ZAMBIA MEDICINES REGULATORY AUTHORITY
PRESS STATEMENT
(FOR IMMEDIATE RELEASE)

STATEMENT ON SPECIFIC BATCHES OF ERYTHROMYCIN STEARATE 250MG TABLETS BP FROM THE HEALTH CENTRE KITS SUPPLIED BY MISSIONPHARMA

Lusaka, 13th November, 2023… The Zambia Medicines Regulatory Authority (ZAMRA) is a statutory body established by the Medicines Allied Substances Act No. 3 of 2013 to ensure all medicines and allied substances being made available on the Zambian Market consistently meet the set standards of quality safety and efficacy throughout the supply chain from the Manufacturer to the consumer.

ZAMRA wishes to clarify on recent reports in public domain on an antibiotic called **Erythromycin Stearate 250mg BP Tablets** which did not meet one of the quality standards.

The named product is among the fifty-eight (58) Medicines and medical supplies in the Health Centre Kit (HCK) supplied by Mission pharma, Denmark and has been imported by **Zambia Medicines and Medical Supplies Agency (ZAMMSA)**, a procuring entity of the Ministry of Health. The Health Centre Kit comprises a combo of medicines and allied substances which may be manufactured by different manufacturers and are assembled for supply to health facilities. ZAMMSA has been importing the said health Centre kits in segments and so far, three (3) consignments have been imported at different timeframes of which ZAMRA has been sampling and testing all the medicines in the Health Centre Kits before the kits are distributed by ZAMMSA to the various health centers across the country. This exercise carried out by ZAMRA is referred to as **pre-distribution sampling and testing** before any public or private entity sells, supplies or distributes medical products for use.

The public may wish to know that the first and second consignments of the kits were sampled and tested before distribution to the public health centers and all products were found to meet the requirements for the tested parameters. However, products from the third shipment were sampled and

tested, and some batches of the Erythromycin Stearate 250mg BP Tablets did not conform to the quality standard of dissolution

Therefore, as a standard practice the Authority in this case advised ZAMMSA to secure the product in question for disposal or return to the supplier.

ZAMRA wishes to assure the public that there is no need to be alarmed regarding the affected batches of Erythromycin Stearate BP 250mg tablets as none has been distributed by ZAMMSA. Further, in the pharmaceutical manufacturing space world over, such occurrences are not unusual. This happens also in other industries such as motor vehicles, mobile phones, food to mention just a few and regulators are established for such reasons to protect the public.

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