Options Assessment for Regulatory Harmonisation of Livestock Products in Sub Saharan Africa

SUMMARY

Veterinary Medicines Directorate

BILL & MELINDA GATES foundation

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Veterinary Medicines Directorate

An Executive Agency of the Department for Environment, Food & Rural Affairs (Defra)

The Veterinary Medicines Directorate (VMD) authorises veterinary medicines in the UK; protecting public and animal health, the environment and promoting animal welfare using veterinary medicines. The VMD is also responsible for Veterinary Medicines Regulations (VMR) which set out UK controls on veterinary medicines.

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Noel Joseph
Project Lead

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Executive summary

Overall the current state of regulation of veterinary medicines in Sub-Saharan Africa (SSA) is poor, despite the need being high. Initiatives to improve veterinary medicines regulation have not yielded the realisation of the potential improvement envisaged, either in terms of quantity or speed. A general failing has been to approach the development of capability using harmonisation as the tool/solution as opposed to harmonisation as an objective. This has led to insufficient attention on developing national competent capacity and capability for all aspects of medicines regulation to an acceptable level for the realisation of the benefits of a harmonised process.

Even in the most advanced regional harmonisation structure for veterinary medicines (the European Union) many authorisations are national. For example, in the United Kingdom (UK) one third of authorised medicines on the market were approved through a UK National Marketing Authorisation application process. Hence building national capability and capacity is a critical ingredient for ensuring availability of safe medicines.

A root-cause analysis of the strengths and weaknesses of current and previous harmonisation initiatives and a regulatory and institutional capacity gap analysis has led to the development of a roadmap to success to improve veterinary medicines regulation, availability and subsequent improvement in livestock production. A key basic need is to ensure IT capability, without which the development of initiatives (national or regional) will continue to be compromised.

Other factors, such as language groupings (Francophone, Anglophone), existing networks and national legislation, should also form part of a weighted go/no-go decision tree to inform where investment should be targeted and on what.

Industry also has a key role to play by ensuring that they have a local presence in some of the SSA countries to enable optimal stakeholder engagement.

Absent from all initiatives has been the introduction and use of benchmarking tools that can allow a medicines regulatory body to monitor improvement over time and be used in a proficiency scheme format to enable comparability between national bodies. As part of that continuing improvement programme several twinning schemes should be established. Over time the 'developed' competent medicines regulatory body should increasingly give way to an African country so that African development is driven by partner African countries.

Development of national competent capacity and capability is key to successful harmonisation

Introduction

Livestock plays an important economic role in SSA. Most of the farming population in the majority of SSA countries are subsistence farmers with a dependency on livestock. It is important therefore that these farmers have access to good quality, safe and efficacious medicines. Fragmented markets, and inadequate and uncoordinated control and enforcement, allows counterfeit and illegal products to penetrate the market. This project builds on the work previously done by the Bill & Melinda Gates Foundation (and others) and scopes the regulatory landscape to assess how to improve national capability and competency, and the feasibility of regulatory co-operation, harmonisation and/or convergence in SSA.

As a first step it investigated harmonisation efforts, including non-medicine initiatives, which have either been tried or are in place in SSA and other parts of the world with a view to identifying key lessons for successful harmonisation/convergence.

There followed an analysis of the applicable legislation, regulatory systems, institutions and the governance mechanisms related to the registration, and the sale and use of Veterinary Medicinal Products (VMPs). An economic situation and political environment review were also conducted for each country and the regions to examine their impact, if any, on the ability of a country/region to regulate medicines and to successfully harmonise its VMP regulatory process.

The assessment covered the following 28 selected countries from SSA.

- **West Africa** - Burkina Faso, Côte d'Ivoire, Ghana, Mali, Mauritania, Niger and Nigeria;
- **Central Africa** - Cameroon, Central African Republic, Chad, Democratic Republic of Congo, Congo and Gabon;
- **East Africa** - Eritrea, Ethiopia, Kenya, South Sudan, Sudan, Tanzania and Uganda;
- **Southern Africa** - Angola, Botswana, Malawi, Mozambique, Namibia, South Africa, Zambia and Zimbabwe.

The project reviewed each country's framework for regulating VMPs, from pre-registration and registration processes to post-marketing surveillance.

This is a summary report of the key findings and is presented in three sections. Section 1 covers the key lessons from the review of different harmonisation efforts; Section 2 highlights key findings from the analysis of the 28 SSA countries, and Section 3 sets out the summary conclusions and a proposal for future engagement in the SSA region.

The key elements of the methodology applied and its limitations in the analysis are presented in Appendix 1.

Background, objectives and scope

The analysis and outputs of this study was used to develop a roadmap of the potential interventions and efforts for the Bill & Melinda Gates Foundation (BMGF) to support improved medicines regulation and practices mandating animal health products and technologies in SSA. Given the long precedent and existing efforts for regulatory improvement and convergence, and recognising that progress in some areas has been slow, BMGF are particularly aiming to identify practical, cost-effective and feasible options with greatest potential for impact and success.

Key barriers to increasing productivity in the livestock sector in SSA and South Asia are, limited availability of, and poor access to, affordable, safe and quality assured animal health products and technologies. Limited availability and access jeopardise not only livestock productivity through the inability to treat disease resulting in production losses, but also the ability to prevent and contain disease outbreaks including zoonoses. According to the World Organisation for Animal Health (OIE), zoonotic diseases account for over 60% of emerging diseases in humans and pose a risk to the efforts of the One Health approach to improving wellbeing in these countries. As a result, the nutritional benefits and income potential that deprived livestock keepers can derive from livestock are diminished, particularly amidst current and projected economic growth in the region. Regulatory barriers further constrain domestic markets and regional trade of quality assured and regulated animal health products. This is largely driven by a lack of progress in some countries in committing to establishing national and regional systems for harmonising and enforcing the regulations guiding the development, production, import and sale/delivery of these products and technologies. There is strong evidence that such constraints are proving a disincentive for the private sector's commitment to undertake the necessary opportunities to meet demand.

While there have been previous efforts to improve capability, harmonise and enforce standards and processes in human medicines and veterinary vaccines, individual countries and regions still lack credible and established institutions, streamlined processes and governance mechanisms, and consistent regulatory standards.

The BMGF Livestock team developed as an initiative from a recognised need to address challenges specific to livestock farming systems and over 900 million deprived livestock keepers in SSA and South Asia. The initiative's purpose is to help create better access to good husbandry practices and modern agricultural production technologies – and in turn stabilise and enhance livestock keepers' income generating potential through:

- improved production and reduced losses;
- improved access to market and the ability to generate greater margins; and
- preservation and enhanced viability of the natural environment through increased and well targeted investment for sustainable development of the livestock sector and environment.

Objectives

The project objectives were to:

1) investigate in detail current national Veterinary Medicines Regulation (VMR) setup and the feasibility of regional harmonisation of VMR,
2) develop and assess practical options and trade-offs with the greatest potential for impact and success, that will inform future efforts to address the regulatory and enabling environment for the BMGF livestock portfolio in SSA, and
3) provide an analysis and evidence base to help support BMGF internal investment and engagement decision by the end of 2019.

Scope

The scope of the project included:

- An independent evaluation of past and current global, regional and national efforts around VMR and Veterinary Medicines Regulation Convergence (VMRC) to date, including an analysis of challenges and obstacles from previous BMGF and other external efforts;
- Case studies of non-SSA animal health (including antimicrobial resistance (AMR)/antimicrobial use (AMU)) and/or non-livestock SSA regional harmonisation efforts that present opportunities for direct engagement with civil society, private sector/industry and other stakeholders;
- Regulatory standards gap analysis. This included a list of regulations, those prioritised for harmonisation and range of regulatory scope - including overlap with human health, an assessment of the current status of existing regulations at a country and regional level, as well as key regulatory gaps;
- Regulatory systems and governance mechanisms gap analysis. This included an assessment of existing regulatory capacity and development of options on the structure and components of the regulatory systems and governance mechanisms necessary for any harmonisation/convergence effort to be a success;
- A review of the required organisational roles (technical bodies for setting standards, political, enforcement capacity and institutions, etc.) and candidate organisations to drive these efforts, as well as a framework for assessing capacity of these institutional options;
- Diagnostic assessment of root causes underlying barriers to effective regulatory systems. Based on the assessments above, production of a summarised report identifying the root causes and bottlenecks to effective regulatory standards, convergence and enforcement, including articulation of a vision for these efforts;
- Development of a blueprint/decision model for VMR and VMRC actions that outlines key principles, 'go' or 'no go' decision points, and criteria for advancing VMR and VMRC at a regional and national level. This includes an outline of the key risks associated with these efforts; and
- Development of an evidence based, costed, prioritised (sequenced) roadmap of political and technical options defining the pathways for regional and country-led convergence. This includes costs to BMGF, resource and cost implications, trade-offs and potential impact at a country level, and an assessment of the donor organisations and current convergence and harmonisation efforts that are directly relevant to each option.

Exclusions

This project did not cover:

- All the SSA countries. It instead reviewed 28 countries, around seven from each regional block;
- Broader animal health issues and legislation, e.g. disease prevalence or the management and the provision of veterinary services;
- Systems and mechanisms outside of VMPs, and
- Clause by clause comparisons of the legislation. Instead a broader provision-based approach was adopted.

SECTION 1: Case studies

Agriculture and livestock farming contribute significantly to food security and trade, with many millions of people reliant on it for their livelihoods. Therefore, animal health is closely linked to the welfare of people both directly and indirectly. Animal disease is a major constraint to the veterinary sector and use of poor quality or counterfeit veterinary medicines exacerbates this issue leading to negative socio-economic impacts. Regional economic communities (RECs) have sought to rectify this through harmonised efforts to register high-quality products and facilitate cross-border trade.

Joint efforts in the registration of animal health products and technologies, underpinned by predictable timelines coordinated to high-standards, are instrumental to product control, quality and traceability.

"Study the past if you would define the future"

- **Confucius**

This section assesses the impact of previous and current harmonisation efforts in human and animal health around the world. This includes an analysis of the status of global and regional efforts on Veterinary Medicines Regulations (VMR) and Veterinary Medicines Regulatory Convergence (VMRC) to date. It also examines Sub-Saharan Africa (SSA) regional VMR harmonisation efforts, such as those in the East African Community (EAC), Southern Africa Development Community (SADC) and the West African Economic and Monetary Union (WAEMU) also known as the Union Economique et Monétaire Ouest Africaine (UEMOA). In addition to these African regional initiatives, other regional initiatives such as; the Association of South East Asian Nations (ASEAN), the European Union (EU) and the global International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) were also examined.

Non-livestock SSA initiatives such as the New Partnership for Africa's Development (NEPAD) focusing on the African Medicines Regulatory Harmonisation (AMRH) in human medicines and the Africa Biosafety Network Expertise (ABNE); as well as the ZAZIBONA initiative on human medicines (national regulatory medicines authorities of Zambia, Zimbabwe, Botswana and Namibia) was also reviewed. Other global efforts such as the global agreement on the Application of Sanitary and Phytosanitary Measures (SPS) were also studied.

The review of each of the above initiatives explored its origin, governance structure, resourcing, and legal and political characteristics. For each case study the successes, challenges faced, and lessons learned were highlighted, concluding with practical recommendations and improvements that may be considered for a successful harmonisation in the regulation of VMPs in the SSA context.

A brief summary of the initiatives studied is given below:

European Union (EU): The current European regulatory system for medicines is based on a network of all the National Competent Authorities (NCAs) for human and veterinary medicines from EU Member States and countries in the European Economic Area (EEA), plus the European Commission (EC). The network serves a population of over 500 million people with 24 official languages. Much of the structure of the veterinary

regulatory system originally stems from the human system. It has taken over 30 years to reach the current level of harmonisation of veterinary medicines regulation throughout the EU. Legislation has been regularly reviewed and updated in light of experience, and it has been through this process that the harmonisation procedures and agreements have been, and continue to be, refined.

The European Medicines Agency (EMA) is an agency of the EU responsible for the scientific evaluation, supervision and monitoring of safety for medicines authorised in the EU. As an agency, the EMA draws on staff from across the NCAs of the member states. It has established scientific committees and working parties to support its work. These have expertise in a scientific field and are composed of members selected from the list of European experts maintained by the EMA.

The regulatory network includes 50 NCAs, 20 that deal with both human and veterinary medicines and 16 that deal with veterinary medicines only, while the remaining 14 deal with human medicines only.

The EU has a flexible system of authorisation comprising a national procedure, a multi-national procedure (mutual recognition and decentralised procedures) as well as an EU-wide procedure (centralised). In a national procedure, a company submits its application to the NCA of the selected country and the authorisation that is issued will only be valid in the country concerned. Once a product is authorised in an EU member state, no other national application can be made in the EU. In such situations, a mutual recognition application (MRP) is required whereby the new country makes an authorisation decision based on review of the original evaluation report. In the case of the decentralised procedure (DCP), the applicant can submit the application in any number of member states and selects an NCA to lead the evaluation process (the Reference Member State). At the end of the procedure, a marketing authorisation (MA) is issued in those member states that were part of the procedure. A Centralised procedure is where the application is made to the EMA and the evaluation is conducted by the EMA's Committee for Medicinal Products for Veterinary Use (CVMP). Once a positive opinion is issued by the EMA, the EC then issues the MA which is valid throughout the EU/EEA. Some types of products can only be authorised through the Centralised procedure. In all cases, applications are made electronically and communication between NCAs is facilitated by an IT system.

All the procedures have legally defined timeline and arbitration procedures for cases of disagreements.

Southern African Development Community (SADC): The SADC region was formed by Treaty in 1992 and currently consists of 16 countries in Southern Africa. The region recognised the benefits of harmonisation early and sought support and training from a number of organisations, namely FAO, OIE, GALVmed and HealthforAnimals. Despite these efforts and the issuing of the guidance document for the harmonisation of national legislations for VMPs, the SADC region has thus far not been able to establish harmonisation procedures.

East African Community (EAC): The EAC was founded in 1967 with Kenya, Uganda and Tanzania. It collapsed in 1977 but was revived in 2000, now comprising of six countries. The treaty lays the foundation for harmonisation of drug registration procedures. The EAC was the first region in Africa to commence an initiative to improve and coordinate the regulation of medicines, in particular vaccines. This was started in 2012 through a project initiated by GALVmed and supported by BMGF. Although some of the member countries have no regulatory agencies established, the EAC managed to adopt a number of guidelines and establish technical working groups. This allowed the MRP to commence resulting in the authorisation in two countries of the first product through the MRP. Additional authorisations are in progress.

West African Economic and Monetary Union (WAEMU): Also known as UEMOA (Union

Economique et Monétaire Ouest Africaine) is a regional organisation of eight West African countries. Since 2006, WAEMU countries adopted a regional framework for the harmonised registration and sale of livestock health products, including VMPs, through the support of ANSES (the French Agency for Food, Environmental and Occupational Health & Safety). This harmonisation of VMP registration and control is governed by Community legal texts and allowed the establishment of a centralised authorisation system for the placing on the market of VMPs under the responsibility of the WAEMU Commission, which is authorised to issue MAs. Post-authorisation activities are the responsibility of the individual countries.

International cooperation on harmonisation of technical requirements for registration of veterinary medicinal products (VICH): This is an international programme of co-operation between the veterinary regulatory authorities and the animal health industries of the EU, Japan, and the United States of America (USA). Australia, New Zealand, Canada, and South Africa are observers while the OIE is the associate member and enables wider global acceptance of the VICH guidelines through the VICH Outreach Forum to non-VICH countries/regions. Almost 60 guidelines have been developed to date.

Association of Southeast Asian Nations (ASEAN): This is a broad harmonisation agreement between ten South East Asian countries. ASEAN countries have diverse regulatory requirements for medicines. Although there is a broad acceptance of VICH standards, differences between countries have persisted despite harmonisation efforts in the region.

New Partnership for Africa's Development (NEPAD): This case study reviewed NEPAD and two initiatives established by NEPAD; the AMRH for human medicines and the Agency Biosafety Network of Expertise (ABNE). NEPAD was established in 2001 with the aims to provide an overarching vision and policy framework for accelerating economic co-operation and integration among African countries. One of its goals is to implement functional regulatory frameworks for both agriculture and health. The NEPAD Agency is the implementing agency of the African Union (AU). The AMRH initiative was driven by the need to remove barriers that hinder patient access to healthcare products in Africa and endorsed by the RECs. The initiative focused on harmonising each national regulatory system and therefore reducing the time taken to register priority medicines through collaborative agreements. The AU Model Law on Medicinal Products Regulations, endorsed in 2016, is to establish an effective and efficient system of medicinal products regulation and control and ensure that such products meet the required standards of safety, efficacy and quality. This will also promote harmonisation. It is at different levels of domestication and implementation by the 12 African countries. AU's objective to establish a single African Medicines Agency (AMA) by the end of 2018 is delayed, though the African Heads of State agreed again to its establishment at their meeting in 2019. The establishment of the AMA will build upon the pre-existing structures that have already started implementing the AMRH programmes within the framework of the Pharmaceutical Plan for Africa.

The NEPAD agency established the ABNE in 2008 to promote the advancement of science and technology for agricultural development in Africa. It was established as a biosafety resource network for African regulatory and policymakers. The overall goal is to enhance the capacity of African countries to build and support science, technology and innovation for economic development; hence to harness modern agricultural biotechnology to support the improvement of food security, income and livelihoods; while minimising any risks to the environment and human health. ABNE services are demand-driven, needs-based, and are offered in consultation with national stakeholders. Because African countries are at various levels of biosafety capacity and biotechnology development, ABNE tailors its services to the biosafety needs of individual countries.

World Trade Organisation (WTO) agreement on the application of Sanitary and Phytosanitary measures (SPS): The Agreement on the application of SPS harmonisation initiative extends WTO principles in terms of animal health, plant health and food safety, and is of economic significance for livestock agriculture globally, such that the majority of countries adopt SPS compatible legal frameworks and policies. Complying with SPS standards is essential for African regions to benefit from international trade in agricultural products. SPS applies WTO objectives to the protection of human, animal, and plant health by providing standards to facilitate the evaluation and harmonisation of disease risks arising through trade. To promote harmonisation, a formal co-operation between the Codex Alimentarius Commission for food safety, the OIE, and the International Plant Protection Convention (IPPC) was established to set standards that WTO member states should use as a basis for national SPS methodologies. SPS bridged the gaps between OIE, Codex, and IPPC, applying common methodology, to facilitate risk management and trade in agricultural products.

From the review of the above initiatives, the following elements were identified as key for a successful harmonisation/convergence effort:

Key elements:

- A positive and active political will from all countries involved and a willingness from all concerned parties to make the system work;
- A collective and agreed legal framework with a clear mandate on which the initiative is based, adoption of the necessary regulatory texts with a realistic, appropriate and clearly defined transition period;
- An established semi-autonomous agency (National Competent Authority; NCA) responsible for the regulation of medicines (optimally a veterinary only NCA) to help expedite the implementation of the initiatives by allocating adequate and sustainable resources;
- A steering group to facilitate the domestic implementation in each partner country, providing expert knowledge on how the process should be translated;
- The development of facilitating bodies, such as a regional Committee or Central Agency, comprised of motivated individuals from each component country who are accountable for progress;
- Efficient mechanisms for appeal and arbitration;
- Establishment of technical working groups to aid confidence building between participating countries;
- Building on existing successful initiatives;
- Ability to identify and leverage concurrent higher profile, related initiatives with shared strategies and / or objectives;
- Identifying harmonisation champions to drive the harmonisation initiative at the different stages of development;
- Establishing ownership of key activities and employing standard project management tools to drive the initiative;
- Common requirements (technical documents), agreed upon by a technical working group, and an agreed registration procedure with realistic timelines that will be adhered to by each partner country. These should be appropriately translated, publicised and made available to applicants. Appropriate training should be provided to key players to ensure these high standards will be met. Whenever available, internationally agreed guidelines (e.g. VICH) should be adopted;
- Excellent communication and communication infrastructure to allow secure sharing of information between the National Regulatory Authorities as well as communicating with stakeholders;
- Establishment of a quality control mechanism for VMPs, involving a network of audited laboratories (with suitable scientific equipment and personnel);
- support from bodies experienced in the regulation of VMPs as well as in the process of working with other countries on VMR;

- Seeking input from stakeholders on a regular basis to identify challenges and to improve the system;
- Sufficient administrative support to manage the process efficiently;
- Recognise what success (for given resources) looks like in advance;
- Ensure funding is adequate and sustainable, and
- Ensure economic benefits of harmonisation efforts are clear and the initiative is demonstrably cost effective.

SECTION 2: Sub-Sahara Africa diagnostic summary

Introduction

This section presents an analysis of the applicable legislation, regulatory systems and governance mechanisms related to the registration, sale and use of Veterinary Medicinal Products (VMPs) within the selected 28 target countries in Sub-Saharan Africa (SSA) as well as the economic situation and the political environment for the countries as well as the four regions in SSA (Central Africa, East Africa, Southern Africa and West Africa). The information presented is intended to highlight some of the constraints in current regulatory systems and any possibilities to be considered within the context of the options assessment for regulatory harmonisation at a regional and continental level.

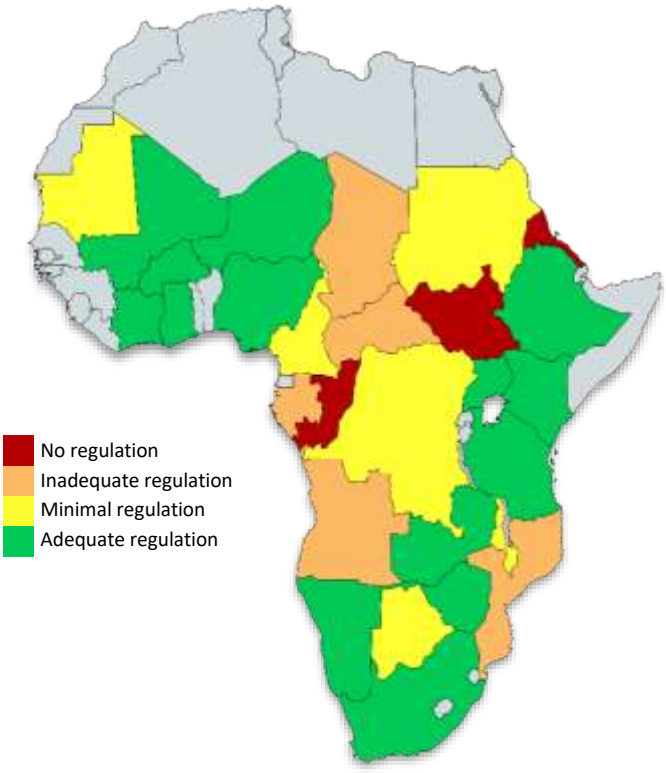

Figure 1: Status of VMP regulation in SSA.

In addition, the legislative frameworks and regulatory processes that govern the registration of VMPs have been further reviewed and analysed to better understand how well they may function in improving the availability of good quality, effective and safe veterinary medicines. The term 'registration' in this context includes both the process of assessing application dossiers for VMPs as well as issuing marketing authorisations (MAs) or product licences.

The methodology including country ability factor and readiness scoring and limitations are described in Appendix 1.

Raising awareness of the importance of veterinary medicines and their impact on human health and society is key to success

Regulatory analysis

The regulation of VMPs in SSA varies across countries and regions. Differences appear throughout levels of legislation, guidelines and the powers and abilities of competent authorities and agencies responsible for the regulation of VMPs. While some countries have comprehensive legislation and competent authorities with roles and mandates clearly stated in the legislative process, others do not. That said, there are similar gaps and challenges occurring across the 28 countries.

The assessment found that VMPs were often much less prioritised when compared to medicines for human use across the region, irrespective of the impact the veterinary sector has on a

country's economy and public health. This may indicate a lack of awareness of the importance of the livestock sector and its contribution to society, particularly at a policy level. However, in general, there is a demand by farmers to have access to good quality VMPs.

Institutional analysis

The institutional setup in SSA varied within regions and between regions. A number of countries have invested in the establishment of a veterinary only regulatory agency while in others an agency deals with both human and veterinary medicines. In the latter case, the ministry responsible is the Ministry of Health, usually with limited input from the Ministry of Agriculture/Livestock. In the remaining countries where veterinary medicines are regulated in some form, the responsibility remains within a department in the Ministry of Agriculture/Livestock. The exception to the above is South Africa where veterinary medicines are regulated by two entities; the 'Stock Remedies (Act 36)' through the Ministry of Agriculture and the rest (Act 101) through South African Health Products Regulatory Authority (SAHPRA), the newly formed joint human and veterinary agency.

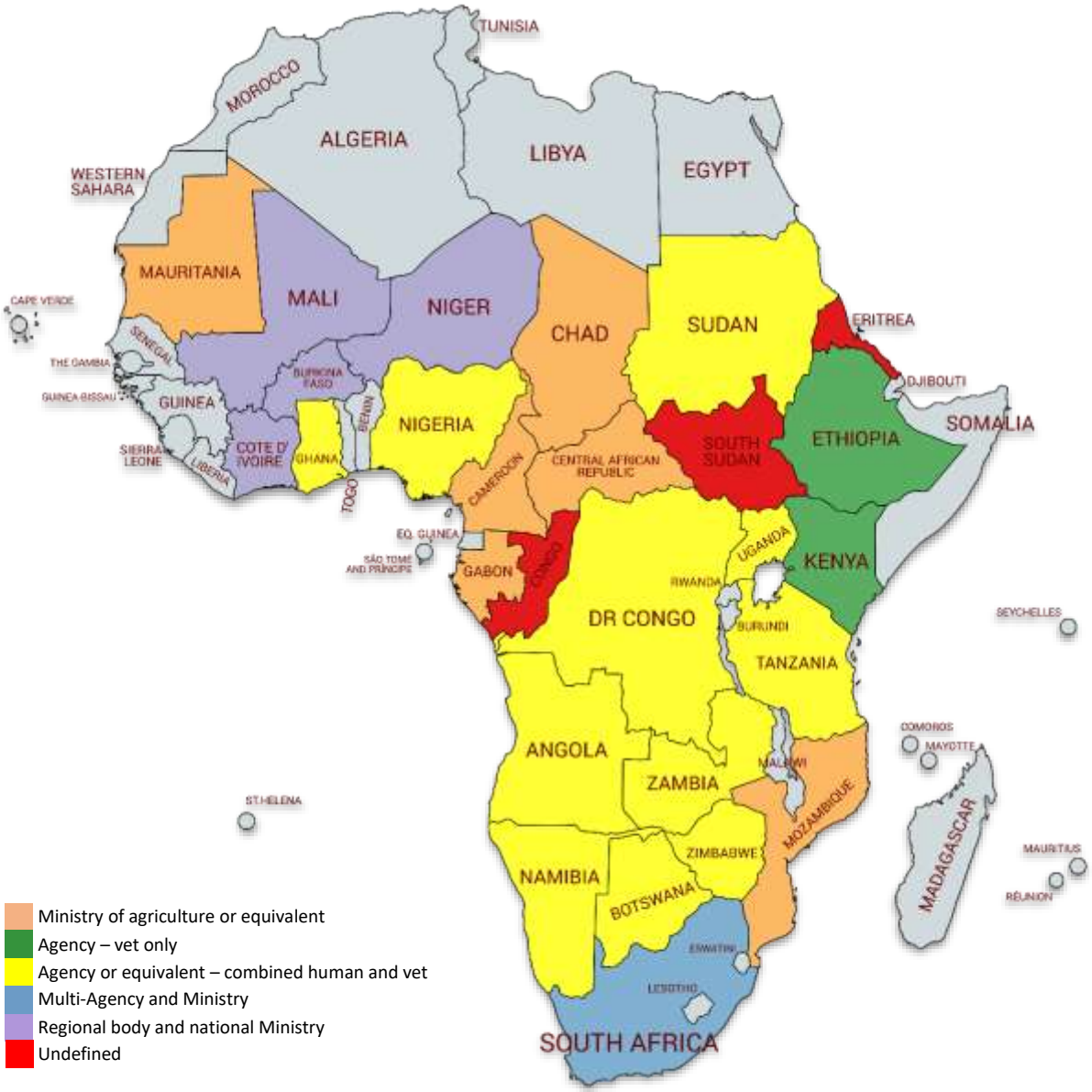

Figure 2: Institutional set-up for the regulation of VMPs in SSA.

Political analysis

This was undertaken specifically in the context of Veterinary Medicines Regulation (VMR) harmonisation. It therefore focussed on internal and external violence, on infrastructure and government outreach throughout the country, and on specific problems for livestock holders. While not mentioned in every one of the 28 African country studies, population growth, farmer-nomadic herder conflict and the changes in the natural environment, such as desertification, deforestation and soil degradation play an important role in competition over the distribution of land. The claims of humans, their animals, and their plants are all legitimate, and a holistic solution is beneficial. In some countries, the population has been concentrated in a very small part of the habitable land. Governments' responses have been variable.

Economic analysis

An overview of the outputs from the ARIMA modelling exercise (auto-regressive integrated moving average) shows that the marginal change in gross value of output across different countries corresponds with the total size of the livestock populations in those countries. These results provide an indicator of the potential benefits of improvements to livestock productivity in the region, but without incorporating the costs of production in the diverse systems present in the region they are not a measure of added value to the economy. However, the findings illustrate that relatively small improvements in productivity at the level of the animal can produce significant change when considered at the population level. Ongoing studies performed in the region aim to measure the gap between current and attainable yields per animal, showing significant improvements are possible.

Regional Economic Communities (RECs) in Africa

The African Union (AU) recognises the following Regional Economic Communities as organisations or "Pillars" within its membership for the purposes of achieving greater economic integration:

- The Arab Maghreb Union (UMA)*
- The Common Market for Eastern and Southern Africa (COMESA)
- The Community of Sahel-Saharan States (CEN-SAD)
- **The East African Community (EAC)#**
- **The Economic Community of Central African States (ECCAS)**
- **The Economic Community of West African States (ECOWAS)**
- **The Inter-Governmental Authority on Development (IGAD)#**
- **Southern African Development Community (SADC)**

RECs in **bold** indicate those included in this report.

*UMA is not a signatory to the Protocol on Relations between the RECs and the AU.

#In October 2013, on the side lines of an AU Extraordinary Summit, IGAD and EAC Foreign Ministers decided to explore the possibility of merging these two RECs.

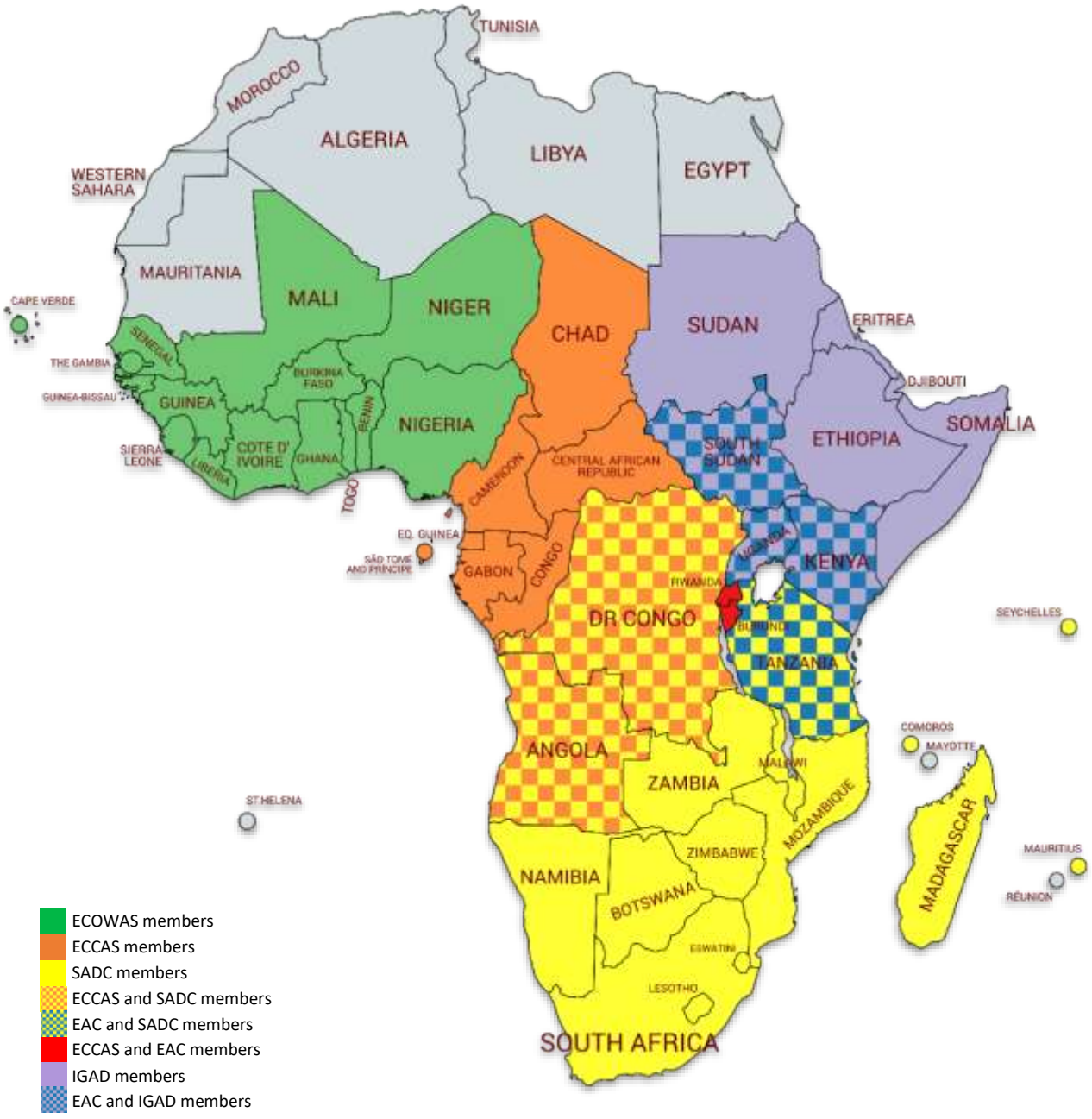

Figure 3: Membership of SSA African Regional Economic Communities.

Regional analysis

Four African regions were considered in the analysis; Central, East, West and Southern African regions. The analysis included broad recommendations for the countries included as well as a general recommendation for the region the details of which would be refined in consultation with the countries concerned.

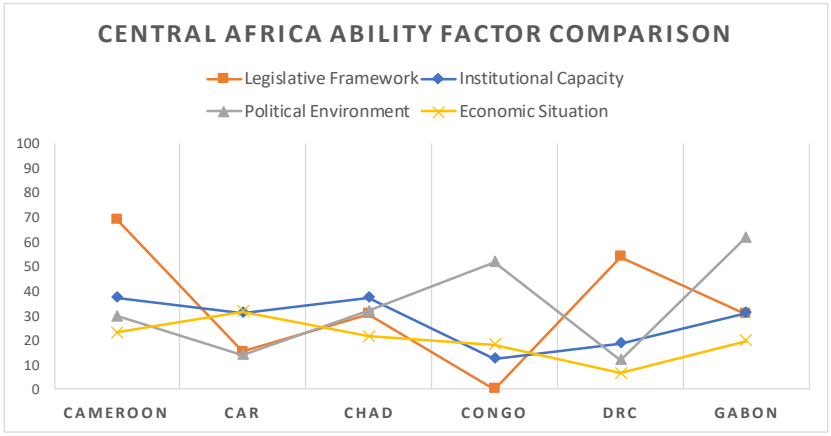

Figure 5: Combined 'Ability Factors' in Central Africa.

Central Africa

The assessment of six countries (Cameroon, Chad, Central African Republic, Gabon, Congo and DRC) within Central Africa revealed that the regulation for VMPs within the region is mostly inadequate and sometimes non-existent (e.g. Congo). Countries scored low in the 'Readiness Score' assessment in all four measures, when compared across all four SSA regions. These countries have very variable legislative frameworks with inadequate institutional capacity to implement and enforce regulatory standards.

Individual country synopses are at Annex 1.

Figure 4: Central Africa sample countries.

The assessment in Central Africa found little evidence of effective VMP regulation. Only Cameroon and DRC were identified to have a legislative framework establishing regulatory standards and structures for VMPs. This may be as a result of both countries having greater livestock population compared to the other countries within the region.

Central African countries had the lowest 'Political Environment' and 'Economic Situation' scores in comparison to the rest of SSA. This is likely to have impacted on the governing institutions within the countries, resulting in a limited ability to legislate and establish regulatory structures for both VMPs and human medicines. The assessments also noted a constant reshuffling of government ministers, which is affecting continuity within relevant ministries. Even where countries have managed to legislate, there are limited or non-functional regulatory systems, so that standards are not enforced. In some of these countries, availability and access to human medicines remains a far more critical issue.

The review did not obtain enough information to understand how enforcement measures are implemented within countries. Political and economic assessments revealed the lack of political stability and low economic development within the region which may impact on the ability of governments to prioritise and establish a framework for VMP regulation. Additionally, informed assumptions can be made, that the lack of infrastructure in the countries within this

region may be an obstacle for the dissemination of information from government to local levels and the inability of relevant authorities to implement enforcement measures. This is further exacerbated by a lack of communication between various government departments that may be responsible for enforcing various aspects related to the availability and accessibility of VMPs.

According to the OECD list, the DR Congo is the riskiest state with the highest political and security stability problems. All other Central African countries, except for Gabon, are also on the list. Chad and Congo are equally at risk politically and score second highest in security fragility. Only Cameroon is rated with a medium political fragility.

Recommendations for countries

The following recommendations are suggested to overcome the identified challenges:

1) **Establish and define the roles and mandate of the competent authorities.**
   In countries where there is no established legislation, appropriate legislation adhering to international standards should be put in place, which should include establishment of regulatory bodies with clearly defined roles and responsibilities.

2) **Learning lessons from neighbouring countries.**
   Identify best practice and learn from those neighbouring countries where functional systems have been established.

Prospect for harmonisation assessment

The review identified the following barriers to regional regulatory convergence:

Barriers
Weak regulatory systems Countries within Central Africa have very weak regulatory systems for VMPs. This also appears to be the case for human medicines. This presents a great challenge for regional convergence as there is no clear starting point for harmonisation of legislation
Weak political relations between countries or regions Unlike other regions assessed, Central Africa does not have strong regional initiatives amongst neighbouring countries and there is generally limited cooperation between countries in the region
Political will The country assessments identified lack of political will to regulate VMPs within countries or at the regional level
Weak infrastructure The region has weak telecommunications and transportation networks, this hinders stakeholders' engagement on convergence issues

Recommendation for the region

The following recommendation is suggested as a 'quick-win' to overcome the identified challenges at a regional level:

1) **Consider partnerships with other countries.**
   Countries within Central Africa may consider strategic partnerships with neighbouring countries to establish and strengthen their VMP regulation. For example, WAEMU/UEMOA, which is a semi-developed, harmonised regulatory framework within West Africa, could either be expanded or adopted by the Francophone countries in Central Africa.

East Africa

The assessment of East Africa looked at seven countries (Eritrea, Ethiopia, Kenya, South Sudan, Sudan, Tanzania and Uganda). There is evidence of good VMP regulation (Mutual recognition procedure; MRP) in these countries and a degree of cooperation to regulate VMPs at the regional level. For Eritrea and South Sudan no evidence of a system to regulate VMPs were found resulting in a low score and therefore scored poorly in the 'Readiness Score' assessment.

Individual country synopses are at Annex 1.

Figure 6: East Africa sample countries.

There are varying levels of VMP regulation within the region. Countries that are members of the EAC MRP (Kenya, Tanzania and Uganda) scored highly in the 'Readiness Score' assessment because of the existence of good legislative frameworks and functioning regulatory systems. These three countries have high 'Legislative Framework' scores reflecting the presence of a comprehensive legislation supported by clear and accessible guidelines for applicants. This appears to be a result of the harmonisation efforts at the EAC following on from earlier initiatives in preparation for the establishment of the MRP. The assessment identified strong political will within members of the EAC to increase regulatory standards within their individual countries as well as in the region.

Outside of the EAC MRP, Ethiopia and Sudan also have some regulatory capacity and legislative frameworks in place specifically for VMPs. Ethiopia has established a regulatory authority solely for VMPs (the Veterinary Drug and Animal Feed Administration and Control Authority; VDFACA) and Sudan has the National Medicines and Poisons Board (NMPB) for both human and veterinary medicines.

Although there are countries within the region that have high 'Readiness Scores', all countries were affected by the challenges of insufficient resources and funding. For example, Kenya and Uganda have clear regulatory structures in place but a lack of staff and technical competency has inhibited the registration process.

Even where VMP regulation is well established, such as in Uganda, the veterinary department within the National Drug Authority is ill-resourced. In Kenya where regulation is established, this challenge led to the establishment of a separate authority for VMP regulation, the Kenya Veterinary Medicines Directorate, to ensure that VMPs were prioritised.

Ethiopia, Sudan, South Sudan and Eritrea are considered politically high risk. Kenya and Uganda slightly less so, and Tanzania is of minor risk.

Recommendations for countries

The following recommendations are suggested to overcome the identified challenges:

1) **Establish and define the roles and mandate of the competent authorities.**
   In countries where there is no legislation, appropriate legislation adhering to international standards should be established. This should include establishment of regulatory bodies with clearly defined roles and responsibilities.

2) **Learn lessons from neighbouring countries.**
   Identify best practice and learn from those neighbouring countries where functional systems have been established.

3) **Identify additional budget needs and seek appropriate funding.**
   This will include Identifying champions, who can lobby for greater budget allocations to increase human resource and capacity for the relevant departments and authorities.

4) **Encourage non-EAC countries to set up a harmonised system.**
   Explore the potential to harmonise those countries outside EAC through their REC such as the IGAD.

Prospect for harmonisation assessment

Causes of effective regulation in the EAC MRP

The MRP initiative was led by GALVmed and is now run by the EAC commission with support from GALVmed. Although the EAC MRP is still in its infancy and covers only vaccines, it has strengthened the regulatory systems of individual countries through providing technical support for legislation drafting and registration assessments. This has also extended to countries with weaker regulatory capacities, such as Rwanda and South Sudan.

Barriers to effective regulation within the EAC MRP

BOTTLENECKS
Lack of experience for certain VMPs The EAC MRP does not currently include registration of veterinary pharmaceuticals and biologicals (other than vaccines).
Lack of publicity Although the EAC MRP is now functional, it appears the initiative is not well known within the local pharmaceutical industry resulting in few manufacturing companies making use of the procedure.
Insufficient funding The EAC MRP functions at limited capacity due to lack of funding. For example, at the time of review there was no certainty on the continued full-time administrative staff dedicated to the running and coordination of the initiative.

Recommendations for the EAC MRP

The following recommendations are suggested as 'quick-wins' to overcome the identified challenges:

1) **Review of the legislation and guidelines to ensure regulation of veterinary medicines is up to international standards.**
   The EAC initiative must encourage member countries to update their regulatory standards so that international guidelines (such as VICH) are adopted.

2) **Increase awareness of the EAC MRP within the local pharmaceutical industry.**
   The EAC MRP technical working group should ensure that the procedure is well publicised and there is increased communication between regulators in the region and industry.

Barriers to the advancement of regional convergence in East Africa

The review identified the following bottlenecks to regional convergence:

BOTTLENECK
Varying levels of regulatory capacity Although the region has had success in harmonising regulatory standards through reviewing and revising legislation, strengthening regional regulatory capacity is made cumbersome by the number of countries with weak regulatory capabilities. This means that only a few countries can participate in the EAC MRP.

Political tensions
Whilst overall the countries in the region have good political relationships, it has been reported that the harmonisation efforts sometimes suffer from political tensions driven by individual personalities or countries with competing agendas. These political tensions slow progress and can sometimes threaten success.

Recommendation for the region

The following recommendation is suggested to overcome the identified challenges:

1) **Secure funding to continue providing capacity building programmes to countries within the region.**
The success of the EAC MRP for vaccines thus far must be maintained to continue strengthening technical and regulatory capacity within the region. Countries currently not members of the EAC MRP may benefit from joining the initiative, especially if continued capacity building programmes are made an integral part of the process.

2) **Increase the scope of the MRP to include pharmaceuticals.**
The current EAC MRP could be enhanced by including veterinary pharmaceuticals in its scope. This should be done gradually and in a sustainable manner so that the arrangement that is currently in place for vaccines is not jeopardised.

3) **Develop active working relationships with other Pan-African and international organisations.**
To consolidate and enhance what has been achieved, active relationships should be developed with Pan-African bodies, such as the AU-PANVAC, and integrate it within the authorisation process. Furthermore, international bodies such as the FAO and the OIE could continue to play a supportive role in capacity building.

4) **Embed sustainability.**
The countries in EAC would benefit from having a benchmarking tool that would allow them to measure themselves and each other over time, so that a culture of continuous improvement is introduced and maintained.

5) **Encourage non-EAC countries to set up a harmonised system.**
Explore the potential to harmonise those countries outside EAC through their regional economic community such as IGAD.

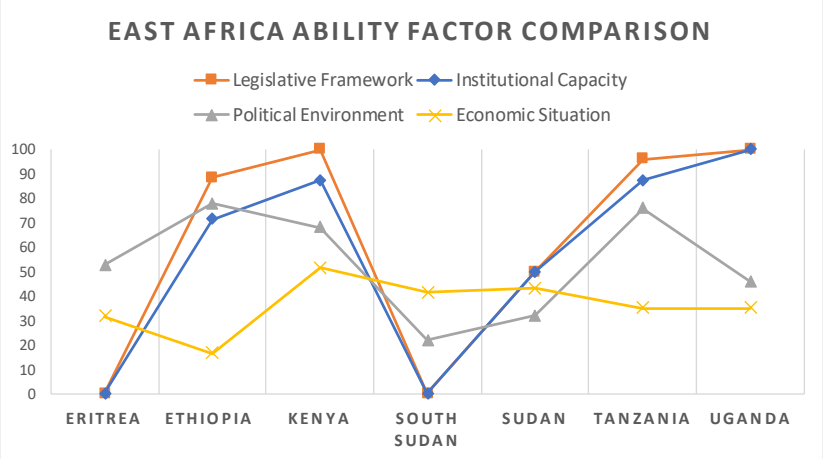

Figure 7: Combined 'Ability Factors' in East Africa.

West Africa

The assessment of West Africa included at seven countries. Four are members of the West African Economic & Monetary Union (WAEMU) centralised system for VMP registration (Burkina Faso, Côte d'Ivoire, Mali and Niger), and the remaining three (Ghana, Mauritania and Nigeria) are not part of any regional harmonisation initiative for VMP regulation. These countries generally have good legislative frameworks and institutional capacity to implement and enforce regulatory standards.

Individual country synopses are at Annex 1.

Figure 8: West Africa sample countries.

Countries within West Africa exhibited the highest level of harmonisation within SSA with WAEMU countries scoring high for 'Legislative Framework', which is above the average for SSA. Countries within WAEMU have successfully harmonised and adopted WAEMU legislation into their national legislative frameworks for regulating VMPs. The three countries (Ghana, Mauritania and Nigeria) outside of WAEMU also have good VMP 'Legislative Framework' scores. However, Mauritania is a notable outlier within the West African region and scores consistently below the regional averages. The strong presence of VMP legislation within the region suggests a high political will within the region to regulate VMPs, despite low levels of economic development and political stability across the countries.

'Institutional Capacity' scores in the region reflect the presence of regulatory authorities capable of carrying out key regulatory functions and to implement and enforce the regulatory standards (i.e. legislative framework). It should, however, be noted that the scores for individual countries that are part of the WAEMU centralised system may be skewed due to the assessment taking into consideration the capacity of the WAEMU centralised registration system for VMPs. MAs are issued by WAEMU's Regional Committee for VMPs (CRMV). For example, Côte d'Ivoire had high institutional capacity, due to half of the regulatory functions being carried out within the WAMEU structures. However further analysis into the national regulatory system revealed unclear and fragmented regulatory structures, which are not instantly apparent in the scores.

Whilst the countries in West Africa rank highly in terms of 'Legislative Framework' and 'Institutional Capacity' scores, there are economic and political issues within the region that present different challenges for VMP regulation. Though great effort has been placed on drafting legislation, political and economic factors present challenges to effective implementation.

A root cause identified for ineffective regulation is insufficient financing of VMP regulation within countries. This results in regulatory structures not performing to the desired and appropriate standards. Although countries within the region have good 'Institutional Capacity' scores compared to the rest of SSA, there are significant gaps in the regulatory structures in practice. For example, whilst the assessment identified regulatory authorities responsible for VMP registration in each country, the registration process was often slow and inefficient. Where relevant information was available, regulatory authorities reported a lack of resources and competent staff, and technological capacity to

effectively regulate VMPs in their countries. The WAEMU centralised system for registration, had reportedly assessed only 5% of the submitted dossiers from its inception up until 2015 due to insufficient capacity. This scenario is understood to be the same for most countries within the region, where regulatory authorities and other relevant bodies are unable to increase their operating capacity due to insufficient resources.

Inadequate regulatory structures and insufficient funding make it difficult for regulators to appropriately enforce regulatory measures. This, along with lack of coordination between relevant departments/authorities and clearly defined roles in some of the countries (e.g. Côte d'Ivoire and Mauritania), results in poor enforcement. Additionally, different political and economic factors may impede appropriate enforcement of regulatory standards.

In terms of political fragility, Côte d'Ivoire and Mauritania are the riskiest, followed by Nigeria, Niger, Burkina Faso, and Mali.

Recommendations for countries

The following recommendations are suggested to overcome the identified challenges:

1) **Redefine the roles and mandate of the competent authorities.**
   Legislation mandating the roles of relevant authorities should be reviewed to ensure clarity and should identify all the departments and authorities involved in VMP regulation, including the importation of VMPs.

2) **Identify additional budget needs and seek appropriate funding.**
   This will include Identifying champions, who can lobby for greater budget allocations to increase human resource and capacity for the relevant departments and authorities.

3) **Encourage non-WAEMU countries to set up a harmonised system.**
   Explore the potential to harmonise all of West Africa, or along linguistic lines either through ECOWAS or the West African Monetary Zone (WAMZ) for the English-speaking countries.

Prospect for harmonisation assessment

The existence of a centralised procedure within WAEMU allows registration procedures for VMPs between the member states to be managed centrally. Support from ANSES and good political will within the countries allowed for the successful implementation of the system.

The table below highlights the bottlenecks for effective VMP regulation within WAEMU.

BOTTLENECK
Process for the registration of VMPs According to WAEMU, the slow pace of the registration process is due to the poor quality of registration dossiers submitted. However, it is unlikely to be the sole cause of the delay. There are also contributory human resource challenges.
Inadequate regulatory standards The WAEMU legislative framework establishes regulatory standards for the regulation of VMPs for its member states. There are some gaps; most importantly, the legislation does not address Good Manufacturing Practice (GMP). It appears, however, that some GMP inspections are conducted by WAEMU and some by the NRA. Clarity on this could help improve the process.

Recommendations for WAEMU

The following recommendations are suggested to overcome the identified challenges:

1) **Establish and publish guidelines for the registration process.**
   WAEMU should ensure that all guidelines are available and easily accessible to applicants. This will help applicants build complete dossiers and reduce the number of poorly constructed dossiers, thereby increasing the efficiency of the process.

2) **Publish and apply clear timelines for the registration process.**
The published timelines should be adhered to, by both the applicants and the CRMV. This should include time limits by which applicants have to respond to any requests for information needed for the completion of the dossier.

3) **Improve the way CRMV reviews dossiers.**
CRMV should explore how to improve the efficiency of its structure, composition, and methods of operation. Efficient and timely evaluation processes would increase the number of dossiers reviewed, and ultimately the number of MAs issued by WAEMU.

4) **Clarify and improve the GMP inspection & post-authorisation processes.**
The WAEMU Commission should develop and clarify processes for GMP inspection and post-authorisation activities. The roles and responsibilities of the CRMV and the different NRAs should be made clear and should be well resourced and communicated.

5) **Conduct impact measurements.**
Evaluate the number of applications received in a year and MAs issued; evaluating the number of days to issue MAs; evaluating the number of dossiers waiting for review at a specific point in time; and seek input and feedback from industry.

Barriers to the advancement of regional convergence in West Africa

The review identified the following bottlenecks to regional convergence:

BOTTLENECK
Varying levels of regulatory capacity Although the region has had success in harmonising regulatory standards through the Centralised process, some countries still have weak national capability. Lack of clarity in the designation of responsibility (e.g. of GMP inspections) highlights the need for these countries to develop their capability and capacity.
Political tensions Certain regions in some countries have political and/or security concerns and these are likely to limit the effectiveness of regulators.

Recommendations for the region

Ghana, Nigeria and Mauritania are neither part of the WAEMU nor other harmonised initiative for VMPs. Political and economic differences, as well as language barriers, in the ECOWAS member countries, represent obstacles to achieving region-wide harmonisation. Additionally, political relations between Francophone and Anglophone countries in the region are weak, which hinders significant levels of regional collaboration.

The following recommendations are suggested to overcome the identified challenges:

1) **Encourage ECOWAS to increase its involvement in VMP regulation.**
Currently there are two groups within ECOWAS; the West African Monetary Zone (WAMZ) and the WAEMU. As the WAEMU already has established a harmonised system, the WAMZ countries should be encouraged to also develop a harmonised system. These two systems can then eventually operate under the auspices of ECOWAS.

2) **WAEMU should consider other harmonisation approaches.**
Currently only the centralised system exists in the WAEMU countries. A more flexible form of harmonisation, such as the MRP, should be considered as an additional option.

1) **Encourage non-WAEMU countries to set up a harmonised system.**
Explore the potential to harmonise all of West Africa, or along linguistic lines either through ECOWAS or the WAMZ for the English-speaking countries.

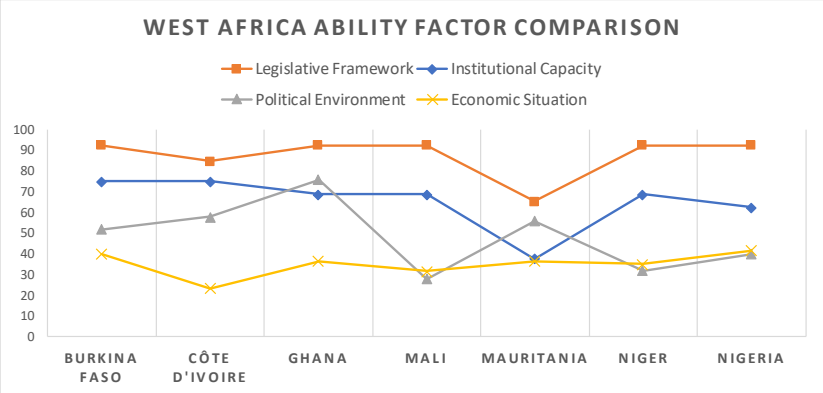

Figure 9: Combined 'Ability Factors' in West Africa.

Southern Africa

The assessment of Southern Africa included eight countries (Angola, Botswana, Malawi, Mozambique, Namibia, South Africa, Zambia and Zimbabwe). The countries appear to have varying capacity to effectively regulate VMPs within their countries and some of them (e.g. Angola and Mozambique) have inadequate regulatory systems in place. Common issues have been identified across the countries which may benefit from harmonisation of VMP regulation at a regional level. Some of the countries in the region, such as South Africa and Botswana are in the process of establishing and restructuring their regulatory institutions with a view to improving the capacity and efficiency of their operations.

Individual country synopses are at Annex 1.

Figure 10: Southern Africa sample countries.

There are differing levels of VMP regulation within the countries in Southern Africa. In several countries (Malawi, Namibia, South Africa, Zambia and Zimbabwe), regulatory standards for VMPs are present and defined in legislation and accompanying guidelines. Botswana and Malawi are actively working to improve and update their legislative frameworks, to align with international regulatory standards. In all the countries assessed, there is evidence that there is capacity at the legislative level to draft, approve and implement legislation for VMP regulation.

The countries have greater political stability compared to the other regions assessed. This may contribute to the ability of relevant departments to continuously review and update regulatory standards.

Although half of the countries assessed have medium to high 'Legislative Framework' scores, there are gaps in legislation and the overall regulatory system. In Mozambique there is no legislation in place for addressing VMPs, whilst in Angola it appears that VMPs are only superficially mentioned in legislation, which is targeted to human medicines. Botswana and Malawi appear to be taking steps to review and update their legislation to address legislative gaps, however, what each country has identified as a gap remains unclear at the time of writing. In other cases (Malawi, Zambia and South Africa), it is not clear if and how Immunologicals are regulated, and by which department/authority.

In addition to gaps in regulatory standards, it is clear that there is a lack of institutional capacity in all countries in the region. In the four countries (Malawi, Zimbabwe, Zambia and South Africa) where regulatory systems are established in legislation, there is a reported lack of human resources, technical capability, and financial resourcing. This seems to significantly impede the ability of the NRAs, and other agencies in these countries, to effectively regulate VMPs.

The assessment could not clearly identify the root causes of ineffective regulation, due to the limited information obtained in the country studies. For example, South Africa scores the highest for 'Legislative Framework', 'Political Environment' and 'Economic Situation' in the assessment. However, the NRA in charge of regulating VMPs has been functioning at limited-to-no capacity for the past four years. This appears, although to a lesser extent, in other countries within the region, where countries have good 'Readiness Scores', but ancillary factors, not reviewed as part of the report, impede current regulatory efficacy.

On political fragility, South Africa, Namibia and Botswana have no entries. Zimbabwe has a severe political fragility risk, whereas, Malawi and Zambia have minor risks.

Recommendations for countries

The following recommendations are suggested to overcome the identified challenges:

1) **Identify additional budget needs and seek appropriate funding.**
   This will include Identifying champions who can lobby for greater budget allocations to increase human resource and capacity for the relevant departments and authorities.

Prospect for harmonisation assessment

Despite previous efforts, no regional harmonised initiative is in place for VMP regulation. SADC does not presently have a harmonised initiative for any aspects of VMP regulation. There have been efforts in the past to harmonise VMP regulation through issued regulatory guidelines by the SADC secretariat, however, this effort has had little impact.

Some of the NRAs within SADC have a history of cooperating amongst themselves to utilise resources and share knowledge. Currently, the Zambia, Zimbabwe, Botswana and Namibia (ZAZIBONA) initiative (which now includes Angola, DRC, Seychelles and South Africa) conducts assessments of human medicines, and inspections of manufacturing and testing facilities. ZAZIBONA has recently received Council of Ministers approval to expand to VMPs. This would provide a strong foundation for further harmonisation of VMP regulation within the region.

The following challenges were identified as bottlenecks for the advancement of regional convergence within SADC:

BOTTLENECKS
Weak regulatory systems Some of the countries assessed in this review lacked adequate regulatory structures and human resource capacity to effectively regulate VMPs (e.g. Mozambique, Malawi). This in turn can be an incentive for these countries to participate in harmonisation initiatives as it provides opportunities to share resources and knowledge with countries that have more experience.
Different levels of political will There is evidence of some political will in the countries to regulate VMPs within their national NRAs. However, at the SADC level, there is evidence of insufficient political will and commitment to implement region-wide harmonisation for VMPs. Nevertheless, ZAZIBONA countries have agreed to work together on VMPs and this may encourage SADC to expand the initiative further.

Recommendations for the region

The following recommendations are suggested, to overcome the identified challenges:

1) **Harmonise regulatory standards within SADC.**
This will give the countries with weak regulatory systems the opportunity to gain assistance and support from other experienced countries, to develop and establish up-to-date regulations. However, this is legislative framework dependent.

2) **Expand the remit of ZAZIBONA to include VMPs.**
The ZAZIBONA initiative has been successful in bringing NRAs to share resources and knowledge in the evaluation of human medicines. The Council of Ministers have recently agreed to expand this to VMPs. Following on from the human medicines experience, this can provide an opportunity to establish a harmonisation initiative for VMPs in the Southern Africa region, which would enjoy better member state involvement and support and could then be expanded gradually to the wider SADC region.

3) **Facilitate cooperation and mutual understanding between regulators and the SADC secretariat in order to effectively implement regional harmonised VMP regulation.**
This may include sensitising the political actors at the national and regional level of the importance of VMP regulation. Soliciting human and financial resources to support the activities of SADC secretariat may also assist in embedding and continuing the harmonisation work in a productive way.

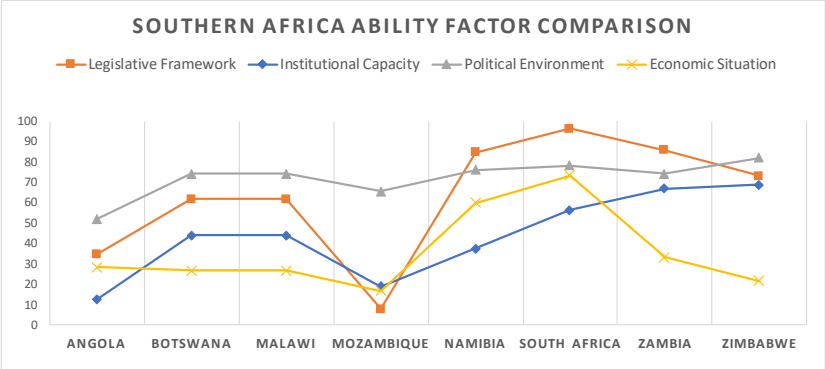

Figure 11: Combined 'Ability Factors' in Southern Africa.

SSA overview on the prospects for harmonisation

The 'Prospect for Harmonisation' assessment considered what would determine a successful (and sustainable) implementation of any regulatory harmonisation initiative at country-level (a 'bottom-up' approach) and other ancillary factors which would determine whether VMPs could be made available and accessible within these countries through effective regulation. Figure 12 sets out how each region compared to the other regions in terms of individual 'Ability Factors' and provides a ready reference for gauging the general strengths and weaknesses of each region with respect to the different indicators used.

Except for 'Economic Situation', there are certain regions which clearly demonstrate strengths with respect to a particular 'Ability Factor'. For example, West Africa (in general) has a strong legislative framework, in terms of its countries having regulatory systems geared towards effective regulation of VMPs, while Southern Africa has a political environment which is conducive to ensuring that VMPs can be made available across the relevant nations.

That said, none of the regions reviewed as part of this assessment had a good score in the 'Economic Situation' indicator, even though they may have large livestock populations. This pan-African economic underdevelopment is a major challenge affecting all SSA countries. It appears to be a common denominator with respect to impeding regulation within individual countries, restricting the implementation of authorisation procedures, and consequently reducing the prospect for harmonisation across the various African regions.

Achieving harmonisation on a regional level is a complex undertaking and any approach to increasing prospects for regional harmonisation should focus on:

i. establishing a functional and operational regulatory system in individual countries which are considered a suitable candidate for harmonisation;
ii. ensuring that there is a robust IT infrastructure to facilitate regulatory activity within and between countries;
iii. encouraging knowledge and resource sharing between countries, in order to increase cooperation and regional standardisation whilst reducing resource burdens;
iv. addressing fundamental issues which affect the political will for achieving harmonisation, whether this is through helping shift national policy or incentivising the private sector; and
v. providing participant nations with ownership of the harmonisation process so that the resulting harmonised regulatory framework is not one that has been imposed.

Recommendations for countries

The following general recommendations are suggested to overcome some of the identified challenges:

1) **Increase awareness of the veterinary sector.**
   Where there is lack of prioritisation, efforts must be made to raise awareness of the importance of the veterinary sector, its impact on human health, particularly in the context of the One Health alliance and especially within the senior political circles responsible for national policies and budgets. It will also be necessary to focus on the importance of effective regulation in preventing trans-boundary diseases.

2) **Drafting of appropriate legislation and necessary guidelines related to VMPs and establishing systems to implement the legislation.**
   These should clearly define the roles and mandate of the relevant authorities, including, for example, the department for veterinary services, NRAs and customs.

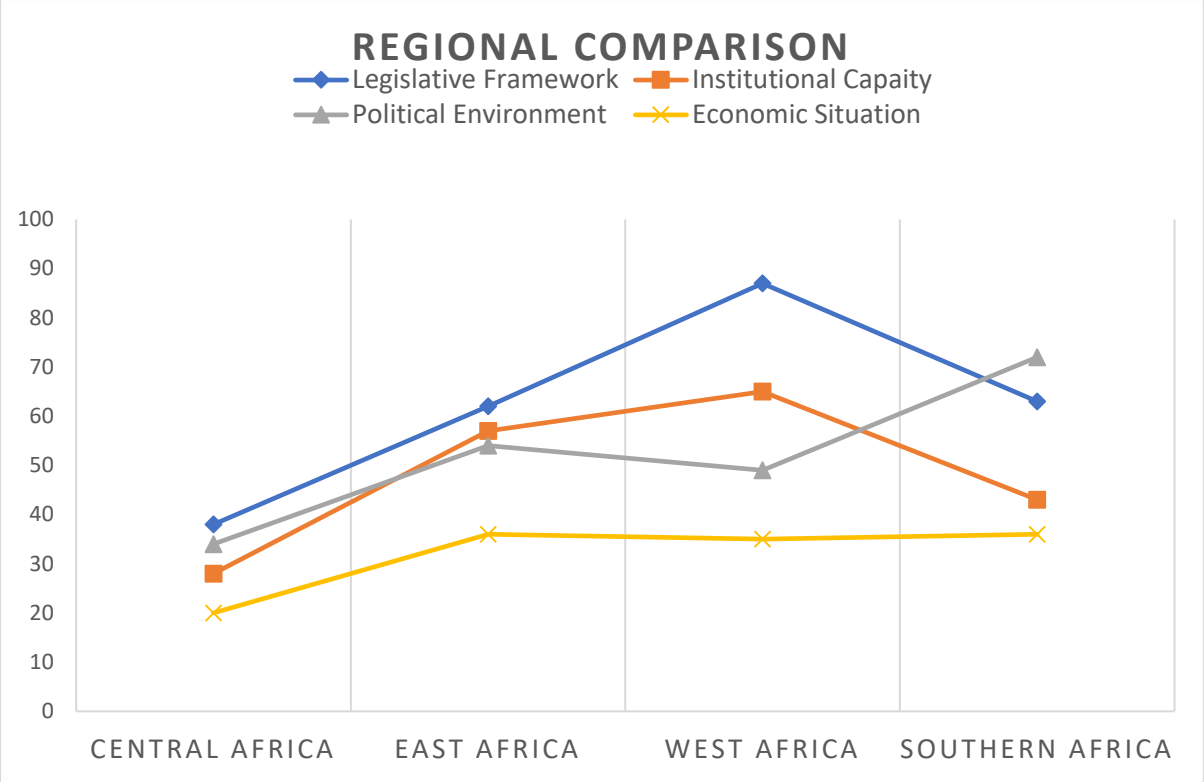

Figure 12: Comparison of regional performance with respect to individual 'Ability Factors'.

3) **Review of the legislation and guidelines, and revision to include missing key provisions.**
Countries should ensure that all key provisions are present in legislation and that complementary guidelines, detailing regulatory standards and requirements are available and accessible to the public.

4) **Establish a regulatory authority to regulate VMPs.**
In the absence of an NRA regulating VMPs, a human medicine regulator should be identified. Where present, efforts should be placed to include VMP regulation within the scope and mandate of the human medicine regulatory authority, as a starting point, with the aim being to have a standalone veterinary authority, if possible, desirable or affordable.

5) **Improve the capacity of the regulatory authority in charge of VMP regulation.**
By undertaking recruitment campaigns for appropriate internal staff, training staff for effective regulation, and allocating a larger budget for human resources.

6) **Partnerships - with neighbouring NRAs/MRAS and/or other countries.**
Countries should seek assistance from neighbouring countries with more developed VMP regulatory systems in order to strengthen regulatory and technical capability. A twinning arrangement with established and competent national regulators from developed countries could also assist in the development of capability of national regulators.

7) **Review NRA fees structures.**
NRAs can improve self-sustainability by ensuring application fees cover operational and development costs.

SECTION 3: Conclusion and proposal

Conclusion

The level of regulation and regulatory capacity varied greatly between countries and regions. In some of the Sub-Saharan Africa (SSA) countries, livestock wealth is very important for their economies and contributes significantly to their national wealth (e.g. Botswana and Namibia). Other countries are yet to enjoy the economic benefit from their livestock sector (e.g. Ethiopia). However, there is a growing realisation of the potential benefit and countries have started restructuring and improving their regulatory system to ensure that it is fit for purpose. Kenya and Ethiopia can be cited as examples where they established Veterinary Medical Product (VMP) only agencies. However, all agencies face human and financial resource issues that currently prevents them from fully discharging their duties. Therefore, support to improve the skills of the regulatory personnel and increase their capability is critical.

Improved and harmonised approaches would benefit almost all countries in SSA

Over the years there have been several initiatives to improve veterinary medicines regulation, but they have not fully yielded the desired outcome. These and other relevant initiatives were reviewed and a number of key elements that need to be in place for a successful harmonisation have been identified. These elements will have to be embedded in any future effort.

The political and economic analyses highlighted the challenges each of the countries face and their impact in any new initiative. The review of the Regional Economic Communities (RECs) also highlighted that some of the RECs have put livestock health/wealth in their agenda and are likely to support any initiative designed to improve the sector.

A root-cause analysis of strengths and weaknesses of harmonisation initiatives has led to the development of a roadmap to improve veterinary medicines regulation, and availability and subsequent improvement in livestock production. The key basic need is to ensure IT capability, without which development initiatives (national or regional) will continue to be compromised. Building the capability of regulators on the continent is also fundamental to any improvement in the authorisation and availability of VMPs. This increased capability would facilitate countries working together which will greatly advance harmonisation/convergence at both regional and continental level.

Industry is largely absent in most of SSA countries and the authorisation procedures are largely left to local importers. Local presence in SSA countries could allow the opening of channels of communication for dialogue with a view to improving the regulatory system.

An approach has been developed that sets out the strategic direction and goals for future harmonisation initiatives for the effective regulation of medicines that could then result in a regulatory harmonisation and improved livestock economy. Lessons from past and current efforts on harmonisation have been taken on board in deriving the proposed approach.

Any consideration of investment in the livestock sector in SSA must be holistic in its

approach. That is, the availability of good quality and efficacious VMPs once authorised, must be supported by a good distribution network, availability and access to veterinary professionals as well as appropriate control on the medicines' application and use.

One of the ways that availability of VMPs can be improved is harmonisation and/or convergence of the regulatory systems so that countries agree to set the same or equivalent standards and requirements. This will optimise the efficiency of the authorisation of VMPs on a regional basis, thereby increasing the size of the market and incentivise companies that produce good quality, safe and efficacious medicines.

Improved and harmonised approaches could benefit almost all countries in SSA. However, the success of any such initiative will have varying level of achievement as it depends on several factors in each of those countries. Therefore, it is necessary to develop a systematic approach that is likely to increase the chances of success. A key factor is the initial choice of countries/regions.

Ideal candidate countries are those that have recognised and invested in their livestock sector. These countries are more likely to fully engage in any process of development and change in their regulatory framework, leading to harmonisation and/or convergence. Success from these countries would then encourage others to be part of the harmonised approach and the benefits would cascade. Other countries in the region can be included over time, as their legislative framework develop, thereby reaching most if not all within the same REC. A scoring system has been developed using data published by international organisations that would help identify these countries and the order in which they can be included.

Having a regulatory framework is the next important element that needs to be in place. The level of detail in the legislation varies between countries but there must be a system that provides a mechanism in the first place, no matter how basic, for the authorisation of VMPs in the country. Absence of relevant legislation precludes countries from being ideal initial candidates. However, engagement could start early to assist them to develop legislation that is fit for purpose. Having a regulatory framework would also indicate that there are official bodies that are designated to manage the process(es). This, in turn, shows that there are specific interlocutors that could be engaged in driving the harmonisation and/or convergence. A scoring system has been developed that allows scoring of these aspects within each of the countries selected. Furthermore, the presence of a REC would legally underpin and potentially facilitate any co-operation or agreement between the countries within the REC. The approach should also utilise and encourage already functioning regional partnerships within a REC with a view to its expansion.

SSA has several RECs that are recognised by the African Union (AU). If a harmonisation and/or convergence drive is to be undertaken and supported in all the RECs, this could ultimately act as a foundation of a continental-wide harmonisation and/or convergence drive which builds on the level of harmonisation achieved in each of the RECs. International organisations such as the World Organisation for Animal Health (OIE) and Food and Agriculture Organization of the United Nations (FAO) could play an important supporting and enabling role, and engagement and involvement of both, as well as others who have been active in this sphere, would be critical from the early stages.

Lack of human, technical, financial and other resources means that most of the regulators in SSA do not have the capacity required to perform all the key regulatory functions. Paradoxically, there may be resistance by some countries from being part of a harmonisation initiative as they may see it as loss of control. The approach that is being proposed will enhance the capacity to control, while at the same time facilitate access to good VMPs, as the regulatory process would be efficient and draw on expertise from the region that may

compensate for particular expertise absence in a given country. Countries could collaborate during the evaluation of the dossiers or inspections as the pressure to have expertise in each field would be reduced, and each country could choose to specialise in a particular field (centres of excellence) in the full knowledge that quality, safety and efficacy of the approved products would not be compromised. Some countries may decide not to establish specific bodies with the responsibility of VMP authorisation but may instead contribute to the running of any regional body so that they can benefit from the collective regional effort. The global scientific guidelines that have already been established by the Requirements for Registration of Veterinary Medicinal Products (VICH) should form the basis for a common standard.

In expanding the approach to a Pan-African level, the veterinary version of the human African Medicines Regulatory Harmonisation (AMRH) initiative is proposed. This Pan-African model would therefore build on the expertise in each country and on the level of harmonisation established in each of the RECs. The AU Heads of State and Government adopted the treaty for the establishment of the African Medicines Agency (AMA) earlier this year. This is to be achieved through coordinating national and sub-regional regulatory systems for medical products, providing regulatory oversight of selected medical products, and promoting cooperation, harmonisation and mutual recognition of regulatory decisions. VMPs are currently not mentioned in this initiative and work must start to include VMPs within AMA's remit given the size of the VMP market in the continent. This would model the EU regulatory framework.

Any initiative needs to be supported by a functioning, reliable and secure IT system. Investment in this area in the early stages is a critical element for success.

Proposal

It is proposed to categorise the 28 SSA countries into three groups. Group 1 countries are countries that the review consider best able to benefit from investment as their economic situation, political environment, legislative framework and institutional capacity scores indicate that these countries are already engaged and invested in the national VMP process. Therefore, they are more likely to best benefit from further investment in the sector and become influential in participating in and championing harmonisation in their region.

Also, in developing the proposal the following principles were followed:

- Any harmonisation approach is only as functional as the functionality of the systems and processes within the individual countries that are part of it. For this reason, emphasis is placed on ensuring that sufficient VMP legislation and the appropriate supporting systems and processes are in place at the country level as a prerequisite for regional harmonisation.
- Already functioning regional partnerships should be utilised and encouraged, even if they are not part of an established REC, in addition to those in established RECs.
- Any quick-win countries/scenarios that could act as a pilot example for the harmonisation process should be identified.

In order to determine which countries will be categorised into each Group, the following criteria were applied.

Group 1 countries have:

- an adequate legislative framework in place;
- a fair amount of institutional capacity;
- a relatively high per capita investment in the livestock sector; and
- membership of a REC or a recognised regional partnership

The above is demonstrated by high scores in the relevant indicators. Group 2 and 3 countries will have lower overall scores.

Other countries in the region can be added over time, as their ability factors develop, thereby reaching most if not all within the same REC. In parallel, engagement with the relevant RECs should commence so that the RECs could play their rightful part in facilitating the cooperation and harmonisation efforts.

In expanding the blueprint to a Pan-African level, the veterinary version of the human AMRH initiative is proposed as a key agent of change. This Pan-African model would therefore build on the above and will benefit from the enhanced expertise within the National Regulatory Authorities in the different regions. This, in a way, would model the EU VMP regulatory framework.

ANNEX 1: Individual country synopses

Central Africa:

Cameroon

The regulation of VMPs is based on a legislative framework that is governed and implemented by the Ministry of Livestock, Fishing and Animal Industries (Ministère de l'Élevage, des Pêches et Industries Animales - MINEPIA). The legislation regulating VMP registration is relatively recent and is complemented by several decrees and ordinances. The latest review of the legislative framework and the regulatory system took place in 2008. New decrees were introduced which laid out detailed requirements and rules for the regulation of VMPs in Cameroon.

Cameroon is a member of Economic Community of Central African States (ECCAS) and the Central African Economic and Monetary Community (CEMAC). Cameroon is also a member of the CEBEVIRHA, a CEMAC agency with a mission to contribute to the development and harmonisation of the farming and animal industry sectors, and to optimise necessary production for food safety. In the past, CEBEVIRHA has attempted to initiate VMP harmonisation amongst CEMAC members. There is currently no MRP within ECCAS or CEMAC.

Central African Republic (CAR)

MAs for VMPs are issued by the Ministry of Livestock and Animal Health (Ministère de l'Élevage et de la Santé Animale or MESA), which was created in 2016. Within MESA sits the General Directorate of Veterinary Services and the Department of Medicine and Veterinary Pharmacy, which oversees VMP registration. Before MESA was created, the agency in charge of VMP regulations was the Pharmacy Directorate from the Ministry of Health, which regulates human medicines.

CAR is a member of ECCAS, which have shown historical desire to harmonise VMP registration. However, for various reasons – including political relations within the region, this has not happened. It is also a member of CEMAC, which promotes the harmonisation of agriculture and farming regulations. CAR is also part of CEBEVIRHA.

Chad

The legislation regulating VMPs is based on legislation governing both human and veterinary medicines. Legislation on VMPs appears to be outdated, incomplete, and lacks additional texts to provide detailed instructions for the implementation of the regulatory standards established in legislation. Many of the legal texts have not been revised since 1966. According to the Chad OIE PVS report (2016), the legislation is recorded in the Official Republic Journal, but accessibility to the legislation is poor with the texts not always available to those involved in veterinary services. Therefore, the veterinary service providers are generally not aware of their legal rights and obligations.

In 2014, the Veterinary Services Directorate in Chad requested support from the OIE to help improve veterinary services performance through the PVS Pathway, showing the country's willingness and engagement in improving its veterinary legislation. Chad is a member of ECCAS, CEMAC and CEBEVIRHA.

Congo

A National Pharmaceutical Policy was adopted in 2004 to ensure harmonious development of the pharmaceutical sector and to improve access to, and the quality of, medicinal products for the population. The inappropriate use and distribution of prescriptions, the disparity of the prices of medicinal products, as well as a lack of

information, human resources, regulations and legal framework on pharmaceuticals, have been identified as part of the constraints to achieving the development of the pharmaceutical sector. A report from the Ministry of Health and Population (2013) emphasises the critical situation of health structures in the country, characterised by dysfunction such as insufficient stock of essential drugs, the high cost of pharmaceutical products and the inappropriate conditions of storage and distribution. The situation regarding human medicine is critical in the Republic of Congo. The situation regarding VMPs does not appear to be any better, as there are no legislative systems for the regulation of VMPs in the country.

The Republic of Congo is not part of any MRP. It is a member of ECCAS, CEMAC and CEBEVIRHA.

Democratic Republic of Congo (DRC)

The regulation of VMPs is managed by the same agency regulating human medicines. The Direction de la Pharmacie et du Médicament (Department of Pharmacy and Medicine, DPM) is responsible for the registration of pharmaceutical products and sits under the Ministry of Public Health. There are several legislative texts regulating VMP registration. According to the DPM, actions have been undertaken to separate veterinary medicine legislation from human medicine legislation, although there is no available documentation to confirm this.

The DRC is not part of any MRP. It is a member of the SADC which encourages harmonisation of medicine registration procedures. The DRC continues to update its legislation to reflect international standards as part of SADC's human medicines registration harmonisation effort. DRC is also a member of ECCAS.

Gabon

Decrees and ordinances regulate the pharmaceutical sector and the import and distribution of both human medicines and VMPs, but these are incomplete and lack additional texts to strengthen the legislation. According to the legislation, the regulatory authority responsible for the registration of VMPs is the General Directorate of Livestock, which sits under the Ministry of Agriculture. However, in practice, it is the Medicine and Pharmacy Directorate (Direction du Médicament et de la Pharmacie) which oversees VMP registration.

Authorities in Gabon have requested and obtained funding from the African Union – Inter-African Bureau for Animal Resources (AU-IBAR) to support the development of new legislation under the Veterinary Governance Program (VET-Gov), with the support of the OIE. A legislative text has been developed, but it is not yet in force. Gabon is a member of ECCAS and CEMAC. It is also a member of the CEBEVIRHA.

East Africa:

Eritrea

The Eritrean National Medicines Policy 2007 was developed by the country's Ministry of Health to guide the pharmaceutical sector in the areas of quality assurance and regulation, supply management, manufacture, monitoring and evaluation. This policy however, only makes one mention of veterinary medicine in which it says that "Regulations and guidelines concerning veterinary medicines will be developed by concerned Ministry in accordance with the National Medicines Policy. Particular care will be taken to prevent adverse effects on human health due to residual concentration of medicines in food products of animal origin used for human consumption".

Moreover, the revised and updated 5th edition of the Eritrean National List of Medicines by the Ministry of Health in 2010, which is a major component of the Eritrean National Medicine Policy, does not include VMPs.

A draft "Veterinary Surgeons Act" only details the provisions that are appropriate for the regulation of the practice of veterinary medicine and surgery by registered veterinarians in Eritrea. There is no reference to VMPs in this Act.

Eritrea is a member of IGAD.

Ethiopia

Before the mid-1990s both human and veterinary medicines were regulated by the Drug Administration and Control Authority established in 1999 under the Ministry of Health. The need to regulate the use of VMPs resulted in part-decentralisation of veterinary activities led by the Ministry of Agriculture and Livestock Resources. In 2011, a Proclamation to provide relevant laws for VMP regulations was made. The veterinary service in Ethiopia is under the umbrella of the Ministry of Agriculture and Livestock Resources in the Directorate of Veterinary Services. The Veterinary Drugs and Animal Feed Administration and Control Authority (VDFACA) was established in 2011 and became operational in 2013. The VDFACA has sole responsibility for regulating the production, distribution and use of VMPs, ensuring safety, efficacy and quality of the products and helping enhance the productivity and health of the livestock population.

Ethiopia is an observer in the EAC MRP as it is not a member of the EAC. The VDFACA has expressed interest in developing a Memorandum of Understanding with the EAC so that Ethiopia could participate in the EAC MRP, this is yet to happen. Ethiopia is a member of IGAD.

Kenya

In comparison to the other countries within the EAC, the regulatory process for VMPs in Kenya is better established. Separate national bodies have been established with responsibility for the registration of VMPs and human medicines. The Veterinary Medicine Directorate - Kenya (VMD Kenya) functions as a semi-autonomous agency within the Ministry of Agriculture, Livestock, Fisheries and Irrigation, and is responsible for the regulation of VMPs. Although VMD Kenya was set up in 2014, its operations were stalled in 2016 due to a court petition filed by the Kenya Pharmaceuticals Distributors Association.

The intention of the petition was to block the transfer of regulatory function from the Pharmacy & Poisons Board (PPB) to VMD Kenya. The petition was dismissed in a court ruling and VMD Kenya was relaunched in late 2017. It is noted that few VMPs were successfully processed by the PPB.

As a member of the EAC, Kenya is part of the initiative to harmonise the registration requirements for VMPs. This initiative has seen the introduction of harmonised

guidelines for the registration of Immunological Veterinary Products which have been adopted into national regulatory systems and led to the introduction of the MRP for the region. Currently, Kenya is acting as the reference country for two products taken through MRP in the EAC. Kenya is also a member of IGAD.

South Sudan

The infancy of the country (independence in 2011) is reflected in the absence of a regulatory system for VMPs. There was no evidence of a National Regulatory Authority responsible for registering or regulating VMPs. There is evidence of structures and institutions for the regulation of livestock shown by South Sudan's membership to the FAO and the OIE. It is not clear if this extends to livestock products, such as VMPs.

South Sudan is a member of both the EAC and IGAD.

Sudan

Following a Supreme National Drug Policy created in 2005, the Medicines and Poisons Law of 2009 was approved by the Ministry of Health and received a presidential assent. This repealed a previous law that governed medicines regulation in Sudan. The Medicine and Poisons Law of 2009 allows for the publication of regulations and guidelines by the National Medicines and Poisons Board, which is Sudan's National Regulatory Authority.

Sudan is a member of IGAD.

Tanzania

The Tanzania Food and Drugs Authority (TFDA) is an executive arm under the Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGE). TFDA is responsible for regulating quality, safety and effectiveness of food, medicines, cosmetics, medical devices and diagnostics. The TFDA does not include the Zanzibar Food and Drug Authority which is a semiautonomous body under the Zanzibar MOHCDGE, and only operates within Zanzibar.

Tanzania is a member of the EAC and SADC and is gradually moving towards the harmonisation for human and veterinary medicines. Regulations and guidelines are more developed for human drugs than veterinary drugs.

Uganda

Uganda's medicines regulatory system has its foundation in a comprehensive legislative framework that is continuously being revised to meet international standards. There are increasing efforts to strengthen the regulation of VMPs. The National Drug Authority is responsible for the regulation of both human and veterinary medicines.

As a member of the EAC, Uganda is part of the initiative to harmonise the registration requirements for VMPs. This initiative has seen the introduction of harmonised guidelines for the registration of immunological veterinary products which have been adopted into national regulatory systems and led to the introduction of an MRP for the region. Uganda recently registered the first vaccine under the EAC MRP.

West Africa:

Burkina Faso

The regulation of VMP registration was governed by a decree from 1998, before it became a member of the WAEMU (UEMOA in French) centralised registration procedure for VMPs. Since then, Burkina Faso enacted a new decree in 2018 containing provisions relating to veterinary pharmacy. Another decree in 2016 established the General Directorate of Veterinary Services, in French; Direction Générale des Services Vétérinaires (DGSV) as the NRA responsible for VMP regulation. The DGSV sits under the Ministry of Animal Resources and Fisheries. The legal framework for regulating VMPs in Burkina Faso is therefore detailed as a result of domesticating the WAEMU regulations and directives into its national legislation. As part of the centralised system, MAs are issued by the WAEMU Commission which is composed of eight members who must be nationals from each member state.

In the WAEMU countries, the NRAs are responsible for all other aspects related to the importation, inspection and quality controls of VMPs. Burkina Faso is a member of ECOWAS.

Côte d'Ivoire

Côte d'Ivoire is a member of WAEMU (UEMOA), which established a centralised system in 2006 for the registration of VMPs. As a result, the WAEMU Commission is the only authority authorised to issue market authorisations in the region. The legislation in Côte d'Ivoire is currently being reviewed to adopt the WAEMU regulations and directives into the national legislative framework. However, the current legislation related to manufacturing, import and distribution of VMPs is based on a law from 1996.

In the WAEMU countries, the NRAs, the Directorate of Veterinary Services, established under the Ministry of Animal Resources and Fisheries are responsible for all other aspects related to the importation, inspection and quality controls of VMPs. Côte d'Ivoire is a member of ECOWAS.

Ghana

The Food and Drugs Authority (FDA) which sits under the Ministry of Health, is the body responsible for the regulation of food, human medicines, food supplements, herbal and homeopathics, VMPs, cosmetics, medical devices, household chemical substances, tobacco and tobacco products and the conduct of clinical trials protocols.

The Veterinary Services Directorate (VSD) within the Ministry of Food and Agriculture has the mandate to establish an animal health system which provides quality animal health services to enhance livestock production and productivity. The VSD's functions, amongst others, include assisting in the formulation of sound animal health policies that will provide a congenial animal health environment to increase livestock production. The VSD is a national collaborator of the FDA.

Ghana is a member of ECOWAS which presently does not have an MRP.

Mali

As a member state of WAEMU (UEMOA), the registration of VMPs is regulated using the centralised system established by the WAEMU Commission in 2006, and officially implemented in 2009. As a result, a law has been adopted by the National Assembly in 2016 which adopts the WAEMU regulations and directives related to veterinary pharmacy. This new law addresses important elements previously not present in the legislation, such as provisions on pharmacovigilance, VMP controls and importation.

In the WAEMU countries, the National Regulatory Authorities, the National

Directorate of Veterinary Services established under the Ministry of Livestock and Fisheries is responsible for all other aspects related to the importation, inspection and quality controls of VMPs. Mali is a member of ECOWAS.

Mauritania

Regulation of VMPs is governed by primary and secondary legislation, with the presence of decrees specifically related to veterinary pharmacy. In 2009 the Commission Nationale des Autorisations de Mise sur le Marché was established under the Ministry of Rural Development by decree and is in charge of reviewing marketing authorisation application dossiers. A Directorate of Veterinary Services established under the Ministry of Livestock (Direction des Services Vétérinaires), oversees coordinating activities related to veterinary pharmacy. However, its precise role related to VMPs are not clearly specified and it is unclear how both Ministries communicate and function together.

Mauritania is not part of an MRP. Although a founding member of ECOWAS, Mauritania decided in 2000 to leave the organisation in order to focus on its membership within the Arab Maghreb Union.

Niger

Niger is a member of WAEMU (UEMOA). In 2006 the WAEMU established a centralised system for the registration of VMPs, which was officially implemented in 2009. As a result, the WAEMU Commission is the only authority in Niger authorised to issue MAs in the region. In Niger, VMPs are regulated by a decree specific to veterinary pharmacy which was drafted in 2011 and adopts the WAEMU regulations and directives for VMP registration into the national legislative framework. These regulations and directives include provisions that govern the harmonised registration procedure for VMPs in the region.

In the WAEMU countries, the NRAs, the General Directorate of Veterinary Services, are responsible for all other aspects related to the importation, inspection and quality controls of VMPs. Niger is a member of ECOWAS.

Nigeria

The National Agency for Food and Drug Administration and Control (NAFDAC) is the body responsible for the regulation of both human medicines and VMPs. It was established in 1992. NAFDAC's mission is to safeguard public health by ensuring that only approved quality drugs, food and other regulated products are manufactured, imported, distributed, advertised, sold and used in Nigeria.

Nigeria does not participate in an MRP within the region, nor is it part of the WAEMU/UEMOA centralised registration system. Nigeria is member of ECOWAS.

Southern Africa:

Angola
Angola has recently begun reviewing the legislation and structures that establish the regulation of all medicines within the country. A National Pharmacy Policy was established in 2010 along with a new law establishing a regulatory system for all medicines in Angola. The National Directorate of Medicines and Medical Equipment is the NRA which sits under the Ministry of Health.

Angola is a member of SADC. There have been efforts to harmonise the regulation of VMPs within SADC, however Angola has not been an active participant.

Botswana
The Botswana Medicines Regulatory Authority (BoMRA) which sits under the Ministry of Health and Wellness is responsible for the regulation of all medicines (human and veterinary). BoMRA was established in 2013 by the Medicines and Related Substances Act. The Department of Veterinary Services within the Ministry of Agriculture has an important role in the regulation of veterinary medicines as they are responsible for issuing Import Permits following authorisation.

Botswana is a member of SADC and has participated in previous harmonisation efforts within the region. Presently, Botswana is not part of a MRP or a centralised system for VMP regulation.

Botswana is also a founding member of the ZAZIBONA initiative for Human medicines in SADC. The initiative is currently reviewing options to incorporate the harmonisation of VMPs.

Malawi
The Pharmacy, Medicines and Poisons Board is responsible for the regulation of VMPs. It was established in 1988 by the Pharmacy, Medicines and Poisons Act, 1988 and sits under the Ministry of Health and Population. Prior to this law, there was no effective means of controlling the type and availability of medicines on the market.

Malawi is a member of SADC. There is currently no MRP within the SADC region, however, the region has in the past initiated harmonisation of VMP regulation within member states.

Mozambique
The regulation of VMPs is governed by the Ministry of Agriculture and Food Security (Ministério da Agricultura e Segurança Alimentar; MASA) established in 2016. The National Veterinary Directorate (Direcção Nacional de Veterinária) is in charge of regulating VMPs, which includes the regulation of imports and distribution of VMPs. There is no legislation governing the registration of VMPs and therefore no NRA with the responsibility to do so. Mozambique has in the past received assistance for reviewing their legislative framework from the OIE through the Veterinary Legislation Support Programme. As a result, draft Regulations from 2016 are pending approval, which will, once approved, implement a system for the authorisation of VMPs and mandate the MASA with the responsibility of registering them.

Mozambique is a member of SADC. There have been efforts to harmonise the regulation of VMPs within SADC, however there is currently no MRP within the SADC region.

Namibia
The Namibia Medicines Regulatory Council is the NRA in charge of regulating VMPs in Namibia and sits under the Ministry of Health and Social Services. The legislative framework governing the regulation of VMPs in Namibia builds on and is based upon the South African legislation which was used previously to govern Namibia.

Namibia is a member of SADC and has participated in harmonisation efforts for veterinary medicines within the region. Namibia is a founding member of the Collaborative Medicines Registration Process involving Botswana, Namibia, Zambia, and Zimbabwe (ZAZIBONA) harmonisation initiative for Human medicines in SADC. The initiative is currently reviewing options to incorporate the harmonisation of VMPs.

South Africa

VMPs are regulated by two regulatory authorities, one under the Department of Health (DoH) and the other under the Department of Agriculture, Forestry and Fisheries (DAFF). There are separate legislative texts and guidelines in each department that constitute the overall regulatory framework. Until 2017, the Medicines Control Council (MCC) was the National Medicines Regulatory Authority under DoH, that registered and regulated human medicines and VMPs. Following concerns about the inefficiency of the MCC caused by lack of resources, the authority was replaced by the South African Health Products Regulatory Authority (SAHPRA). The Agricultural Inputs Control Directorate (AICD), a DAFF sub-directorate, is the other authority regulating VMPs within South Africa. The demarcation of roles of the two authorities is not clear.

South Africa is a member of SADC. There is currently no MRP within the SADC region, however the region has in the past initiated harmonisation of VMP regulation within member states. South Africa has also joined the ZAZIBONA initiative.

Zambia

The Zambia Medicines Regulatory Authority (ZAMRA), formerly known as the Pharmaceutical Regulatory Authority, is the National Medicines Regulatory Authority. ZAMRA, which is under the Ministry of Health, was established under the Medicines and Allied Substances Act No. 3 of 2013. This Act repealed and replaced the Pharmaceutical Act 2004. The ZAMRA is mandated to regulate and control the manufacture, importation, storage distribution, supply, sale and use of medicines and allied substances.

Zambia is a member of SADC which has in the past initiated efforts to harmonise the regulation of VMPs, but no further progress has been made. Zambia is also a founding member of the ZAZIBONA initiative for Human medicines in SADC. The initiative is currently reviewing options to incorporate the harmonisation of VMPs within their current process.

Zimbabwe

The regulation of VMPs is under the Ministry of Health. Zimbabwe has a long history of regulating VMPs and despite its economic and political struggles, there are continuous efforts to improve regulatory standards. The Medicines Control Authority of Zimbabwe is the body responsible for the authorisation of both human and veterinary medicines.

Zimbabwe is a member of SADC and has participated in harmonisation efforts for veterinary medicines within the region. Zimbabwe is a founding member of the ZAZIBONA harmonisation initiative for human medicines in SADC. This initiative is currently reviewing options to incorporate the harmonisation of VMPs within their current framework.

APPENDIX 1: Methodology

Research methodology

The key objective was to ensure that all the required information was obtained, and the quality of the information gathered would allow for robust assessment and reporting. Gathering the same type of data from various sources was considered an appropriate way of validating the information presented in this report as well as helping the consistency of the analyses.

The review relied on three different means for obtaining information:

i. **Desk-based research:** this included a thorough review of relevant available information. Primary sources of information included legislation, policy documents, guidelines governing VMP regulation in the target countries, and National Regulatory Authorities' (NRAs) or National Medicines Regulatory Authorities' (NMRAs) websites, publications and forms. Secondary sources included previous reports commissioned by the OIE, VET-Gov[1], the World Bank and GALVmed, as well as other, smaller independent studies conducted in the last decade;

ii. **Questionnaire survey:** Questionnaire were available in both English and French. The main objective of the questionnaire was to capture and validate key legislative and regulatory information from the perspective of an NRA or national officials and other relevant individuals – for example, OIE delegates, and

iii. **Interviews and country visits:** follow-up interviews were conducted with the respondents of the questionnaire and other relevant personnel within the NRA/NMRA to clarify discrepancies and to draw on their views and understanding of the regulatory landscape. Where possible, the Director for Veterinary Services or Chief Veterinary Officer were also interviewed. Information gathered through limited country visits has also been incorporated.

To maintain consistency in the way information was obtained and recorded, it was ensured that all potential questionnaire respondents received the same version of the questionnaire and that information obtained through the desk-based research was recorded, in a semi-automated data capture template. The use of this template both helped to steer researchers with regards to the granularity of information being sought and helped to improve consistency in how information was recorded by various researchers.

Following the processing and review of all the collected information, a legislative and regulatory system gap assessment was conducted. This was based on highlighting the significance of key elements lacking (whether legislative or otherwise) in the country's VMP regulatory system. In addition, an assessment of a country's prospect for harmonisation was also carried out using a modified Political, Economic, Social, Technological, Environmental and Legal (PESTEL) analysis.

PESTEL is a method used to identify and analyse the drivers of change in a strategic environment. It is often used by businesses to determine macro-level factors which can affect the prospects of success (with respect to a specific objective) but it can also be extrapolated for application in other contexts.

Prospect for harmonisation assessment methodology

[1] Vet-Gov is an AU-IBAR programme which publishes on livestock matters.

As the primary focus of this assessment was the regulatory frameworks of specific countries; what would determine a successful (and sustainable) implementation of any regulatory harmonisation initiative at the country-level (a 'bottom-up approach') was considered together with other ancillary factors which would determine whether VMPs could be made available and to some extent accessible within these countries. Based on observations made in previous VMP and non-VMP related regulatory harmonisation initiatives in Africa, there was an indication that successful country-level implementation of a harmonised regulatory framework is underpinned by the country's ability to adopt legislation, guidelines and standards domestically.

In order to assess a country's ability to achieve the Strategic Objective, primary factors that would help drive (or impede) efforts to make necessary changes at country-level were considered. These factors, which are termed 'Ability Factors', are identified as being a country's (i) Legislative Framework, (ii) Institutional Capacity, (iii) Political Environment and (iv) Economic Situation. These Ability Factors incorporate some of the macro-level factors typically utilised in a PESTEL analysis. Each Ability Factor has been described in further detail below.

Legislative framework: considers how adequately the legislative framework establishes regulatory standards for VMPs and the supporting regulatory structures that implement and enforce regulatory standards;

Institutional capacity: considers the country's ability to implement regulatory standards set out in the legislative framework and the capacity of governance mechanisms to support the regulatory authority and wider regulatory structures in their mandate. This factor also takes into consideration the technological capacity of institutions as well as their structure, sustainability and politics;

Political environment: considers two factors, firstly - the political environment surrounding the regulation of VMPs and the ability of political actors to champion implementation of regulatory standards for VMPs. Secondly, it considers indirect environmental factors which may enhance or impede a country's ability for making VMPs available and accessible within the relevant territory. This could include the presence of war, territorial conflicts and sectarian violence. The political environment within a country is deemed to serve as either an immediate promoter or antagonist for any regulatory shift at country-level;

Economic situation: considers the economic drivers which directly affect internal and external investments into livestock health within a country. This takes into consideration the importance of livestock with respect to the local population and for economic development. The economic situation of a country, similar to the political environment, is deemed to serve as either an immediate promoter or antagonist for any regulatory shift at country-level.

A high-level scorecard was developed to rate each country's performance with respect to the 'Ability Factors'. The scorecard relied on a set of objective and binary questions designed to gauge each 'Ability Factor' on an individual basis. Furthermore, the questions were purposefully designed so that they could be answered with information gathered as part of this assessment. Where a category of information was already available (for example – number of employees carrying out specific tasks at each country's NRA) then no questions which would draw on such information were included. This was done intentionally, so that all countries within this assessment could be rated as equally as possible.

Depending on how each question was answered (per 'Ability Factor'), a score of 1 (and in some instances 2) or 0 was given, with a higher score reflecting a more positive

response. There are instances where informed assumptions were made to answer specific questions. This was due to gaps in the information obtained on a country. In such cases, a 50% risk factor was applied to the score.

Finally, to calculate a country's rating with respect to an individual 'Ability Factor', the sum of the scores (for all the questions relating to that 'Ability Factor') was divided by the number of questions answered. The higher the value of the resulting number, the better the country's rating with respect to that 'Ability Factor'.

The benefit in rating each of the four 'Ability Factors' independently per country is that it can help inform a more bespoke intervention or investment strategy that tackles particular deficiencies. For example, in a country where the Legislative Framework and Institutional Capacity rate well, but Political Environment rates low, a more appropriate intervention for improving the prospects for harmonisation may be around highlighting the importance of VMPs to policy makers with respect to the importance of VMPs, instead of investment into building institutional capacity.

The assessment also took the weighted average of the four 'Ability Factor' ratings and arrived at what is termed as the 'Readiness Score', a single and holistic score which represents how likely a country will be in achieving its strategic objective. A higher 'Readiness Score' correlates with a better prospect for harmonisation. In calculating the 'Readiness Score', each of the Legislative Framework and Institutional Capacity ratings were weighted 30% lower than the Political Environment and Economic Situation ratings. This is because, irrespective of how robust a country's legislation is and how well-resourced its institutions are, without the necessary political will and drive (informed by the political and economic environment within a country), implementation of harmonised legislation and regulatory framework would probably not succeed.

The assessment comes with some caveats. Firstly, PESTEL analyses rely on multiple sources of data, including different perspectives. Much of the data gathered through this research could not be verified due to access or time limitations. This potentially impacts how each country ultimately rates against a particular 'Ability Factor'. However, as information becomes verified, scores and ratings can be updated.

Another limitation is that PESTEL analyses, by their nature, tend to over-simplify the data being used. This is partially because the sources and the type of data can be limited, and outputs are intended to be objective. Nonetheless, a PESTEL analysis can be improved over time as new sources and types of data become available, adding new dimensions (or macro-level) factors which can also be considered when assessing prospects for success.

Lastly, the determination of risk rates and relative assessment of 'Ability Factors' are subjective in nature. This is because there is no exact science in determining how much an informed assumption is worth or to what degree political will promotes or impedes the path to success. These are simply ratios we have selected.

Limitations

There are several limitations and caveats to the study. These are primarily based on challenges inherent to the nature of the methodology used. These limitations and caveats are set out as follows:

Verifying information: The assessment relied on a combination of desk-based research, survey responses and one-to-one interviews with NRA/NMRA officials or other individuals involved in the registration of VMPs at country-level, including for example – senior officials at a country's Directorate of Veterinary Services. This meant that there was additional confirmation that the information obtained was valid. However,

for certain countries, information could only be obtained from a single source – most often through desk-based research, either by obtaining copies of legislation and/or copies of historical legislative reviews.

The drawback of relying on information from a single or a limited number of sources is that the quality of the information cannot be verified. Whilst all possible measures had been taken to confirm information, there are instances where this was not possible. Therefore, the assessment is based on the information obtained plus any pre-existing insight that may have been available on the regulatory system for a specific country.

Accessing information: Related to the point made above, there are a few instances, where relevant information could not be obtained from any sources (or was very scarce). This was particularly the case in the assessment of South Sudan, Eritrea and nearly all central African countries. Consequently, the information for those countries is considerably briefer and contributed to their low readiness scores. Whilst some additional information was gained through discussions with NRA officials and other relevant people, all possible avenues were exhausted (in the allotted time) for the desk-based research for the countries presented in this report.

Timescale limitations: The delivery of this report was time sensitive and a short time was available to carry out assessment of the countries. The challenge posed by this timescale was that it provided a limited time to carry out surveys and one-to-one interviews. Often, the request to complete the questionnaire and/or agree to an interview date were met with objections related to (i) the respondent being too busy, (ii) the respondent travelling and (iii) the respondent requiring authorisation, which would be subject to an internal authorisation process. Additional time may have provided a better opportunity to obtain first-hand information from individuals on the ground.

However, in previous studies involving the participation of officials on the ground, longer timescales had not always yielded better participation levels.

Inconsistencies: In the assessment, there were several instances where information obtained through the desk-based research appeared to be significantly inconsistent with information provided by the official who completed the survey, or that obtained during country visits. For example, in reviewing applicable legislation for the Central African Republic, it was noted that the legislation was over a decade old and not yet in force. Yet, the questionnaire as completed by an official, suggested that the legislation was being enacted and was applicable. In such instances, follow-on interviews were sought, however, this was not always possible. Such inconsistence makes it difficult to provide a robust assessment. They do, however, highlight a general limitation within the country's regulatory body, where an apparent disconnect exists between various government departments and the legislation.

Notes: