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REQUEST FOR EXPRESSIONS OF INTEREST

IN THE SUBMISSION OF PRODUCT APPLICATIONS FOR THE CENTRALISED ZAZIBONA JOINT ASSESSMENT PATHWAY FOR PHARMACEITICAL PRODUCTS

INTRODUCTION

ZAZIBONA[1], the collaborative initiative of the Southern African Development Community Medical Products Regulatory Harmonisation (SADC MRH) is inviting applicants and pharmaceutical manufacturers to submit an Expression of Interest for Product Evaluation utilising the ZAZIBONA Centralised Pathway (ZAZIBONA CP). Applicants using the CP will receive a scientific opinion on the quality of their product. The scientific opinion serves as a recommendation to the participating Member States. All 16 SADC Member States participate either as Active or Non-Active Member States, based on their internal capacity to conduct assessments and current Good Manufacturing Practice (cGMP) inspections, or as Observers[2].

Positive recommendations can be used by applicants for expedited review and registration with the participating Active Member States at the time of lodging an application for registration (marketing authorisation). The Heads of Agencies have made a written commitment to finalise applications supported by a ZAZIBONA CP recommendation within 90 days of submission.

This call for EOIs covers a period of 18months, that is, from July 2025 to December 2026.

SUMMARY OF THE CENTRALISED JOINT ASSESSMENT PROCEDURE

Centralisation of the procedure was piloted from March 2024 with the aim of improving efficiency both pre and post the recommendations, and thereby improving access to safe,

[1] A SADC work sharing initiative focusing on joint dossier assessments and joint determination of the Good Manufacturing Practice status of the manufacturing facilities seeking registration of their human medical products in the region. Founded in October 2013 with support from the WHO Prequalification team and various support partners, the initiative was formally endorsed by the SADC Ministers of Health in 2014 and became part of the SADC Medicines Registration Harmonisation (MRH) programme in 2015.

[2] ZAZIBONA **Active Member States**: Botswana, DRC, Malawi, Mozambique, Namibia, South Africa, Tanzania, Zambia and Zimbabwe.
ZAZIBONA **Non-Active Member States**: Angola, Comoros, Eswatini, Lesotho, Madagascar, and Seychelles.
ZAZIBONA Observers: **Mauritius**

effective, and good quality medicines in the region. As the piloting draws to a close, the ZAZIBONA initiative is preparing to open for the submission of new applications.

The ZAZIBONA initiative no longer accepts any applications except through the centralised procedure. Applications are no longer required to be lodged at country level but must be **submitted centrally** to ZAZIBONA. Applicants utilising the ZAZIBONA CP **should not simultaneously lodge applications** with any of the Member States as the joint assessment pathway is an alternative pathway for the Member States. Lodging the applications simultaneously will result in counterproductive duplicate evaluation of the same product.

ZAZIBONA charges cost recovery fees for the services it provides. A cost recovery fee is levied for each product application. The cost recovery fee shall be paid **centrally.** This fee shall be independent of application fees levied by the Member States when an applicant uses a positive recommendation to seek registration (marketing authorisation).

ZAZIBONA CP will provide **FOUR (4), quarterly submission entry points annually.** The planned submission and timing of applications is intended to enable a predictable work plan and planning for the requisite capacity and resources to provide for a pathway that is as efficient as possible. Until further notice, each entry point will provide for a maximum of 10 product slots.

Product applications will be evaluated centrally. Assessors evaluating the products will be drawn from a common pool of ZAZIBONA assessors seconded by the participating Member States. Communication on products shall be central, through the ZAZIBONA Administrative Office.

OVERVIEW OF THE PROCESS

ZAZIBONA has transitioned into a centralised process for the provision of either a positive or a negative scientific recommendation to the participating Member States on the quality and safety of the product under consideration. The following steps apply to the ZAZIBONA CP:

- **STEP 1** – NOTIFICATION OF INTENTION TO SUBMIT
  ALL applicants intending to utilise the ZAZIBONA Collaborative Procedure (CP) between July 2025 and December 2026 are required to formally notify ZAZIBONA of their intension to submit an application. This notification must be made through the submission of a completed **Pre-Submission Form**.

The Pre-Submission Form should indicate realistic and well-considered, anticipated submission dates. These proposed submission dates should reflect the time point when the applicant has confidence in their ability to submit a complete, high-quality product dossier. Additionally, the form must specify the countries of interest for registration, should the application receive a positive recommendation.

Applicants are also expected to commit to commercialising the product within one (1) year of positive recommendation in at least two (2) of the participating Active Member States.

Send the pre-submission form to all the following mailbox addresses:

administrator@zazibona.com

coordinator@zazibona.com

sakhi.vee@gmail.com

The window for submission of pre-submission forms will open from the 1st June 2025 and will be closed on the 15th June 2025.

- **STEP 2** – COMPILATION OF PLANNED SUBMISSION TIMETABLES

  ZAZIBONA will review the submitted pre-submission forms. ZAZIBONA will then notify applicants, in writing, of their proposed timetable based on the submissions. Submission timetables will be based on the declared intended submission date, and public health priority of the products. Pre-submission meetings will be scheduled where necessary.

- **STEP 3** – VERIFICATION OF PROPOSED TIMETABLES

  Applicants will be required to review and formally respond to the proposed submission timetable. Acceptance of the timetable is expected; however, applicants may request modifications or decline the proposed schedule with justifications.

  The dates for dossier submission and the joint plenary assessment sessions are generally fixed and non-negotiable. Other milestones within the timetable may be subject to adjustment based on mutual agreement and operational feasibility.

- **STEP 4** – SUBMISSION OF PRODUCT APPLICATION DOSSIERS

  All product dossiers must be submitted **centrally** via the ZAZIBONA submission portal and not to the individual Member States. Applicants are required to upload their dossiers

along with proof of payment through the portal, in accordance with the agreed submission timetable.

Product dossier applications must be submitted in English and in the Common Technical Document (CTD) format (Modules 2 to 5), electronically as a Pdf searchable document centrally through the ZAZIBONA submission portal. Applicants must use the ZAZIBONA QOS and BTIF (where applicable). For compilation of Module 1, applicants should refer to the Guidance for the Submission of the SADC MRH/ZAZIBONA Centralized Procedure Module 1 of the CTD accessible from the ZAZIBONA website.

Please note that failure to upload the restricted part of the Drug Master File after screening will result in automatic rejection. Provisions for secure upload by the DMF holder will be made.

Product samples will only be submitted upon request. Initial submissions will only need to be accompanied by mock-ups.

Dossier uploads must strictly adhere to the designated submission windows, which are scheduled as follows:

1st Submission Window: Opens on 1 July 2025 and closes on 7 July 2025
2nd Submission Window: Opens on 04 August 2025 and closes on 18 August 2025
3rd Submission Window: Opens on 17 November 2025 and closes on 1 December 2025
4th Submission Window: Opens on 2 February 2026 and closes on 16 February 2026
5th Submission Window: Opens on 20 April 2026 and closes on 1 May 2026
6th Submission Window: Opens on 08 June 2026 and closes on 22 June 2026

Historically, ZAZIBONA has received approximately 40 to 50 applications per year. Based on this trend, the procedure has been structured to accommodate **60 applications** in the next 18 months (until December 2026). **Each submission window will accept a maximum of ten (10) product applications**, plus any additional strengths (line extensions) associated with those products.

- **STEP 5** – PROFORMA AND PAYMENT OF SCREENING FEES

  All applications will undergo an initial screening process prior to evaluation. The screening and evaluation phases are distinct and sequential. Applicants must ensure that the screening fee is paid in full before uploading the product dossier for assessment.

❖ **STEP 6** – SCREENING OUTCOME

Products that pass screening will progress to assessment. Applicants will be notified in writing, and the notification will be accompanied by a proforma invoice for the evaluation phase.

Products that fail screening will receive a list of deficiencies. Applicants will have **15 days** to address these deficiencies. An applicant can pay the screening fee again and resubmit the dossier for screening. Applicants will be allowed up to two (2) screening cycles.

❖ **STEP 7** – PRODUCT EVALUATION AND DETERMINATION OF GMP STATUS

Assessment of products will only proceed on receipt of proof of payment. Assessment of product(s) submitted will include evaluation of:

- product dossiers, which must include product data and information as specified in the SADC guidelines for submission available on the ZAZIBONA website.
- manufacturing sites, which must adhere to good manufacturing practices (GMP). Separate cost recovery fees are charged for the GMP determination.
- clinical sites (if applicable), which must adhere to good clinical practices (GCP).

Applications will be tabled at the quarterly joint assessment sessions. Dates for the quarterly assessment sessions will be published on the ZAZIBONA website along with cut off dates for submissions, to allow applicants to align submissions with meeting dates. The tentative dates for the remainder of 2025 are:

- 01 - 05 September
- 17 - 21 November

Queries will be deliberated on in the joint assessment session and the agreed list of queries communicated centrally.

Applicants will be allowed two (2) review cycles, after which a recommendation will be made. An additional cycle may be added in exceptional cases. Requests for extensions on the basis of generating new data will seldom be granted – applicants are advised to submit complete applications from the onset.

Tracking will facilitate separation of applicant response time and ZAZIBONA review time.

Compliance with cGMP will be determined either through inspections (on site or remote) or desk review in accordance with prevailing criteria. The specific route will be determined after successful screening. The initial dossier evaluation will also take into account areas of focus.

❖ **STEP 8** – COMMUNICATION OF ZAZIBONA RECOMMENDATION

The final decision remains a **recommendation,** which shall be valid for 12 months.

A written positive recommendation can be used by the applicant to support expedited review and finalisation of the application by any of the member states that have product registration processes within 90days. Applicable country specific requirements are published on the Member State information platforms. These requirements will not be technical in nature.

Updating the dossier to reflect clarifications and commitments made during the review cycle shall be a pre-requisite to issuance of the written positive recommendations. Applicants are encouraged to work on this simultaneously as part of the review cycles and part of the mandatory update of the Quality Information Summary (QIS). Only updated dossiers can be submitted for expedited review in seeking registration (marketing authorisation) from the participating Member States.

ROLES AND RESPONSIBILITIES

ZAZIBONA CP involves several stakeholders who have different roles in the process.

The role of the applicant/manufacturer

i. Compilation of current CTD dossier including completion of the supporting assessment documents in Module 1 (including QOS and QIS).
ii. Payment of cost recovery fees (refer to the section on fees)
iii. Submission of a complete application through the online submission portal.
iv. Responding completely and accurately to queries raised and adhering to the prescribed response timelines and paying particular attention to submission cut off dates.
v. Updating the CTD dossier to address queries raised and to include commitments made during the centralised evaluation.

vi. Taking cognisance of the country specific requirements when submitting products for registration.

The role of the ZAZIBONA coordination office

i. Acknowledgement of receipt of the application fees and the applications
ii. Management of the product evaluation cycles.
iii. Communication with applicants on progress of applications
iv. Sharing of list of approved/rejected products with the Member States upon completion of the assessment process.
v. Issuance of written scientific recommendation to applicants. Positive recommendations shall only be issued upon receipt of an updated dossier from the applicant.

The role of NMRA staff

i. Seconding review experts for the primary and second review of applications and any responses to queries in line with assessment best practices.
ii. Deliberating and concurring on queries to be raised, and the final recommendation in terms of quality and safety of the product.
iii. Timely evaluation of initial submissions and responses.
iv. Recognising the ZAZIBONA recommendations and utilising them for reliance for expedited and abridged review of applications for registration (marketing authorisation).

SCOPE OF PRODUCTS

Products eligible for assessment under the ZAZIBONA initiative consist of all essential medicines and medicines used in the treatment of the SADC priority diseases or conditions listed below:

a. HIV/AIDS
b. Tuberculosis
c. Malaria
d. Acute respiratory infections
e. Diarrhoea
f. Diabetes
g. Pneumonia
h. Cardiovascular

i. Cancer
j. Obstetrics
k. Gastroenteritis and colic
l. Reproductive health products
m. Products included in the list of United Nations Commission for Life-Saving Commodities for Women and Children Final UN Commission Report_14sept2012.pdf (unfpa.org)

Medical products that may be of public health importance from a regional perspective that do not necessarily fall into the categories specified above can still be considered for eligibility by applicants expressing an interest in their review using this joint assessment pathway.

ZAZIBONA does not consider products that are WHO Prequalified as there are adequate processes based on reliance at country level. In response to industry requests, products approved by Stringent Regulatory Authorities (SRAs) can be considered provided that the applicant submits the full SRA assessment reports as well as associated documentation in line with the WHO SRA CRP process. Ref: https://extranet.who.int/pqweb/medicines/faster-registration-fpps-approved-sras

Whilst biologicals and medicines other than small molecule generic applications were included in the piloting of the ZAZIBONA CP, these products are excluded from the current Expression of Interest. Applicants can consider the continental procedure for these products at this time; or make direct applications to the Member States.

ELIGIBILITY

All applicants interested in obtaining marketing authorisation in the SADC region are eligible for the process on the condition that they pay the required cost recovery fees and submit an Expression of Interest. Prior registration is required to access the Expression of Interest submission form on the ZAZIBONA submission portal.

COST RECOVERY FEES

The Medicines Control Authority of Zimbabwe is the current Implementing Agency tasked with the responsibility to receive and verify cost recovery fees. Proforma invoices shall be

generated and issued through the ZAZIBONA submission portal. Proof of payment must accompany submissions at each process step, as guided by the ZAZIBONA submission portal.

Cost recovery activities include maintenance of the ZAZIBONA Service Desk, administrative, technical and administrative staff costs; as well as the convening of the joint assessment sessions, which costs are currently shared with our strategic financial partners. ZAZIBONA cost recovery fees are determined jointly by the Heads of Agencies (SADC Medical Products Regulatory Forum). Informed by the costs incurred during the piloting of the centralised procedure the cost recovery fees are as follows:

Dossier evaluation: Small molecule generic applications

Item No.	**Service**	**Fees (USD)**
Initial application		
1.	Screening	**600**
2.	Product dossier evaluation	**4,400**
Total		**5,000**
Line extension		
1.	Screening	**600**
2.	Product dossier evaluation	**2,400**
Total		**3,000**

cGMP determination

Dosage Form	**Fees**	**Number of days**
General oral solid dosage (OSD) form facility	USD 8000	3 per facility
General OSD and Oral liquid dosage form facility	USD 8000 + 2000	4 per facility
General Small Volume Parenteral up to 2 (Vial and Ampoules) in one facility *2 can be ampoules + vials/ Ampoules + Pre Filled Syringes	USD 10 000	3 per facility
General Small Volume Parenteral (SVP) up to 3 dosage presentations in one facility Ampoules/Vials/PFS	USD 12 000	4 per facility

• Any additional in stand alone with separate utilities will be charged USD 10 000		
General Large Volume Parenteral	USD 10 000	3 per facility
Specialised dosage form as follows a. Metered dose Inhalers/ b. Oncology OSD/ c. Oncology SVP/ d. Penicillin OSD/ e. Penicillin SVP/ f. Cephalosporin OSD/ g. Cephalosporin SVP	USD 10 000 per facility	3 per facility

TIMELINES

ZAZIBONA timeline from receipt of an application as well as the evaluation cost recovery fees to the final recommendation (scientific application shall be no longer than 9months, excluding applicant response time. Specifically,

- ZAZIBONA Joint Assessment Sessions: as per specific dates published.
- Confirmation and acknowledgement of receipt of pre-submission forms: within 5 working days of submission.
- Screening: within 14days from receipt of the application and payment of screening cost recovery fee.
- Q1 assessment: within 90days of payment of the full evaluation cost recovery fee. Thereafter the evaluation report shall be tabled at the next available joint assessment session.
- Q1 List of Queries: within 7days from the completion of a Joint Assessment session. For an assessment report to be tabled at a particular Joint Assessment session, it must have been received 3months before the Joint Assessment session. Cut-off dates will be published to assist applicants to manage the timelines.
- Q2 assessment: within 60days from receipt of applicant response to first Consolidated List of Queries (c1LoQs).

- Q2 List of Queries: within 7days from the completion of a joint assessment session. For query responses to be tabled at a particular Joint Assessment session, they must have been received 2months before the Joint Assessment session. Cut-off dates will be published to assist applicants to manage the timelines.

- Final assessment: within 60days from receipt of applicant response to c2LoQs. This will culminate in the ZAZIBONA recommendation.

- Communication of recommendation: within 14days from the completion of the Joint Assessment session in which a final recommendation is made. Applications shall be notified of the intention to issue a positive recommendation upon receipt of an updated dossier. Negative recommendations shall be communicated in writing within 7days from the completion of the Joint Assessment session.

In the event that ZAZIBONA exceeds the timeline to recommendation beyond 11months, applicants shall be entitled to a 10% reduction of the cost recovery fee payment with the next application.

- Recommendation to feedback on final registration decision: within 90days of submission of application at country level, provided country specific requirements have been met.

CONTACT PERSONS

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Mrs Sakhile Dube-Mwedzi,
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Assessments Coordinator
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Zazibona Administrative Office

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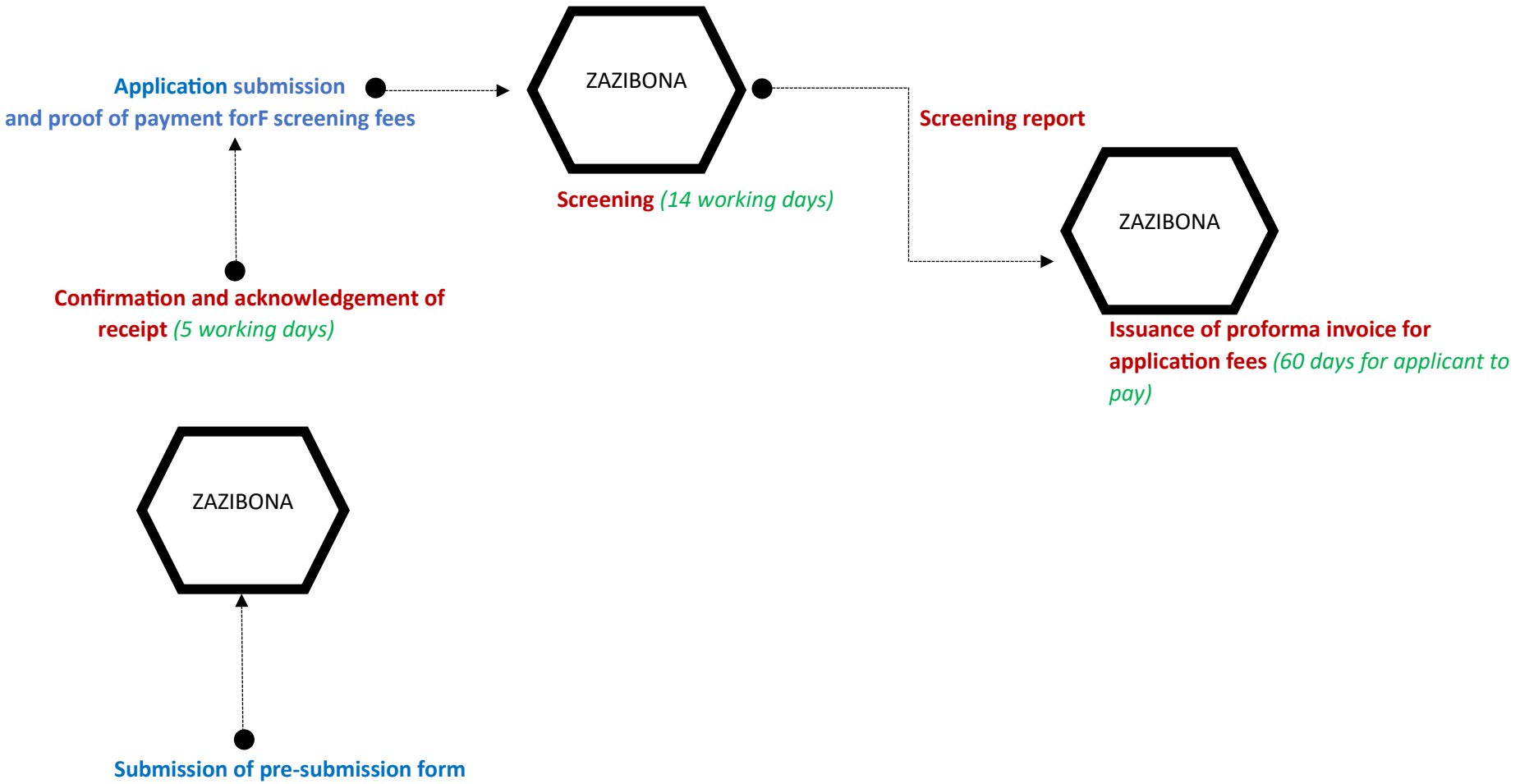
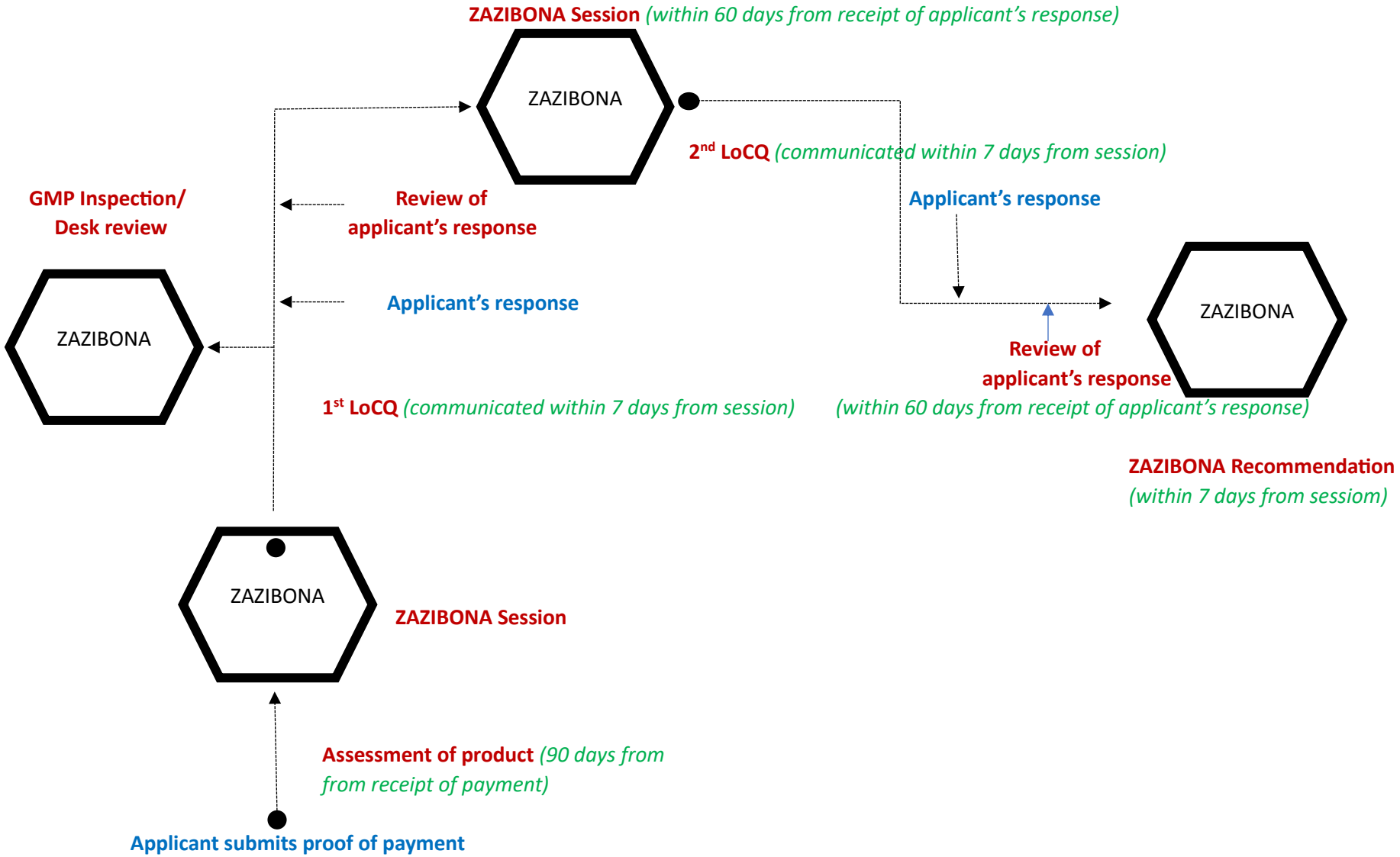
APPENDIX I – PROCESS FLOW

Part 1



Part 2


ZAZIBONA Session (within 60 days from receipt of applicant's response)
ZAZIBONA
2nd LoCQ (communicated within 7 days from session)
GMP Inspection/
Desk review
Review of
applicant's response
Applicant's response
ZAZIBONA
ZAZIBONA
Applicant's response
Review of
applicant's response
(within 60 days from receipt of applicant's response)
1st LoCQ (communicated within 7 days from session)
ZAZIBONA Recommendation
(within 7 days from sessiom)
ZAZIBONA
ZAZIBONA Session
Assessment of product (90 days from
from receipt of payment)
Applicant submits proof of payment