



EXPRESSION OF INTEREST: SADC MEDICINES REGULATORY WORKSHARING, ZAZIBONA COLLABORATIVE PROCESS

In an effort to encourage widespread access to medicines in the Southern African Development Community (SADC) region, SAHPRA invites applicants to submit Expressions of Interest (EOIs) for evaluation of applications through the Zazibona collaborative process.

The Zazibona process is a work-sharing initiative amongst National Medicines Regulatory Authorities (NMRAs) in Zambia, Zimbabwe, Botswana, Namibia, South Africa, The Democratic Republic of Congo, Tanzania, Malawi and Mozambique.

The visions of the Zazibona initiative are:

- A region in which good-quality medicines are available to all those who need them
- Reduction of time to taken to register products in the individual countries
- Efficient utilisation of resources through work-sharing in assessment of products and inspection of manufacturing facilities

Zazibona collaboration does not represent replacement of the need to submit applications for registration in participating countries in line with national requirements. Applications that qualify for the Zazibona initiative may be selected for collaborative evaluation based on:

- Number of participating countries to which the application has been submitted
- Unmet public health need in the SADC region

Certain aspects of the evaluation will be done through work-sharing, as decided and allocated by the Zazibona coordinator. Other, country-specific aspects will need to be evaluated by each NMRA. Final registration decisions are the responsibility of individual participating authorities. Where countries agree that it is necessary, variations to the products which have been registered under this collaboration will be handled through the same process.

It is envisaged that applicants will benefit from accelerated registration processes, a single set of questions during assessment process and – in principle – harmonised regulatory decisions, which could make any post-registration variations easier.

Any product meeting the criteria of an essential medicine¹ is invited to be submitted for assessment via Zazibona collaborative process. Special preference is given to medicines

¹WHO Model Lists of Essential Medicines for Adults and Children, latest editions

that are vital to expanding treatment programmes, where there are currently limited options for medical practitioners in the participating countries.

Products that are eligible to be submitted for evaluation through the Zazibona process exclude those which have been WHO prequalified. For WHO prequalified products, the WHO-NMRA collaborative procedure can be considered by the suppliers of these particular products.

Procedure for the EOI

Applications for evaluation of medicines via the Zazibona collaborative process must be accompanied by a formal agreement that information may be shared amongst all the participating NMRAs. The information will be treated as confidential by all participating countries, in line with applicable national legislation and arrangements. In applying for product evaluation through the Zazibona collaborative process, applicants are requested to submit a cover letter (clearly indicating interest to participate in Zazibona), product dossier in the CTD format, product sample and site master file to at least two of the participating countries, Country-specific submission requirements must also be adhered to. Country-specific requirements include especially:

- Application fees in each country
- Statutory forms to be completed for each country
- Country-specific labelling requirements

Please note that applications that qualify for reliance-based review based on registration with one of SAHPRA's recognised regulatory authorities (RRAs) are not precluded from being evaluated at Zazibona. If a product has been registered by an RRA, an applicant may still include an EOI for Zazibona in the relevant application.

Documents to be submitted

1. Cover letter, in English, expressing:
 - 1.1. interest in participating in the Zazibona process and information on whether the product is already registered in any Zazibona participating country;
 - 1.2. confirmation that the information submitted in the product dossier is "true and correct";
 - 1.3. confirmation that the same dossiers and data have been submitted to all participating countries;
 - 1.4. consent to sharing of the product related information, during pre-registration and in post-registration assessment process, amongst Zazibona NMRAs, with WHO staff and with external experts, who support the process and are bound by confidentiality undertakings;
 - 1.5. commitment to apply for the same variations in all Zazibona countries where the product is registered.
2. Product dossier, in English, organised in CTD format for submitting product data and information. For the purpose of generic registration, data demonstrating the quality of raw materials and finished formulation are necessary, as well as demonstration of bioequivalence with an acceptable comparator. Details are specified in the relevant guidelines that reflect harmonised SADC position. Only an electronic copy of the dossier should be submitted.

3. A product sample (for example a package of 100 tablets), for evaluation of product appearance, container material and labelling, and to enable, under exceptional circumstances, chemical and pharmaceutical analysis. In the case of a sample of which the labelling does not correspond to national requirements, a mock-up should be submitted, demonstrating the design of final labelling.
4. A site master file for each manufacturing site of the product, in the requisite format.
5. A populated QOS and BTIF (for bioequivalence studies) and Biowaiver form (If applicable), completed in the WHO format, which may be found on the Website using the following links:

<https://extranet.who.int/prequal/key-resources/documents/quality-overall-summary-product-dossier-qos-pd>

<https://extranet.who.int/prequal/key-resources/documents/application-form-presentation-bioequivalence-trial-information>

<https://extranet.who.int/prequal/key-resources/documents/application-biowaiveradditional-strength-22-november-2018>

<https://extranet.who.int/prequal/key-resources/documents/application-form-application-biowaiver-biopharmaceutics-classification>

Specific details regarding documentation required for collaboration in the Zazibona initiative, as well as information on the mechanism of work-sharing and interaction with applicants, are specified in other documents which can be found on the website.

Retrospective application of Zazibona approval

South Africa joined Zazibona as a participating country in March 2016. For products that have been approved by Zazibona prior to March 2016, reports from the worksharing meetings will be used by SAHPRA to facilitate the assessment process. An application that was evaluated through Zazibona worksharing should indicate this in the cover letter, and include all relevant documents and evaluation reports in the submission.

This process will also be applied for any product not submitted to SAHPRA at the time of assessment at Zazibona by a participating country.

Expected timelines

The Zazibona collaborative evaluation process is designed to achieve registration within a total time of 11 months, during which the applicant will have two windows of opportunity to respond to consolidated lists of regulatory questions, in a period of 60 days. Total regulatory time therefore is 210 days, which corresponds to timeframes of established regulatory authorities. Additional information can be obtained from focal persons in Zazibona NMRAs.

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