Invitations for Expression of Interest (EOI) to register medicinal products via the Zazibona collaborative process

The Zazibona project is a pilot of collaboration between national medicines regulatory authorities (NMRAs) in Zambia, Zimbabwe, Botswana and Namibia. These are four neighbouring countries in Southern Africa which have a combined population of around 34 million.

The visions of the Zazibona project are:

- A region in which good-quality medicines are available to all those who need them
- Reduction of time to taken to grant marketing authorisation in the individual countries
- Efficient utilisation of resources through work sharing

The project objective is to pilot a model of collaboration to facilitate access to good-quality medicines through worksharing in assessment of products and inspection of manufacturing facilities. Products that meet assessment criteria are then granted marketing authorisation in the participating countries, in which applications for registration would have been submitted. Where countries agree that is necessary, variations to the products which have been registered under this collaboration will be handled through the same process.

Zazibona collaboration does not represent replacement of the need to submit applications for registration in participating countries in line with national requirements. However, as described in this document, in order to facilitate cooperation among Zazibona authorities, certain modifications are expected. Although closely collaborating on assessments and inspections, final registration decisions are fully in responsibility of individual participating authorities.

It is envisaged that manufacturers of needed medicines will benefit from accelerated registration processes, single set of questions during registration process and in principle harmonized registration decisions, which will make easier any post-registration variations.

Any medicinal product meeting criteria of essential medicine[1] is invited to be submitted for registration via Zazibona collaborative process. Special preference is given to medicines that are vital to effective treatment and to expanding treatment programmes, where there are currently limited options for medical practitioners in the participating countries.

Products that have been already registered in any Zazibona country or other products jointly accepted by participating authorities are eligible to the collaborative process, provided there is an agreement between the participating countries.

The invited generic products exclude those which have been WHO prequalified and registered by well resourced regulatory authorities, because other registration mechanisms can be applied. For WHO prequalified products, the WHO-NMRA collaborative procedure can be considered by the suppliers of these particular products.
Innovator products which have not been registered by SRAs are accepted for the procedure. Manufacturers who are based in the four countries involved in the collaboration are also encouraged to apply.

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

The condition to include a medicinal product in collaborative process is to submit registration application for invited medicines according to Zazibona recommendations and provide an agreement with information sharing among participating regulatory authorities. All participating countries treat the shared information as confidential in line with applicable national legislation and arrangements.

In applying for product registration through the Zazibona collaborative mechanism, applicants are requested to submit a covering letter (clearly indicating interest to participate in the Zazibona project), product dossier in the CTD format, product sample and site master file to all the participating countries according to the individual requirements. The country specific requirements include especially:

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

Documents to be submitted

1. Covering letter, in English, expressing
   1.1. interest in participating in the Zazibona project and information, whether the product is already registered in any Zazibona country,
   1.2. confirmation that the information submitted in the product dossiers is "true and correct"
   1.3. confirmation that the same[2] dossier and data have been submitted to all participating countries
   1.4. consent with sharing of the product related information during registration and in post-registration period among Zazibona authorities and with WHO staff and external experts, who support the process and are bound by confidentiality undertaking.
   1.5. commitment to apply for same variations and post-registration changes in all Zazibona countries that registered the product.
2. Product dossier, in English, organized in CTD format for submitting product data and information. For the purpose of generic registration data demonstrating quality of raw materials and finished formulation are necessary, as well as demonstration of bioequivalence with acceptable comparator. Details are specified in the relevant guidelines that reflect harmonized SADC position. Paper copy and 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 case of having a sample with labelling not corresponding to national requirements, there should be submitted a mock-up demonstrating design of final labelling.
4. A site master file, for each manufacturing site of the medicinal product, in the requisite format.

Details of documentation required for Zazibona collaboration, mechanism of Zazibona worksharing and interactions with applicants are specified in other documents.

[2] Specific national administrative documents, labelling and product information texts as submitted in the module 1 of the dossier do not represent a difference between dossiers of the same technical content.

The Zazibona collaborative process is designed to achieve registration within 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 regulatory deadlines of established regulatory authorities. At the end of the process the applicant will be provided with an assessment report, which can be used in support of registrations of the respective product in other countries.

Additional information can be obtained from focal persons in Zazibona participating NMRAs.