ZAZIBONA CIRCULAR 1 OF 2023

Date: 21 December 2023

To: All ZAZIBONA Stakeholders

Re: FINALISATION OF PENDING ZAZIBONA APPLICATIONS

The SADC Medical Products Regulators Forum (SADC MRF) will initiate the pilot of the regional centralised procedure for the evaluation of medicinal products in January 2024. This centralised ZAZIBONA procedure replaces the procedure that previously required submission of applications in at least two Member States. It is however noted that there are a number of pending applications from the previous process that have not been finalised.

The Forum is committed to concluding these products. To that effect, the following measures will be implemented. In the case of:

1. **Products with pending queries previously communicated to applicants**.
   Applicants will receive written confirmation of the outstanding queries. Applicants will be given 2months to submit their responses. Where responses are not received by the 31st March 2024, the pending products will be recommended for rejection.

2. **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.

3. **Products undergoing the initial review cycle where queries have not yet been communicated to applicants**.
   Assessment of these products will run parallel to the pilot. 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.

Faithfully,

S. Dube-Mwedzi (Mrs)

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