

Annex IV: Confirmation of acceptance of application for consideration in ZaZiBoNa process

Dear applicant,

We refer to your product, submitted for registration in the following countries....., which was considered during the 'ZaZiBoNa' co-operation meeting held in (*state city and country*) from (*State date*) to review submissions for expressions of interest.

As an outcome of this meeting regulatory assessors from participating countries agreed that your product is acceptable for assessment. The rapporteur country for your application is therefore (*State country*).

Although each participating regulatory authority has to communicate directly with each country specific applicant for registration with comments and questions, these comments and questions will be in case of your registration submission identical. You are expected to reply to each respective regulatory authority with the same response, which will again be reviewed within the scope of the mutual co-operation of participating countries. However it is strongly recommended that any responses with additional data should be prioritized for submission to the rapporteur.

In order to manage your application in the most effective way, all participating authorities agreed that you be given 90 days from the date of any request to submit a full comprehensive response. Please note that part responses to all or some of the questions will not be acceptable. In the event this timeline cannot be kept, please notify the rapporteur of the date of expected communication and submission of requested data.

We sincerely hope that this type of collaboration will facilitate and accelerate not only the ongoing registration of your product, but also will help to facilitate post-registration regulatory maintenance of the product.

In case your application for registration has not been submitted to all participating countries, the submitted data will however be reviewed by assessors from all participating countries. As an effect of this, should you wish to submit the same product and the same data for registration in the other ZaZiBoNa countries, you can expect an expedited review process.

Should you need any further information, please contact any of the regulatory authority mentioned above.