



RECOMMENDATIONS

CONSIDERING

1. The need for sustainable and affordable supply of good quality, safe and efficacious *veterinary medicinal products* (VMP) to benefit livestock keepers in the SADC region;
2. The need to promote the use of vaccines, good animal husbandry and biosecurity best practices in the fight against anti-microbial resistance, as a strategy to limit the need to use antimicrobials and as per the guidance provided by the WHO Global Action Plan and the OIE Strategy on antimicrobial resistance and prudent use of antimicrobials in animal health;
3. The benefits that a harmonised registration system, including appropriate requirements for different categories of VMP, can bring to individual *National Regulatory Authorities* (NRA), applicants and livestock keepers in the SADC region;
4. The challenges industry faces due to multiplicity of procedures in place in different SADC Member States with different requirements;
5. 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 VMP is sometimes circumvented by individual applications for import permits;
6. 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;

RECOGNISING

7. Earlier initiatives aimed at fostering regional harmonisation of registration of VMP, such as the 2010 joint OIE – GALVmed seminar on veterinary products (Johannesburg, South Africa) and the 2011 SADC Guidelines for the Regulation of Veterinary Drugs in SADC Member States;

8. The OIE standards on the production, testing and registration of veterinary vaccines, as published in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (specifically Chapters 1.1.8, 1.1.9, 3.4, and 3.7. as well as the disease-specific chapters under section 2) ;
9. The OIE network of experts and Reference Centres offering expertise on VMP;
10. The harmonised technical requirements for use in VMP registration provided by the VICH Guidelines¹;
11. Experiences acquired and methodologies developed for VMP in other regions of Africa, i.e. in the *West African Economic and Monetary Union* (WAEMU) and GALVmed's support in developing harmonised registration documentation and a *Mutual Recognition Procedure* (MRP) in the *East African Community* (EAC);
12. Experiences acquired and methodologies developed in Africa for medicines and vaccines for human use, i.e. the WHO's *African Vaccine Registration Forum* (AVAREF, Africa-wide, vaccines) and the Zazibona² initiative (SADC-wide, collaborative medicines registration review process);
13. AU-PANVAC³'s role in assuring the availability of good quality vaccines in the African continent and in promoting the harmonisation process in various regions of the African continent;
14. AU-IBAR⁴'s role in promoting livestock related policies, strategies and legislations in various regions of the African continent;
15. Willingness of the industry as expressed by the representatives during the present meeting to work with and support NRA's in harmonising registration requirements towards Mutual Recognition and the need for early involvement of stakeholders in developing a practical system;

PARTICIPANTS RECOMMEND:

In general:

1. To identify champions within each national, regional and international organisation involved and for the SADC Secretariat to be the champion amongst the organisations;
2. To encourage advocacy by regional and international organisations on the topic of harmonisation;

¹ International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.

² SADC-wide initiative, named after the 4 founding countries (Zambia, Zimbabwe, Botswana, and Namibia).

³ African Union – Pan-African Veterinary Vaccine Centre.

⁴ African Union – Inter-African Bureau for Animal Resources.

To the *National Regulatory Authorities (NRA)* in the SADC Member States:

1. Use the relevant baseline international standards of the OIE as a guide to harmonise regulations across the region;
2. Provide information for submission of dossiers to applicants in a transparent manner e.g. publishing updated information on accessible websites;
3. Provide an updated searchable list of authorised products, in an accessible manner (website);
4. Provide a (electronic) tracking system for the dossiers that have been submitted and thereby improve communication, feedback and progress within the dossier approval process;
5. Establish smooth communication lines and collaboration with the *Departments of Veterinary Services (DVS)* where the NRA is governed by the Ministry of Health, applying or adopting a One Health approach;
6. Conduct a national self-assessment of the existing systems, where suitable supported by the OIE PVS Pathway mechanism., including the option of extending the scope of Zazibona (by the end of 2018);
7. Set up a *SADC Technical Working Group (TWG)* and nominate experts to the TWG, representing the NRA (by end of 2017);
8. Develop common guidelines including technical requirements for registration of medicines and / or update the existing SADC Guidelines by the end of 2018 (through a TWG), where appropriate adopt EAC Guidelines (vaccines) and domesticate VICH Guidelines (pharmaceuticals/vaccines);
9. Formalise the willingness to collaborate between the NRAs (through a region-wide MoU); this would also allow for 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;
10. Where there is no NRA, the Member State should consider establishing such an authority within the relevant Ministry, e.g. the Ministry of Health or of Agriculture, based on legislation, processes, guidelines and standards that have already been developed and practised by other countries and regions, taking into account the OIE Terrestrial Manual Chapter 3.4;
11. Conduct at least one joint pilot assessment of a submission for a veterinary medicinal product (by the end of 2018);

To the *Departments of Veterinary Services (DVS)* in the SADC Member States:

1. Use the relevant baseline international standards of the OIE as a guide to harmonise regulations across the SADC region;
2. Establish smooth communication lines with the NRA, where the NRA is governed by the Ministry of Health, applying or adopting a One Health approach. Where relevant, to formalise the collaboration between the DVS and the NRA (e.g. through a national MoU);

3. Endorse the establishment of a TWG by the LTC with the support of its members, the *Chief Veterinary Officers (CVO)* and nominate experts to the TWG, representing the DVS (and ensuring consistency in the membership). The proposal for harmonisation of registration requirements shall be presented at the next LTC meeting;
4. Whilst recognising that registration of VMP is an NRA function, formalise the involvement of the DVS with respect to registration of VMP in general, and registration of veterinary vaccines in particular, e.g. in respect of strains, post-marketing surveillance and adverse drug reactions (with the assistance of AU-PANVAC);
5. Raise awareness on the positive outcomes of harmonisation of registration through broad information campaigns.

To the SADC Secretariat:

1. Facilitate and promote the pooling of national experts and drive the establishment of a SADC *Technical Working Group (TWG)* including public health and animal health representatives;
2. Establish an electronic (IT) platform for the sharing of documents, and – in general – raise awareness of the SADC work already conducted in this area (i.e. Guidelines);
3. Lead the process of updating the existing SADC Guidelines and expanding them to provide more specific technical guidance;
4. Support capacity-building (with OIE, GALVmed, AU agencies and relevant national stakeholders);

To industry:

1. Support the establishment of national and eventually a broad regional industry association which can interact with e.g. SADC Secretariat and NRAs at a regional level;
2. Where these exist, for national industry associations to nominate members to the SADC TWG; this could be extended to other external experts and researchers e.g. on wildlife-related products, specific vaccine-types, etc.
3. Support capacity building of NRAs and DVS through agreed mechanisms and in line with best practice, avoiding any form of conflict of interest;

To the African Union technical agencies (AU-PANVAC and AU-IBAR):

1. Provide political support for harmonisation initiatives in the SADC region;
2. Support capacity-building (with OIE, GALVmed, SADC and relevant national stakeholders), in particular, in areas relevant to the production of quality veterinary vaccines in the SADC region;
3. Assist countries without a functional NRA for VMPs, with a list of AU-PANVAC – approved veterinary vaccines, based on previous assessments conducted, for other countries;



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4. Support and facilitate increased third party testing of vaccines, as part of post-marketing surveillance.

To GALVmed:

1. Avail the relevant sections of the EAC Technical Documents in French;
2. Share knowledge, tools, best practise, lessons learned in harmonising registration requirements and developing MRP in the EAC;
3. Support follow up joint activities, possibly aligned with planned capacity-building efforts underway (OIE focal points' training seminars) and other capacity-building efforts (with OIE, AU agencies, SADC and relevant national stakeholders);

To the OIE:

1. Avail the relevant sections of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (specifically Chapters 1.1.8, 1.1.9, 3.4, and 3.7.) in French;
2. Include aspects of registration of VMPs in the ongoing capacity-building programmes including training seminars of OIE Focal Points, twinning agreement, veterinary legislation support (with GALVmed, AU agencies, SADC and relevant national stakeholders);
3. Support nurturing a good collaboration between NRA and DVS, as a tangible implementation of the One Health concept;
4. Support follow up joint activities, possibly aligned with planned capacity-building efforts underway (OIE focal points' training seminars) and other capacity-building efforts (with GALVmed, AU agencies, SADC and relevant national stakeholders);
5. Provide advice, as necessary, on minimum requirements for GMP in veterinary vaccine manufacturing facilities (through OIE Collaborating Centres).