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Southern African Regional Programme
on Access to Medicines and Diagnostics

Regulatory Harmonisation Initiatives
9 July 2015

Project purpose

SARPAM aims to promote a more efficient and competitive market for essential medicines in order to meet the health needs of poor and underprivileged people in the Southern African Development Community (SADC)

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Project overview

- Initiated as a support programme for the SADC Pharmaceutical Business Plan, through the Department for International Development (DFID-UK) between 2009 and 2014, and now continues to operate as a regional programme through engagement with various partners and facilitators in the public and private sectors
- Programme was designed in consultation with the SADC Secretariat, Member States (MS) and other stakeholders

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Background to Regulatory Harmonisation

- 1995 SEAMRAC (Southern and Eastern African Medicines Regulatory Authority Conference) initiated by South Africa (MCC & PMA) & Zimbabwe (MCAZ & PMA)
- 1999 SADC Ministers of Health committed to regulatory harmonisation in line with Article 29 of the Protocol on Health
- Variation in NMRAs level of development among MS, capacity building needs vary from support in setting up where none exist to strengthening existing functions
- Capacity constraints relate to inadequate professional staff, technical knowledge and expertise
- Case for regulatory harmonisation in the SADC region has been clearly articulated
- SARPAM provided technical and logistical assistance to MS

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SARPAM Initiatives & Achievements

- Revival/Re-activation of **SADC Regulators Forum** with clear Terms of Reference
- **SADC Medicines Regulatory Strategic Framework 2015-2020** driven by the SADC Regulators and developed through consultations and involvement of key stakeholders – SARPAM support provided
- Nov 2013 SADC Health Ministers agreed to **adopt ICH CTD format** for applications for registration
- **SADC Regional registration guidelines** updated and aligned to CTD format
- Facilitated review and benchmarking of the **Lesotho Draft Medicines Bill**
- Facilitated work sharing & collaboration in dossier assessments and GMP inspections among SADC countries
- **7 countries** assessed Coartem® 80 mg/480 mg tablet dossier (2014)

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SARPAM Initiatives & Achievements cont.

- Facilitated exchange visits and **Technical Assistance** between countries:
  - Lesotho & Zimbabwe on Medicines Bill (2013)
  - Zambia & South Africa on CTD and QMS (2013)
  - Botswana & South Africa on CTD (2014)
  - Seychelles & Zimbabwe on Quality Control Lab (2014)
- Supported **ZAZIBONA** – 4 regulatory authorities with support from WHO Prequalification Team on collaborative procedure for medicines registrations (Zambia, Zimbabwe, Botswana and Namibia)
  - **6 joint dossier assessments** leading to **9 products** recommended for **registration in < 12 months**
  - **More than 40 medicines** at various stages of assessments with at least 20 to be finalised in 3-6 months
  - **Joint GMP inspection of 2 manufacturing facilities** in India in Nov 2014
  - **20 staff from regulatory authorities trained** in assessment of active pharmaceutical ingredients (API)
- Future plan to publish EOIs for manufacturers to submit applications for registrations for identified 10 SADC priority diseases

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Challenges and Lessons Learnt

- Bureaucratic inertia of SADC Secretariat
- Variation in level of development of NMRAs (capacity, technical knowledge, expertise)
- Commitment and accountability required from players - **long working hours including weekends at times**
- Work Sharing & Collaboration can work - **more similarities than differences**
- Consolidated assessment reports & list of questions to applicants provide better outcomes
- Leverage on existing strengths among Regulators
- Additional technical assistance from WHO Prequalification Team
- Potential benefits exist for Pharma Industry & Regulators

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Regulatory Harmonisation – Way Forward

SADC Regulatory Framework Strategic Objectives – agreed to by all 15 Member States

1. To ensure that at least 80% of Member States have National Medicines Regulatory Authorities (NMRAs) that meet WHO standards by 2020
2. To strengthen and expand areas of technical cooperation among Member States' NMRAs by 2017
3. To ensure that at least 80% of MS have adopted/implemented harmonised standards for medicines registration by 2017
4. To facilitate capacity building initiatives for medicines regulatory systems for MS by 2020
5. To promote information sharing on medicine regulatory activities among MS by 2020

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Targets/Indicators

1. Project initiation 2015	8. Approved minimum standards for functional NMRA by 2017
2. Model MOU to facilitate technical cooperation among MS in place by 2015	9. Lists of registered medicines available on MS websites by 2017
3. Training needs assessment report available by 2015	10. List of centres of specialisation and excellence identified for key regulatory functions by 2017
4. Application of updated regional registration guidelines by 2015	11.At least 3 joint activities conducted annually between and among MS
5. ICT needs of MS identified by 2015	12. At least 80% of MS adopted/adapted and use SADC CTD by 2020
6. Regional training plan developed by 2016	13. Total Quality systems that support medicines registration in MS in place by 2020
7. Regional harmonised standards(labelling, packaging, scheduling) agreed by 2017	

Implementation

- MOU signed between SADC-WB-NEPAD for implementation of AMRH programme in SADC region
- Implementation to be guided by SADC Regulatory Strategic Framework – 5 year plan
- Participatory approach through consultations with regulators from SADC MS, technical partners and Pharma industry
- NEPAD Model Law on Medical Products Regulation and Harmonisation in Africa will facilitate achievement of minimum standards for functional NMRAs
- SADC & MS recognise need for Pharma Industry involvement through representative organisations. Pharma Industry to present representative to SADC Sec

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Thank You – Q&A

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