



Call for Expression of Interest and Dossier submissions

1.1 Background

Harmonisation of regulatory requirements, collaboration and information sharing is one strategy to leverage on the existing resources in the region to improve access to quality veterinary medicinal products (VMPs) by reducing the registration timelines, eliminating unnecessary duplication of efforts, managing the increasing workload and building capacity in individual member states in the SADC region. Southern African Development Community (SADC) saw the need and published the 'Regional Guidelines for the Regulation of Veterinary Drugs in SADC' member states in 2011, designed to strengthen the regulatory framework for regulation of veterinary drugs at national and regional level. However, the use of these guidelines at national and regional level needs to be evaluated as this forms the basis for regional harmonization.

An *ad hoc* SADC Technical Working Group (TWG) was formed, and expanded on the SADC harmonisation objectives, establishing the SADC VMP harmonisation initiative platform. The major mandate of this TWG was to develop a SADC VMP collaborative platform for joint assessment, GMP inspection and pharmacovigilance activities. The project builds upon lessons learnt from the SADC harmonisation initiative called 'Zazibona', a collaborating framework for assessment and GMP inspection for human medicinal products and facilities respectively, by the SADC member states and other regional collaborative initiatives e.g., the EAC.

The project is designed to improve the regional collaboration in the registration and control of VMPs in SADC region to ensure that only safe, efficacious, and quality products are available for use in the region, thus improving animal health. The SADC NMRAs from actively participating members states in collaboration with FAO/OIE/WHO and other global partners will be involved in the execution of the project in accordance with the SADC VMP harmonisation initiative's governance structure.

1.2 Call for Expression of Interest and dossier submissions

The **Veterinary Medicines Zazibona: the SADC VMP Collaborative Procedure** would like interested applicants to submit Expression of Interest (Eoi) and submit dossiers for review for **the second pilot phase of the SADC VMP joint assessment procedure.**

The SADC VMP joint assessment procedure provides a platform for joint assessment of VMP applications for registration and Good Manufacturing Practices (GMP) of manufacturers of VMPs by the National Medicines Regulatory Authorities (NMRAs) of actively participating of SADC MS namely *Botswana, South Africa, Tanzania, Zambia and Zimbabwe*. Namibia and Malawi are observers and other SADC MS willing to participate may also benefit from this procedure. The SADC VMP collaborative initiative shall make efficient use of the limited resources to ensure timely access to good quality, safe and efficacious veterinary medicines to the end users in the SADC region, while at the same time building regulatory capacity of the participating NMRAs. The Initiative is earmarked to aid reduction in the workload in participating member states by avoiding duplication of assessment efforts, improve / increase mutual trust and confidence in the regulatory



capacities of all collaborating members states, thus facilitating successful recognition and reliance procedures, provide a platform for training and capacity building in other regulatory fields; and possibly reduce registration timelines. In return, Industry will have access to a wider market for distribution of their VMPs that would have gone through this collaborative initiative.

1.3 Inclusion and exclusion criteria for the SADC VMP Collaborative Procedure

The SADC VMP Collaborative Procedure will consider EoIs from Manufacturers or Applicants willing to participate in this VMP registration collaborative initiative. The Applicants should submit applications for registration of VMPs that are used in the treatment or prevention of the following diseases identified by various **Status of Animal Health in SADC Region Bulletins**,

- | | |
|-------------------------|--|
| 1. Rabies, | 9. Theileriosis, |
| 2. Lumpy Skin Disease, | 10. Peste Des Petis Ruminants, |
| 3. Heartwater, | 11. Newcastle Disease, |
| 4. Fowl Pox, | 12. Contagious Bovine Pleuropneumonia, |
| 5. Blackleg, | 13. African Horse Sickness, |
| 6. Brucellosis, | 14. Foot rot, |
| 7. Anaplasmosis, | 15. Babesiosis, |
| 8. African Swine Fever, | 16. Contagious Pustular Dermatitis, |
| | 17. Rift Valley Fever. |

Other VMPs that control diseases not listed above may qualify for joint assessment if they are considered of public health importance by the *ad hoc* SADC TWG for harmonisation of VMPs. Applications for registration of veterinary pesticides or acaricides and biological/immunological products will be excluded from this phase of the joint Veterinary Medicines Zazibona joint review pathway.

1.4 Submission of Eoi and Applications for consideration in the SADC VMP Joint assessment process

1.4.1 Eoi

To be considered in the Veterinary Medicines Zazibona Phase 2, an applicant should target and select at least two of the SADC NMRAs participating in this collaborative initiative, as listed in section 1.6.

The Eoi and dossier submission window is effective from 20th January 2025 and will close on the 17 February 2025. During this time, industry are invited to complete the “Intention to submit application – ‘Veterinary Medicines Zazibona’” form to submit their full dossiers following the procedures as outlined in each agency including the appropriate fees if applicable. Please notify the coordinators: Dr I Ravengai at iravengai@bomra.co.bw and Dr A T Sigobodhla Alice.sigobodhla@sahpra.org.za of your intention to submit as soon as possible and also when you have finally submitted. At the close of the submission window (**17th February 2025**), applications will be jointly reviewed by the participating members of the Veterinary Medicines Zazibona Initiative.



1.4.2 Applications

Manufacturers or applicants must submit their complete dossier(s) to at least two active Member States, in accordance with the technical and procedural guidelines.

The application will comprise of:

1. Completed signed and dated statutory NMRA application form
2. Completed signed and dated common SADC application form
3. Application for registration as prescribed by the draft SADC VMP registration guidelines

The applications need to be submitted directly to at least two Member State(s) as stated above.

1.4.3 Guidelines for use in assessment of applications

The technical guidelines used for assessment of veterinary pharmaceutical medicinal products are the Guidelines for Registration of Veterinary Pharmaceuticals. These technical guidelines can be obtained from the websites and contact points of the SADC NMRAs participating in this collaborative initiative listed in section 1.5.

1.5 SADC MS Contact Details

Country and Agency	Contact details
Botswana Medicines Regulatory Authority	Website: www.bomra.co.bw Emails: iravengai@bomra.co.bw
	
Medicines Control Authority of Zimbabwe	Website: www.mcaz.co.zw Emails: mcaz@mcaz.co.zw ; zmakoni@mcaz.co.zw
	



South Africa Health Products Regulatory Authority	Website: www.sahpra.org.za Emails: alice.sigobodhla@sahpra.org.za
	
Tanzania Medicines and Medical Devices Authority	Website: www.tmda.go.tz Emails: saidir@nm-aist.ac.tz
	
Zambian Medicines Regulatory Authority	Website: www.zamra.co.zm Emails: pharmacy@zamra.co.zm ; dndambasia@zamra.co.zm
	

1.6 Process Flow for the SADC VMP Joint assessment Procedure

The SADC VMP collaborative joint assessment procedure is designed to achieve registration and or regulatory decision within a total timeline of 12 months for a maximum of 2 review cycles. Process guidelines on how the SADC VMP collaborative joint assessment is carried out may be obtained from the websites and contact points of the SADC NMRAs participating in this collaborative initiative listed in section 1.5.

1.7 Critical Veterinary Medicines Zazibona Timelines to Regulatory Decisions

	Time (Days)	Activity
Pre-submission		Eol published
	-30	Companies send in completed “Intention to submit application – ‘Veterinary Medicines Zazibona” form as Eol in taking part in pilot process
		Companies simultaneously submit dossiers in at least two NMRAs for review
Start of procedure		



0	<p>Meeting 1: Dossier received and start of the assessment process, assumption that the concerned product passed validation screening in concerned countries</p> <p>Rapporteur and secondary reviewer assigned</p>
60	Rapporteur circulates Assessment Report 1 (AR1) to Veterinary Medicines Zazibona countries
90	<p>Meeting 2: Discussion of VMP AR and common position on compliance (<i>other</i>: inspection triggers)</p>
105	List of Questions round 1 (LoQ1) forwarded to the applicant, response time 45 days (90 days maximum)
150	Rapporteur receives Responses 1 from the applicant and starts assessment
165	Rapporteur circulates VMP AR2 (assessment of responses1) and LoQ2 to Veterinary Medicines Zazibona NMRA's and reviewer, reviewer assesses the VMP AR2 and LoQ2
180	Meeting 3: Discussion and common position
195	LoQ2 forwarded to the applicant, response time 45 days (90 days maximum)
240	Rapporteur receives Responses 2 from the applicant and starts assessment
255	Rapporteur circulates VMP AR3 (assessment of responses2) and proposed position on registration to Veterinary Medicines Zazibona NMRA's and reviewer, reviewer assesses the VMP AR3 and proposed position
270	Meeting 4: Discussion and adoption of position on non/recommendation of registration
285	Rapporteur circulates final Veterinary Medicines Zazibona position
330	Countries are expected to decide on registration and reject/register
360	Meeting 5: Collection of information on National Registrations (differences recorded) and dates.

Your Faithfully,

Daniel Ndambasia (Dr)

Chairperson: Ad Hoc VMP Zazibona TWG