Adverse events monitoring

- Medicines used for TB preventive treatment regimens are generally safe and well tolerated. However, adverse reactions sometimes occur, as is the case with all medicines. Contact your health care provider if you experience any side effects or adverse drug reactions.

Reporting of Adverse Drug Reactions (ADRs)

MCAZ is the National Centre for Pharmacovigilance (PV) in Zimbabwe. PV is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. ADR reports should be completed and submitted to MCAZ.

Patient/Consumer reporting can be done online via the following link: https://primaryreporting.who-umc.org/ZW

Hard copy ADR forms are available on request from the Medicines Control Authority of Zimbabwe (MCAZ) and electronic copies can be downloaded from this link: https://www.mcaz.co.zw/?smd_process_download=1&download_id=2500

The (MCAZ) also has an electronic platform for reporting ADRs/ side effects, called the Electronic Pharmacovigilance (e-PV) System, with both online and offline reporting capabilities through Android/iOS mobile applications and Desktop applications for Windows/ MacOs/ Linux –based operating systems (MCAZ Pharmacovigilance) and web-based reporting is available via the following link: https://e-pv.mcaz.co.zw/

Contact: +263772145191-3

+263(242)736981-7

Email: mcaz@mcaz.co.zw

Website: www.mcaz.co.zw

MCAZ Medicines Control Authority of Zimbabwe

A guide to Latent TB prevention, adverse event monitoring and reporting

What is Tuberculosis (TB)?

Tuberculosis (TB) is disease caused by bacteria (M. tuberculosis), that most often affects the lungs. Tuberculosis is curable and preventable. TB is spread from person to person through the air when people with lung TB cough, sneeze or spit and they propel the TB bacteria into the air.

Not everyone infected with TB bacteria becomes sick. As a result, two TB related conditions exist: latent TB infection and active TB disease. Persons with latent TB infection do not feel sick and do not have any symptoms. They are infected with M. tuberculosis, but do not have active TB disease.

TB Preventative Therapy (TPT)

TB Preventative Therapy (TPT)

TPT is medication given to people with LTBI (inactive TB) to prevent the progression to active TB. Studies have shown that preventive treatment reduces the overall risk for progression to active TB. The main treatment options for LTBI with strains presumed to be drug-susceptible regardless of HIV status include:

- Daily Isoniazid monotherapy for 6 months (6H)
- Rifampicin plus isoniazid daily for 3 months (3HR)
- Rifapentine and isoniazid weekly for 3 months (3HP)

For contacts of patients with DR-TB (Drug-resistant TB), 6 months of Levofloxacin is used.

Drug-drug and drug-herb interactions

- When two drugs are given together, there can be a change in either of the drug's effect on the body. A drug-drug interaction (DDI) can increase or decrease the action of either or both drugs, or can be the cause of an adverse event. Medication for TPT may interfere with a number of medicines, including oral contraceptives. There is also a potential interaction between some commonly used herbs/herbal products and commonly used standard medications. It is important to inform your healthcare provider of any medicines or herbal products that you are taking.