Zazibona Collaboration

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SADC

- SADC is a regional economic group with 16 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)

Zazibona

- Work sharing initiative in SADC (medicines assessments and GMP inspections)
- Founded in October 2013 by 4 countries

- Common challenges
  - Huge backlogs & Long registration times
  - High staff turnover
  - Limited capacity to assess certain types of products e.g biologicals
  - Inadequate financial resources

Trivia

- When and where was the first Zazibona assessment session held?
- When was the first Zazibona inspection conducted?
- How many countries participate in the Zazibona collaboration?
- How many countries are active members of the Zazibona collaboration? *Name the countries*
- How many countries are non –active members of the Zazibona collaboration? *Name the countries*

13 Participating SADC Member States

Botswana (2013)
Dem. Rep. Congo (2017)
Namibia (2013)
South Africa (2016)
Zambia (2013)
Zimbabwe (2013)
Mozambique (2017)
Tanzania (2018)
Malawi (2018)

Angola
Seychelles
Swaziland
Madagascar

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

As at November 2019

Zazibona

- Formed based on memorandum of agreement signed by the HoAs (NMRA Agreement to participate)
- SADC Ministers of Health approved/ endorsed the initiative in November 2014
- Active member or observer status granted based on capacity to do assessments and GMP inspections

OBJECTIVES

- To reduce regulatory workload
- To develop mutual trust and confidence in regulatory collaboration
- To test the mechanism of co-operation among regulatory authorities
- To provide a platform for training and capacity building
- To ultimately facilitate harmonization of regulatory requirements in the region

PROCESS

- Dossier submitted & fees paid to all countries where the manufacturer is interested in marketing the product
- Submission in at least 2 countries to be eligible
- Consent from manufacturer
- One country (rapporteur) conducts the first review, second country (co-rapporteur) does the second review of the product. QA done by WHO
- Sovereign decision making by countries

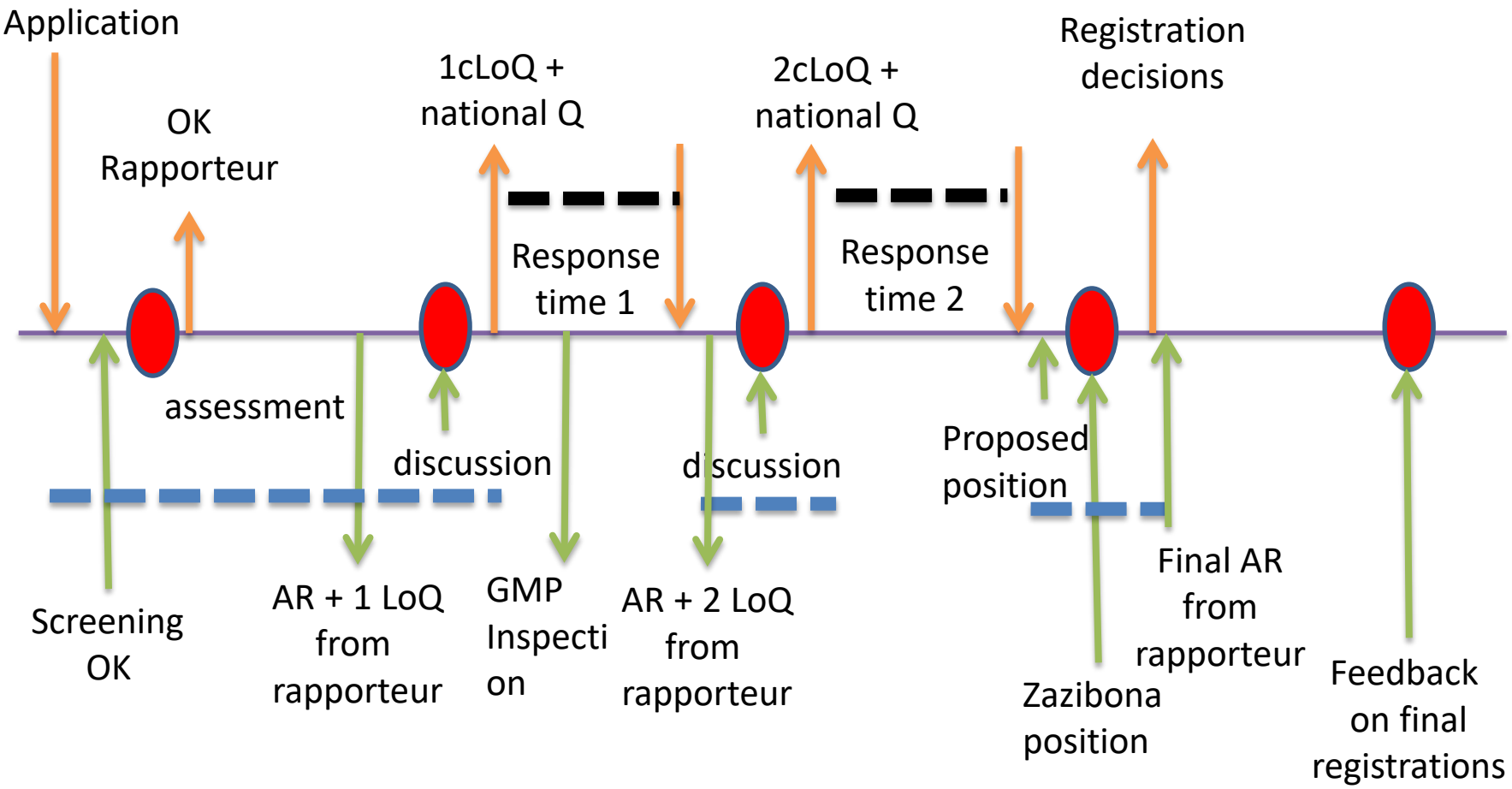
GMP Inspection

- Initiated after submission and assessment of a product
- Assessment report is a vital tool in the inspection
- Inspection conducted by inspectors from at least 2 of the active countries
- An observer from the non-active countries is also included
- Inspection valid in all the countries where the product would been submitted

GMP Inspection

- 38 on-site inspections conducted to date
- 19 Desk reviews conducted
- Eligibility criteria for desk review decided by Zazibona inspectorate

Assessment process



How does it work ?

Common Pr…
Pr…

M…facturer's Consent

Median Time to Recommendation ?

330 days

Consensus

Consolidated Assessment reports (CAR)

Consolidated list of Q to applicant (CLOQ)

1 Primary Assessment + 9 Countries = 9 CAR + 

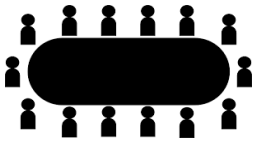
6 years on…Where are we?

Since 2013

2| meetings/Year of Heads of Agencies (HOA)

15 Training Sessions

24 # of Assessment Sessions: 4|year



38 Manufacturers inspected for GMP compliance: 4 schedules |year

12| Average # of products per session

ZAZIBONA

56% Positive vs 20% Negative vs 24% Withdrawn

289 in Total (November 2019) = 87 Pending Responses from Manufacturers or under review + 202 Product Finalised

Products registered using Zazibona process

- Botswana 80
- Mozambique 1
- Namibia 82
- South Africa 4
- Zambia 78
- Zimbabwe 74

As at June 2019

Drug approval by therapeutic area

Top 5

Antihypertensive **16%**

Anticancer **13%**

Antibiotic **13%**

ARV **11%**

Anticonvulsant **8%**

SRA Collaborative procedure

- Zazibona does not assess ‘SRA’ approved products

UNLESS

- Full assessment reports from the reference SRA can be availed
- This is done through the SRA Collaborative procedure

Benefits

- Patients

  -Improved access to quality assured medicines

- Regulators

  Reduced workload – no duplication of work done by other NMRAs for the same product

  Capacity building of assessors and inspectors through sharing of available expertise

  Improved effectiveness of medicines registration processes

  Efficient use of limited resources

  Regulatory intelligence through improved information sharing and networking with other NMRAs in the region

Benefits

- **Manufacturers**

- Enlarged market access
- Reduced regulatory workload – Common submission to participating countries and joint GMP inspections.
- Faster time to registration (where submissions comply with technical requirements).

Challenges

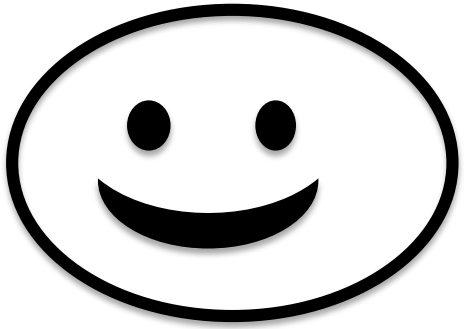
- Differences in capacity and inadequate human resources in agencies sometimes leads to poor or no implementation of recommendations at country level
- Getting buy-in from manufacturers because of differences in ZAZIBONA process and some country processes (less stringent)

Challenges

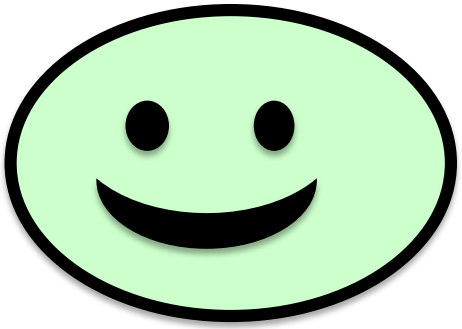
- Submission is not centralised and the process is not clearly detailed in some agencies which can be challenging for manufacturers
- Submission of different dossiers to countries by some manufacturers
- Country specific requirements e.g labelling problematic for manufacturers
- Lack of electronic information systems to enable tracking and follow up of products

Guidelines in development

- Variations TWG working on a SADC Variations guideline
- Biosimilars TWG working on a guideline
- Work on the labelling guideline continuing



Regulators



Patients

Manufacturers