MINISTERIAL STATEMENT

ON

**THE NON-COMPLIANCE OF ERYTHROMYCIN PROCURED BY ZAMMSA**

BY

**THE MINISTER OF HEALTH (MRS MASEBO), MP**

Madam Speaker, I want to thank you for granting me this opportunity to update the House and the nation at large on the non-compliance of erythromycinprocured from Mission Pharma by the Zambia Medicines and Medical Supplies Agency (ZAMMSA). The House may wish to recall that on Thursday, 9th November, 2023 during the Matter of Urgent Public Importance segment, the hon. Madam Speaker directed me to issue a detailed ministerial statement on the erythromycin tablet. This is one of the fifty-eight health products contained in a health centre kit that failed a dissolution test conducted by the Zambia Medicines Regulatory Authority (ZAMRA).

Madam Speaker, I wish to put it on record that this year alone, we have received 14,100 health centre kits out of the expected 42000 kits supplied by Mission Pharma. These health centre kits were received in two batches of 7,050 each. The first batch was received in July, 2023 and distribution was concluded in August, 2023. The second batch of the health centre kits was received in the last week of September, 2023.

Madam Speaker, the House may wish to note that ZAMRA is a statutory body established under the Medicines and Allied Substances Act, No. 3 of 2013 with the main mandate to regulate and control all activities related to medicines and allied substances in the country. This is to ensure that all medicines and allied substances consistently conform to acceptable standards of safety, quality and efficacy throughout the pharmaceutical supply chain. This mandate protects the Zambian public from consuming counterfeit and/or substandard medicines.

Madam Speaker, in order for ZAMRA to carry out this important function effectively, a National Drug Quality Control Laboratory (NDQCL) has been established as prescribed by the Act to verify the safety, quality and efficacy of medicines and allied substances manufactured in or imported into the country. The NDQCL issues Certificates of Analysis for every test conducted. The in-country quality control system put in place by ZAMRA is part

of our stringent quality control process for all medicines supplied to the Zambian Market. The House may wish to note that the Act allows ZAMRA to collect samples and test them for their quality, safety, and integrity.

Madam Speaker, as part of the regulatory procedure for all products procured, ZAMMSA is required to submit samples from each consignment received to the NDQCL for compliance testing before distribution to health facilities. On 25th October 2023, of the fifty-eight items in the health centre kits that were submitted to ZAMRA for testing, only Erythromycin 250mg tablets batch number TK293 was found to be non-compliant with respect to the dissolution test conducted. The rest were compliant.

Madam Speaker, the House may wish to know that a total of Sixteen batches of Erythromycin 250mg tablets were tested at the NDQCL and two batches (No. TK297 and No. TK291) met the standard procedure test requirements and a Certificate of Analysis was issued, whilst one batch (No. TK293) with an expiry date of 5th May, 2026 did not meet one parameter of dissolution requirement. Thirteen batches out of the total sixteen are still undergoing quality control test analysis for the final stage 2 and 3 testing and results are expected to be ready by 16th November, 2023.

Madam Speaker, the House may wish to note that several meetings have been held between the Ministry of Health, ZAMRA, ZAMMSA and the health centre kit supplier (Mission Pharma). Taking into consideration the urgency to start the distribution process of the health centre kits, a decision was made to remove the non-compliant Erythromycin tablets from the remaining 6,067 health centre kits. This decision was made after taking careful consideration that some health facilities may struggle to access medicines during the rainy season and that any further delays could adversely impact on the availability of commodities in health facilities.

In addition, Madam Speaker, the House may wish to note that it was agreed that a third-party independent laboratory would conduct a re-test of samples for erythromycin tablets at the cost of the supplier. The Research Institute of Industrial Pharmacy (RIIP) in South Africa which is a World Health Organisation (WHO) pre-qualified laboratory will conduct the re-testing.

Madam Speaker, the *Zambia* Medicines and *Medical* Supplies Agency (ZAMMSA) commenced the distribution of Health Centre kits on 2nd November, 2023. The 6,067 heath center kits are to be distributed without the non-compliant commodity. The 983 health center kits will be distributed as a full kit, but without the Erythromycin being contained in them.

It should be noted, Madam Speaker, that the in-country quality control test is an intentionally recognised standard procedure and if non-compliance of certain products, a recall can be issued at any point in the supply chain system. However, for the case of Erythromycin tablets, a recall does not apply because the product has not yet been distributed to the delivery services points.

I wish to put it on record that ZAMMSA has not distributed defective health centres kits to any public health facility. Those that have any doubts can visit ZAMMSA and they will find the tablets we are talking about. Therefore, it is incorrect to imply that there has been a recall of medicines because we have not distributed the commodity in question. All the batches that failed the test have been quarantined at ZAMMSA. Should the retest results from South Africa confirm the non-compliance then, the supplier; Mission Farmers will be required in accordance with in accordance with the contract to replace as per the contractual agreement.

Madam Speaker, as I conclude, I wish to assure the House and the nation at large that the New Dawn Government under the able leadership of His Excellency Mr Hakainde Hichilema, the President of the Republic of Zambia and indeed, this hon. Minister of Health is committed to the provision of equity of access to good, quality, safe, efficacious medicines and a medical supplies to all Zambians.

Madam Speaker, I also want to appeal colleagues out there to please stop misleading the public. It is very dangerous because health should not ever be politicised.

Madam Speaker, I thank you.