Follow up of recommendations of the joint GALVmed / OIE workshop on harmonisation of the registration of veterinary medicinal products in the SADC region:

Perspective of the NRAs

Regional Workshop for OIE National Focal Points for Veterinary Products (Cycle V): Ezulwini, Swaziland, 6 - 8 December 2017

Dr A T Sigobodhla

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

BACKGROUND

No single country, including well-resourced countries can efficiently and effectively independently regulate and control its own market, in this globalised world.

What attributes to the slow progress in SADC region: absence of

- An enabling environment due to issues of political, social and economic nature
- Non-functional regulatory framework in some countries
- Implementation challenges due to: lack of resources, human capacity, expertise and infrastructure necessary to implement regulatory systems

Only isolated sharing of experiences by like-minded members states is realised at various platforms without a coherent harmonised system

Key Questions

Three quarters of the world population is in developing countries

- Accounts for less than 10% of the global pharmaceutical market.
- Ten countries – Algeria, Egypt, Kenya, Ivory Coast, Libya, Morocco, Nigeria, South Africa, Sudan, and Tunisia: account for 70 percent of the 20.8 billion dollar African pharmaceutical market

Livestock fastest growing agricultural subsector

- Agricultural GDP is 33% per cent
- Rapidly increasing demand for livestock products, population growth, urbanisation and increasing income in developing countries
- Food demand from livestock products in sub-Saharan Africa : from 200 kcal per person per day in 2000 to around 400 kcal per person per day in 2050

KEY OBJECTIVES

To improve access to veterinary medicinal products

The need for sustainable and affordable supply of good quality, safe and efficacious veterinary medicinal products (VMP)

The need to promote the use of vaccines

- -To fight against AMR: WHO Global Action Plan
- -Restricted use of some essential antimicrobials in animal health

To realise the benefits that a harmonised registration system has

- -National Regulatory Authorities (NRA)
- -Applicants
- -Livestock keepers in the SADC region

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

CURRENT CHALLENGES

- The challenges industry faces due to multiplicity of procedures in place in different SADC Member States with different requirements

- The absence of formal registration systems in some SADC Member Countries and the existence of parallel approval systems in other Member Countries whereby registration of VMPs is sometimes circumvented by individual applications for import permits

- The competent authority for the registration of VMP, the NRA, is often under the Ministry of Health and is responsible for the registration of human medicinal products as well

CONSIDERATIONS

Earlier initiatives aimed at fostering regional harmonisation of registration of VMPs

- 2010 joint OIE – GALVmed seminar on veterinary products (Joburg, South Africa)
- 2011 SADC Guidelines for the Regulation of Veterinary Drugs in SADC Member States;

The OIE standards

- on the production, testing and registration of veterinary vaccines (*Manual of Diagnostic Tests and Vaccines for Terrestrial Animals:* Chapters 1.1.8, 1.1.9, 3.4, and 3.7. as well as the disease-specific chapters under section 2)

CONSIDERATIONS….cont

The OIE network of experts and Reference Centres

The harmonised technical requirements for registration: VICH Guidelines

Experiences acquired and methodologies developed in other regions of Africa

- *West African Economic and Monetary Union* (WAEMU)
- GALVmed's support in developing harmonised registration documentation
- *Mutual Recognition Procedure* (MRP) in the *East African Community* (EAC)

Experiences acquired and methodologies developed in Africa for medicines and vaccines for human use

- WHO's *African Vaccine Registration Forum* (AVAREF, Africa-wide, vaccines)
- **Zazibona** initiative (SADC-wide, collaborative medicines review process)

CONSIDERATIONS….*cont*

AU-PANVAC's role

- Assuring the availability of good quality vaccines in the African continent
- Promoting the harmonisation process

AU-IBAR's role in: promoting livestock related policies, strategies and legislations in various regions of the African continent;

Willingness of the industry to work with and support NRAs in:

- Harmonising registration requirements towards Mutual Recognition
- Early involvement of stakeholders in developing a practical system
- International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.
- Zazibona.
- AU-PANVAC
- AU-IBAR

RECOMMENDATIONS TO THE NRAs

- Use OIE relevant baseline international standards: as a guide to harmonise regulations
- Transparency and access of information for submission of dossiers to applicants
- Updated, accessible searchable list of authorised products
- Electronic tracking system of the submitted dossiers: communicate on progress
- Smooth communication lines and collaboration with *Departments of Veterinary Services* (DVS) and the NRAs in the Ministry of Health
- National gap-analysis of the existing systems in place, supported by the OIE PVS Pathway mechanism, including the option of extending the scope of Zazibona (by the end of 2018).
- Set up a SADC *Technical Working Group* (TWG) and nominate experts to the TWG, representing the NRA

RECOMMENDATIONS TO THE NRAs...*cont*

- Develop common technical requirements for registration of medicines and / or update the existing SADC Guidelines by the end of 2018 (through a TWG), in some cases adopt EAC Guidelines (vaccines) and VICH Guidelines (pharmaceuticals/vaccines)
- Formalise collaboration between the NRAs (through a region-wide MoU); include Ministry of Health staff (i.e. NRA staff) to be availed to e.g. the SADC TWG, should it become part of the *Livestock Technical Committee* (LTC) system;
- Where there is no NRA, the Member State should consider establishing such an authority or visible contactable representation, based on relevant, supporting legislation and national guidelines, based on SADC Guidelines, together with the provision of the necessary resources;
- Conduct at least one joint pilot assessment of a submission for a veterinary medicinal product

THANK YOU

health
Department:
Health
REPUBLIC OF SOUTH AFRICA