REPUBLIC OF LIBERIA
LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)
P. O. Box 1994
2nd & 3rd Floors, Clay Building
Sekou Toure Avenue, Mamba Point, Monrovia

FOR IMMEDIATE RELEASE

LMHRA Clarifies Media Reports of Counterfeit Medication

PRESS RELEASE

Monrovia, Liberia — July 31, 2025: The attention of the Board of Directors and the Management of the Liberia Medicines & Health Products Regulatory Authority (LMHRA) has been drawn to recent trending media reports on a medical event that occurred at the St. Joseph's Catholic Hospital in January 2025 and the resultant regulatory response of the LMHRA. While it is not standard practice of the LMHRA to litigate sensitive health issues in the media, it is expedient in this instance to lend some clarity on this matter.

Following the death of a 16-year-old boy at the St. Joseph's Catholic Hospital in January 2025 and the subsequent release of the investigative report by the Liberia Medical & Dental Council (LMDC), the LMHRA launched an independent investigation into the medical products that were used in order to identify the cause(s) of the Adverse Drug Reaction (ADR), assess the regulatory status of the drugs involved and proffer measures to prevent future occurrences.

The findings of the LMHRA's independent investigation revealed that:

- The Anesthesia Bupivacaine spinal injection with Tradename Marcaine® Spinal Heavy (0.5%), in additional to five other medications, were administered to the patient
- Adverse Drug Reaction (ADR) which the patient experienced is not uncommon in medical practice
- Attribution of ADR to a drug after a concoction of medications has been administered, is rather inconclusive in the absence of further medical investigation including testing
- All of the medications administered during the procedure met the basic regulatory requirements as stipulated by the LMHRA with the exception of the Anesthesia Bupivacaine spinal injection
- The regulatory violation of the Bupivacaine spinal injection was that the labeling was done in a foreign language. This contravenes chapter 2, section 1, number 3 of the regulations for labelling of medicines and health products. It states that **"all information contained on the label of medicines and health products must be in English".**
- In 2022, G2 Pharmacy applied to the LMHRA for the registration of Bupivacaine spinal injection and after the drug dossier review, were granted registration for a period of three years and has since been importing the drug into the country.
- The investigative team, on inspection of the pharmacy of St. Joseph Catholic Hospital noted that 24 packs of the anesthesia drug, Bupivacaine spinal injection, was still in stock and all had inscriptions in a foreign language.

After a review of the findings, the LMHRA Management Team carried out the following Regulatory actions:

- The remaining 24 packs of Bupivacaine spinal injection found in the St. Joseph Catholic Hospital Pharmacy were removed from the premise and taken to the LMHRA's Central Office.
- The Regulatory lapses of G2 pharmacy relative to the labeling of the Bupivacaine spinal injection in a foreign language were referred to the LMHRA Hearing Board for further investigation
- The hearing Board, having done its investigation into the matter, recommended that G2 Pharmacy be fined the sum of US$10,000.00 (Ten thousand US Dollars) to which the G2 Pharmacy took an appeal. Having reviewed the Act of 2010 and the "Regulations on Mislabeling" and recognized that the recommended fine was far beyond the maximum fine for the offense, the management of LMHRA approved the appealed fine of $1,500.00 which the G2 Pharmacy has since paid.

- The Board of Directors also recommended that the LMHRA management team carry out the following actions:
    - Conduct Post Market Surveillance to remove all Bupivacaine Spinal Injection in circulation.
    - Plan and conduct refresher trainings for ADR reporters in health facilities
    - Develop a Standard Operating Procedure (SOP) relative to the importation of drugs in small quantities (orphan products)
    - Develop an information dissemination system that will promptly provide information on ADR to the general public.

The LMHRA assures the general public that it remains committed to its core mandate of protecting the health of the Liberian population by ensuring that only quality medicines and health products are in circulation in Liberia.

-30-

Signed: _____ 31-07-25

Momoh B. Siryon
Communications Manager, LMHRA