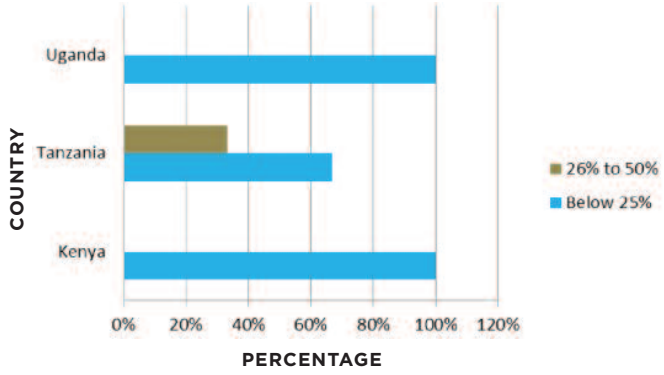
Based on the results from the analysis of the respondents' views, there are disparities between the figures on the ground and the proposed actions for MRP implementation. The timelines set out in the table do not match up to the results, which are tilted towards not integrated and moderately integrated. This, therefore, reflects that the proposed actions have not been fully implemented.

It is necessary for the Partner States' NRAs to show commitment and for the TWG to put in place mechanisms to track the action points agreed upon in their meetings to be able fast track adoption of the MRP in their respective NRAs.

4.3.8 Veterinary sector representation

Figure 4.15 shows the respondents' opinion of the veterinary sector representation in their respective NRAs by percentage.

Figure 4.15 **Perception of veterinary sector representation in Kenya, Tanzania and Uganda**

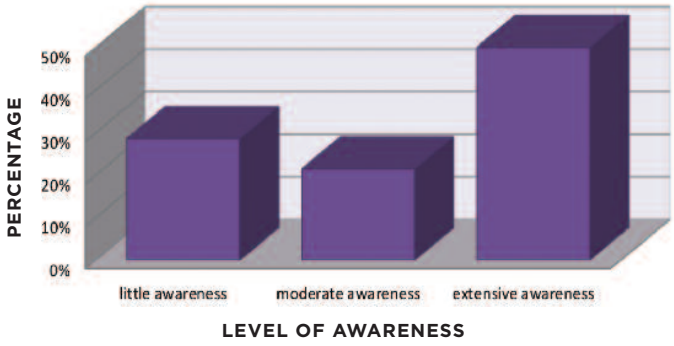


According to Figure 4.15, respondents from Kenya and Uganda believe that the representation of the veterinary sector in their NRA is below 25% while those from Tanzania are split, with 67% asserting their representation to be below 25% and 33% believing it is between 26% and 50%. These results could be attributed to the fact that the mandate to register both human and veterinary medicines in Kenya, Uganda and Tanzania lies in the NRAs, which are all under the Ministry of Health. Therefore, as seen in the above results, the perception by the stakeholders in veterinary medicines registration is that the veterinary aspects of drug regulation and registration may be under-represented. This would be a factor to consider that would accelerate or derail the adoption of MRP by the NRAs and, therefore, the need for adequate capacity building of the veterinary officers involved in the MRP process to lead advocacy within their NRA to enhance ownership by all stakeholders in the NRA.

4.3.9 Level of awareness of veterinary medicines registration requirements

The respondents' views on the level of awareness of veterinary medicines registration requirements in their NRAs were as indicated in Figure 4.16, with 50% extensive awareness, 21% moderate awareness and 29% little awareness.

Figure 4.16 **Level of awareness of veterinary medicines registration requirements in the EAC**



The NRAs' mandate covers both human and animal health and with about half of the responses indicating they are knowledgeable on the veterinary medicines registration requirements, an accelerated adoption of the MRP is envisaged.

4.3.10 Summary of findings on the opinions of respondents on MRP implementation

1. A large majority of stakeholders, as per the responses, are not conversant with EAC legal provisions that support the implementation of the Council of Ministers' decision. The level of awareness among the private sector on the EAC Council of Ministers' decision is lower than that of the public sector.
2. There is a general lack of awareness on the legal basis upon which the MRP derives its mandate. The respondents believe there is still a lack of awareness among key stakeholders on the MRP and the EAC harmonization efforts on registration of veterinary vaccines. The respondents believe that increased sensitization among key stakeholders in both government and private sector will increase awareness and enhance the adoption of the MRP.
3. Lack of awareness on the EAC-led MRP activities among the relevant stakeholders in Partner States points to the weak or inadequate linkages between the veterinary and livestock sectors in Partner States and the EAC Sectoral Council on Agriculture and Food Security that is charged with coordinating the Agricultural and Livestock agenda within the EAC.
4. There is low or inadequate publicity and dissemination of information by the TWG on the ongoing MRP activities.
5. The EAC Partner States involved in the MRP activities have a sense of ownership of the process based on their support for EAC involvement in their NRA activities.
6. A majority of the respondents express familiarity with the MRP although there is still a significant proportion that is unfamiliar with the processes involved in MRP.
7. The views on whether the MRP is aligned with the Partner States' technical requirements are largely influenced by how familiar one is with the proposed MRP.
8. There are disparities in the opinions on the status of implementation of the MRP with those on the proposed actions by the TWG that would put implementation way ahead of the results recorded. The results show that the MRP implementation has either not begun or is moderately integrated in the NRAs.
9. There is a perception by the respondents that the veterinary sector input is not adequately represented in the NRAs as a result of the NRAs being domiciled in the line Ministries of Health. Hence, the veterinary sector issues like the adoption of the MRP are perceived as not being adequately prioritized. There is a need for more veterinary professional involvement in veterinary drug regulation activities. There is no resistance or bad faith among the non-vets in the regulatory authorities with respect to MRP, they are supportive.
10. There is general awareness on the requirements for veterinary medicine registration in the NRAs of the EAC Partner States.

4.3.11 Policy recommendations

1. Based on the level of awareness among the private sector representatives, there is a need for more intensive stakeholder engagement through increased sensitization and awareness creation on the EAC Council of Ministers' decision within the private sectors in all the EAC Partner States.
2. There is also a need to undertake intensive sensitization by the EAC Secretariat on the EAC legal provisions upon which the MRP derives its mandate.
3. There is a need to disseminate this information further among the relevant stakeholders through sensitization meetings and use of other information media like the NRA and livestock sector websites in EAC Partner States.

4 To further accelerate MRP adoption and build a sense of ownership, there is a need to provide a robust rationale for MRP uptake in the EAC and put forward a strong case for the expected benefits from the MRP process.

5 To enhance familiarity with the MRP, it is essential that stakeholders are further sensitized on how the MRP works and the technical requirements as stipulated in the MRP. There is also a need for intensive training and capacity building.

6 The TWG should have mechanisms to track proposed action points of their meetings so that they are able to determine the different stages of implementation of the MRP in Partner States. The NRAs should also show commitment and follow through on proposed actions like publishing the MRP on their websites.

7 There is a need for capacity building of veterinary stakeholders in the NRAs to lead advocacy efforts and policy dialogue in pushing the veterinary agenda within their NRA. This should enhance ownership of the MRP by the NRA regardless of the veterinary or human aspects.

8 There is a high level of awareness of requirements for veterinary medicines registration and this could serve to accelerate MRP adoption based on the requirements as set out in the MRP which are not very different from the conventional Partner States requirements. Therefore, the NRAs and the EAC should take advantage of this and focus on the areas of alignment of NRA's registration requirements with the MRP.

4.4 Strategies for implementation of MRP

4.4.1 Stakeholder sensitization

The respondents were asked their opinion on the different levels of sensitization needed for the stakeholders, as categorized below. Stakeholder sensitization was put forward as a strategy for effective MRP implementation.

Table 4.4 **Mean scores on the level of stakeholder sensitization needed**

S/No.	Stakeholders	Mean	SD
1.	Government/public sector	4.28	0.61
2.	Private sector	4.21	1.18
3.	Veterinary professionals and para-professionals	4.14	0.86
4.	Local livestock farmers' groups and associations	3.57	1.50
5.	Manufacturers, importers and distributors of vaccine products	4.42	1.08

Ranking scale: 1 = no sensitization; 2 = little sensitization; 3 = moderate sensitization; 4 = intensive sensitization; 5 = very intensive sensitization. Cut-off point = 3.0.

Table 4.4 shows the ranking of the level of stakeholder sensitization the respondents thought was still required to effectively implement the MRP. Data obtained from the respondents shows that manufacturers, importers and distributors of vaccine products (mean = 4.42) required the highest level of sensitization on the implementation of MRP in the EAC. This may be because the manufacturers, importers and distributors of vaccine products require good knowledge of the procedures for the registration, marketing and distribution of vaccine products in any of their target countries. The government sector (mean = 4.28) was also ranked highly because they are directly involved in veterinary medicines registration in the NRAs.

Generally, based on these rankings the respondents felt there was a need for more intensive sensitization among all the key stakeholders involved in veterinary medicines registration. Increased sensitization efforts will lead to better outcomes during the implementation of the MRP. Therefore, there is a need to widen the scope of sensitization and make it more intensive for increased understanding of the MRP among the relevant stakeholders.

4.4.2 Extent of change required to align national regulations on registration with the MRP

a) Extent of change required as per the MRP components

The opinions of the respondents were sought with regard to the desired change required in the respective legal frameworks against the MRP aspects, the kind of change required and possibility of implementing within the current legal frameworks. Table 4.5 shows the rankings for the extent of change required to align national regulations with MRP.

Table 4.5 **Mean scores of the extent of change required to align national regulations with the MRP**

S/No.	Components of the MRP	Mean	SD
1.	Dossier assessment can be done by competent authority of another country within the EAC Partner States	3.72	1.19
2.	Inspections of premises can be done by competent authority of another country within the EAC Partner States	3.36	1.36
3.	Appeals may be heard by the TWG and experts	3.63	1.62
4.	Safety and efficacy trials done in other countries might be acceptable under certain circumstances in place of local trials	3.54	1.36

Ranking scale: 1 = no sensitization; 2 = little sensitization; 3 = moderate sensitization; 4 = intensive sensitization; 5 = very intensive sensitization. Cut-off point = 3.0.

Data from Table 4.5 shows the ranking of the various aspects of the MRP against the national regulations on veterinary medicine registration to determine the extent of change required in implementing the MRP. The majority (mean = 3.72) believed that their regulatory frameworks align to the MRP aspect that allows dossier assessments to be done in another Partner State of the EAC. This is because the regulations in these EAC Partner States are not specific to the physical location for carrying out dossier assessments. There is a need for further sensitization of stakeholders on the key aspects of MRP so as to enhance understanding on how they fit in with their national regulations.

b) The kind of change required in legislation

Table 4.6 shows the rankings of the kind of change required in legislation to realize MRP.

Table 4.6 **Mean scores of the kind of change in legislation that is needed to realize MRP**

S/No.	Recommended change in legislation	Mean	SD
1.	New primary legislation and repeal of the old primary legislation	2.6	1.71
2.	Complete overhaul of the subsidiary regulations and repeal of old regulations	2.3	1.49
3.	New guidelines and regulations to supplement old ones	3.2	1.61
4.	Amendments to the primary legislation	4.0	1.41
5.	Amendments of the subsidiary regulations	4.0	1.41

Ranking scale: 1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree. Cut-off point = 3.0..

Data in Table 4.6 shows that the respondents are mostly in agreement that there needs to be amendments in primary legislation (mean = 4.0) and subsidiary regulations (mean = 4.0) to realize mutual recognition. This means that the MRP can be effectively implemented within the current system but may require changes in either the primary or subsidiary regulations.

The respondents do not believe that the MRP requires new primary legislation (mean = 2.6) or a complete overhaul of the subsidiary regulations (mean = 2.3). These statements were ranked below the cut-off point and therefore are not significant as recommendations to changes in regulations.

The respondents' views that change is needed in the primary and subsidiary legislation is reflective of the lack of understanding of the key components of the MRP and how it fits in within the legislative framework. Consequently, it is necessary that all stakeholders involved are sensitized on the MRP process and training is done on how to incorporate the MRP within the current existing structures.

c) Possibility of implementation of MRP within the legal framework of Partner States

The mean scores on implementing MRP within the current framework are as shown in Table 4.7.

Table 4.7 **Mean scores on implementing the MRP within the legal framework of Partner States**

S/No.	Statement	Mean	SD
1.	Possibility of implementing the MRP within the current framework	3.18	1.66
2.	Possibility of implementing the MRP without changes to the primary legislation	2.09	0.94
3.	Modification required in primary legislation for implementation of the MRP	3.63	1.20
4.	Modification needed in subsidiary legislation for implementation of the MRP	3.90	1.22
5.	The MRP requires technical harmonization and not legal harmonization	2.09	1.57

Ranking scale: 1 = strongly disagree; 2 = disagree; 3 = neutral; 4 = agree; 5 = strongly agree. Cut-off point = 3.0.

Data in Table 4.7 show that the majority (mean = 3.90) of respondents agree that modification is needed in the subsidiary legislation for the implementation of MRP in the region. Other significant results show that modification is required in primary legislation for implementation of MRP (mean = 3.63), and that there is the possibility of implementing MRP within the current framework (mean = 3.18). The options of modifying subsidiary and primary legislation may be deemed easier and faster for the implementation of MRP by the relevant stakeholders.

4.4.3 Possible opportunities and challenges in implementation of the MRP

The following is an analysis of the possible opportunities, challenges and strategies in the implementation of MRP.

a) Possible opportunities in implementation of MRP

Table 4.8 shows the rankings of statements with the possible opportunities in the implementation of the MRP.

Table 4.8 **Mean scores of opportunities for implementation of the MRP**

S/No.	Opportunities for implementation	Mean	SD
1.	Basis for Partner States to meet minimum international requirements in their national regulations	4.63	0.67
2.	The MRPs work for the common objectives of the NRA	4.63	0.67
3.	Alignment with EAC objectives in the EAC integration agenda	4.63	0.50
4.	Inclusivity of relevant stakeholders in the process of mutual recognition of registration requirements	4.09	1.30

Ranking scale: 1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree. Cut-off point = 3.0.

The rankings for opportunities for the implementation ranked favourably with respondents asserting that the MRP will provide a basis for Partner States to meet minimum international requirements in their national regulations (mean = 4.63), the MRP works for the common objectives of the NRAs (mean = 4.63), the MRP is aligned to objectives in the EAC agenda (mean = 4.63) and that there is inclusivity of relevant stakeholders in the process of mutual recognition of registration requirements (mean = 4.09). All the statements pointed to significant opportunities in MRP implementation. The results show the respondents believe the EAC is a valuable platform for action in pushing for the harmonization and implementation of the MRP. The MRP implementation opens up the doorway to implementing regional consistencies in the national laws and policies governing the veterinary sector and veterinary medicines regulation and registration. There is also a belief that inclusion of stakeholders serves to enhance MRP adoption.

b) Possible constraints in the implementation of MRP

Table 4.9 shows the rankings of the possible constraints in the implementation of MRP in the EAC.

Table 4.9 **Mean scores of possible constraints in implementation of the MRP**

S/No.	Constraints	Mean	SD
1.	Financial resource constraints	4.18	0.87
2.	Human resource constraints	3.63	1.12
3.	Different levels of implementation by Partner States	4.09	0.70
4.	Different governance structures in the Partner States	3.63	1.20
5.	Lack of political commitments	3.81	1.40
6.	Differences in implementation strategies	3.81	0.87
7.	Lack of supportive policies	3.63	1.02
8.	Change and control mechanisms in reviewing policy and legislation	3.81	0.75
9.	Challenges with stakeholder engagement	3.36	1.20

Ranking scale: 1 = strongly disagree; 2 = disagree; 3 = neutral; 4 = agree; 5 = strongly agree. Cut-off point = 3.0.

The ranking of the possible challenges that would hinder effective implementation of the MRP, as listed in Table 4.9, showed that the respondents expect financial resource constraints to be a major challenge (mean = 4.18). The different levels of implementation by the Partner States follows (mean = 4.09). The range of the rankings between 3.63 and 4.18 shows that most of the respondents agree that the listed challenges could hamper effective MRP implementation. It is, therefore, necessary to put in place measures in the implementation plan that will address these challenges and mitigate any negative effects that they may have on the implementation process.

c) Strategies in implementation of MRP

Table 4.10 shows the scoring of the possible strategies that could be employed in implementation of the MRP.

Table 4.10 **Mean scores on implementing strategies for the MRP**

S/No.	Strategies	Mean	SD
1.	Increased awareness creation about MRP and its benefits, especially to target stakeholders	4.81	0.40
2.	Formulation and development of policies and frameworks that support MRP implementation	4.45	0.93
3.	Improvement in the enforcement of national regulations in line with the MRP	4.27	1.00
4.	Integration of the MRP into the existing regulatory and legislative frameworks	4.63	0.67

Ranking scale: 1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree. Cut-off point = 3.0.

Data in Table 4.10 shows the proposed strategies in the implementation of MRP as ranked by the respondents. The responses were all statistically significant with the support of increased awareness creation about MRP (mean = 4.81) and the formulation and development of policies that support MRP implementation (mean = 4.45) ranking highly. The proposed strategies for MRP implementation ranked favourably among the respondents. This was thought to be a consequence of the statements being relevant as practical steps that could accelerate MRP adoption in the Partner States. There is a need to consider the use of these strategies for the effective implementation of MRP.

d) Factors that may influence implementation of MRP

The respondents ranked the factors that were likely to influence implementation of the MRP as listed in Table 4.11.

Table 4.11 **Mean scores of factors that may influence implementation of the MRP**

S/No.	Factors likely to influence adoption of the MRP	Mean	SD
1.	Financial implications	3.85	1.16
2.	Technical aspects for achieving harmonization of registration requirements	3.71	0.99
3.	Administrative issues in the NRAs	3.64	1.00
4.	Capacity needs for implementation of the MRP	3.85	1.23
5.	Inadequate awareness about the MRP	3.5	1.50

Ranking scale: 1 = not likely to influence; 2 = a little likely; 3 = likely; 4 = highly likely; 5 = will definitely influence. Cut-off point = 3.0.

Financial implications and capacity requirements ranked highest with mean = 3.85 as the determinants most likely to influence MRP implementation, followed by technical aspects for achieving harmonization of registration requirements (mean = 3.71), administrative issues (mean = 3.64) and inadequate awareness (mean = 3.5). These factors were thought of as significant in the implementation of MRP because the respondents believed they would be most relevant during implementation and would be most impacted by the MRP process.

Therefore, it is necessary to have in place strategies that will mitigate any negative aftershocks arising from these factors when implementing MRP. These results will help form a basis for the prioritization of the resources in effecting strategies during implementation.

e) Current challenges in veterinary medicine registration

The rankings by the respondents in terms of difficulties encountered in veterinary vaccine registration are as shown in Table 4.12.

Table 4.12 **Mean scores of challenges in veterinary medicines registration**

S/No.	Difficulties in vaccine registration	Mean	SD
1.	Delay in registration of veterinary medicines	4.07	1.07
2.	Lack of effective coordination arising from multi-agency involvements in the process	3.5	1.28
3.	Lack of qualified personnel	3.0	1.10
4.	Cost implications for registering in each Partner State	4.14	1.09
5.	Duplication of efforts in submitting multiple applications	3.85	1.35
6.	Corruption in the sector	3.14	1.23
7.	Inability to introduce a change, e.g. in manufacture or testing until all relevant authorities have approved the change, according to their individual timeframes	3.57	1.016

Ranking scale: 1 = strongly disagree; 2 = disagree; 3 = neutral; 4 = agree; 5 = strongly agree. Cut-off point = 3.0

The data from Table 4.12 help to understand the magnitude of the respondents' opinions on the problems encountered in veterinary medicines registration. The statement on cost implications for registering through MRP in each Partner State (mean = 4.14) was the weightiest challenge anticipated by the respondents. This is evidence of the lack of sensitization on the MRP cost implications, which will be exactly the same as separate national applications. Stakeholders believe that the administrative costs add up significantly when a drug is registered in different countries at different times and this issue is resolved through the MRP. The statement on the lack of qualified personnel was ranked lowest (mean = 3.0). The respondents do not think the lack of qualified personnel was a major challenge in veterinary medicines registration in EAC Partner States. Therefore, there is a need to address challenges that might hinder implementation based on their priorities and paying particular attention to issues of costs, delays in registration, and challenges of multiple registrations among others.

f) Strategies for addressing challenges in veterinary medicine registration through MRP

The respondents ranked the strategies in Table 4.13 as being able to address the identified challenges in veterinary medicine registration through the MRP.

Table 4.13 **Mean scores of solutions to these challenges through the MRP**

S/No.	Solutions through the MRP	Mean	SD
1.	Speedy process in registration of veterinary medicines	4.64	0.63
2.	Improved coordination from multi-agencies involved in the MRP implementation	4.35	0.84
3.	More qualified personnel involved with implementation	4.14	0.94
4.	Reduced cost of registering medicines in each Partner State	4.0	0.96
5.	One-stop shop in making applications by applicants in the Partner States	4.28	0.91
6.	Efficiency and effectiveness in operations in the system which reduces corruption	3.92	0.99
7.	Ability to introduce a change, e.g. in manufacture or testing simultaneously following harmonized approval date by relevant Partner States	4.0	0.78

Ranking scale: 1 = strongly disagree; 2 = disagree; 3 = neutral; 4 = agree; 5 = strongly agree. Cut-off point = 3.0.

The respondents ranked the possible solutions likely to address the difficulties encountered in veterinary medicine registration as seen in Table 4.13. The majority (mean = 4.64) agreed that MRP will be useful in speeding up the process of registration of veterinary medicines in the region. This may be due to the fact that MRP has specific timelines for the registration process. Respondents also ranked improved coordination from multi-agencies involved in MRP implementation (mean = 4.35) as a significant solution that the MRP will offer in veterinary medicine registration in the region. This is because the MRP will help in registering veterinary medicines in more than one country of the EAC at the same time. The favourable rankings of the solutions help to build the rationale for MRP and therefore there is a need to sensitize stakeholders on how the MRP will solve problems in veterinary medicines registration in the region.

g) Expected benefits of MRP

Table 4.14 shows the ranking of the expected benefits from the harmonization process.

Table 4.14 **Mean scores of the benefits expected from the harmonization process**

S/No.	Factors likely to influence adoption of the MRP	Mean	SD
1.	Improve quality, safety and efficacy of veterinary vaccine in the EAC	4.42	0.75
2.	Eliminate duplication of tasks by applicants and NRAs in the EAC	4.92	0.26
3.	Reduce delay in registration of veterinary medicines	4.64	0.63
4.	Reduce time for applicants to obtain MAs	4.64	0.63
5.	Build trust between NRAs	4.28	0.91
6.	Increase international trade of livestock and livestock products	4.21	0.97
7.	Reduce counterfeits and substandard veterinary medicines	3.78	1.18

Ranking scale: 1 = strongly disagree; 2 = disagree; 3 = neutral; 4 = agree; 5 = strongly agree. Cut-off point = 3.0.

The statements as ranked in Table 4.14 are all significant with respect to the expected benefits of implementing MRP. The elimination of the duplication of tasks by applicants and NRAs in the EAC (mean = 4.92) was ranked highest by the respondents who agree that this would be the highest benefit from the MRP process. Therefore, based on the results, it is important to focus on the benefits that are expected from the MRP in building the case for the implementation of MRP within Partner States, in order to get buy-ins among the relevant stakeholders in the Partner States.

h) Financial implications of MRP implementation

The financial implications of implementing the MRP were thought to be a major determinant of the implementation process and the respondents' views with respect to the level of financial implications they expect from the process is as shown in Figure 4.17.

Figure 4.17 **Financial implications of MRP implementation**

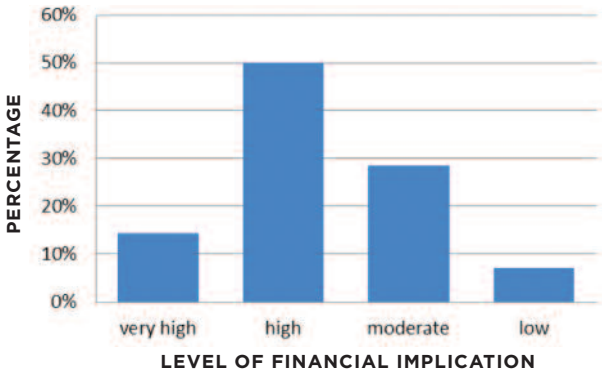
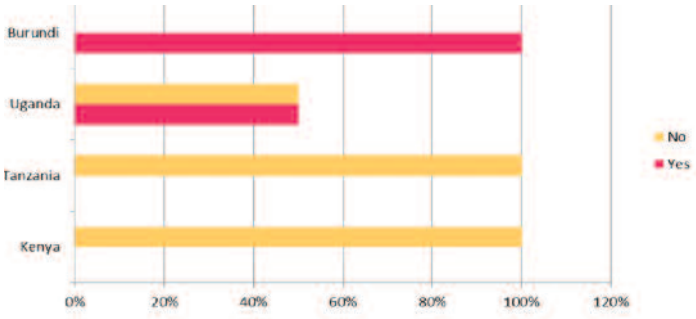


Figure 4.17 shows that about 50% of the respondents believed that the implementation of the MRP would have high financial implications. About 29% believed it will have moderate financial implications, while 14% believed that it will have very high financial implications, and only 7% think it will have low financial implications.
The majority of the respondents believed that MRP implementation will have high financial implications because it will require additional roles and responsibilities on the NRA professionals who form part of the TWG and the CGMR. This, it is thought, will attract extra remuneration and, therefore, the cost implications will have to be catered for during implementation. Other administrative costs may also arise, which have to be taken care of. It is thus prudent for a cost–benefit analysis to be conducted to justify to those who will bear these extra expenses why it is necessary to do so and to put in place sustainability mechanisms.

i) EAC correspondence with NRAs of EAC Partner States

Figure 4.18 shows the EAC correspondence with NRAs of individual Partner States as perceived by the respondents.

Figure 4.18 **EAC correspondence with NRAs of individual Partner States**



In Figure 4.18, respondents from Burundi regard the EAC correspondence to be adequate, with 100%, while those from Kenya and Tanzania are both at 100% believing the correspondence between the EAC and their respective NRA is not adequate. The results from Tanzania may be due to the perception that the MRP initiative is spearheaded by GALVmed and not the EAC which gives the MRP mandate under the EAC decision. The Kenya results may be attributed to the push and pull factors between the VMD and PPB. Burundi results reflect the EAC as a partner who is working to support Burundi in veterinary medicines registration through the MRP initiative. Therefore, the respondents ought to be sensitized on the MRP as an initiative supported by the EAC and that it is binding to the Partner States. Therefore, official communication from the EAC carries some weight in the adoption of MRP in Partner States.

j) Sustainability and capacity requirements for MRP adoption

Table 4.15 shows the rankings by respondents on the possible sustainability and capacity requirements for MRP adoption.

Table 4.15 **Sustainability and capacity requirements for MRP adoption**

S/No.	Factors likely to influence adoption of the MRP	Mean	SD
1.	Employ technically qualified personnel in the NRAs for MRP implementation	4.35	0.72
2.	Training and retraining of existing personnel with respect to the MRP	3.71	1.13
3.	Integrate issues on the MRP into the veterinary curriculum in universities	3.28	1.06
4.	Use of high technology equipment by the regulatory authorities	4.5	0.51
5.	Integrate the MRP into the EAC and national regulatory frameworks and policies	4.5	0.51

Ranking scale: 1 = strongly disagree; 2 = disagree; 3 = neutral; 4 = agree; 5 = strongly agree. Cut-off point = 3.0.

The data in Table 4.15 show that the majority (mean = 4.5) of respondents agree that the use of high technology equipment by the regulatory authorities and the integration of the MRP into the EAC and national regulatory frameworks and policies are significant in the sustainability and capacity requirements for MRP adoption. The integration of MRP into the frameworks of NRAs and the EAC, it is believed, would allow uptake of the MRP as part of the guidelines and, therefore, easier operationalization in Partner States.

These measures for sustainability as ranked by the respondents are all significant and, therefore, should be taken in order to give MRP a strong foundation within the national regulatory set-up of the individual Partner State.

k) Support of MRP adoption by relevant national ministries

Figure 4.19 shows respondents' views on the level of support accorded to the veterinary sector by the relevant line Ministries in Partner States. Around 29% felt they were very supportive, 29% believed that the support was average, another 29% felt that the support was little, while only 14% thought there was no support.

Figure 4.19 **Support for mutual recognition adoption by relevant national ministries**

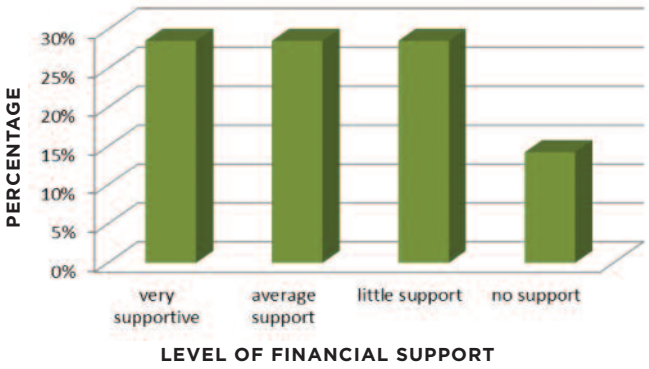
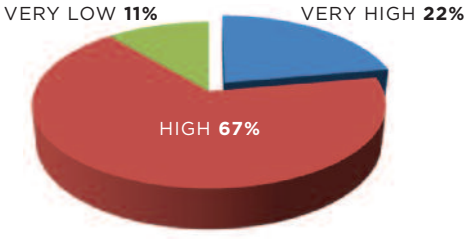


Figure 4.19 shows the level of support in veterinary medicines registration coming from different government sectors spread across the NRAs in the Ministries of Health and the veterinary sectors in the Ministries of Agriculture. Both the Agriculture and Health Ministries are significant in the process of adoption of MRPs. There should be targeted advocacy and policy dialogue between the two Ministries to be able to harness the synergies of cooperation when domesticating MRP.

l) EAC cooperation with Partner States

Figure 4.20 shows the level of cooperation between the EAC Secretariat and Partner States.

Figure 4.20 **EAC cooperation with Partner States**



In Figure 4.20, about 67% of respondents believed that there was a high level of cooperation between the relevant veterinary governance and administrative structures in EAC Partner States and the EAC Secretariat. About 22% rated the cooperation as very high and the other 11% thought it was very low. The high level of cooperation between the EAC and the Partner States as perceived by the respondents may be as a result of the strong involvement of the EAC Secretariat in the MRP initiative through the TWG activities.

Cooperation between the EAC Secretariat and the administrative structures in EAC Partner States is a huge determinant in the implementation of MRPs, in that the MRP is an EAC-driven process and is aimed at achieving the EAC objectives of integration.

4.4.4 Summary of findings on strategies for implementation of the MRP

1. The respondents believe there is a need for more intensive sensitization among key stakeholders.
2. The respondents largely hold the view that that there is change required to align national legislation and regulations on veterinary medicine registration with the MRP.
3. The EAC is thought to be a valuable platform among the respondents that is useful in pushing the MRP agenda.
4. Financial and technical capacities as well as stakeholder engagement were listed as major interventions required for lowering or removing barriers to the implementation of MRP.
5. The MRP will require additional roles and responsibilities on the part of NRA professionals who form part of the TWG and the CGMR. This, it is thought, will attract extra remuneration and, therefore, the cost implications will have to be catered for during implementation. Other administrative costs may also arise which have to be taken care of. It is thus prudent for a cost–benefit analysis to justify to those who will bear these extra expenses why it is necessary to do so and to put in place sustainability mechanisms.

6 The MRP, being an EAC initiative, is supported in law through the laws of Partner States that guide ratification and domestication of the regional community's policies into their national systems. Any EAC initiative undertaken within the legal framework of the EAC is binding to the Partner States and, therefore, official communication from the EAC ought to carry some weight in adoption of MRP in Partner States. Based on the results, it would appear that most of the respondents are not well aware of the legal jurisdiction of the EAC and thus ought to be sensitized on the same.

7 The respondents agree, based on the mean scores, that there are some capacity needs that ought to be addressed for sustainability of the MRP project. These are measures that must be taken in order to give the MRP a strong foundation within the national regulatory set-up of the individual Partner State.

8 The respondents also highlighted the need for stronger involvement of the EAC Secretariat in the mutual recognition initiative to support and accelerate the adoption of MRPs.

4.4.5 Policy recommendations

1 There is a need to widen the scope of sensitization and make it intensive to be able to reach many relevant stakeholders and to increase understanding of the MRP concept and process.

2 There is a need for stakeholder engagement, capacity building and policy dialogue on how to incorporate MRPs within the current existing legislative and regulatory structures.

3 The implementation of MRPs should be adopted as an avenue for addressing regional inconsistencies in veterinary medicines registration.

4 It is necessary to put in place measures in the implementation plan that will address these challenges and mitigate any negative effects that they may have on the implementation process.

5 These results provide a basis to prioritize resources towards capacity building of NRA for MRP adoption in the individual Partner States.

6 In building the case for implementation of MRPs within Partner States, it is necessary to focus on the benefits that are expected from the MRP to be able to get buy-in among the relevant stakeholders.

Photo credit: GALVmed/Karel Prinsloo

5 Summary of findings, conclusions and recommendations

5.1 Summary of findings

EAC laws and policies

1 The EAC Treaty of 2000 that establishes the EAC is a legally-binding document among the EAC Partner States with the mandate to foster integration and cooperation in the EAC region. Therefore, the EAC Partner States are expected to participate in activities that advance the integration processes across the economic, social and political pillars of the EAC. Consequently, as per the provisions of the EAC, the Partner States are expected to adopt and ratify the EAC resolutions and decisions.

2 There are EAC regional legal and policy documents that are anchored on the provisions of the EAC Treaty which enhance cooperation and integration through laid out plans and strategies. These legal documents include the EAC Common Market Protocol and Customs Union Protocol.

3 The MRP is legally binding on Partner States as anchored on the Council of Ministers' decision with reference to the functions and the effects of the Council of Ministers' decision as spelt out in Chapter 5 of the EAC Treaty. The EAC Council of Ministers' decision is legally mandated based on the functions and roles as prescribed in the EAC Treaty and Common Market Protocol.

4 Harmonization of technical requirements for veterinary medicines registration is supported by the Common Market Protocol. The objectives of the Common Market Protocol set out the areas of cooperation and integration and takes special cognisance of the powers of the Council of Ministers to issue directives and decisions.

5 The growth and sustainability of the agricultural sector in the EAC will be impacted positively by the adoption of MRPs by Partner States. *Article 108* of the EAC Treaty is a significant provision that forms the basis for harmonization of regulations for veterinary medicines registration and sets out the nature of cooperation in plant and animal diseases control within the EAC Partner States.

6 The EAC has a four-year development strategy (2012 to 2016) that has a focus on strengthening the agriculture and livestock productive sectors. The implementation of the MRP would help towards achieving this goal in the EAC through the prevention and control of animal diseases leading to an increase in livestock production and trade in livestock among the EAC Partner States as aligned with the Development Strategy. The EAC Vision 2050 also emphasizes the need for Partner States to be committed to investing in improvement of the livestock sector in order to contribute to the reduction of poverty and enhance income generation in rural areas. This will be bolstered by the implementation of MRPs.

7 The human health aspect will also be influenced through veterinary medicines registration under the MRP and, therefore, Chapter 21, *Article 118 (d)* of the EAC Treaty that touches on harmonization of drug registration procedures aimed at achieving good control of pharmaceutical standards are applicable in the implementation of MRPs. This is because the MRP seeks to ensure the safety and quality of veterinary medicines and, by extension, limit the negative effects of animal diseases to human health.

8 There exists an EAC Regional Pharmaceutical Manufacturing Plan of Action 2012–16 (RPMPA) that supports the development of local veterinary medicine manufacturing capacity in order to provide a sustainable source of affordable quality medicines in the EAC. This will complement the veterinary aspect of veterinary medicines registration through MRP.

9 The EAC has an Agriculture and Rural Development Strategy that outlines the strategic interventions identified for the acceleration of agricultural sector development in the EAC Partner States. The primary focus areas of the strategy that influence MRP implementation are on improving food security and increasing intra- and inter-regional trade and commerce (EAC, 2015c).

Summary of findings, conclusions and recommendations

10 The EAC strategy on control and prevention of transboundary animal and zoonotic diseases also gives weight to the implementation of the MRP, which will allow access to veterinary medicines for the control of transboundary animal diseases within the EAC.

11 There is inadequate or a lack of sanctions by the EAC on non-compliance with the resolutions and decisions based on the EAC Treaty.

12 There is a lack of clarity on the implementation strategy by the EAC on its regional decisions once they have been adopted by the policy organs.

EAC Partner States national laws and regulations

1 All the Partner States' laws on veterinary medicines registration address and emphasize the important aspects of safety, quality and efficacy. The MRP is aligned with these requirements of safety, quality and efficacy.

2 There are no definitive timelines for the registration process in the laws that govern veterinary medicine registration. The MRP has a clear pathway with specific timelines that include a cap of 210 days from the beginning of the registration process to the granting of an MA. This may pose a challenge during implementation in the individual NRAs.

3 The EAC countries are at different levels of implementation of MRPs. Rwanda, Burundi and South Sudan are still in the formative stages of establishing NRAs and, therefore, are not actively engaged in the process of domesticating the MRP guidelines. Kenya, Tanzania and Uganda have functional NRAs but are at different stages of implementation. Uganda is leading in the implementation and, as at the last TWG meeting, the NRA was only awaiting official communication from the EAC to NDA to fully adopt the MRP guidelines. Tanzania is willing to adopt the MRP guidelines but feels there is a need for further stakeholder engagement, sensitization and advocacy. Kenya is also willing but the issues relating to the push and pull between the existing NRA and proposed NRA for veterinary medicine is constraining the process.

4 There is a lack of a clear distinction between the human and veterinary aspects in the laws and regulations dealing with registration of drugs. The legal documents are not specific on veterinary aspects of drug regulation and mostly the same procedures are used for both human and animal medicine registration.

5 The NRAs are mandated under the line Ministries of Health dealing with human and not animal health while the veterinary sector is largely governed by the Ministries of Agriculture. Kenya has proposed to set up a NRA to deal specifically with veterinary medicine.

6 The funding for the three functional regulatory authorities is mainly from fees collection. Therefore, the MRP would be able to sustain itself depending on the applications received through it.

7 The NRAs execute their mandates as laid out in the Acts through subsidiary legislation, regulations, guidelines and procedures. These are drawn through ministerial directives in line with the functions and objectives stipulated in the Acts and do not necessarily need amendments of the primary legislation.

8 There are other laws within the livestock and agriculture sector that are peripherally involved in drug and vaccine regulation. These are mainly the animal diseases Acts in Kenya, Uganda and Tanzania, which are engaged in activities of transboundary disease control and management and control of animal epidemics. Therefore, they are given some mandate to regulate veterinary medicines, mostly to do with importation during certain circumstances.

9 The NRAs are the main veterinary medicine regulators that are involved in veterinary medicines registration. Therefore, veterinary involvement may not be as robust as it should be.

Summary of findings, conclusions and recommendations

Mechanisms and strategies for implementation of MRPs

1 The majority of stakeholders are not conversant with the EAC legal provisions that support implementation of the Council of Ministers' decision. The level of awareness among the private sectors on the EAC Council of Ministers' decision is lower than that of the public sector.

2 There is a general lack of awareness on the legal basis upon which the MRP derives its mandate. The respondents believe that there is still a lack of awareness among key stakeholders on the MRP and the EAC harmonization efforts on the registration of veterinary vaccines. The respondents believe that increased sensitization among key stakeholders in both government and the private sector will increase awareness and enhance adoption of the MRP.

3 The lack of awareness on the EAC-led MRP activities among the relevant stakeholders in Partner States points to the weak or inadequate linkages between the veterinary and livestock sectors in Partner States and the EAC Sectoral Council on agriculture and food security that is charged with coordinating the agricultural and livestock agenda within the EAC.

4 There is low or inadequate publicity and dissemination of information by the TWG on the ongoing MRP activities in the region.

5 The EAC Partner States involved in the MRP activities have a sense of ownership of the process based on their support for EAC involvement in their NRA activities.

6 A majority of the respondents express familiarity with the MRP although there is still a significant proportion that is unfamiliar with the processes involved in MRP.

7 The views on whether the MRP is aligned with the Partner States' technical requirements are largely influenced by how familiar one is with the proposed MRP.

8 There is a perception by the respondents that the veterinary sector input is not adequately represented in the NRAs as a result of the NRAs being domiciled in the line Ministries of Health. Hence, the veterinary sector issues such as the adoption of the MRP are perceived as not being adequately prioritized. There is a need for more veterinary professional involvements in veterinary drug regulation activities. There is also no resistance or bad faith among the non-vets in the regulatory authorities with respect to MRP as they are supportive.

9 There is general awareness on the requirements for veterinary medicines registration in the NRAs of the EAC Partner States.

10 The respondents believed that there is a need for more intensive sensitization on the MRP process among key stakeholders.

11 The respondents largely hold the view that there is a change required to align national legislation and regulations on veterinary medicine registration with the MRP. This could be attributed to a lack of understanding of the MRP concepts or processes.

12 The EAC is thought to be a valuable platform that is useful in pushing the MRP agenda.

13 Financial and technical capacities as well as stakeholder engagements were listed as major barriers to the implementation of the MRP. The MRP will require additional roles and responsibilities from the NRA professionals who form part of the TWG and the CGMR. It is thought this will attract extra remuneration and, therefore, the cost implications will have to be catered for during implementation. Other administrative costs may also arise which have to be taken care of. It is thus prudent for a cost–benefit analysis to justify to those who will bear these extra expenses why it is necessary to do so and to put in place sustainability mechanisms.

14 The MRP, being an EAC initiative, is supported in law through the laws of Partner States that guide ratification and domestication of the regional community's policies into their national systems. Any EAC initiative undertaken within the legal framework of the EAC is binding to the Partner States and, therefore, official communication from the EAC ought to carry some weight in the adoption of the MRP in Partner States. Based on the results, it would appear that most of the respondents were not well aware of the legal jurisdiction of the EAC and thus ought to be sensitized on the same.

15 The respondents believe that there are capacity needs that ought to be addressed for sustainability of the MRP project. These are measures that must be taken in order to give the MRP a strong foundation within the national regulatory set-up of the individual Partner States.

16 The respondents also highlighted the need for stronger involvement of the EAC Secretariat in the mutual recognition initiative to support and accelerate adoption of the MRP.

5.2 Conclusions

EAC laws and policies

1 The harmonization of technical requirements of veterinary medicines registration and subsequent MRP in the EAC derives its mandate from the EAC Council of Ministers' decision (EAC/CM30/DECISION 34). This decision, based on the analysis, is anchored on a sound legal foundation aligned with the provisions of the EAC Treaty and Common Market Protocol.

2 The MRP seeks to advance the agenda on harmonization of regulations on veterinary medicines registration within the EAC. This is in line with the EAC provisions as stipulated in the EAC Treaty and Common Market Protocol, which aim to foster integration and cooperation among the Partner States. These harmonization efforts are aligned with the overall integration agenda of the EAC. The MRP, it is hoped, will enhance trade in livestock and livestock products among the EAC Partner States.

3 The supportive provisions of the EAC are focused on the growth and development of the agriculture and livestock sectors, which will be greatly improved by implementation of the MRP. Therefore, these productive sectoral targets are aligned with the MRP's objective of providing access to safe, quality and efficacious veterinary medicines that will lower livestock mortality and morbidity and enhance livestock production. There will also be enhanced cooperation in the agriculture and livestock sector among Partner States.

4 The EAC strategy on control and prevention of transboundary animal and zoonotic diseases also gives weight to the implementation of the MRP which will allow access to veterinary medicines for the control of transboundary animal diseases within the EAC.

5 The need to regulate and control veterinary products in circulation within the EAC in terms of quality, safety and efficacy is also aligned to the MRP, which seeks to make the process of veterinary medicine registration more efficient and cost-effective.

EAC Partner States national laws and regulations

1 The NRAs in the EAC are the main authorities mandated to undertake veterinary medicines registration.

2 The MRP is not a replacement for the national registration procedures and works to complement the existing national regulations on veterinary medicines registration. An pplicant may still opt to apply for MAs in one country of the EAC where they will only be required to use the normal registration procedures for that particular country.

3 Lack of or weak policy frameworks and legislation guiding the veterinary vaccine sector has exacerbated the problem of access to and control of veterinary medicines leading to enforcement challenges by the NRAs.

4 Harmonization and joint activities is expected to reduce workload and improve overall regulatory performance.

5 Effective implementation requires the commitment of Partner States' NRAs.

Mechanisms and strategies for implementation of the MRP

1 Given the role played by livestock production in the continent, availability and access to safe and effective veterinary products is highly important. The use of veterinary medicines requires regulation and legislation as in all other sectors.

2 Resources are required to undertake sensitization, capacity building, policy advocacy, and other TWG and CGMR activities.

3 The respondents are willing to adopt the MRP provided there is necessary capacity building, sensitization and financial and technical support towards its actualization.

4 The majority of stakeholders are in support of the harmonization process and the MRP.

5.3 Policy recommendations EAC

EAC laws and policies

1 The EAC Secretariat should sensitize the TWG on the processes necessary for the approximation of laws that may be carried out in order to enhance MRPs. This is in line with the general provisions of the EAC Common Market Protocol Part 1, *Article 47 (1)* which states that the Partner States undertake to approximate their national laws and to harmonize their policies and systems, for the purposes of implementing the Common Market Protocol.

2 The EAC Secretariat should strengthen policy advocacy and stakeholder sensitization on the legal provisions that give mandate to the harmonization process and the MRP.

3 There should be targeted efforts by the EAC Secretariat and TWG aimed at inclusivity of key players in veterinary medicine registration including representatives of veterinary services, NRAs, veterinary councils and private sector actors (applicants).

4 There is a need for active dissemination of information on the MRP through the EAC website and other relevant EAC stakeholder forums by the EAC Secretariat, the TWG and GALVmed.

5 NRAs in the EAC should be encouraged and supported to access and adopt best practices from already established trade blocks like the EU in the implementation of mutual recognition in veterinary medicines registration.

EAC Partner States' national laws and regulations

1 The NRAs should engage in disseminating information about the MRP by publishing the harmonized technical documents on their website and communicate on the availability of the MRP for applicants in the EAC.

2 GALVmed should facilitate further sensitization meetings with relevant stakeholders to create awareness on MRP sensitization among Partner States of the EAC.

3 There is a need for policy dialogue among the legal officers in the NRA and the TWG members for sensitization on the legal ramifications of the MRP process in their respective NRAs.

4 There is a need for clarification from the PPB and/or VMD on the transitional arrangements involved and its implications for the adoption of the MRP in the Kenya regulatory framework.

5 Recommendations from previous sensitization activities by NRAs should be shared in the TWG meetings to enhance understanding of the issues in implementing the MRP in each Partner State and acting on them. There is also a need for sensitization of the other NRAs to adopt best practices from Uganda on MRP implementation.

6 There is a need for policy dialogue and sensitization on the differences in regulations in individual Partner States in order to enhance harmonization and approximation of laws and policies in the EAC.

7 The TWG members should lead efforts in advocacy and sensitization of the MRP as an EAC-led initiative supported by GALVmed to get buy-in and ownership within their Authority.

Summary of findings, conclusions and recommendations

8 The EAC Secretariat should formally communicate to the NRAs on the EAC roadmap for implementing the MRP. The TWG should also put in place measures for the translation of the MRP harmonized documents into French to allow for smooth adoption into the French-speaking countries in the EAC.

9 There is a need for the EAC to incorporate he South Sudan NRA into the TWG as a Partner State of the EAC.

10 There is a need to facilitate policy dialogue and advocacy by GALVmed, majoring on the need for the MRP and expected benefits in the EAC Partner States.

11 Capacity building on the MRP is needed across the EAC NRAs. This can be done by the respective TWG members involved in their particular NRA.

12 NRAs should incorporate activities of the TWG in their respective work plans and there is a need for adequate dissemination of information from the TWG on the status of their activities.

13 There is a need for GALVmed, in partnership with the NRAs, to undertake pilot programmes and activities to test the practicability of the MRP in the EAC Partner States and enable review and revisions in accordance with the regulatory frameworks in the EAC.

14 There is a need to strengthen collaboration and partnership among the Partner States' NRAs and the EAC through stakeholder sensitization meetings and joint capacity building activities by the EAC on the laws on veterinary medicines registration in Partner States.

Mechanisms and strategies for implementation of MRP

1 There is a need for training and capacity building of NRAs and veterinary sector professionals on the technical requirements for MRP.

2 Intensive stakeholder sensitization, policy dialogue and advocacy by the EAC and GALVmed on the MRP initiative for internalization and implementation in the EAC should be undertaken at both national and regional levels. This intensive lobbying, advocacy and sensitization of the NRAs on the MRP should be undertaken with the aim of creating awareness and a sense of ownership of the MRP process in the Partner States. The NRAs should be able to incorporate the MRP into their operations, work plans and budgets as a consequence of this action.

3 The EAC MRP initiative could adopt best practices from the EAC-MRH on harmonization of human medicine registration initiative whose implementation is currently underway. The two initiatives are both mandated through the EAC and, therefore, the processes of ratification and domestication could be borrowed from the EAC-MRH, which is way ahead in the process. This ought to be facilitated by the EAC Secretariat, which has been involved in the TWG and is familiar with the EAC protocols and processes.

4 Strengthening of the linkages between the Partner States' NRAs and the veterinary sector players through advocacy and joint capacity building activities should be facilitated by GALVmed.

5 The TWG should develop a clear roadmap and implementation plan with clear timelines for the roll-out of the MRP in the EAC Partner States. There is a need to undertake test runs and pilot activities before complete adoption of the MRP so that there is room to revise and refine the harmonized technical documents before they are published.

6 The EAC Secretariat should put in place effective communication channels to the NRAs so that information from the EAC MRP initiative activities is disseminated to the relevant parties in the NRAs with decision making capacity.

Summary of findings, conclusions and recommendations

7 GALVmed should strengthen partnerships and collaborations among the private sector and NGOs such as the ATPS to proactively engage in advocacy efforts towards MRP domestication in Partner States. Synergy among the various key stakeholders involved in veterinary legislation (FAO, OIE, GALVmed, AU-IBAR) would be useful to provide capacity for lobbying and advocacy.

8 The implementation of the MRP is highly dependent on Partner States' representatives involved in these efforts pushing the agenda within their particular departments in their home countries to create buy-in and ownership in the NRA. This would help to promote trust and confidence in the adoption of these MRPs.

9 There should be a robust rationale and justification for harmonization of regulations among the EAC Partner States. Clearly outlined economic benefits of the MRP to the applicant, the NRA and the farmer are necessary to enhance government involvement in the process. This should also involve a stronger linkage of the animal health aspect to the public health that affects human health, which will give the MRP initiative more gravitas in implementation.

10 There is a need for more involvement of legal practitioners to provide veterinarians in EAC Partner States with the opportunity to review the principles of quality legislative drafting and how to involve stakeholders in legislation, policy making and capacity building for enforcement. There should be a multi-policy approach to address MRP implementation challenges.

11 GALVmed should engage farmers' groups and associations as part of the key beneficiaries of a streamlined veterinary medicines registration process in the EAC. This cohort of stakeholders should be sensitized on the potential benefits of the MRP and expected impact on their livestock-keeping activities.

12 There is a need to strengthen the collaboration between private and public sector entities to ensure the effective implementation of MRPs. The inclusion of private sector input in efforts of veterinary drug regulation in the TWG would be a step in the right direction. Efforts should be made by the EAC and NRAs to source funds, especially from private agencies and development partners to support the harmonization process and uptake of MRPs.

13 There is, therefore, a need for GALVmed to engage in programmes/activities that will increase their visibility among relevant stakeholders in the region.

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Annexes

ANNEX 1: **Specific objectives and research questions**

The specific objectives that were used to arrive at the three broad objectives were:

1. Review and analyse veterinary policies and regulations in each EAC Partner State, looking at the extent to which they are aligned to the Council of Minister's decision on the harmonization of regulations for the registration of veterinary products for mutual recognition in the sub-region.
2. Assess the constraints and opportunities for the harmonization of regional veterinary regulations for the registration of veterinary products for mutual recognition in EAC Partner States.
3. Identify the laws and regulations that need to be amended or revised in order to facilitate the implementation of a harmonized registration system for veterinary products for mutual recognition.
4. Identify the processes required for the actualization of mutual recognition cascading the regional level decision.
5. Identify mechanisms and strategies that will facilitate and enhance national level ratification, domestication and actual implementation of the harmonized registration system agenda.

The key questions that guided this study were:

1. To what extent are countries' policies and regulations on registration of veterinary products aligned to the Council of Minister's decision?
2. What are the policy constraints and opportunities for the harmonization of regional veterinary regulations for the registration of veterinary products in EAC Partner States?
3. What laws and regulations have to change at the country levels?
4. What processes are required in order to actualize mutual recognition cascading the regional level decision?
5. What processes or mechanisms can be put in place to ensure national level ratification, domestication and actual implementation of the decision?
6. What is the current status of implementation of the decision on harmonization of regulations for the registration of veterinary medicines for mutual recognition in the EAC Partner States?
7. What are the capacity requirements for achieving effective harmonization of registration of veterinary products for mutual recognition in the Partner States?

ANNEX 2: **List of sample target respondents**

S/No.	Country	Name
Directors of Veterinary Services (government officials)		
1.	Burundi	Deogratias Nsanganiyumwami
2.	Burundi	Alfred Niyokwishimira
3.	Burundi	Lionel Nyabongo
4.	Kenya	Julia Kinyua
5.	Kenya	Nathan Kipkorir Songok
6.	Rwanda	Gafarasi Mapendo
7.	South Sudan	Aluma Araba Ameri
8.	Tanzania	Abdu Amman Hayghaimo
9	Tanzania	Peter Mgelwa Kingu
10.	Uganda	Nicholas Kauta
National Regulatory Authority players (Technical Working Group (TWG) and Coordination Group for Mutual Recognition (CGMR))		
11.	Burundi	Gerard Nishemezwe
12.	Burundi	Joseph Nyongabo
13.	Kenya	Johnathan Meriakol
14.	Kenya	James Mbaria
15.	Kenya	Obadiah Njagi
16.	Rwanda	Jean Claude Rukundo
17.	Tanzania	Rosemary Aaron
18.	Tanzania	Emmanuel Mutakyahwa
19.	Tanzania	Christopher Migoha
20.	Uganda	Noel Aineplan
21.	Uganda	Daniel Etuko
Private sector actors and partners (practitioners, manufacturers, importers, distributors)		
22.	Kenya	Karim Shamshydin
23.	Kenya	Ken Mbogori
24.	Kenya	Johnathan Orengo
25.	Kenya	Joseph Odhiambo
26.	Kenya	Joshuah Madieka
27.	Kenya	John Muchibi
28.	Kenya	Evelyn Lusenaka
29.	Kenya	Mary Wanjiru Mathenge
30.	Tanzania	Henry Mbwille
31.	Tanzania	Nderingo Ngowi
32.	Tanzania	Henry
33.	Tanzania	Ansalem Kessy
34.	Uganda	Elizabeth Okello
35.	Uganda	Emma Mbabazi
36.	Uganda	Alice Banga
37.	Uganda	Paul Bogere
38.	Uganda	Steven Venny Rubanga
39.	Uganda	Diana Nalwanga
40.	Uganda	Patrick Opondo
41.	Uganda	Ronald Wangwe Welikhe

Annexes

ANNEX 2: **List of sample target respondents**

S/No.	Country	Name
Veterinary officers and representatives from veterinary councils/boards/associations		
42.	Kenya	Kenneth Wameyo
43.	Tanzania	Bedan Manyama Masuruli
44.	Tanzania	Sero Luwongo
45.	Uganda	Martin Kasirye
46.	Uganda	Florence Masembe Kasirye
Legal officers working with line Ministries of Veterinary Services (government officials)		
47.	Burundi	Richard Gahungu
48.	Kenya	Rizpha Mukonyo David
49.	Rwanda	Josephine Uwizeyimana
50.	Tanzania	Lyimo Herman Clement
51.	Uganda	Mr Isaac Singura Karekona
EAC, AU and OIE partners		
52.	OIE	Sam Wakhusama
53.	AU-PANVAC	Nick Nwankpa
54.	EAC	William Olaho Mukani
55.	EAC	Timothy Wesonga
56.	EAC	Paul Chacha

ANNEX 3: **List of respondents**

S/No.	Country	Name
Directors of Veterinary Services (government officials)		
1.	Burundi	Lionel Nyabongo
2.	Kenya	Nathan Kipkorir Songok
National Regulatory Authority players		
3.	Burundi	Gerard Nishemezwe
4.	Kenya	Obadiah Njagi
5.	Uganda	Noel Aineplan
6.	Uganda	Elizabeth Okello
Private sector actors and partners		
7.	Uganda	Steven Venny Rubanga
8.	Uganda	Patrick Opondo
9.	Uganda	Ronald Wangwe Welikhe
Veterinary officers and representatives from veterinary councils/boards/associations		
10.	Tanzania	Bedan Manyama Masuruli
11.	Tanzania	Sero Luwongo
12.	Uganda	Martin Kasirye
13.	Uganda	Florence Masembe Kasirye
Legal officers working with line Ministries of Veterinary Services		
14.	Tanzania	Lyimo Herman Clement
EAC, AU and OIE partners		
15.	OIE	Sam Wakhusama

ANNEX 4: **TWG and CGMR members**

S/No.	Name	Representing	Role	email address
1.	Gerard Nishemezwe	Burundi	TWG and CGMR	genishemezwe@gmail.com
2.	Joseph Nyongabo	Burundi	TWG	niyongabojeef@yahoo.fr
3.	Johnathan Meriakol	Kenya	TWG	meriakol@yahoo.co.uk
4.	James Mbaria	Kenya	TWG and CGMR	mbariajm@gmail.com
5.	Obadiah Njagi	Kenya	TWG	Jesse.mwere@gmail.com
6.	Jean Claude Rukundo	Rwanda	TWG and CGMR	ndokurujohn@yahoo.fr
7.	Isadore Gafarasi	Rwanda	TWG	igafarasi@yahoo.fr
8.	Rosemary Aaron	Tanzania	TWG	rosemaryaaron@yahoo.com
9.	Emmanuel Mutakyahwa	Tanzania	TWG	rutamuta75@yahoo.com
10.	Christopher Migoha	Tanzania	CGMR	christophermigoha@yahoo.com
11.	Noel Aineplan	Uganda	TWG and CGMR	amnoel@nda.or.ug
12.	Daniel Etuko	Uganda	TWG	detuko@nda.org
13.	Gilly Cowan	GALVmed	Facilitator	gilly.cowan@galvmed.org
14.	Elizabeth Okello	GALVmed	MR-Coordinator	eapokello@yahoo.co.uk
15.	Timothy Wesonga	EAC	TWG associate	twesonga@eachq.org
16.	William Olaho Mukani	EAC/AU-IBAR	TWG associate	williamolahomukani@gmail.com
17.	Nick Nwankpa	AU-PANVAC	TWG associate	nicknwankpa@yahoo.com

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executivedirector@atpsnet.org

ANNEX 5: **Questionnaire**

A Policy Scoping Study on Harmonization of Registration Requirements for Veterinary Products for Mutual Recognition among East African Community Partner States

Dear Respondent,

Thank you for accepting to complete this survey. The African Technology Policy Studies Network (ATPS) on behalf of its partner, the Global Alliance for Livestock Veterinary Medicines (GALVmed), is undertaking this survey in Partner States of the East African Community (EAC). The aim of the survey is to assess the status of Partner States with regards to the implementation of the EAC Council of Ministers' decision (2014) on the harmonization of registration requirements for veterinary products and for mutual recognition procedures (MRPs) among EAC Partner States. The survey elicits information on the strategies/mechanisms that may facilitate the adoption and implementation of the harmonization decision. Your contributions by way of responding to this survey would be invaluable. We assure you that any information you provide will remain confidential.

SECTION A: **BACKGROUND INFORMATION**

1. Name of respondent: _____
2. Gender: Male ☐ Female ☐
3. Country: _____
4. Sector: Government/public sector ☐ Non-governmental organization ☐
   Private sector ☐ Other (specify) _____
5. Name of organization/institution: _____
6. Name of department: _____
7. Designation: _____
8. Telephone number: _____
9. Email: _____

SECTION B: **NATIONAL LEGISLATION, REGULATIONS AND POLICIES**

10. Kindly list the current veterinary laws and policies in your country that influence the livestock sector and veterinary practice and the **year** of enactment or latest review.

S/No.	Veterinary legislation and policy	Year of enactment/review
1.		
2.		
3.		
4.		
5.		

11. Specifically list **national laws** in your country that govern the **registration** of immunological veterinary products (IVPs) and the **year** of enactment or latest review.

S/No.	Laws on IVP registration	Year of enactment/review
1.		
2.		
3.		
4.		
5.		

12. Specifically list any other **national guidelines and regulations** (subsidiary legislation) that are used in the registration of IVPs in your country.

S/No.	Guidelines and regulations on IVP registration	Year of enactment/review
1.		
2.		
3.		
4.		
5.		

13. Is there a functional national drug regulatory authority in your country

Yes ☐ No ☐ ***(if Yes, skip to Q 15.)***

SECTION B: **NATIONAL LEGISLATION, REGULATIONS AND POLICIES**

14. In the absence of a national drug regulatory authority, what is the name of the government body mandated with veterinary drug registration in your country?

_____

15. What is the name of your national drug regulatory authority?

_____

16. Where does the responsibility for veterinary drugs and vaccines registration fall within your National Drug Authority framework?

    a) In a separate agency for veterinary medicine within the authority ☐

    b) In a single agency for both veterinary and human medicine in the same authority ☐

    c) Other (explain) _____

17. Kindly list any other authorities that are involved in veterinary drug and vaccine registration in your country and the respective legislation that gives them the mandate.

S/No.	Other regulatory authority/board	Legislation that gives them the mandate

18. What in your opinion is the relationship among the various authorities within the veterinary vaccine regulation spectrum in your country?

    a) They have an overlapping and conflicting mandate ☐

    b) They are supplementary and supportive ☐

    c) Other (explain)

_____

19. What is the approximate veterinary sector representation in terms of number of veterinary officers in your national drug regulatory authority?

    Below 25% ☐ 26% to 50% ☐ 51% to 75% ☐ Above 75% ☐

20. In your opinion, what is the level of awareness of international recognized standards by the World Organisation for Animal Health (OIE) on veterinary legislation, guidelines and regulations in the veterinary sector in your country?

    Little awareness ☐ Moderate awareness ☐ Extensive awareness ☐

21. To what extent are these OIE international standards integrated into the national veterinary laws and regulations of your country?

    a) Not integrated ☐

    b) Moderately integrated ☐

    c) Very integrated ☐

    d) Don't know ☐

22. In your opinion, what is the level of awareness of registration requirements of veterinary pharmaceuticals and IVPs in your NRA?

    Little awareness ☐ Moderate awareness ☐ Extensive awareness ☐

SECTION C: **HARMONIZATION OF REQUIREMENTS FOR MRPs**

23. Are you aware of the EAC Council of Minister's decision on harmonization of requirements for registration of veterinary immunologicals?

    Yes ☐ No ☐

24. In your opinion, what is the level of awareness of EAC efforts towards harmonization of veterinary registration requirements in your country's veterinary and livestock sector?

    Very high ☐ High ☐ Moderate ☐ Low ☐

25. How familiar are you with the EAC proposed MRPs?

    Very familiar ☐ Familiar ☐ Unfamiliar ☐

26. Rank the following statements with respect to the EAC Secretariat's involvement in MRPs within the context of the EAC integration agenda.

    1 = strongly disagree; 2 = disagree; 3 = neutral; 4 = agree; 5 = strongly agree

S/No.	Statement	1	2	3	4	5
1.	EAC Secretariat has put in place appropriate strategies for veterinary harmonization of registration requirements					
2.	Member states are willing to adopt the EAC Council of Ministers' decision on harmonization of requirements for registration of veterinary immunologicals					
3.	The EAC has the legislative mandate to support the implementation of MRPs					
4.	Others (specify)					

27. Are you conversant with any of the legal provisions of the EAC that support the implementation of the Council of Ministers' decision on harmonization of requirements for registration of veterinary immunologicals?

    Yes ☐ No ☐

28. If Yes, kindly list the ones you know.

    _____

29. What is the level of awareness of MRPs by veterinary stakeholders and prospective applicants in your country?

    Low ☐ Moderate ☐ High ☐ Very high ☐ Don't know ☐

30. Kindly rank the level of sensitization that needs to be done on the following key stakeholders with respect to harmonization of requirements for registration of veterinary immunologicals and MRPs.

    1 = no sensitization; 2 = little sensitization; 3 = moderate sensitization; 4 = intensive sensitization; 5 = very intensive sensitization

S/No.	Stakeholders	1	2	3	4	5
1.	Government/public sector					
2.	Private sector					
3.	Veterinary professionals and para-professionals					
4.	Local livestock farmers' groups and associations					
5.	Manufacturers, importers and distributors of vaccine products					
6.	Others (specify)					

_____

31. To what extent do you agree with the following statements with respect to the benefits expected from the harmonization process?

    1 = no sensitization; 2 = little sensitization; 3 = moderate sensitization; 4 = intensive sensitization; 5 = very intensive sensitization

S/No.	Benefits expected from MRPs for registration of veterinary immunologicals	1	2	3	4	5
1.	Harmonization of registration requirements and regulations will improve the quality, safety and efficacy of veterinary vaccines in the EAC market					
2.	Eliminate duplication of tasks by the respective NRAs in the EAC					
3.	Reduce delay in registration of veterinary vaccines allowing rapid introduction of new vaccines against new diseases					
4.	Reduce time for applicants to obtain marketing authorizations					
5.	Build trust between regulators					
6.	Increase international trade of livestock and livestock products					
7.	Reduce counterfeits and substandard veterinary vaccines and products					
8.	Others (specify)					

_____

32. In your opinion, are the MRPs aligned to your country's registration requirements for veterinary products?

    Yes ☐ No ☐

33. In your opinion to what extent does the national regulatory and legislative framework of your country need to be changed to align with the following aspects of MRPs?

    1 = no changes; 2 = few changes; 3 = moderate changes; 4 = many changes; 5 = complete overhaul

S/No.	Components of the MRP	1	2	3	4	5
1.	Dossier assessment can be done by competent authority of another country within the EAC Partner States					
2.	That joint assessment of dossiers is not part of the MRP process					
3.	That inspections of premises can be done by competent authority of another country within the EAC Partner States					
4.	That appeals may be heard by the Technical Working Group and experts					
5.	That safety and efficacy trials done in other countries might be acceptable under certain circumstances in place of local trials					

34. What needs to happen for your regulatory agency to accept an inspection report done by another country?

    _____

35. Kindly rank the following factors with respect to their influence on implementation of MRPs.

    1 = not likely to influence; 2 = a little likely; 3 = likely; 4 = highly likely; 5 = will definitely influence

S/No.	Factors likely to influence adoption of MRPs	1	2	3	4	5
1.	Financial implications of implementing MRPs					
2.	Technical aspects for achieving harmonization of registration requirements					
3.	Administrative issues in the NRAs					
4.	Capacity needs for implementation of the MRP					
5.	Inadequate awareness about MRPs					
6.	Others (please specify)					
	_____					

36. What is the current status of implementation of the decision on harmonization of requirements for registration of veterinary immunologicals for mutual recognition in your country?

    a) Not begun ☐

    b) Moderately integrated ☐

    c) At an advanced stage ☐

37. How, in your opinion, would you rate the kind of change in legislation needed to realize mutual recognition in your country?

1 = strongly disagree; 2 = disagree; 3 = neutral; 4 = agree; 5 = strongly agree

S/No.	Recommended change in legislation	1	2	3	4	5
1.	New primary legislation and repeal of the old primary legislation					
2.	Complete overhaul of the subsidiary regulations and repeal of old regulations					
3.	New guidelines and regulations to supplement old ones					
4.	Amendments to the primary legislation					
5.	Amendments of the subsidiary regulations					
6.	Others (specify)					

38. Can you list the **specific laws** in your country that govern the following components of the MRP?

S/No.	MRP aspect	Primary legislation (laws/acts)
1.	Dossier assessment of vaccine products	
2.	Inspection	
3.	Appeals	
4.	Clinical safety and efficacy trials	

39. Can you list the specific **guidelines and regulations** in your country that govern the following components of the MRP? And rate it as either supportive (1) or conflicting (2)?

S/No.	MRP aspect	Guidelines/regulations	Supportive = 1 Conflicting = 2
1.	Dossier assessment of vaccine products		
2.	Inspection		
3.	Appeals		
4.	Clinical safety and efficacy trials		

SECTION D: **OPPORTUNITIES AND CONSTRAINTS**

40. In your opinion, how would you rate the following statements with respect to harmonization and mutual recognition within the legal and regulatory framework of your country?

1 = strongly disagree; 2 = disagree; 3 = neutral; 4 = agree; 5 = strongly agree

S/No.	Statement	1	2	3	4	5
1.	Harmonization and MRPs are not possible within the current framework					
2.	It is possible to implement MRPs without changes to the primary legislation					
3.	Implementation of MRPs requires a little modification to the primary legislation					
4.	Implementation of MRPs requires modification to the subsidiary legislation (regulations)					
5.	Implementation of MRPs only requires technical harmonization and not legal harmonization					
6.	Others (specify)					

41. How would you rank the following factors as opportunities with respect to implementation of MRPs?

1 = strongly disagree; 2 = disagree; 3 = neutral; 4 = agree; 5 = strongly agree

S/No.	Opportunities for implementation	1	2	3	4	5
1.	Basis for Partner States to meet minimum international requirements in their national regulations					
2.	MRPs work for the common objectives of the NRA					
3.	Alignment with EAC objectives in the EAC integration agenda					
4.	Inclusivity of relevant stakeholders in the process of mutual recognition of registration requirements					
5.	Others (please specify)					

42. How would you rank the following factors as constraints that would hinder implementation of MRPs?

1 = strongly disagree; 2 = disagree; 3 = neutral; 4 = agree; 5 = strongly agree

S/No.	Constraints	1	2	3	4	5
1.	Financial resource constraints					
2.	Human resource constraints					
3.	Different levels of implementation by Partner States					
4.	Different governance structures in the Partner States					
5.	Lack of political commitment					
6.	Differences in implementation strategies					
7.	Lack of supportive policies					
8.	Change and control mechanisms in reviewing policy and legislation					
9.	Challenges with stakeholder engagement					
10.	Others (specify)					

SECTION E: **MECHANISMS AND STRATEGIES FOR ACTUAL IMPLEMENTATION OF MRPs**

43. What strategies should be taken by national level authorities in implementing MRPs?

1 = strongly disagree; 2 = disagree; 3 = neutral; 4 = agree; 5 = strongly agree

S/No.	Strategies	1	2	3	4	5
1.	Increased awareness creation about MRPs and their benefits, especially to target stakeholders					
2.	Formulation and development of policies and frameworks that support MRP implementation					
3.	Improvement in the enforcement of national regulations in line with MRPs					
4.	Integration of MRP into the existing regulatory and legislative frameworks					
5.	Others (specify)					

44. Kindly rank the difficulties encountered by those involved in the veterinary medicinal product sector in terms of new vaccine registration in East Africa.

1 = strongly disagree; 2 = disagree; 3 = neutral; 4 = agree; 5 = strongly agree

S/No.	Difficulties in vaccine registration	1	2	3	4	5
1.	Delay in registration of IVPs					
2.	Lack of effective coordination arising from multi-agency involvements in the process					
3.	Lack of qualified personnel					
4.	Cost implications for registering in each Partner State					
5.	Duplication of efforts in submitting multiple applications					
6.	Corruption in the sector					
7.	Inability to introduce a change, e.g. in manufacture or testing, until all relevant authorities have approved the change, according to their individual timeframes					
8.	Others (specify)					

45. In terms of challenges in vaccine registration requirements, how would you rate the extent to which the MRP will solve these problems for applicants intending to register in multiple countries?

1 = strongly disagree; 2 = disagree; 3 = neutral; 4 = agree; 5 = strongly agree

S/No.	Solutions through MRPs	1	2	3	4	5
1.	Speedy process in registration of IVPs					
2.	Improved coordination from multi-agencies involved in MRP implementation					
3.	More qualified personnel involved with implementation					
4.	Reduced cost of registering IVPs in each Partner State					
5.	One stop shop in making applications by applicants in the Partner States					
6.	Efficiency and effectiveness in operations in the system which reduces corruption					
7.	Ability to introduce a change, e.g. in manufacture or testing, simultaneously following harmonized approval date by relevant Partner States					
8.	Others (please specify)					

46. How would you estimate the financial implications of MRP implementation?

Low ☐ Moderate ☐ High ☐ Very high ☐

47. In your opinion, do you think an official EAC correspondence to NRAs will accelerate MRP adoption in EAC Partner States without necessarily changing existing regulations?

Yes ☐ No ☐

SECTION F: **SUSTAINABILITY AND CAPACITY FOR INTEGRATION**

48. What are the sustainability issues and capacity requirements for achieving effective harmonization of registration of veterinary products for mutual recognition in the Partner States?

1 = strongly disagree; 2 = disagree; 3 = neutral; 4 = agree; 5 = strongly agree

S/No.	Sustainability and capacity requirements	1	2	3	4	5
1.	Employ technically qualified personnel in the NRAs for MRP implementation					
2.	Training and retraining of existing personnel with respect to MRPs					
3.	Integrate issues on MRPs into the veterinary curriculum in universities					
4.	Use of high technology equipment by the regulatory authorities					
5.	Integrate MRPs into EAC and national regulatory frameworks and policies					
6.	Others (specify)					

49. In your opinion, what is the level of support accorded to the veterinary sector by the relevant national ministry in the harmonization of requirements for registering veterinary products for mutual recognition?

a) No support ☐
b) Little support ☐
c) Average support ☐
d) Very supportive ☐

50. Are there targeted efforts by the government through the ministry to review policy and legislation for good governance and administration in the veterinary sector?

Yes ☐ No ☐

51. How would you rate the level of cooperation between the EAC Secretariat and the relevant veterinary governance and administrative structures in your country?

Very high ☐ High ☐ Very low ☐

ANNEX 6: **Veterinary legislation and policies in Kenya**

S/No.	Veterinary legislation and policies	Year of enactment/review
1.	Animal Diseases Act, Cap 364	2012
2.	Branding of Stock Act, Chapter 357	2012
3.	Cattle Cleansing Act, Cap 358	1967
4.	Code of Ethics Regulations, 2015 under The Veterinary Surgeons and Veterinary Para-Professionals	2015
5.	Fertilizers and Animal Foodstuffs Act, Chapter 345	2012
6.	Hides, Skins and Leather Industry Act, Chapter 359	2012
7.	Kenya National Drug Policy	1994
8.	Kenya Veterinary Policy (draft)	2015
9.	Meat Control Act, Chapter 356	2012
10.	National Livestock Policy	2008
11.	Pest Control Products Act	1982
12.	Pharmacy and Poisons Act, Cap 244[7]	2015
13.	Prevention of Cruelty to Animals Act, Cap 360	2012
14.	Rabies Act, Chapter 365	2012
15.	Registration of drugs rules under the Pharmacy and Poisons Act, Cap 244	2012
16.	Veterinary Medicines Directorate Regulations under the Veterinary Surgeons and Veterinary Para-Professionals Act	2015
17.	Veterinary Surgeons and Veterinary Para-Professionals Act	2011

ANNEX 7: **Veterinary legislation and policies in Tanzania**

S/No.	Veterinary legislation and policies	Year of enactment/review
1.	Animal Diseases Act	2003
2.	Animal Feeds Policy	2003
3.	Animal Identification, Traceability and Registration Act	2008
4.	Animal Prevention of Cruelty Act	1964
5.	Animal Straying Act	1964
6.	Animal Welfare Act	2008
7.	Application guidelines for registration of veterinary medicinal products	2015
8.	Cattle Traders Act	1964
9.	Dairy Industry Act	2004
10.	Delivery of Veterinary Services Policy	2003
11.	Grazing-Land and Animal Feed Resources Act	2010
12.	Guideline for dealing in controlled drugs	2015
13.	Hides and Skins Trade Act	1973
14.	Meat Industry Act	2004
15.	National Agricultural Extension Policy	2015
16.	National Agricultural Policy	2014
17.	National Animal Breeding Policy	2001
18.	National Livestock Policy	2006
19.	Public Health Act	1958
20.	Rabies Act	1964
21.	Tanzania Food, Drugs and Cosmetics Act[8]	2003
22.	Veterinary Act	2003
23.	Veterinary Surgeons' Act	1964

7 Law on registration of veterinary medicines
8 Law on registration of veterinary medicines

ANNEX 8: **Veterinary legislation and policies in Uganda**

S/No.	Veterinary legislation and policies	Year of enactment/review
1.	Animal Breeding Act	2001
2.	Animal Diseases Act, Cap 38	1964
3.	Animal Feeds Policy	2003
4.	Animal Prevention of Cruelty Act, Cap 39	1964
5.	Animal Straying Act, Cap 40	1964
6.	Branding of Stock Act, Cap 41	1918
7.	Cattle Grazing Act, Cap 42	1945
8.	Cattle Traders Act	1964
9.	Dairy Industry Act, Cap 85	2000
10.	Guidelines for registration of Drugs	2014
11.	Hides and Skins Act, Cap 89	1973
12.	Local Government Act	2008
13.	Meat Policy	2003
14.	National Agricultural Advisory Services Act	2001
15.	National Agricultural Extension Policy	2015
16.	National Agricultural Policy	2014
17.	National Animal Breeding Policy	2001
18.	National Delivery of Veterinary Services Policy	2001, 2003
20.	National Drug Policy and Authority Act (Clinical Trials) Regulations	2014
21.	National Drug Policy and Authority Act (Importation and Exportation) Regulations	2014
22.	National Drug Policy and Authority Act (Registration) Regulations	2014
23.	National Drug Policy and Authority Act, Cap 206[9]	1993, 2000
24.	National Drugs Policy	1993, 2000
25.	National Veterinary Drug Policy	Nov 2002
26.	Public Health Act	1958
27.	Rabies Act, Cap 44	1964
28.	Veterinary Drugs Policy	1999
29.	Veterinary Surgeons Act, Cap 277	1958, 1964

ANNEX 9: **Laws on veterinary medicines registration in Rwanda**

S/No.	Laws on veterinary medicines registration	Year of enactment/review
1.	Ministerial order N°008/11.30 of 18/11/2010 determining the organization of veterinary pharmacy practice	2010
2.	Law N°74/2013 of 11/09/2013 establishing Rwanda Food and Medicines Authority (RFMA) and determining its mission, organization and functioning[10]	2013

ANNEX 10: **Veterinary legislation and policies in Burundi**

S/No.	Veterinary legislation and policy	Year of enactment/review
1.	Draft Decree N° 100/of 2016 Establishing, missions, organization and operation of the Burundi Medicines Regulatory Authority (ABREMA)[11]	2016
2.	Loi sur l'exercice de la profession vétérinaire (Veterinary profession law)	2011
3.	Plan National d'Investissement Agricole (Burundi National Agriculture Investment Plan)	2010
4.	Loi sur la police sanitaire des animaux domestiques (Zoo sanitary law)	2009
5.	Document d'orientation stratégique du secteur de l'élevage (Livestock Sector Development Strategy)	2009
6.	Hides and Leather Industry Act	2009
7.	Loi № 1/28 du 24 décembre 2009 relative à la Police Sanitaire des Animaux Domestiques, sauvages, Aquacoles et Abelles (Law on Health Policy relating to domestic and wild animals, aquaculture and bees)	2009

9 Law on registration of veterinary medicines
10 Law on registration of veterinary medicines
11 Law on veterinary medicines registration

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