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ZAZIBONA COLLABORATIVE MEDICINES REGISTRATION INITIATIVE

PROCESS EFFECTIVENESS & EFFICIENCY RATING (PEER-IND)



Pic taken from <https://www.referenceforbusiness.com/management/De-Ele/Effectiveness-and-Efficiency.html>

PEER-IND QUESTIONNAIRE

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INTRODUCTION

The ZAZIBONA collaborative medicines registration initiative was established in 2013 and formally endorsed by the SADC health ministers in 2014. Since its inception, there has not been a formal and structured evaluation of this work sharing programme and for its future direction, although some feedback has been sought from manufactures through stakeholder meetings.

A recent study has been carried out among the nine active members of the ZaZiBoNa work sharing initiative using a similar questionnaire to the one being sent to the applicants, so that the benefit is gained from both key stakeholders.

In recent years, there has been a drive within regulatory agencies to re-engineer their processes for improved efficiency and effectiveness and this often begins with a baseline evaluation of the current process to identify strengths and weaknesses. *Effectiveness* can be defined as 'doing the right thing' often measured by the value derived by customers/stakeholders from an organisation's processes or services while *Efficiency* can be defined as 'doing things right' which saves the organization time and resources.

Study Participants

The PEER Questionnaire is being sent to applicants who have submitted marketing authorisation applications for assessment under the ZaZiBoNa initiative.

AIM

The aim of this study is to evaluate the effectiveness and efficiency of the current operating model of the ZAZIBONA initiative including the challenges it faces as well as identifying opportunities for improvement.

STUDY OBJECTIVES

1. Obtaining the views of the applicants of the ZaZiBoNa initiative about the performance of the programme to date.
2. Identifying the challenges experienced by individual applicants throughout the life cycle of the ZaZiBoNa initiative.
3. Determining the strengths and weaknesses of the initiative
4. Identifying the ways of improving the performance of the work sharing programme.
5. Envisaging the strategy for moving forward

CONFIDENTIALITY

Thank you for agreeing to participate in this survey. **Your responses will be treated in strictest confidence and no identifiers of companies or respondents will be shared with any third party or made public.** External reports or presentations of the data will include only blinded results together with appropriate analytical interpretations.

The questionnaire is divided into five short sections and will take 20 minutes to complete. Thank you for taking time to complete it. We value your input!

A. DEMOGRAPHICS

1. Please state the name of your company _____
2. Please provide your responses to the following questions by writing your answer in the space provided or ticking the relevant box.
 - a. Age: _____years
 - b. Sex: Male Female
 - c. Number of years of regulatory affairs experience: _____years
3. State the SADC countries in which your company markets products

<input type="checkbox"/> Angola	<input type="checkbox"/> Botswana
<input type="checkbox"/> Comoros	<input type="checkbox"/> Democratic Republic of Congo
<input type="checkbox"/> Eswatini	<input type="checkbox"/> Lesotho
<input type="checkbox"/> Madagascar	<input type="checkbox"/> Malawi
<input type="checkbox"/> Mauritius	<input type="checkbox"/> Mozambique
<input type="checkbox"/> Namibia	<input type="checkbox"/> Seychelles
<input type="checkbox"/> South Africa	<input type="checkbox"/> Tanzania
<input type="checkbox"/> Zambia	<input type="checkbox"/> Zimbabwe
4. Do you have a separate record of applications submitted for assessment under ZAZIBONA to facilitate tracking and adherence to deadlines? Yes No

B. VIEWS ON THE BENEFITS OF THE ZAZIBONA INITIATIVE

Select your answers by ticking the relevant box(es)

1. In your view, what are 3 (or more) benefits of the ZAZIBONA initiative to date?

- Leadership commitment/Governance structure
- Clear Operating Model
- Shorter timelines for approval
- Information sharing among regulators
- Building of capacity for assessments
- Sustainable resource base because of self-funding by countries
- `Harmonisation of registration requirements across the region
- Other (Please specify) _____

2. How has the ZAZIBONA initiative benefited you as applicants?

- Reduced burden as applicants compile one dossier (modules 2 -5) for submission to multiple countries
- Savings on time and resources as applicants receive the same list of questions from multiple countries enabling compilation of a single response package
- Shorter timelines for approval compared to that for the individual countries
- Access to various markets at the same time
- Other (Please specify) _____

3. How has the ZAZIBONA initiative benefited patients in the individual countries or in the SADC region?

- Quicker access to quality assured medicines
- Reduced prices of medicines
- Increased availability of medicines
- Other (Please specify) _____

C. VIEWS ON CHALLENGES OF THE ZAZIBONA INITIATIVE

Select your answers by ticking the relevant box(es)

1. In your view, what are 3 (or more) challenges of the ZAZIBONA initiative?

- Lack of detailed information on the process for applicants
- Differences in regulatory performance of the countries
- Dependence on the countries' process for communication with applicants

- Lack of centralised submission and tracking
- Lack of ability to mandate central registration
- Other (please specify) _____

2. What are the challenges faced by applicants submitting applications to the ZAZIBONA initiative?

- Differences in time to implementation of ZAZIBONA recommendations by member countries.
- Lack of clarity about the process for submission and follow up in each country
- Lack of information on country websites and the ZAZIBONA website about the process, milestones, timelines for pending and approved products
- ZAZIBONA process is more stringent than individual country processes for reviews and GMP audits
- Differing labeling requirements in participating countries
- Failure by countries to adhere to promised timelines
- Risk of losing access to all member states once a product is rejected by ZAZIBONA (i.e can no longer pursue registration in individual countries)
- Low motivation and appeal to use the ZAZIBONA route as there are few success stories available or publicized
- Low motivation to use the ZAZIBONA route as other review routes are now being used by individual countries e.g reliance on SRA approvals or other SADC countries are faster
- Other (Please specify) _____

3. In your view, what do you believe are the challenges faced by agencies in reviewing the ZAZIBONA applications? _____

D. IMPROVING THE PERFORMANCE (EFFECTIVENESS AND EFFICIENCY) OF THE WORK SHARING PROGRAMME

Select your answers by ticking the relevant box(es)

Effectiveness can be defined as ‘doing the right thing’ often measured by the value derived by customers/stakeholders from an organisation’s processes or services while *Efficiency* can be defined as ‘doing things right’ which saves the organization time and resources.

1. What are 3 or more ways to improve the effectiveness of the ZAZIBONA initiative in your view?

- Decision-making transparency e.g., publishing Public Assessment Reports
- Make publicly available any information that might help applicants in managing their submissions - templates of documents, lists of Q&A, timelines and milestones, disclosure of internal SOPs, etc.
- Consistency in application of guidelines and decisions
- Use of risk-based approaches e.g., reliance pathways
- Engagement and interaction with stakeholders
- Publishing of pending products
- Publishing of approved products
- Minimising the need for country specific documents
- Other (Please specify) _____

2. What are 3 or more ways to improve the efficiency of the ZAZIBONA initiative in your view?

- Specific and clear requirements made easily available to applicants
- Compliance with target timelines by measuring and monitoring each milestone in the review process
- Use of robust IT systems
- Transparency on metrics and statistics e.g., % completed within a timeline
- Improved central tracking of ZAZIBONA products
- Improved resources e.g., number of assessors
- Centralised system for submission of applications and communication with applicants
- Other (please specify) _____

3. Evaluate the performance of individual countries that you have submitted applications to for review under ZAZIBONA *Please complete only for the countries that you have submitted ZAZIBONA applications to and have experience with*

Measure	Botswana	D.R Congo	Malawi	Mozambique	Namibia	South Africa	Tanzania	Zambia	Zimbabwe
	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
The contact person is known	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
The process for submission of applications is clear	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
The process and timelines for ZAZIBONA products are available on the website	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Communication of queries is carried out timeously (NMT 30 days after a session)	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Registration after a ZAZIBONA recommendation is carried out timeously (i.e in NMT 3 months from the date of the recommendation)	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

E: ENVISAGING THE STRATEGY FOR MOVING FORWARD

1. Rate the following proposals to improve the current ZAZIBONA operating model from 1 – 3, number 1 representing what you think would be **most effective** in improving efficiency and number 3 the **least effective**. *Enter the appropriate number in the space provided before each proposal.*

To continue with the current operating model unchanged.

To continue with the current operating model, but provide full information on the process including timelines and milestones as well as approved products on every participating country's website and on the ZAZIBONA website.

The establishment of a regional administrative body to centrally receive and track ZAZIBONA applications which would be responsible for allocating work, apportioning the applicable fees to countries, tracking of applications and communication with applicants.

2. In your view, would the establishment of a SADC regional medicines agency, if legally possible, be the best strategy for improved performance going forward?
- Yes No

Please explain why? _____

3. In conclusion, what other strategies not previously highlighted can you think of that would strengthen the ZAZIBONA initiative going forward?

Please feel free to use the comment box below to elaborate on any of your answers or to highlight questions and answers that you believe should have been included in this questionnaire.

Name of person completing the questionnaire: _____

Title (position): _____

Date: _____

Thank you for your time and help

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