MCAZ Medicines Control Authority of Zimbabwe

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REF: *B/279/44/216/2018*

18 July 2018

pharmacy@citybyo.co.zw

Dear Sir / Madam

RE: **Suspected ADR reports for the Targeted Spontaneous Reporting (TSR) of Essential Medicines including anti TBs and ARVs Program.**

Thank you for participating in the TSR program. This letter acknowledges receipt of suspected ADR reports you submitted and provides feedback.

The reports were processed and causality assessment was done by the Pharmacovigilance and Clinical Trials (PVCT) Committee, on the 4th of July 2018. The Committee agreed to classify the ADR reports as indicated in the attachment (table 1). Data from the reports was also uploaded into the World Health Organisation (WHO) VigiFlow database for further analysis.

Your contribution to the country's pharmacovigilance program is greatly appreciated. The TSR program is continuing and we look forward to receiving more reports from your health facility.

Many thanks.

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

...R.Manyevere.....
R.Manyevere (Miss)
For: DIRECTOR-GENERAL

Table 1: ADR REPORTS SUMMARY

MCAZ Ref number	Date of Reporting	Patient Details (Initials, gender, age, weight)	SUSPECTED MEDICINE (SM)	ADR reported	CAUSALITY ASSESSMENT
TSRRep 10/2018	29/12/2017	SM, 5years, 15.8kg, Male	Albendazole	Facial rash and puffy face	***Possible:*** *Although it is an uncommon ADR*
TSRRep 11/2018	29/12/2017	TS, 7years, Male	Albendazole	Abdominal pains, vomiting and joint pains as well as general body weakness	***Could not be assessed:*** *Date of treatment commencement was not provided.*

NB: A ***probable*** causality assessment denotes the following:

- Event or laboratory test abnormality, with reasonable time relationship to drug intake.
- Unlikely to be attributed to disease or other drugs.
- Response to withdrawal clinically reasonable.

Possible causality assessment should reasonable meet the following criteria:

- Event or laboratory test abnormality, with reasonable time relationship to drug intake
- Could also be explained by disease or other drugs
- Information on drug withdrawal may be lacking or unclear

Unlikely causality assessment denotes the following:

- Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible)
- Disease or other drugs provide plausible explanations

Certain causality assessment should reasonable meet the following criteria:

- Event or laboratory test abnormality, with plausible time relationship to drug intake
- Cannot be explained by disease or other drugs
- Response to withdrawal plausible (pharmacologically, pathologically)
- Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon)
- Rechallenge satisfactory, if necessary

Unassessable/Unclassifiable causality assessment should reasonable meet the following criteria:

- Report suggesting an adverse reaction
- Cannot be judged because information is insufficient or contradictory
- Data cannot be supplemented or verified

Conditional/Unclassified causality assessment should reasonable meet the following criteria:

- Event or laboratory test abnormality
- More data for proper assessment needed, or
- Additional data under examination