

Regulatory harmonisation: Improving access to safe, effective and quality veterinary medicines across East Africa

The costs of animal disease

In Africa, millions of people depend on livestock for their livelihoods. However, the high prevalence of livestock diseases, such as East Coast Fever and Newcastle disease, to name just a few, are a major constraint to increasing smallholder incomes and enhancing agricultural development, food security and resilience. Accessibility and distribution of high quality veterinary medicines is therefore the best tool to combat animal diseases and help curb economic losses.

Cross-country registration of veterinary medicines

Registering veterinary medicines in Africa through the currently established processes is cumbersome and time consuming, requiring considerable technical information from applicants. Harmonisation of the registration system for veterinary medicines across nations simplifies the process, saves time and resources and helps to ensure drug quality, safety and efficacy.

In 2012, a GALVmed initiative 'Harmonisation of Registration Requirements for Veterinary Immunologicals and Development of a Mutual Recognition Procedure (MRP) in East Africa' was launched to provide support in this critical area. The enterprise was undertaken to assist the East African Community (EAC) in harmonising registration requirements in the established regulatory authorities and strengthening their veterinary vaccine regulatory systems. GALVmed's work commenced with a workshop in Nairobi, involving regulators from eight East African countries – Burundi, Djibouti, Ethiopia, Kenya, Rwanda, Sudan, Tanzania and Uganda. Only three countries already possessed a recognised registration system (Kenya, Tanzania and Uganda). Participants were asked what would be needed to achieve a harmonised system for registering veterinary vaccines and it was concluded that the development of a set of harmonised technical documents was required.

As a result of the workshop, a technical working group (TWG) was formed consisting of participants from the national regulatory authorities of Kenya, Tanzania and Uganda. Burundi, Rwanda and the EAC Secretariat are also members of the TWG whose role was to work on and develop the following registration documents: a harmonised application form to send to EAC Regulatory Authorities when applying for marketing authorisations; harmonised product information templates to be included in the summary of product characteristics, product labels and package leaflets; a guide to the structure of a registration dossier for a veterinary immunological product; and a guide on the data required in the registration dossier to demonstrate product quality, safety and efficacy.

Progress of the Mutual Recognition Procedure (MRP)

The rationale for the MRP is to obtain marketing authorisations for a particular product without incurring long delays. An assessor in one country is responsible for evaluating the registration dossier before writing the assessment report. The same report is then shared with all other regulatory authorities where the applicant seeks marketing authorisations. This eliminates the need for separate applications and time consuming assessments by each country. Gilly Gowan, GALVmed's Regulatory Affairs Consultant said, "MRP saves time, effort and is predictable. Assessors and inspectors from different Regulatory Authorities will build trust in each others' work, enabling valuable veterinary vaccines to be registered quickly and simultaneously in as many EAC countries as the applicant wishes. Once the harmonised Marketing Authorisations are granted there are other advantages for applicants. No longer will they need to wait for the last approval from a Regulatory Authority before making a change to the production, testing or label claims of their product. The approval process will happen simultaneously in all the countries that were involved in the MRP."

Subsequent to the initiative's conception in 2012, encouraging progress has been achieved in the EAC, where a harmonised veterinary medicines registration system is currently being set up. The following accomplishments have been made:

1. Harmonisation of technical documents – Development and refinement of the technical documents across Kenya, Tanzania and Uganda. Kenya, Tanzania and Uganda have stopped using their previously established guidelines to be part of the regional MRP process. Uganda has already registered products using the new guidelines. Burundi and Rwanda also see the significance of MRP and are currently establishing their own regulatory bodies to use the harmonisation documents for immunological veterinary product registration.
2. Acknowledgement of the process – The value of MRP has been identified in other regions. Requests have been received from the economic communities of the South African Development Community (SADC) and Economic Community of Central African States (ECCAS) to assist them in introducing a similar system.
3. Adoption of MRP – In 2013, heads of regulatory authorities in the EAC region met with GALVmed and the African Union Pan African Veterinary Vaccine Centre to recommend the harmonisation process and MRP concept to the EAC Council of Ministers. The process was adopted by the EAC Sectoral Council in September 2014 and by the EAC Council of Ministers in December 2014.
4. Training in good manufacturing practices (GMP) – GMP inspectors from four countries have received training in appropriate inspection of veterinary vaccine manufacturing. The training is on-going and a joint, mock inspection is planned for October 2016 to provide inspectors with confidence in each other's inspection methods.
5. Registration dossier assessment – Twenty assessors from six countries attended training in assessing registration dossiers for veterinary vaccines. By the end of the course they all declared that they are able to train other regulators in the process. Such joint assessment will provide assessors with confidence and trust so that they can accept assessments made by regulators from other EAC countries during MRPs.

Who benefits from MRP?

Dr Zelalem Gebretsadik of the Ethiopian regulatory authority said: "Harmonisation and MRP of vaccine regulation benefits local farmers, product applicants, vaccine producers and regulators. Farmers will enjoy increased availability of safe, effective, quality vaccines at affordable prices in the market for livestock diseases. National medicine regulatory authorities will be better equipped to register medicines in a cost-effective and timely manner by improving regulatory processes and making better use of scarce technical skills. Vaccine producing companies and their local representatives/agents will benefit from simplified and standardised regulatory approval processes. It will become possible to submit dossiers for much-needed medicines simultaneously in multiple countries, and evaluation turnaround times will improve."

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