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;

(e) one from Chipata Central Hospital; and

(f) one from Mumbwa District hospital.

Mr Speaker, the common complaints that were presented were headache, dizziness heart palpitations and vomiting following the Gentamend injection.

Mr Speaker, these were the symptoms that were reported on the recording forms that all health workers trained in pharmacovigilance did from the different facilities.

Mr Speaker, this medicine was imported into the country for supply to public health facilities from a company based in China known as CSPC Pharmaceutical Group Limited and also a company in Kenya known as Medisel (K) Limited.

Mr Speaker, gentamicin injection from the suspected batches was sampled and underwent some routine analysis in-country and some samples were sent to North-West University, in South Africa for quality analysis. However, as a precautionary measure, the Ministry of Health through the Zambia Medicine Regulatory Authority ZAMRA, quarantined any stock of gentamend that were still at Medical Stores and recalled all stock that was already distributed and some are quarantined within the facilities.

Mr Speaker, this drug has been withdrawn from all public health facilities, pending further analysis from North-West University, in South Africa.

Mr Speaker, I want to assure the public that the Government of the Republic of Zambia thorough the Ministry of Health has strengthened activities at ZAMRA, in order to safe guide the public against consumption of any drugs that may be unsafe. To this effect the Government with support from the European Union (EU) has invested in a modern quality control

laboratory that is at seventy per cent completion rate, and is expected to be completed in August 2019. This facility once complete will have a more robust quality control laboratory, which will not require us to refer samples outside the country.

Mr Speaker, the procurement of the state of art equipment to be installed at the modern laboratory is completed and will be installed immediately after construction works are completed. One of the key functions of this laboratory will be to verify the safety, quality and efficacy of medicine and allied substances which are manufactured or imported into the country by person who are authorise or licensed under the Medicine and Allied Substance Act No. 3 of 2013. This is taking place today; however an extra step of batch analysis will be added. The Technical Committee under ZAMRA on pharmacovigillance and clinical trials have already under taken causality assessment to ascertain whether the reactions were indeed caused by this Gentamaicin injection. After considering all the evidence and the audit from interviews from doctors, nurses, anaesthetists and patients, the committee concluded that indeed the Gentamend injection caused the reaction.

Mr Speaker, in conclusion, I want to emphasise that the Patriotic Front Government (PF) lead by His Excellency President Edgar Chagwa Lungu has embarked on a transformational agenda, that aims at attaining universal health coverage and packed by assuring access to safe and efficacious drugs. It is for this reason that we are investing in infrastructure to improve monitoring of drugs in addition to many other interventions, to strengthen the medical supply chain.

Mr Speaker, to this effect I wish to assure the house and the nation at large that the Government through the Ministry of Health is on the ground and as had intensified surveillance cost marketing surveillance for both public and private marketed health commodities. No deaths were recorded and no cases have been reported form 15th March, 2019.

I thank you, Sir.