ZAZIBONA CIRCULAR 1 OF 2024

Date: 24 January 2024

To: All ZAZIBONA Stakeholders

Re: UPDATE ON PILOTING OF THE CENTRALISED PROCESS WITH COST RECOVERY MECHANISM FOR ZAZIBONA

The SADC Medical Products Regulators Forum (SADC MRF) takes this opportunity to advise its stakeholders on the status of the process of transitioning to the centralised process. This centralised ZAZIBONA procedure replaces the procedure that previously required submission of applications in at least two Member States. With the centralised process, products will be submitted for joint review, and the resulting recommendation can be used to support product applications in the participating member states.

Stakeholders are advised to take note of the following:

1. **Maintenance of the ZAZIBONA website**
   We are in the process of upgrading the website. The site is under maintenance until the 5th February 2024. The inconvenience caused in terms of access to information is sincerely regretted.

2. **Registration of applicants to use the ZAZIBONA submission portal**
   Applicants are required to register in order to access the submission portal. Any company or entity anticipating submitting applications during the piloting of this centralised process **must** complete the registration form and email it to: coordinator@zazibona.com

   For the purposes of the Pilot we have had to effect a deadline for applicant registration. Please may all applicants submit their registration forms **by Monday 29th January 2024**.

3. **Stakeholder orientation meeting: 8th February 2024, 09:30hrs CAT**
   A virtual session will be held on Thursday 8th February 2024 from 09:30 – 11:00hrs for orientation of stakeholders on the submission portal. The meeting will facilitate a walkthrough of the submission process using the online Expression of Interest, payment modalities, timelines, handling of queries and general questions and answers.

4. **Opening of the online portal for submission of applications.**
   This is scheduled for the 12th February 2024, following the orientation process.

5. **Pending products**

The first joint assessment session of 2024 will be held from the 26th February to 1st March 2024. The focus of this session will be the conclusion of pending applications.

Verification of pending products will be completed by the 31st January. Communication with applicants regarding pending products is ongoing, in accordance with ZAZIBONA Circular 2 of 2023. Whilst applicants will receive written confirmation of outstanding queries and will be given 2months to submit their responses, applicants are encouraged to submit them as soon as possible for evaluation, to facilitate the conclusion of their applications. Where responses are not received by the 31st March 2024, the pending products will be recommended for rejection.

6. **Products undergoing the initial review cycle where queries have not yet been communicated to applicants**.
   Applicants can expect the first set of queries after the first joint assessment session for 2024, to be held in the last week of February 2024.

7. **Products received after the 1st October 2023**.
   A temporary suspension of receipt of applications for the ZAZIBONA joint assessment procedure was effected on the 1st October 2023. Applicants who were not aware of this and submitted products after this date will be notified in writing of the option to pay the cost recovery fee and have their products evaluated under the new centralised procedure. Alternatively, these applicants can confirm acceptance to utilise the country level pathways in the countries where the applications were lodged.

Faithfully,

S. Dube-Mwedzi (Mrs)

For and on behalf of: **SADC MEDICAL PRODUCTS REGULATORS FORUM**