



**MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD**

PUBLIC NOTICE

**REQUEST FOR COMMENTS ON THE REGULATORY IMPACT
STATEMENTS ON THE PROPOSED PHARMACY AND
POISONS RULES, 2022.**

The Ministry of Health (“**Ministry**”) in consultation with the Pharmacy and Poisons Board (“**the Board**”) has developed 6 sets of proposed Pharmacy and Poisons Rules, 2022, to facilitate effective implementation of the provisions of the Pharmacy and Poisons Act, CAP 244 Laws of Kenya. The proposed rules have been subjected to public participation and comments therefrom incorporated.

The proposed rules include:-

- i. *Pharmacy and Poisons (Guidelines for the conduct of Clinical Trials) Rules, 2022;*
- ii. *Pharmacy and Poisons (Transportation of Pharmaceuticals) Rules, 2022;*
- iii. *Pharmacy and Poisons (Pharmaceutical Waste Management) Rules, 2022;*
- iv. *Pharmacy and Poisons (Pharmacovigilance and Post-Market Surveillance) Rules, 2022;*
- v. *Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022;* and
- vi. *Pharmacy and Poisons (Amendment) Rules, 2022.*

In compliance with section 6 of the Statutory Instruments Act No. 23 of 2013, Regulatory Impact Statements have been prepared about the proposed Rules. The Regulatory Impact Statements and proposed Rules are freely available on the Board’s website accessible via: <https://web.pharmacyboardkenya.org/> and also, on request, at the Board’s offices along Lenana Road, Nairobi during working hours.

This is therefore to request all persons likely to be affected by the proposed Rules to submit written comments on the Regulatory Impact Statements so as to reach the undersigned not later than fourteen (14) days from the date of publication of this notice in the following format:

Rule/Clause	Issue of concern	Justification	Recommendation

Written comments may be sent by way of email through feedback@pharmacyboardkenya.org or submission of written memoranda physically or by post to the nearest Ministry and/or Board offices within the specified period via the addresses below:

Pharmacy and Poisons Board
P.O. Box 27663-00506
Nairobi
feedback@pharmacyboardkenya.org

Cabinet Secretary
Ministry of Health
Afyā House, Cathedral Road
P.O. Box 30016-00100
Nairobi, Kenya
cshealth2015@gmail.com

The public is also notified that they can visit the Board’s offices and seek clarification(s) on specific issues regarding the proposed Rules and the Regulatory Impact Statements between 8:00am and 5:00 pm during official working days.

.....
DR. F. M SIYOI
CHIEF EXECUTIVE OFFICER