Zazibona Collaboration

Farai B. Masekela

Zazibona Assessments Coordinator

23 June 2022

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 vaccines
  - Inadequate financial resources

14 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
Comoros

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

As at May 2022

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
- Focus is currently on Human Allopathic medicines (excludes Complementary, Medical devices etc.)
- Veterinary products collaboration being set up

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

One country (rapporteur) conducts the first review, second country (co-rapporteur) does the second review of the product.

QA conducted by WHO

Sovereign decision making by countries

Dossier Format

SADC CTD Format

Module 1 according to specific country requirements

Adhere to specific country processes e.g eCTD, requirements for hard copies etc.

Samples in line with specific country requirements

Labelling Requirements

- Country specific
- To be submitted with country specific Module 1 requirements
- SADC labelling guideline yet to be implemented
- Language of the labelling to be submitted as per specific country requirements

GMP Inspection

Initiated after submission and assessment of a product

Assessment report is a vital tool in the inspection

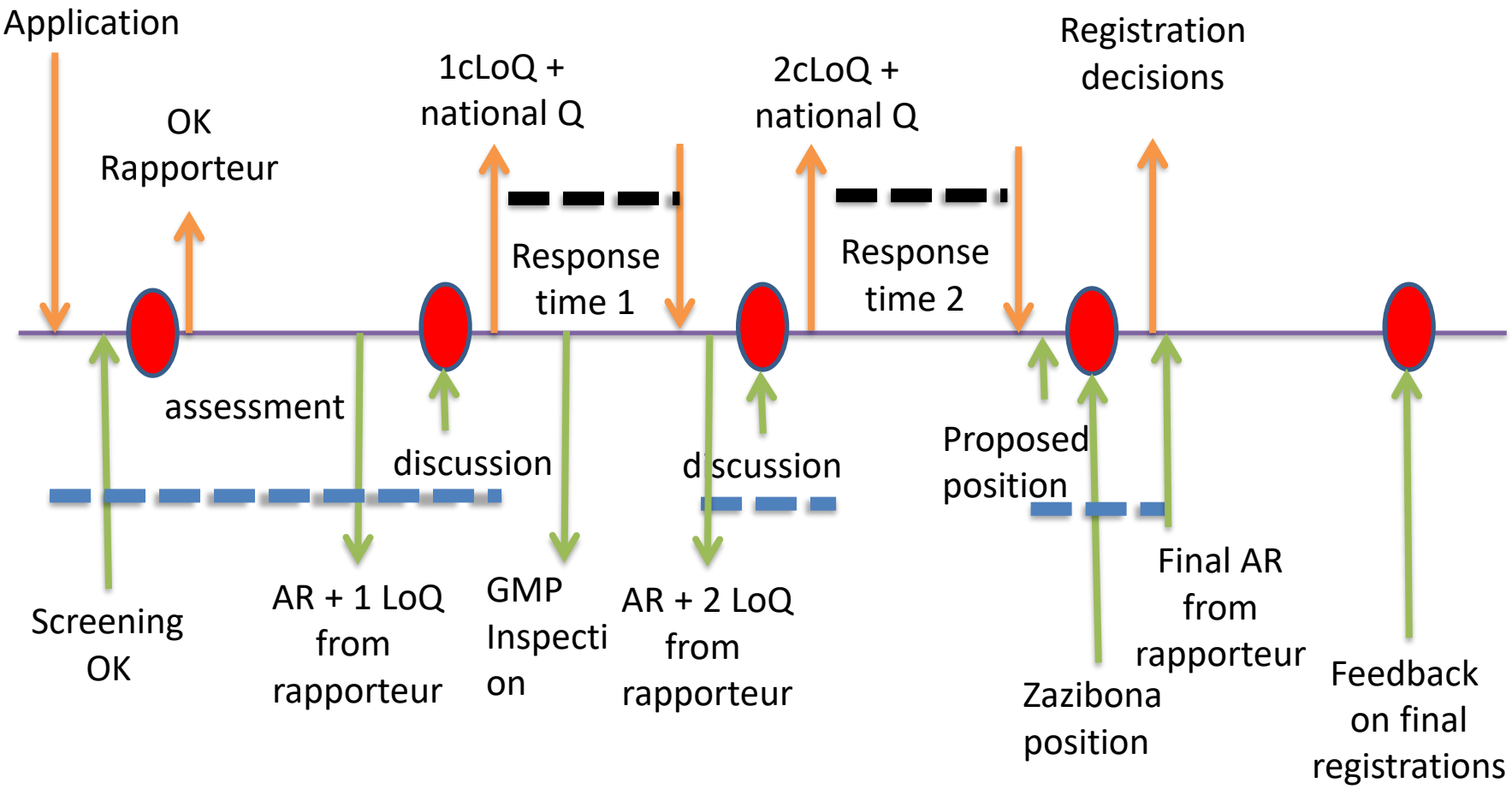
Inspection conducted by inspectors from at least 2 of the active countries

An observer from the non-active countries is also included

Inspection valid in all the countries where the product would been submitted

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 ?

360 days

Consensus

Consolidated Assessment reports (CAR)

Consolidated list of Q to applicant (CLOQ)

1 Primary Assessment + 9 Countries = 9 CAR + 

8 years on…Where are we?

Since 2013

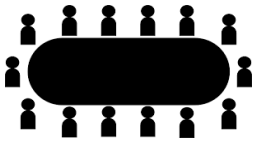
2| meetings/Year of Heads of Agencies (HOA)

15

Training Sessions

38

# of Assessment Sessions: 4|year



48

Manufacturers inspected for GMP compliance: 4 schedules |year

10| Average # of products per session

ZAZIBONA

56% Positive

vs

20% Negative

vs

24% Withdrawn

340 Products.

WHO 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*
- Zazibona does not consider WHO Prequalified products

Post-approval

Zazibona does not handle the following:

- Variations
- Import/export
- Pharmacovigilance

These are handled individually by the countries in line with individual country requirements

Benefits

Patients

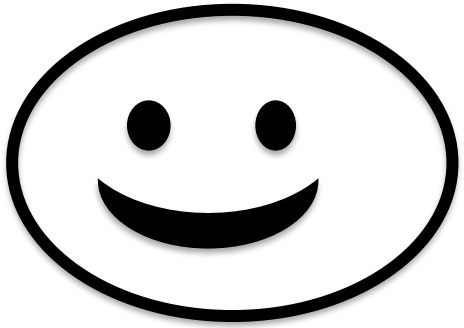
Improved access to quality assured medicines

Regulators

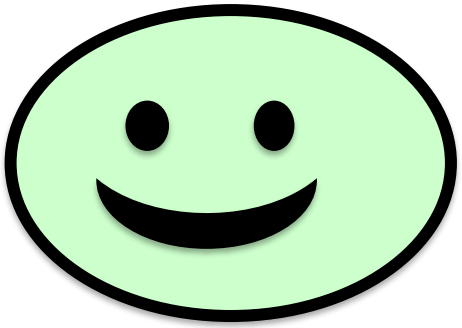
- Reduced workload – no duplication of work done by other NMRAs for the same product
- Capacity building of assessors and inspectors through sharing of available expertise
- Improved effectiveness of medicines registration processes
- Efficient use of limited resources
- Regulatory intelligence through 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).



Regulators



Patients

Manufacturers