

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

- 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 March 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

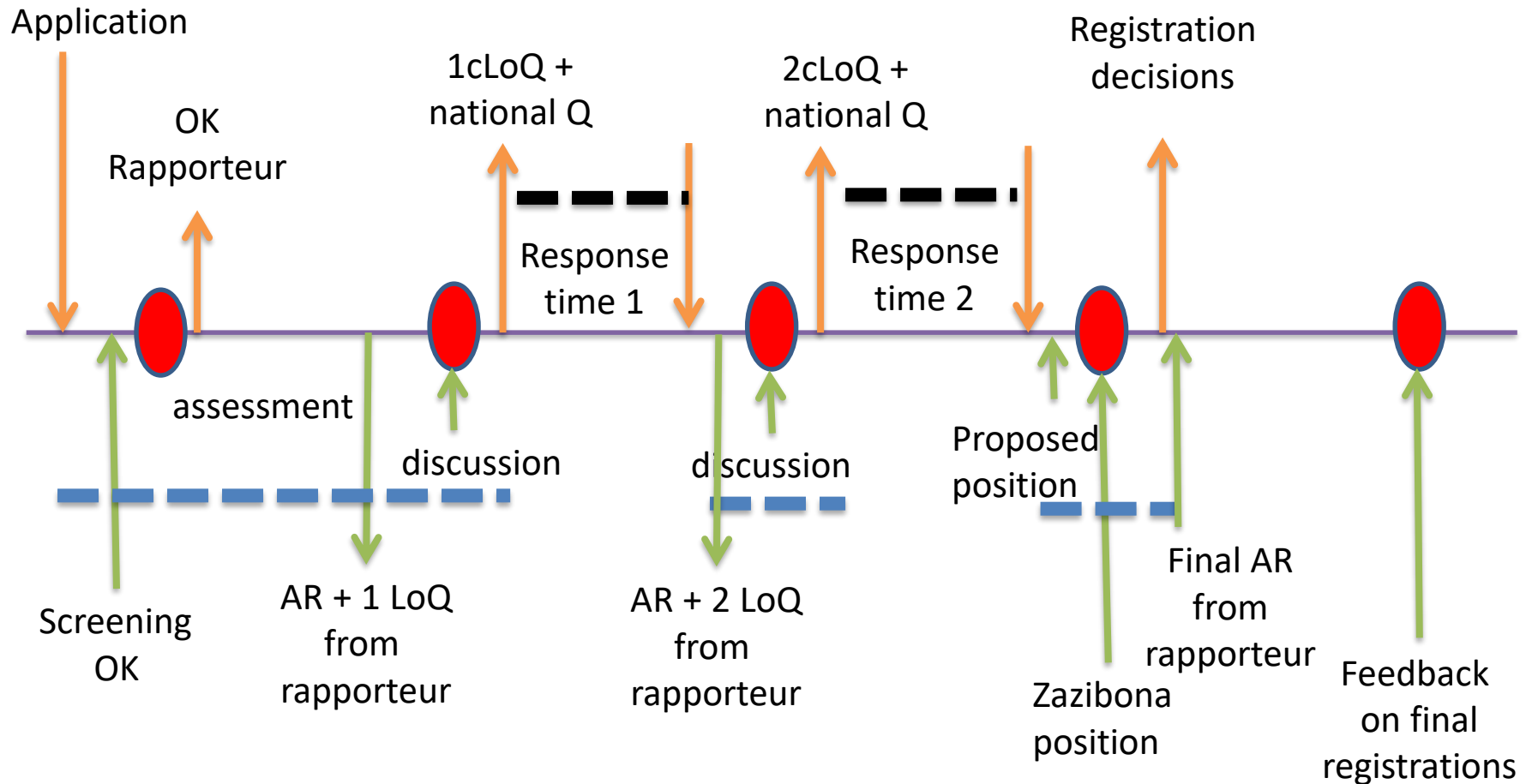
OBJECTIVES

- 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

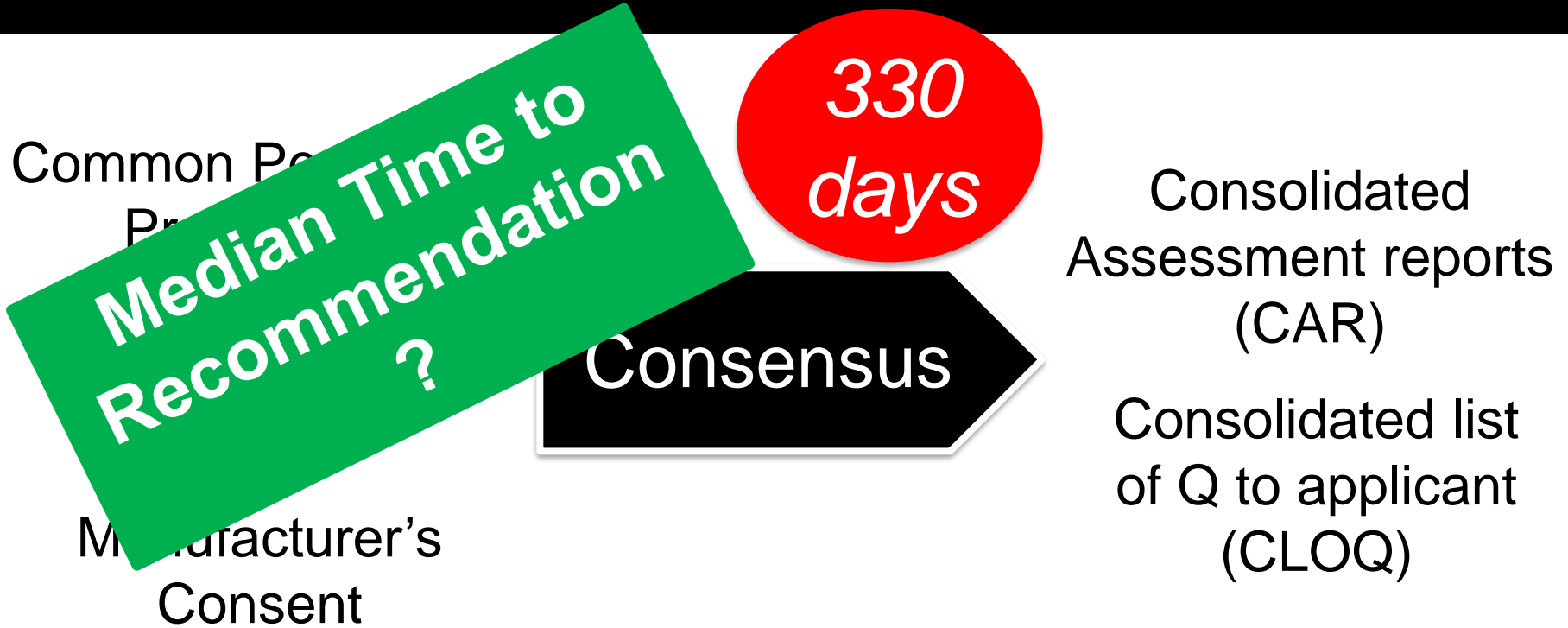
PROCESS

- Dossier submitted & fees paid to all countries 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

Assessment process



How does it work ?



5 years on...Where are we?

Since 2013

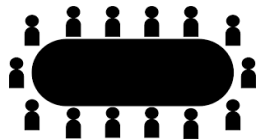
2 | meetings/Year
of Heads of Agencies
(HOA)

15

Training Sessions

22

of Assessment
Sessions: 4 | year

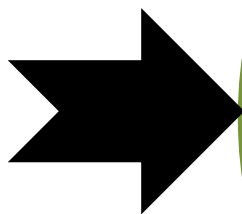


29

Manufacturers inspected
for GMP compliance:
4 schedules | year



12 | Average
of products
per session



ZAZIBONA

59%

Positive

vs

16%

Negative

vs

25%

Withdrawn

258 in Total
(March 2019)

=

77 Pending Responses from
Manufacturers or under
review

+

181 Product Finalised

Work sharing - a form of reliance

- Relying on another country to assess products on your behalf
- Work sharing builds trust and capacity
- Commitment and sacrifice as there was more work in the beginning for countries with more mature systems whilst capacity was built

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

- Building trust and confidence among regulators
- 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

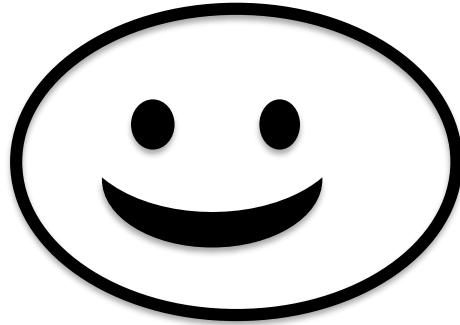
- Submission is not centralised and the process is not clearly detailed in some agencies which can be challenging for manufacturers
- Submission of different dossiers to countries by some manufacturers
- Country specific requirements e.g labelling problematic for manufacturers
- Lack of electronic information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

Other activities

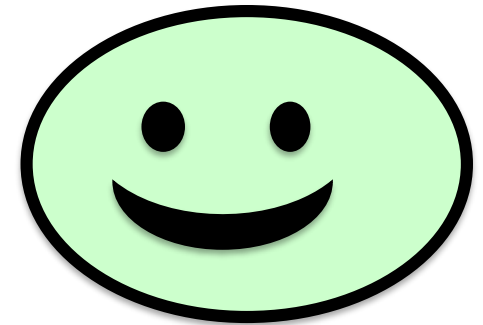
SADC MRH

- Zazibona has been focused on assessments and inspections
- Additional activities to be considered in the next 1 to 2 years

Reliance activities with EMA



Regulators



Patients



Manufacturers