

MEDICINES CONTROL AUTHORITY OF
ZIMBABWE

**The ZAZIBONA Work Sharing
Experience in the **SADC** Region**

Case study:

***South Africa and Zimbabwe Experience
in Work sharing using VICH GLs***

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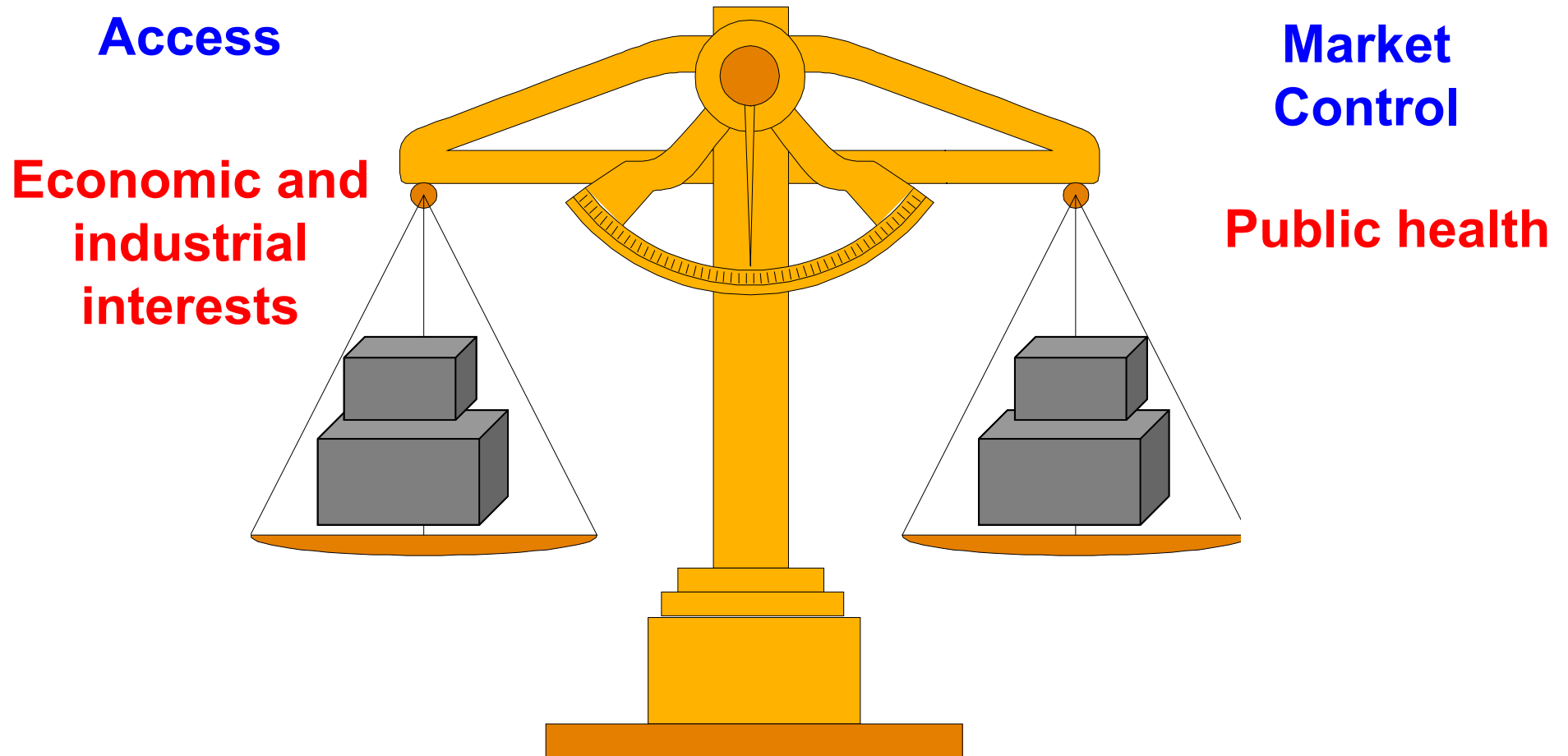
Presentation Outline

- Brief Background
- Objectives of the Collaborative procedure
- Achievements
- ZAZIBONA Process
- The Future

Brief Background

- SADC is a regional economic group with 16 Member States (MS)
- Varying regulatory capacities in the region
 - 11/16 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)

The challenge is to achieve balance



**A single stick may smoke, but it
will not burn. ~ African proverb**

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

Initiation of Work Sharing!



*October
2013*

✓ 4 Countries

✓ 1 Joint Session

✓ 4 Products

ZA



ZI



BO



NA



13 Participating SADC Member States

Botswana
Dem. Rep. Congo
Malawi
Mozambique
Namibia
South Africa
Tanzania
Zambia
Zimbabwe

Angola
Madagascar
Seychelles
Swaziland

***Contribute to the assessments and inspection activities [ACTIVE MEMBERS]**

As at 30 November 2018

Real Work Sharing in Practice!

*Since
2013*



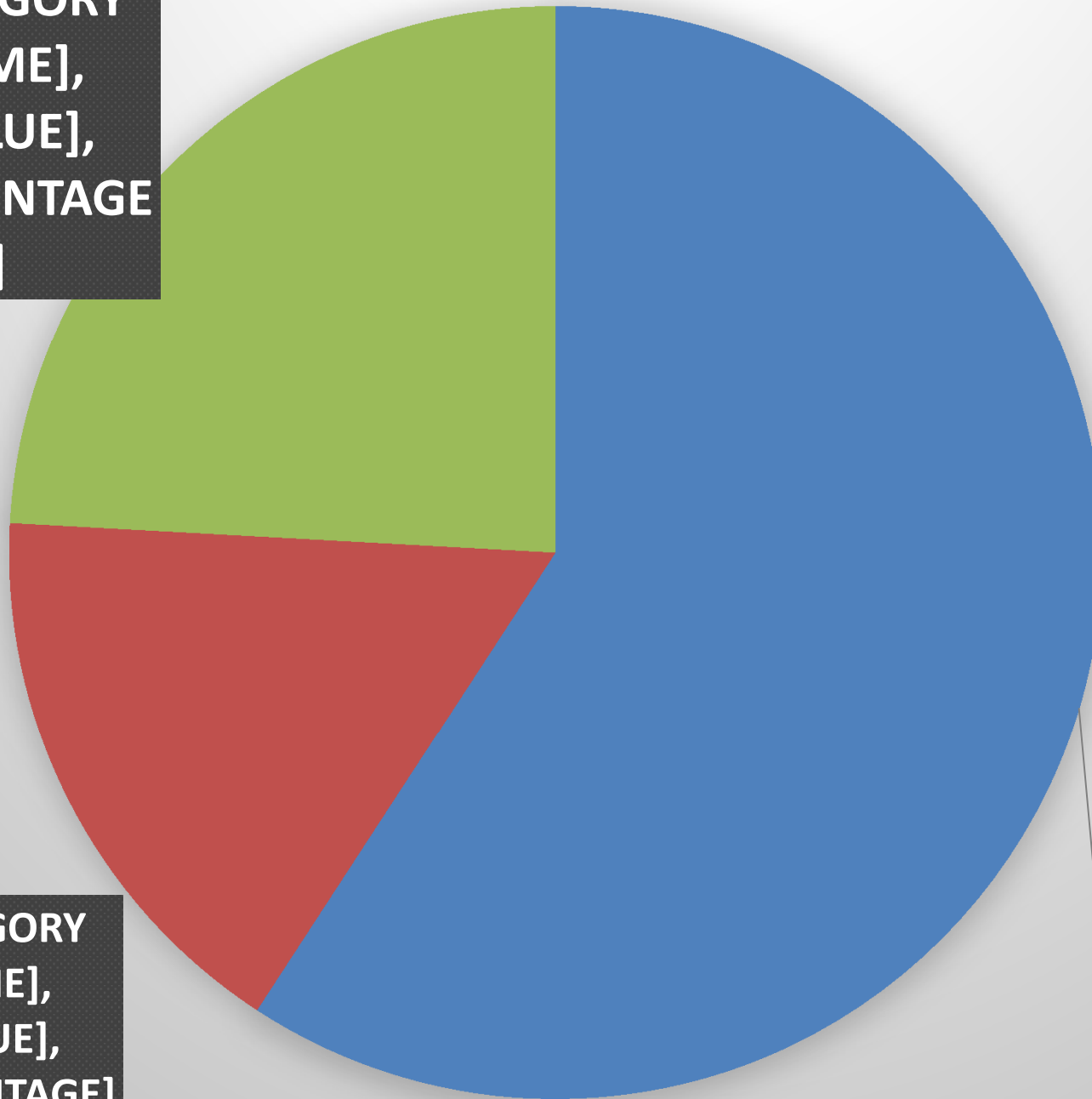
✓ **13** Countries

✓ **20** Joint Sessions

✓ **230** Products Received & Assessed

Human Medicinal Products Finalised 2013 to 2018

[CATEGORY
NAME],
[VALUE],
[PERCENTAGE
]



[CATEGORY
NAME],
[VALUE],
[PERCENTAGE]

[CATEGORY
NAME],
[VALUE],
[PERCENTAGE]

■ Positive Opinion
■ Negative Opinion
■ Withdrawn

The distribution of the applications assessed for 2018

Zazibona hosting country/city and month of session	Number of new products assessed	Number of responses reviewed
Gaborone February 2018	9	21
Lusaka June 2018	11	13
Harare August 2018	7	11
Johannesburg November 2018	17	23
Total # of applications considered	44	67

Secret to success in ZAZIBONA Work Sharing Platform



**Primary
Assessment**

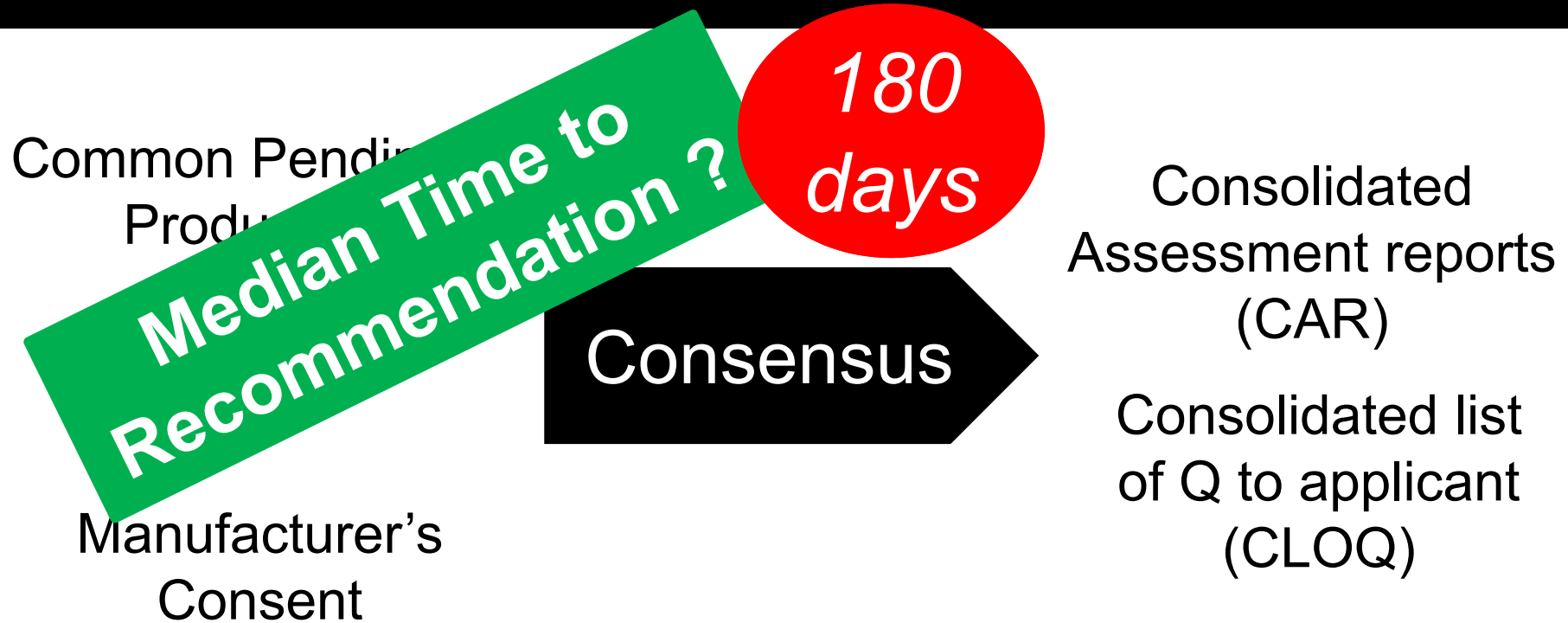


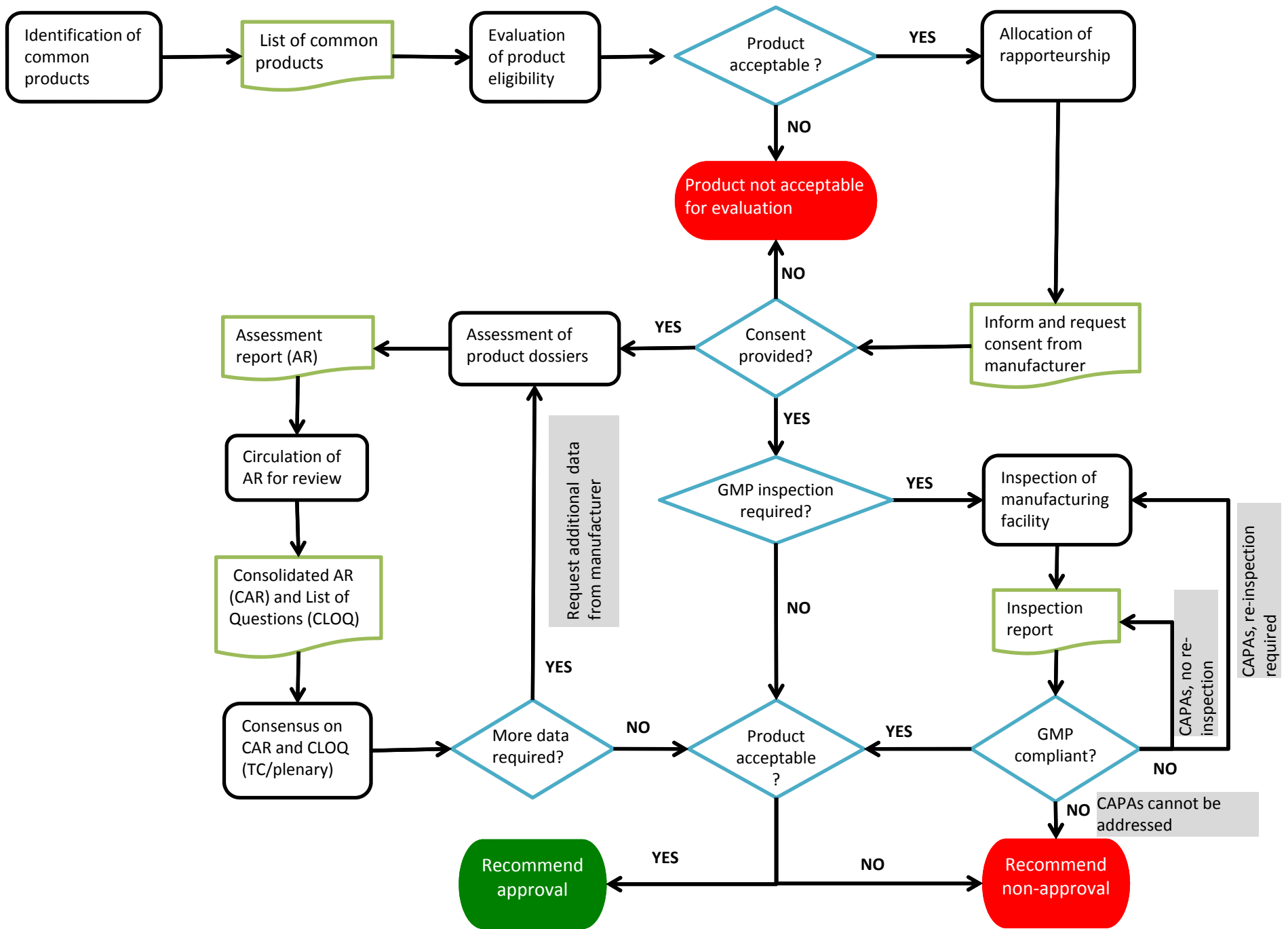
**CAR
&
CLOQ**

**Planned meetings
- 4 meetings p.a.**



How does this work ?





*Can anything good
come out of Africa?*



*Why
Not?*

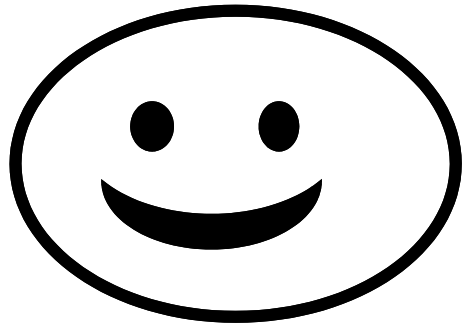


“The recommendation received provides a very in-depth CMC review of the dossier. Please clarify which regulatory authority criteria were followed, i.e. ICH, WHO, South African MCC, etc.”

The future...is bright!



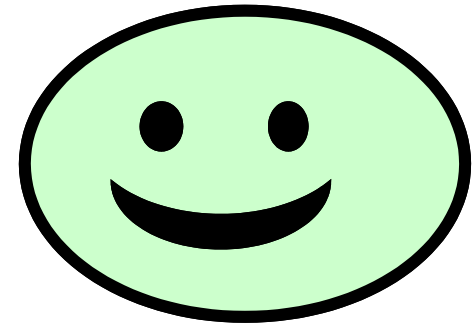
- Veterinary Zazibona is on its way
- Sharing Outcomes
- Participation of others (observers/full participation)
- Adopt sustainable financing
- Publish an Expression of Interest
- Model can be applicable elsewhere



Manufacturers

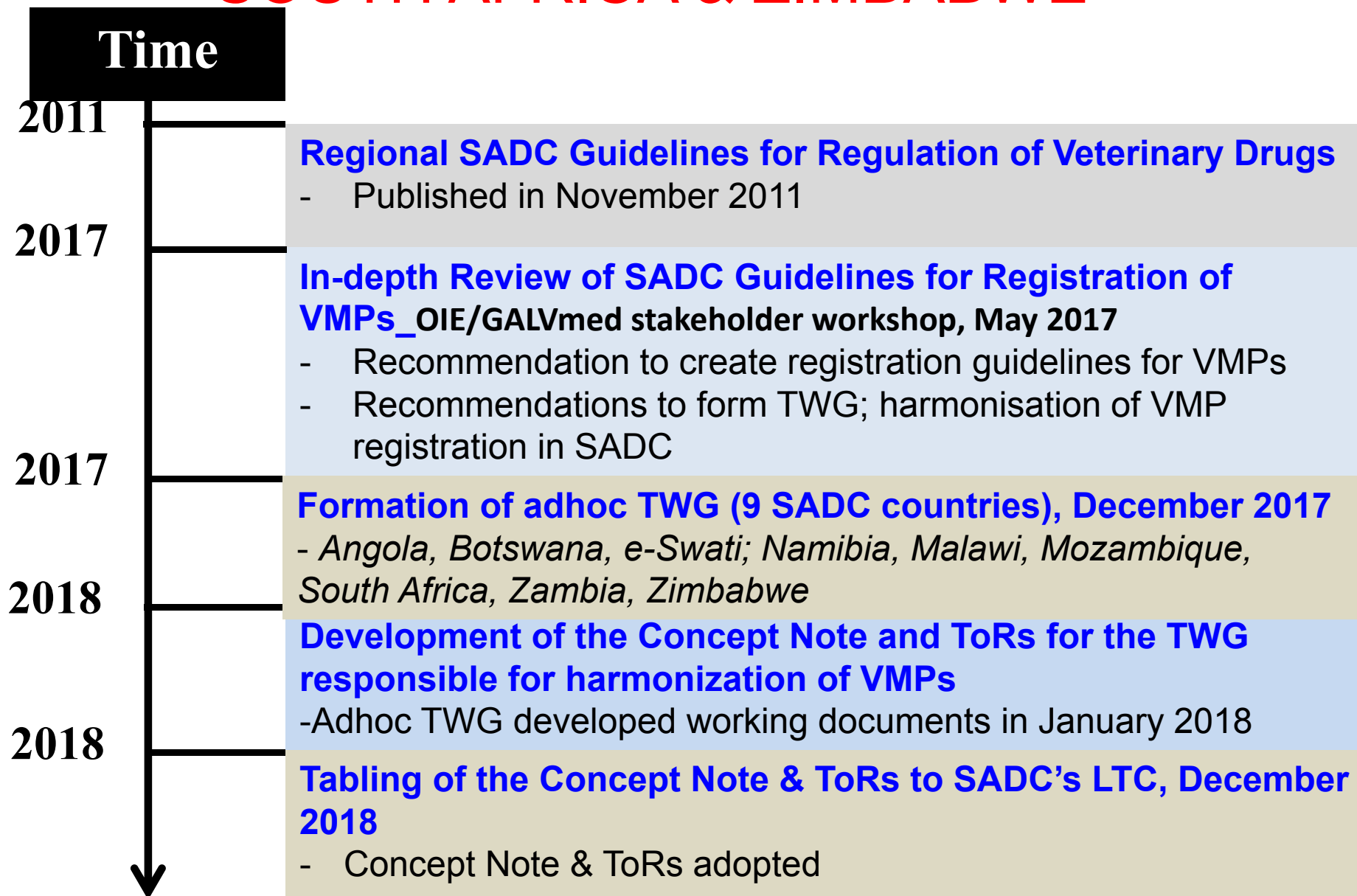


Patients



Regulators

Case Study: VMP harmonisation initiative— SOUTH AFRICA & ZIMBABWE



Harmonisation of VMP Pharmacovigilance Guidelines– SOUTH AFRICA; ZIMBABWE



Acknowledgements

- ZAZIBONA participating countries
- WHO Prequalification Team – Medicines
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- WHO Prequalification Team – Medicines
 - Technical & financial Support
- BMGF
- World Bank