Call for Expression of Interest

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 by SADC member states and other regional collaborative initiatives e.g., the EAC, WAEMU/UEMOA.

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, such as the UK-VMD, 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

The **Veterinary Medicines Zazibona:** the **SADC VMP Collaborative Procedure** would like to call for submission of Expression of Interest (EoI) from Veterinary Pharmaceutical Industry interested in participating in **the pilot 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,
2. Lumpy Skin Disease,
3. Heartwater,
4. Fowl Pox,
5. Blackleg,
6. Brucellosis,
7. Anaplasmosis,
8. African Swine Fever,
9. Theileriosis,
10. Peste Des Petis Ruminants,
11. Newcastle Disease,
12. Contagious Bovine Pleuropneumonia,
13. African Horse Sickness,
14. Foot rot,
15. Babesiosis,
16. Contagious Pustular Dermatitis,
17. Rift Velley Fever.

Other VMPs that control diseases not listed above may qualify for joint assessment if they are considered to be 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 the first phase of the joint Veterinary Medicines Zazibona joint review pathway.

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

1.4.1EoI

To be considered in the Veterinary Medicines Zazibona at least two of the SADC NMRAs participating in this collaborative initiative listed in section 1.6, namely Botswana, South Africa, Tanzania, Zambia and Zimbabwe need to be selected.

The EoI submission window is effective from the 1st April 2022 and will close on the 30th April 2022. During this time, industry are invited to complete the "Intention to submit application – 'Veterinary Medicines Zazibona" form to indicate their intention to submit a dossier for joint assessment. The completed form should be sent to the vmpzazibona@gmail.com and copy the TWG Chairperson (Zivanai Makoni, zmakoni@mcaz.co.zw). At the close of the EoI window, applications will be reviewed by the participating members of the Veterinary Medicines Zazibona Initiative for eligibility to participate in the pilot.

1.4.2Applications

Manufacturers or applicants with successful EoI notifications will be allowed 60 days to 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
4. Letter of permission providing consent to the SADC VMP collaborative initiative and UK-VMD to review company's confidential information.

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 Draft 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

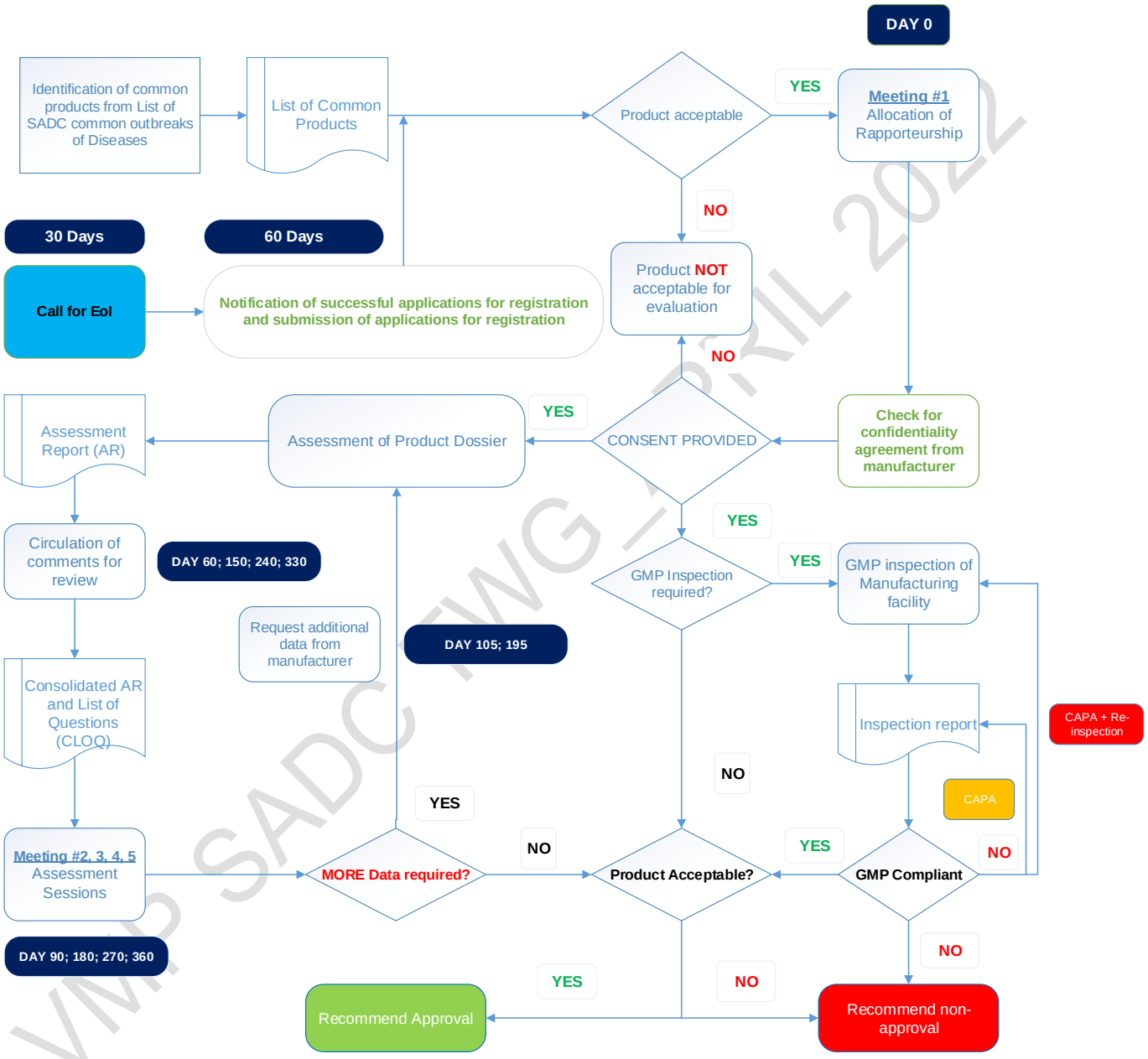
Country and Agency	Contact details
Botswana Medicines Regulatory Authority	Website: www.bomra.co.bw Emails: iravengai@bomra.co.bw
	
Medicines Control Authority of Zimbabwe	Website: www.mcaz.co.zw Emails: mcaz@mcaz.co.zw; zmakoni@mcaz.co.zw
	

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 may be obtained from the websites and contact points of the SADC NMRAs participating in this collaborative initiative listed in section 1.5.

Procedural Aspects for Application for Market Authorization for Veterinary Medicinal Products through the pilot joint Veterinary Medicines Zazibona Assessment Initiative



1.7 Critical Veterinary Medicines ZazibonaTimelines to Regulatory Decisions

	Time (Days)	Activity
Pre-submission		**EoI published**
	30	Companies send in completed "Intention to submit application – 'Veterinary Medicines Zazibona" form as EoI in taking part in pilot process
	60	Successful companies notified and dossiers are submitted for review
Start of procedure		
	0	**Meeting 1**: Dossier received and start of the assessment process, assumption that the concerned product passed validation screening in concerned countries Rapporteur and secondary reviewer assigned
	60	Rapporteur circulates Assessment Report 1 (AR1) to Veterinary Medicines Zazibona countries
	90	**Meeting 2**: Discussion of VMP AR and common position on compliance (*other*: inspection triggers)
	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 NMRAs 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 NMRAs 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.