SADC Collaborative Medicines Registration Initiative (Zazibona)

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MCC, (SAHPRA loading….)

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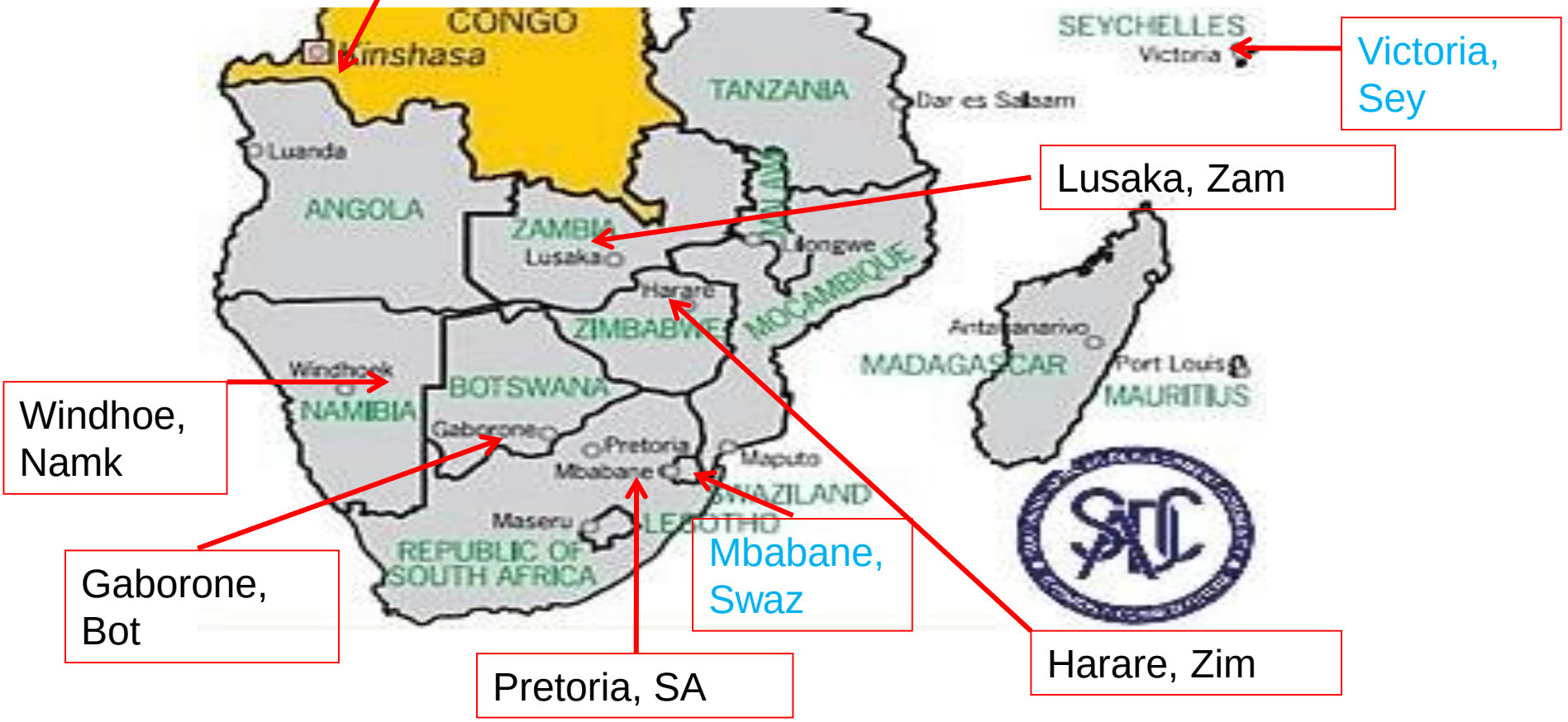
Presentation Outline

- Brief Background
- Objectives of the Collaborative procedure
- How does ZAZIBONA Process work
- Achievements
- The Role of MCC
- What ZAZIBONA is Not
- Concluding Points
- Other related global collaborations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Maputo
SWAZILAND
Mbabane, Swaz
Maseru
LESOTHO
REPUBLIC OF SOUTH AFRICA
Gaborone, Bot
Pretoria, SA
Harare, Zim

Brief Background-Global In

- SADC is a regional economic group with 15 Member States (MS)
- Varying regulatory capacities in the region
  - 11 MS actively issue marketing authorizations
- Harmonisation of registration of medicines
  - Directive issued by SADC Ministers of Health in 1999
  - Work focused on development of technical guidelines (> 22 guidelines developed)

1

Public Health

SADC Protocol on Health 1999

- SADC Pharmaceutical Business Plan 2015 - 2019

2

Economic & Industry Interests

SADC Industrialization Strategy and Roadmap 2015 – 2063

- Strategy on Regional Manufacturing of Essential Medicines and Health Commodities (2016-2020)

SADC – Collaborative Medicines Registration Initiative (Zazibona)

- Endorsed by SADC Ministers of Health & Ministers Responsible for HIV & AIDS in January 2015
  - Expand to other SADC Member States beyond the 4 founding Member States
- **6 Active Participating Member States**
  - Botswana
  - Democratic Republic of Congo (*joined 2017*)
  - Namibia
  - South Africa *(joined June 2016)*
  - Zambia
  - Zimbabwe
- **2 non-active participating Member State**
  - Swaziland *(joined Nov 2016)*
  - Seychelles *(joined 2017)*

Objectives

- Initiative to collaborate in assessment and inspections for medicines registrations with objectives to:
  - Reduce workload
  - **Reduce timelines to registrations**
  - Develop mutual trust and confidence in regulatory collaboration
  - Platform for training and collaboration in other regulatory fields

How does this work ?

Common Submission

Essential medicine

Manufacturer's Consent

Consensus

Consolidated Assessment reports (CAR)

Consolidated list of Q to applicant (CLOQ)

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1 Primary Assessment + 5↑ Countries = 6 CAR + 

Timelines

- **Day 0** of Zazibona process: Meeting 1: Agreement on Rapporteur, assumed that screening in countries is OK
- **Day 75**: Rap circulates the AR1 to Zazibona NRAs and reviewer, reviewer assesses the AR1 and LoQ1
- **Day 90** = Meeting 2: Discussion and common position

  Position on compliance and inspection triggers
- **Day 105:** LoQ1 forwarded to the applicant, response time 45 days (90 days maximum)
- **Day 150:** Rap receives Responses1 from the applicant and starts assessment
- **Day 165**: Rap circulates AR2 (assessment of responses1) and LoQ2 to Zazibona NRAs and reviewer, reviewer assesses the AR2 and LoQ2
- **Day 180**: Meeting 3: Discussion and common position

Timelines

- **Day 195:** LoQ2 forwarded to the applicant, response time 45 days (90 days maximum)
- **Day 240:** Rap receives Responses2 from the applicant and starts assessment
- **Day 255**: Rap circulates AR3 (assessment of responses2) and proposed position on registration to Zazibona NRAs and reviewer, reviewer assesses the AR3 and proposed position
- **Day 270**: Meeting 4: Discussion and adoption of position on non/recommendation of registration
- **Day 285**: Rapporteur circulates final Zazibona position
- **Day 330**: Countries are expected to decide on registration and reject/register
- **Day 360**: Meeting 5: Collection of information on national registrations (differences recorded) and dates

- **WHO PQT-m performs QA on the Assessment Reports**

- **Outcomes of Assessments and Inspections would be made available (Transparency on Decision Making)**

Achievements

Zazibona sesson #	Month of Meeting	Products reviewed	Products finalized[1]	Median time to scientific opinion (finalisation)/ months	Products with Positive Opinion	Products with Negative Opinion	Products withdrawn from the process
1	**Oct-13**	4	4		3	0	1
2	**Mar-14**	9	9		4	5	0
3	**Jun-14**	11	10		5	5	0
4	**Sep-14**	17	15		7	4	4
5	**Dec-14**	7	7		3	4	0
6	**Mar-15**	12	10		6	2	2
7	**Jun-15**	12	8		6	2	0
8	**Sep-15**	15	10		10	0	0
9	**Nov-15**	15	4		0	1	3
10	**Feb-16**	14	6		5	1	0
11	Jun-16	11	1		1	0	0
12	Sep-16	11	1		0	1	0
13	Nov-16	14	0		0	0	0
		152	**85**	**8**	**50**	**25**	**10**

Results

- **Median time** to recommendation: 9 months
  (*including regulators and manufacturer/ applicant's time to respond to queries*) [Target is 270 days (9 months)]
- The **mean review cycles** were 2.5 per product [target is 2 cycles]
- **Average response time**: 3 months for manufacturers to respond to queries [target is 3 months]
- **Median time for final approval** at the national level (after Zazibona process) was 1.5 months (range 0.2 – 6 months) [target is 2 months]. (*based on data from two countries*)

The Role of SA

Full participating MS

- *Assessment of identified common applications*
- *Participate in joint inspections*
- *Development of internal capacity-*
  - *training of assessors and inspectors*
- *Development of SOPs, assessment guidelines and templates*
- Development collaborative/reliance procedure
- Finalisation of Expression of Interest document

What ZAZIBONA is not…

- Replacement of the NMRAs
  - Only focuses on the review and inspection process
  - Actual registration is done at the national level i.e., requires actual submission of product application to the countries following applicable national requirements i.e. application fees *etc.,*
- Centralised procedure
  - There is no central single submission (…yet)
  - But same dossier submission to all the countries based on the SADC CTD and registration guidelines

Concluding Points

- Potential mechanism for improving the regulatory systems in LMICs
  - Efficiency & effectiveness
- Sustainability & Ownership
  - Costs effectiveness (value for money)
  - Reduce the number of assessors per Zazibona session from **three** to **two** per country for 2017
  - Meetings (incl. the conferencing costs) organised and hosted by Member States
- Risk based approach
- Transparency
- Regulatory capacity

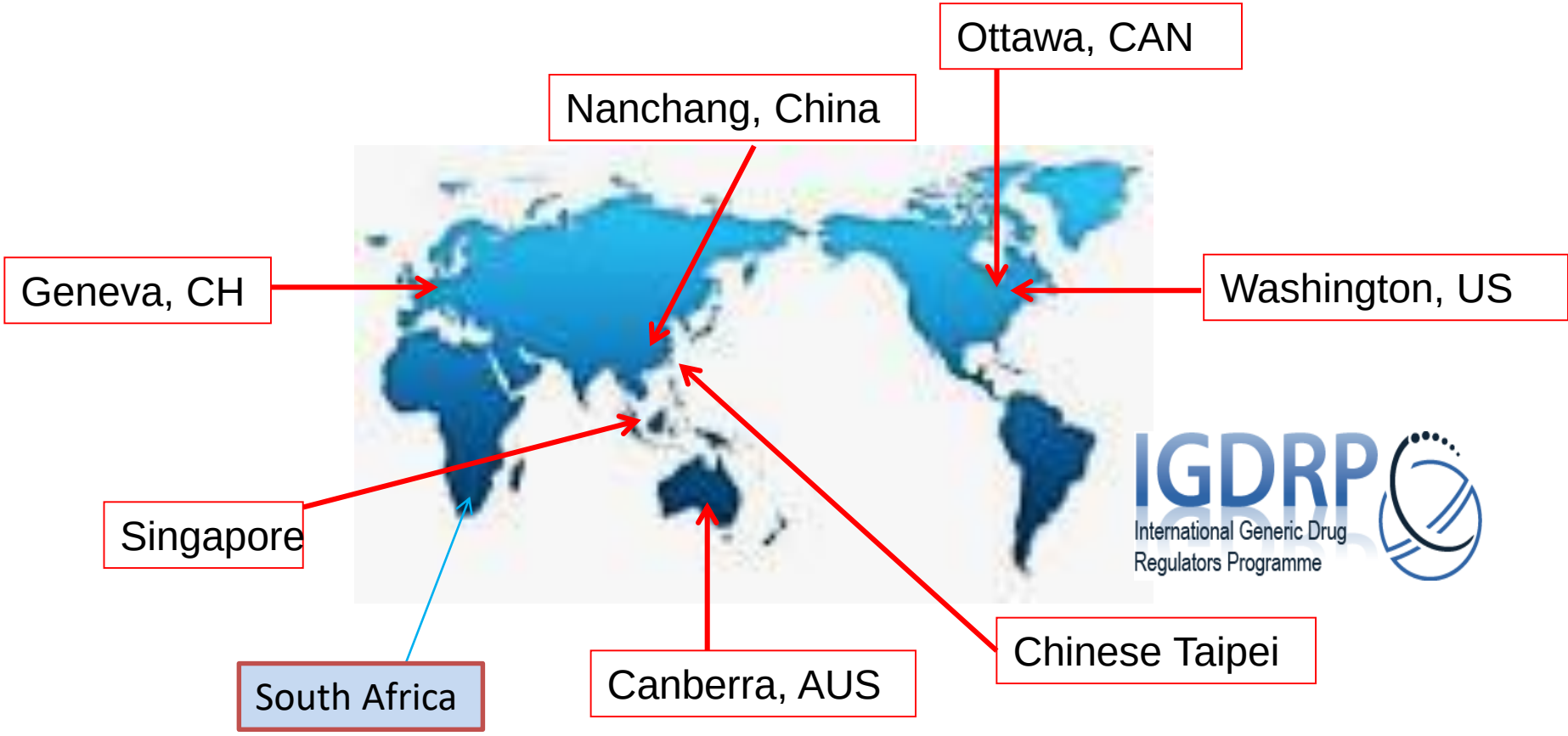
Globalisation

MCC, Global collaborations

- IGDRP(IGDRP+IPRF merger loading…)

➢ Bioequivalence working group

➢ Quality working group


Ottawa, CAN
Nanchang, China
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Canberra, AUS
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IGDRP
International Generic Drug
Regulators Programme

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