MINISTERIAL STATEMENT

STATUS OF THE QUARANTINED GENTAMED INJECTION

The Minister of Health (Dr Chilufya): Mr Speaker, I wish to thank you most sincerely for granting me this opportunity to render a ministerial statement to inform the general public through this august House on the status of the quarantined gentamed injection, which is gentamicin sulphate, 80mg/2ml, due to reports of suspected adverse drug reactions (ADRs).

Sir, in 2013, the Medicines and Allied Substances Act No.3 of 2013 was enacted to establish the Zambia Medicines Regulatory Authority (ZAMRA) as a technical arm of the Government with the overall mandate of assuring the quality, safety and efficacy of medicines being made available to the Zambian public. This is done through a robust registration process, import/export controls, post-marketing surveillance, control of premises and pharmacovigilance activities. Pharmacovigilance activities include receipt, collation, causality assessment and provision of feedback on received adverse drug reactions and medicine quality problems. Pharmacovigilance is intended to facilitate the early detection of medicines that might cause adverse drug reactions or have quality problems.

Mr Speaker, through this highly alert and robust pharmacovigilance system that the Government has set up, ZAMRA received thirty-two suspected adverse drug reaction reports from across the country from January 2019. The drug reactions were reported from the following facilities:

(a) six from Levy Mwanawasa Teaching Hospital;

(b) seven from Kabwe Central Hospital;

(c) ten from Choma General Hospital;

(d) seven from Livingstone Central Hospital;