ZAZIBONA Collaborative Medicines Registration

Alternative/Expedited process to register medicines via the ZAZIBONA collaborative process

Version 01

Date 9 June 2015


Zambia


Zimbabwe


Botswana


Namibia

Introduction

The ZAZIBONA process is a collaboration between national medicines regulatory authorities (NMRAs) in Botswana, Namibia, Zambia, and Zimbabwe. These are four neighbouring countries in Southern Africa which have a combined population of around 34 million. This process may be extended to include participation by other interested SADC Member States.

The vision of the ZAZIBONA process is :

- a region in which good-quality medicines are available to all those who need them;
- significantly reduce time taken to grant marketing authorisation in the individual countries; and
- efficient utilisation of resources within regional national regulatory through work sharing.

The process objective is to promote a collaboration model to facilitate access to good-quality medicines through worksharing in assessment of medicines and inspection of medicine manufacturing and testing 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 may be handled through the same process.

The ZAZIBONA collaboration does not represent the 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 there is close collaboration on assessments and inspections, final national registration decisions are the responsibility of individual participating authorities.

It is envisaged that manufacturers of needed medicines will benefit from accelerated registration processes, a single set of questions during the registration process and in principle harmonized registration decisions, which will facilitate easier review of any post-registration variations. Applications may be submitted by any person that qualifies to be an applicant in each participating country as per national requirements.

Scope of products

Any medicine meeting the criteria of being an essential medicine is invited for submission to be considered for registration via the ZAZIBONA collaborative process Special consideration may be given to medicines that are vital to effective treatment and to expanding treatment programmes, where there are currently limited options for health practitioners in the participating countries. This includes medicines identified for special regional programmes and initiatives.

The focus will however be on the 10 priority disease conditions identified by SADC (Annex 1) plus reproductive health products. Priority will be given to the products included in the List of UN Commission for Live-Saving Commodities for Women and Children.

Any other medicines that are important from a public health perspective may be considered on a case-by-case basis.

Other eligibility criteria
To be eligible for the ZAZIBONA collaborative process an application should have been lodged with at least two (2) ZAZIBONA participating countries.

Products registered by stringent regulatory authorities (SRA) are eligible for an abridged review process provided there access to the assessment reports for which the authorisation was based on.

Applications not eligible
The invited generic products exclude those which have been prequalified by the World Health Organization (WHO), for which an accelerated registration mechanism (WHO PQ Collaborative Registration Process) can be applied.

Applicants are encouraged to make pre-submission consultations on eligibility of their products with their respective national authorities.

Application submission process
As a condition for a medicines dossier to be included in the collaborative process an application should be submitted according to current country requirements plus the additional ZAZIBONA requirements which include an agreement to consent to information sharing among participating regulatory authorities. All participating countries shall treat the shared information as confidential in line with applicable national legislation and arrangements.

In applying for a product registration through the ZAZIBONA collaborative process, applicants are requested to submit a covering letter (clearly indicating their interest to participate in the ZAZIBONA process), a product dossier in the Common Technical Document (CTD) format, product samples and a Finished Pharmaceutical Product (FPP) site master file to all the participating countries according to the individual national requirements. The submissions should comply with the harmonised SADC Registration Guidelines.

The national specific requirements include especially:

- Application fees
- Statutory forms to be completed and to accompany a specific national application
- Country specific labelling requirements

Potential applicants are further advised that participating countries reserve the right to accept or refuse submissions to be considered for this collaboration on a case by case basis. Each NMRA retains the right to assess submitted data and organize site inspections to the extent they deem appropriate.

Applicants are encouraged to submit applications for inclusion in the collaborative process at least 1 month before the meeting of assessors which considers applications received and assignment of rapporteurs. Early submissions facilitate the administrative screening of applications before the meeting of assessors. Assessment meeting dates are published on participating authority websites.

Documents to be submitted are in Annex I

The collaborative 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 assessment questions within a period of 60 days. Total regulatory time for coallborative process is therefore 210 days, which corresponds to regulatory deadlines of established regulatory authorities. Timelines for collaborative process starts at the point of allocation of rapporteurship i.e. within 1 month of the submission, followed by 10 weeks for initial assessment, 2 weeks for sharing assessment report, 8 weeks for the manufacturer/supplier or applicant to respond, and 2 weeks to process the response. The specified timelines are only indicative and may vary depending on the specific dates of the assessment sessions. Products are only considered for 2 review cycles (for the responses) thereafter a final recommendation will be made. The target timelines may vary depending on the number of submissions relative to the available technical capacity of the participating NMRAs. A NMRA reserves the right to make a final determination on any application and may request further information.

Each NMRA will be required to finalise the registration process within a reasonable timeframe after the final recommendation from the collaborative process depending on the schedules of the meetings for the Authorities/Boards/Committees responsible for final regulatory decision at national level.

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

Annex 1: Top conditions/diseases in SADC with an overall regional priority ranking

HIV/AIDS	1
Tuberculosis	2
Malaria	3
Acute respiratory infections	4
Diarrhoea	5
Diabetes	6
Pneumonia	7
Cardiovascular	8
Cancer	9
Obstetrics, Gastroenteritis & colic	10