



JOINT STATEMENT OF THE HEADS OF NATIONAL MEDICINES REGULATORY AGENCIES OF SADC

ON THE PILOT OF THE REGIONAL CENTRALIZED PROCEDURE FOR EVALUATION OF MEDICINAL PRODUCTS

27th October 2023
Cape Town, South Africa

1. Background

The Southern African Development Community (SADC) Medicines Regulatory Harmonization (MRH) was established in May 2011 by the SADC Secretariat with support from the African Medicines Regulatory Harmonization (AMRH) Consortium. The SADC Protocol on Health, through Article 29, outlines the initial mandate for Member States to 'cooperate and assist one another in the harmonisation of procedures of pharmaceuticals, quality assurance, and registration' (SADC, 1999). This mandate was primarily focused on the harmonisation of medicine registration and was subsequently updated in 2016 to include other regulatory functions.

ZAZIBONA¹the collaborative medicines registration initiative founded by four countries, namely Zambia, Zimbabwe, Botswana, and Namibia, with technical support from the World Health Organisation (WHO) to address the varying regulatory capacities of National Medicines Regulatory Authorities (NMRAs), is the founding pillar of the SADC MRH programme. In 2014, the ZAZIBONA initiative was formally endorsed and adopted by the SADC Ministers of Health. Since then, the initiative has grown, and all 16 SADC Member States are now participating either as active participants, non-active participants or observers based on their internal capacity to conduct joint assessments and joint current Good Manufacturing Practice (cGMP) inspections.

2. Joint Statement

We, the Heads of National Medicines Regulatory Agencies of the Southern African Development Community (SADC) during the 2nd Meeting of the SADC Regulators Forum on 27th October 2023, in Cape Town, South Africa:

Noting and acknowledging that the initiative has been instrumental in promoting regional collaboration through joint regulatory activities, work sharing and capacity strengthening to enhance efficiency of national regulatory systems, promote effective use of limited resources, build trust and confidence among regulatory authorities in the SADC region thereby improving public health of Member States by ensuring quick access to life-saving medicines and vaccines.

¹ ZAZIBONA was derived from the first two letters of the four founding countries i.e., Zambia, Zimbabwe, Botswana, and Namibia. The name ZAZIBONA has been maintained even though the initiative has grown to more than just the four founding countries because it has a special meaning in one of the local languages in Zambia (Nyanja) which is 'to look to the future'.

Recognizing the greater shared regulatory responsibility of the NMRA in the SADC region in ensuring access to quality assured medical products through facilitation of pooled procurement and supporting local production by centralizing some priority products for the region and working closely together to provide regulatory oversight.

That these regional collaborations will also contribute to a strong foundation for a well-functioning continental regulatory ecosystem in Africa through the African Medicines Regulatory Harmonisation initiative and eventually the African Medicines Agency (AMA) once operational.

Reaffirm the commitment to strengthening the collaboration, and supporting the recently established centralized regional regulatory pathway for evaluation of selected medicinal products by the ZAZIBONA process by instituting regional collaboration at national level.

We therefore agree to collaborate by:

1. Participating in the pilot of the centralized regional joint regulatory process.
2. Recognizing the regional centralized process in our national guidelines as one of the facilitated registration processes considered eligible for reliance procedures.
3. Sharing information in accordance with existing laws and applicable protocols.
4. Sharing knowledge and building of capacities of SADC Member States NMRA

Confirm that we are committed to expanding and deepening the dialogues on collaboration and regional joint regulatory work to remove duplications amongst national medicines regulatory authorities in the region and on the continent.

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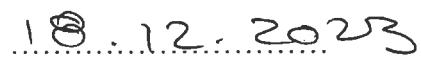
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