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.

ZAZIBONA[1]the 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 NMRAs 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 NMRAs

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.

Issued by:

The SADC Member States National Medicines Regulatory Agencies

On behalf of Angola:

Director General

Agência Reguladora de Medicamentos e Tecnologias de Saúde (ARMED)

Rua Comandante Cheguevara nº 86/86ª, Bairro Maculusso, Ingombotas

Luanda-Angola

On behalf of Botswana:

Chief Executive Officer

Botswana Medicines Regulatory Authority

Plot 112, International Finance Park, Gaborone

Botswana

On behalf of Comoros:

Directeur General

Agence Nationale des Medicaments et des Evacuations Sanitaires (ANAMEV)

Agence Nationale des Médicaments et des Evacuations sanitaires(ANAMEV)

B P 159 Moroni

Comores

On behalf of the Democratic Republic of Congo:

Autorité **C**ongolaise de **R**églementation **P**harmaceutique (**ACOREP**)

66 Boulevard du 30 Juin, Building 5 à sec 4th Flore;

Kinshasa/Gombe

Democratic Republic of Congo

On behalf of Eswatini:

Deputy Director - Pharmaceutical Services

Ministry of Health

Kingdom of Swaziland

On behalf of Lesotho:

Head - Pharmacy Policy and Regulation

Ministry of Health Headquarters, Constitutional Road,

Maseru

Lesotho

On behalf of Madagascar:

Chef de Service de Pharmacovigilance

Agence du médicament de Madagascar

8, Rue Karija Tsaralalàna

Antananarivo 101

Madagascar

On behalf of Malawi:

Director General

Pharmacy and Medicines Regulatory Authority

Box 30241

Lilongwe 3

Malawi.

On behalf of Mauritius:

Ministry of Health and Wellness, Mauritius

Emmanuel Anquetil Building

Port Louis

Mauritius.

On behalf of Mozambique:

Autoridade Nacional Reguladora de Medicamento, IP

Agostinho Neto Avenue, N° 1527,

PO Box n° 264

Maputo

Mozambique

On behalf of Namibia:

Namibia Medicines Regulatory Council

Ministry of Health and Social Services

Private Bag 13366

Windhoek

Namibia

On behalf of Seychelles:

Chief Analyst

Medicines Regulatory Unit,

Public Health Authority,

Seychelles Hospital, Blue Roof, Mont Fleuri, Mahe,

Ministry of Health

P.O. Box 52,

Seychelles

On behalf of South Africa:

South African Health Products Regulatory Authority

Loftus Park, Building A, 402 Kirkness St, Arcadia,

Pretoria, 0083

South Africa

On behalf of Tanzania:

Director General

Tanzania Medical Devices Authority (TMDA)

TMDA HQ

P.O. Box 1253,

Dodoma

Tanzania

On behalf of Zambia:

Director General

Zambia Medicines Regulatory Authority

Department of Medicines Control

Plot No. 2350/M

Off Kenneth Kaunda International Airport Road

P. O Box 31890,

Lusaka

Zambia

On behalf of Zimbabwe:

Director-General

Medicines Control Authority of Zimbabwe

106 Baines Avenue

P. O. Box 10559

Harare, Zimbabwe

..... 18.12.2023

Mrs Katiza Mangueria Date

Director General

Agência Reguladora de Medicamentos e Tecnologias de Saúde (ARMED)

SADC Chair Member State