Tanzania and Implementation of East Africa Mutual Recognition of Veterinary Medicines

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Introduction

Tanzania has the third largest livestock population in Africa (after Ethiopia and Sudan), but the competitiveness of Tanzania’s livestock sector faces many challenges, including lack of access to good-quality, effective, safe veterinary drugs and vaccines, especially for smallholders. Availability of good-quality, affordable, effective inputs (including veterinary drugs, vaccines, and compound animal feed) in the market is critical to increasing productivity and ensuring the safety of the animals.

Taking these challenges into consideration, in 2017, Tanzania launched a livestock master plan, which highlighted, among other things, the need to increase the availability and quality of veterinary drugs and vaccines to improve productivity and livestock health for eventual public consumption. The government asked the Tanzania Food and Drugs Authority (TFDA) and the Ministry of Livestock and Fisheries to establish measures and mechanisms to increase the availability of drugs and vaccines in the country. The TFDA has entered into a memorandum of understanding with the Tanzania Veterinary Council to minimize overlap of functions between them and to increase the availability of quality regulatory services.

On November 28, 2014, the East African Community (EAC) developed and adopted mutual recognition procedures (MRPs) on harmonization of immunological veterinary products (IVPs) for EAC member states. This was made into effect in September 2016 through the EAC Council of Ministers’ decision note number EAC/CM 34/Decision 35, which is legally binding on all partner states because it is based on a Council of Ministers decision based on Chapter 5 of the EAC treaty, put this harmonization into effect. This was meant to increase efficiency by avoiding duplication of assessments of the same product by different regulatory authorities. With Tanzania participating in implementation of the established EAC MRPs, the number of registered good-quality animal drugs and vaccines would increase because registration procedures would be harmonized, allowing products registered in any EAC country to be marketed in all partner states and through collaborative evaluation and inspection of vaccine manufacturing facilities, which expedites the registration process.

This would benefit more than half of households, most of them in rural areas engaged in livestock production and affected by the problem because of limited availability of IVPs (IFC 2018). The availability of good-quality drugs and vaccines is limited in rural areas where small-scale livestock holders live, so these livestock holders are more likely to be affected than those living in peri-urban areas. The fact that these livestock holders have a very low level of compliance with good animal husbandry practices and good veterinary practices, which increases morbidity and mortality of their livestock, exacerbates the problem of limited access to a variety of modern medicines.

There are several advantages to adopting and implementing the MRP:

- Accelerates availability of good-quality, efficacious veterinary vaccines
• Avoids duplication of assessment by partner states and improves predictability because it uses harmonized guidelines and standard operating procedures (SOPs)
• Builds trust among regulatory bodies of the EAC partner states through collaborative evaluations and inspections of manufacturing facilities
• Enables rapid introduction of vaccines against new diseases
• Helps in developing the capacity of partner states with less-developed regulatory systems in evaluation of applications and good manufacturing practice (GMP) inspections

**EAC MRP**

The process of registering an IVP under the EAC MRP involves three key players: the applicant, the reference country (RC) (the primary country in which the applicant wants to register and market the product), and the concerned countries (CCs) (the secondary country(ies) in which the applicant intends to market the product.

The applicant submits the application for registering an IVP to the regulatory authority in the RC. If the RC is satisfied that the product is eligible for MRPs, the applicant sends identical application forms and dossiers to the RC and CCs and pays the necessary fees to each country, including the GMP inspection fee. The regulators assess the dossiers of the RC, and the CCs may review the dossiers if they wish. An assessment report from the RC’s regulatory body, including GMP reports, is sent to the CCs for review. The CCs may seek additional information on quality, safety, and effectiveness. If the application is found to comply with the requirements, it is provided with market authorization in the RC and CCs. If there are disagreements regarding the decision, the MRPs provide mechanisms for resolutions. The MRPs also provide mechanisms for the applicant to appeal decisions of the RC or CCs.

The time frame for completion of each step has been provided under the MRPs to ensure timely provision of market authorization and to reduce the length and lack of predictability of the process under the current system, in which each partner state evaluates and registers separately.

**EAC Support of Implementation**

The EAC Secretariat, through its Department of Agriculture, has supported the smooth adoption of MRPs by:

• Developing documents used in registration of IVPs, such as harmonized guidelines for registration of IVPs, SOPs used in registration of IVPs, screening checklists for applications and application forms for registration of IVPs to harmonize the registration process
• Training EAC country evaluators and inspectors on evaluation of IVP applications and GMP inspection
• Facilitating joint assessment of dossiers based on Decision EAC/CM 34/Directive 42 to expedite processes and build capacity of evaluators from partner states
• Supporting alignment of relevant regulations and guidelines of partner states with the EAC MRP as part of harmonizing regulation of veterinary vaccines

As of December 2018, only one IVP has been registered under the EAC MRP initiative; two were in the process of being registered.

Despite the above efforts, there are several factors inhibiting MRP adoption, including limited awareness of the players at the EAC Secretariat on MRPs and lack of coordination and monitoring of implementation of MRPs at the partner state level by the EAC Secretariat. In addition, there is no harmonized system for regulation of veterinary medicines in the partner states, limiting trust among the countries. Different countries have different laws, inspection systems, laboratory capacities, and management of control systems. If harmonization were greater, partner states would have more trust in the other states’ veterinary medicine regulatory systems and more faith that veterinary products approved in other countries comply with the quality, safety, and efficacy levels in their own.
Status of Implementation of MRP by Government of Tanzania

The TFDA, which is under the Ministry of Health, is the regulatory authority responsible for implementation of the MRP in Tanzania in consultation and collaboration with other key stakeholders such as the Directorate of Veterinary Services (and the Veterinary Council of Tanzania of the Ministry of Livestock and Fisheries. EAC directives are channelled to partner state ministries responsible for East Africa Cooperation (MEACs). The directive is then sent to the appropriate ministry for implementation, often through the institution(s) or agencies that the mandate affects. The Tanzania MEAC sent the directive on MRPs directly to the TFDA on March 21, 2017, instead of through the Ministry of Health. Because the regular procedure was not followed, the TFDA insists that it lacks an official directive from its parent ministry.

The TFDA's unwillingness to comply with the directive may be reasonable, considering that the TFDA has participated in all EAC initiatives related to MRP development:

- TFDA inspectors and dossier evaluators have been trained on MRP guidelines and SOPs.
- TFDA is using the harmonized EAC guidelines for registration of IVPs in processing applications for registration of IVPs.
- TFDA is involved in the EAC joint assessment of dossiers for registration of IVPs and conducting GMP inspections of manufacturing facilities on a pilot basis.

Next Steps

As an immediate step toward advancing EAC MRP implementation, the Tanzania MEAC could officially communicate the EAC MRP directive to the Ministry of Health so that the ministry can then direct the TFDA to implement the EAC MRP according to agreed-upon procedures and protocols.

There are some additional actions that could be taken at the EAC and partner state levels to enhance effective implementation of the MRP.

- **Government of Tanzania Level**
  - Identify and support actions required for effective implementation of MRPs by TFDA
  - Support training on evaluation of dossiers and GMP inspection techniques of IVPs for more evaluators and inspectors
  - Support harmonization of functions between TFDA and veterinary division of Ministry of Livestock and Fisheries

- **EAC Level**
  - Support involvement of EAC Secretariat in adoption and implementation of MRPs in partner states by emphasizing importance of MRPs
  - Support harmonized systems for regulation of veterinary medicines among partner states, for example, by developing and implementing similar legislation, guidelines, and inspectorate systems
  - Strengthen capacity to monitor implementation of MRPs by requiring partner states to submit reports on implementation and taking measures to overcome challenges associated with effective implementation by partner states
  - Support policy advocacy and education of key stakeholders at EAC Secretariat so that they help in attainment of objectives for which MRPs were established

Conclusions

Effective implementation of the MRP will enhance faster registration and availability of good-quality, safe, effective IVPs and may lower IVP costs. Availability of such products would increase the productivity of the livestock sector, improving the situation of livestock keepers, especially those in rural areas. To build trust and confidence in experts, further joint assessments and GMP inspections need to be undertaken. Once the partner states are confident in each other’s ability to assess dossiers and GMP inspection, it is believed that there will be no need for joint assessments.
References
