THIRD SCHEDULE r. 5 (2) (c)
LABELLING REQUIREMENTS
The final copy of the label of an investigational health product shall contain the following minimum information— (a) a statement indicating that the product is for "clinical trial purpose only"; (b) the recommended storage conditions; (c) the protocol code or identification; (d) the name, address and telephone number of the sponsor, contract research organisation or investigator; (e) the pharmaceutical dosage form, route of administration, quantity of dosage units, and in the case of open trials, the identifier and the potency; (f) the batch and code number; (g) a clinical trial reference code allowing identification of the clinical trial, site, investigator and sponsor, if not given elsewhere; (h) the identification number or treatment number and, where relevant, the visit number of a participant; (i) the directions for use; (j) the period of use in month and year format and in a manner that avoids any ambiguity; and (k) the complete physical address of the manufacturing site.

Made on the 8th June, 2022.

MUTAHI KAGWE,
Cabinet Secretary for Health.

LEGAL NOTICE NO. 96

THE PHARMACY AND POISONS ACT

(Cap. 244)

THE PHARMACY AND POISONS (PHARMACOVIGILANCE AND POST MARKET SURVEILLANCE) RULES, 2022

ARRANGEMENT OF RULES

Rule

PART I – PRELIMINARY

refurbishing or modifying the product, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf;

"medical device" means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose;

"passive surveillance" means that no active measures are taken to look for adverse effects other than the encouragement of health professionals and others to report safety concerns;

"parallel importer" means a person licensed to import medicinal substance other than the marketing authorization holder or his or her technical representative of the following medicinal substances which should have been granted marketing authorization in Kenya—

(a) patented medicinal substances under section 58(2) of the Industrial Property Act, 2001;

(b) non-patented medicinal substances;

(c) generic medicinal substances;

"pharmacovigilance" means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible health product related problem;

"post-marketing surveillance" has the meaning assigned under the Act;

"pharmacovigilance electronic reporting system" means a suite of software applications implemented by the Pharmacy and Poisons Board for collection and processing of information on suspected Adverse drug reactions or adverse events and suspected poor-quality health products or technologies;

"product" means a health product and technology;

"qualified person for pharmacovigilance" means an individual appointed by a marketing authorization holder or a parallel importer as the main person responsible for ensuring that the company meets legal obligations for monitoring of the quality, safety and efficacy of the product marketed in Kenya;

"quality control testing laboratory" means the National Quality Control Laboratory, the Pharmacy and Poisons Board Quality Control Laboratory and other sub-contracted quality control laboratories as defined by the Board;

"quality defect" means attributes of a health product or health technology or component which may affect the quality, safety or efficacy of the product, or which are not in line with the approved market authorization requirements;

"quarantine" means the isolating, holding and restricting movement, physically or by other effective means a medical product and health technology. During quarantine period the product is not available for distribution or use;

"rapid alert system" refers to a system designed to ensure a timely, proportionate, accurate and consistent response to health events arising from sub-standard and falsified health products and technologies which represent a significant threat to health and safety of the public;

"recall" means the removal of a specific batch of a health product and technology from the market for products that do not meet marketing authorization requirements including reasons relating to deficiencies in the quality, safety, efficacy or effectiveness;

"withdrawal" refers to the total removal of health products and technologies from the market for reasons relating to deficiencies in the quality, safety, efficacy leading to cessation of its market authorization;

"wholesale dealer" means entity or individual licenced as such by the Board and as provided by section 27 of the Act.

Objects and purpose.

4. The purpose of these Rules shall be to—

(a) improve patient care and safety in relation to the use of health products and technologies;

(b) improve public health and safety in relation to the use of medicines;

(c) facilitate the detection of problems related to the use of health products and technologies and the communication of the findings in a timely manner;

(d) facilitate the assessment of benefit, harm, effectiveness and risk of a health product or technology, leading to the prevention of harm and maximization of benefits of the health product or technology;

(e) encourage the safe, rational and more effective, including cost effective, use of medicines;

(f) increase the trust of patients on medication and health care system;

(g) enhance distribution of information needed to improve drug prescribing and regulation;

(h) promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public;

(i) strengthen the processes of monitoring quality, safety and efficacy of medical products and health technologies;

(j) enhance prevention, detection and response to substandard medical products and health technologies in Kenyan market;

(k) enhance monitoring of status of market authorization of medical products and health technologies in Kenya; and

(l) promote understanding, education training in post-marketing surveillance programs and activities and their effective communication to the public.

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(l) promote understanding, education training in post-marketing surveillance programs and activities and their effective communication to the public.

PART II — THE NATIONAL PHARMACOVIGILANCE SYSTEM

Establishment of the Centre.

5. (1) The Board shall establish a National Pharmacovigilance Centre which shall set up and manage the national pharmacovigilance and post marketing surveillance system to receive and maintain all relevant information about suspected adverse drug reactions and adverse events to health products or health technologies which have been authorised by the Board.

(2) The Centre shall be the single, government recognized integrated system with the clinical and scientific expertise to collect, collate, analyse and give advice on all information related to drug safety.

(3) The Centre shall, through the national system, collect, manage, assess, analyse, identify signals and communicate safety information related to health products and technologies authorised by the Board.

(4) The Centre shall consist of—

(a) the national pharmacovigilance and post marketing quality surveillance system with designated and qualified staff;

(b) the national spontaneous reporting system with reporting forms comparable to the international standards;

(c) the national database for collating and managing safety reports; and

(d) expert committees to provide technical assistance on causality assessment, risk management and case investigation of pharmacovigilance related issues.

(5) The system shall contain data and reports from—

(a) public, private and faith-based health facilities;

(b) other ministry departments, county health departments and public health programs;

(c) health practitioners, health organizations and institutions;

(d) marketing authorisation holders;

(e) regional economic communities;

(f) international agencies; and

(g) patients or members of the public.

Stakeholders under the system.

6. The system shall work with the support of the ministry responsible for matters related to health, County governments, healthcare providers, health regulatory bodies, the pharmaceutical industry, marketing authorisation holders, public health programs members of the public, development partners and other relevant stakeholders.

Roles and responsibilities of healthcare providers.

7. A health care provider shall—

(a) promote rational drug use;

(b) conduct patient education on adverse drug reactions and adverse events including counselling on medication use;

(c) detect and initiate appropriate clinical management and treatment of patients presenting with adverse reactions or events;

(d) report all suspected adverse drug reactions and adverse events and send the reports immediately to the County Vigilance focal persons or directly through the Pharmacovigilance Electronic Reporting System;

(e) utilize the collated data on adverse drug reactions and adverse events for decision making at the facility level; and

(f) participate in capacity building of other health care providers and public on pharmacovigilance.

Responsibility of patients and members of the public.

8. A patient or the general public shall report, to the Board, any suspected adverse effect or suspected poor-quality health product or technology dispensed to them.

Roles and responsibilities of public health programs.

9. The Ministry through its designated public health programs and in collaboration with the Board shall—

(a) provide public information during the launch of new drug regimens;

(b) ensure training of health facility staff in use of medicines or regimens and monitoring for any adverse events that may arise;

(c) conduct passive and active surveillance of medical products and health technologies in collaboration with the Board;

(d) when necessary, be called upon by the Board and to determine the risk-benefit assessment of health products and technologies, in order to update treatment guidelines and initiate new training and communications to health providers and the general public;

(e) provide technical support to the investigation teams on quality and safety issues at the County and Sub-County levels;

(f) conduct post-marketing quality surveys of health products and technologies;

(g) participate in activities of the National Pharmacovigilance and Post-marketing surveillance Technical Working Group;

(h) make programmatic decisions as concerns matters related to quality, safety and efficacy of health products and technologies;

(i) conduct education, training and advocacy to the relevant stakeholders;

(j) plan and budget for pharmacovigilance activities; and

(k) mobilize resources for pharmacovigilance and post marketing surveillance activities.

Role of county governments.

10. (1) The County governments shall, in collaboration with the Ministry responsible for matters related to health and the Board —

(a) plan and budget for pharmacovigilance activities at county level;

(b) implement pharmacovigilance and post market surveillance activities within the county;

(c) coordinate and participate in the investigations of serious adverse reactions, events, signals and quality defects of health products and technologies;

(d) conduct post market quality surveys of health products and technologies;

(e) submit safety reports and reports on suspected poor quality health products and technologies to the Board within the prescribed timelines;

(f) notify the Board in cases of quality defects that have high public health impact including quality defects that affect vaccines and other biological products within twenty-four hours;

(g) notify the Board on serious adverse events and serious adverse reactions within twenty-four hours;

(h) participate in training of healthcare professionals and the public on pharmacovigilance and post market surveillance in the county in collaboration with the other stakeholders;

(i) facilitate dissemination of feedback on pharmacovigilance and post marketing surveillance including information on product quarantine or recalls within 24 hours of receipt of communication, from the Board to the health care professionals where necessary; and

(j) collaborate with the National Pharmacovigilance and Post Marketing Surveillance Technical Working Group established under these Rules.

(2) The County Government shall designate a County Vigilance focal person to coordinate the implementation of the pharmacovigilance and post market surveillance activities within the County in collaboration with the Board.

(3) A person shall qualify for designation as the County vigilance focal person if that person has—

(a) at least Bachelor's degree in pharmacy; and

(b) valid practicing license issued by the Board.

Responsibilities of a marketing authorisation holders.

11. (1) A marketing authorization holder, parallel importer or local technical representative shall be responsible for the quality and compliance with the conditions of the marketing authorization and all other aspects of the health product or technology they have placed in the market.

(2) Every marketing authorization holder, local technical

representative and parallel importer shall establish and maintain a pharmacovigilance system for managing safety information of health products and technologies they have placed in the market.

(3) A marketing authorization holder or a parallel importer shall—

(a) appoint a qualified person to be responsible for pharmacovigilance;

(b) prepare reports to the Board in accordance with the requirements of the Act and these Rules;

(c) upon request by the Board, provide additional information necessary for the evaluation of the risks and benefits of a medicinal product;

(d) inform the Board of any prohibition or restriction imposed by the regulatory authorities of any country in which the medicinal substance or health technology is marketed and of any other new information which might influence the evaluation of the benefits and risks of the product in a timely manner;

(e) be responsible for the accuracy of the documents and of the data submitted;

(f) establish and maintain an updated pharmacovigilance system master file which shall be made available to the qualified person for pharmacovigilance;

(g) ensure that the pharmacovigilance system master file is readily available for inspection, at the site where it is kept;

(h) notify the Board on serious medical device (including in vitro diagnostics) incidents and any field safety corrective actions taken in a timely manner;

(i) submit to the Board, in electronic and hard copy, the pharmacovigilance system master file not later than seven days after receipt of the request from the Board; and

(j) submit to the Board a surveillance or data collection plan for review.

Qualified person for pharmacovigilance

12. (1) A person shall be qualified for appointment under rule 11(3)(a) if the person—

(a) is a resident of Kenya;

(b) has a Bachelor's Degree in Pharmacy;

(c) has a certificate, diploma, fellowship or post graduate training in good pharmacovigilance practices from an institution recognized by the Board; and

(d) has a valid practice license issued by the Board.

(2) A person appointed to be responsible for pharmacovigilance under rule 11(3)(a) shall—

(a) maintain the marketing authorization holder's pharmacovigilance system master file;

(b) have sufficient authority to influence the performance of the quality system and the good pharmacovigilance practices;

(c) have oversight over the functioning of the pharmacovigilance system in all relevant aspects including quality management system;

(d) act as a single point of contact for the Board on all matters relating to the product safety and quality of their marketed products including pharmacovigilance inspections;

(e) be aware of the validation status of the adverse reaction database if applicable, including any failures that occurred during validation and the corrective actions that have been taken to address the failures;

(f) prepare and submit safety reports that include the following to the Board through established channels and as stipulated by the Board—

(i) adverse events to health products and technologies;

(ii) periodic safety update reports and periodic benefit-risk evaluation reports;

(iii) company-sponsored pre- and post-registration study reports;

(iv) field safety corrective action reports and field safety notices;

(v) ongoing pharmacovigilance evaluation during the post-authorization period; and

(vi) field safety corrective action reports and field safety notices.

(g) ensure that any request from the Board for additional information deemed necessary for the evaluation of the risk-benefit ratio of a marketed product, is provided to the Board fully and promptly;

(h) oversee the safety profiles of the company's marketed products and any emerging safety concerns;

(i) ensure that all personnel involved in pharmacovigilance activities, which may include customer service and sales representatives etc. have their specific duties recorded in a written description and have adequate authority to carry out their responsibilities;

(j) ensure that all personnel involved in pharmacovigilance activities are aware of the principles of pharmacovigilance that affect them, and they receive relevant training;

(k) ensure that training is provided prior to implementation of new

or revised procedures and that the training records are maintained; and

(l) participate in post-authorization safety studies and provide results as requested by the Board.

Investigations for adverse drug event.

13. The Board shall conduct investigations, relating to a health product or technology where—

(a) a serious adverse reaction or event is reported;

(b) it is suspected or found that a product does not comply with the requirement of the Act;

(c) there is an international alert with regard to such a product;

(d) it is recalled in Kenya or in any other country;

(e) there is need for additional investigations into the product;

(f) there is need for educational initiatives to improve the safe use of the products;

(g) there is a change in the scheduling or manufacture of the product to make it safer;

(h) for regulatory and health promotion interventions, as the situation may warrant, including change in supply status or withdrawal; or

(i) the Board for any other reason considers it fit to conduct an investigation on the product.

Good pharmacovigilance practices.

14. Every marketing authorisation holder, health practitioner and other stakeholders in pharmacovigilance shall comply with good pharmacovigilance practice requirements issued by the Board.

PART III — POST-MARKETING SURVEILLANCE SYSTEM

Enforcement.

15. (1) The Board shall establish mechanisms to prevent, detect and respond to the risk of substandard and falsified medical products and health technologies.

(2) The Board shall implement and enforce regulatory actions to prevent and respond to risk of substandard and falsified medical products and health technologies. Such regulatory actions include but not limited to quarantine, recalls, withdrawals of medical products and health technologies, restriction of import or sale of products, suspension of registration, licences and marketing authorization or revocation of registration, licences and market authorizations.

Sampling of medical products and health technologies.

16. (1) An authorised officer who obtains a sample of any medical product for testing, examination or analysis shall notify the person or owner from whom the sample was obtained of his intention to submit a sample thereof to the Board for examination or analysis by an approved analyst.

(2) An authorized officer shall collect adequate quantities of the dosage unit of sample to allow for initial testing and repeat testing in cases of non-compliance and for any arising disputes.

(3) Every authorized officer or appointed officer shall follow the guidelines issued by the Pharmacy and Poisons Board regarding procedure of collecting samples for test, examination or analysis.

Recalls and withdrawals.

17. (1) The Board shall recall any medical product or health technology for which a notice has been issued by the Board to remove, ban or withdraw from use in accordance with section 3A(d), 3B(2)(l) and 3B(2)(m) of the Act, if the medical product does not meet the required standard or specification or its continued use would pose a risk to safety and health of the public.

(2) The Board shall undertake the following classes of recall—

(a) class I recall where there is a reasonable probability that the use of, or exposure to, a defective product will cause serious adverse health consequences or death;

(b) class II recall where the use of, or exposure to a defective product may cause temporary adverse health consequences, or where the probability of serious adverse health consequences is remote;

(c) class III recall where the use of, or exposure to a defective product is not likely to cause adverse health consequences.

(3) A person shall not sell, offer or expose for sale or supply medical product subjected to recall.

(4) The Board may recall any medical product or health technology based—

(a) on a certificate of analysis issued by the Pharmacy and Poisons Board Quality Control Laboratory;

(b) on the recommendation of Quality, Safety and Efficacy Committee;

(c) on safety alerts issued by the World Health Organization or any other competent National Regulatory Agency;

(d) on quality alerts issued by the World Health Organization or any other competent National Regulatory Agency; or

(e) on quality notification submitted to the Board by manufacturers or market authorization holders.

(5) The Board may recall such medical products or health technologies by—

(a) issuing a product recall notice on the Pharmacy and Poisons Board website;

(b) broadcasting or publishing to the general public through mass media; or

(c) issuing a product alert notice on receipt of reliable information of a falsified, smuggled, diverted, adulterated or prohibited medical product in circulation.

(6) A recall may be a permanent or temporary removal of medical product in order to correct a particular product quality defect or safety issue such as a labelling error.

(7) A recall shall be enforced on part of a consignment, one or more batches, or on the entire product, depending on the extent of the quality defect or safety (1) In the event of a recall, the Board shall—

(a) carry out investigations into the quality or safety issue;

(b) carry out an evaluation of the health risk posed by a product being recalled or considered for recall taking into account, among others, the following factors—

(i) whether any disease or injuries have already occurred from the use of the product;

(ii) whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health risk supported by scientific documentation or statements that the conclusion is the opinion of the individual making the health risk determination;

(iii) assessment of the degree of seriousness of the health risk to which the populations at risk would be exposed;

(iv) assessment of the likelihood of occurrence of the risk; and

(v) assessment of the consequences (immediate or long-range) of occurrence of the risk.

(c) assign the recall a classification in the form of Class I, Class II, or Class III, to indicate the relative degree of health risk of the product being recalled or considered for recall;

(d) ensure effective implementation of the recall;

(e) carry out special good manufacturing practices inspection of manufacturing site if deemed necessary by the Board;

(f) suspend or revoke certificate of registration and any related licenses for a period as shall be determined by the Board, if in the opinion of the Board—

(i) the quality defect or safety issue is persistently reported;

(ii) the quality defect or safety issue is resulting from negligence or deliberate omissions by the manufacturer; or

(iii) the findings of the Good Manufacturing Practice inspection are not satisfactory.

Responsibilities of Market authorization holders.

18. A market authorization holder shall—

(a) recall every defective batch, consignment or entire product of the particular product under recall;

(b) ensure recalls are implemented in an effective manner and within given time frames and in levels specified in the recall guidelines issued by the Board;

(c) inform the Kenya Medical Supplies Authority and other central procurement agencies of the recall to ensure recalls of products circulating in the public sector;

(d) inform the ministry responsible for matters related to health and the county governments of the recall action to ensure recalls of products circulating in the public sector;

(e) collaborate with the Board on action taken to prevent or reduce risks posed to the health and safety of the public by the specific batch or entire product;

(f) liaise with manufacturer if the market authorization holder is not the manufacturer of the medical product, to investigate the reasons for the reported quality defect or safety issue and to implement corrective and preventive actions;

(g) correct the quality defect or safety issue and seek approval from the Board before re-supplying the product to the market;

(h) provide certificates of analysis for new batches as requested by the Board;

(i) release new batches to the market only after obtaining approval from the Board;

(j) voluntarily recall a medical product in part or whole if the Board approves such a recall after evaluation of the reasons and justification of the recall;

(k) inform the Board within twenty-four hours (24) of receiving information on the quality defect or safety issue that forms the basis of the recall;

(l) furnish the Board with all such information that is relevant to recalls as and when required by the Board;

(m) submit to the Board a weekly progress report of recall and the final report after completion of a recall which includes reconciliation between supplied and recovered quantities of the product; and

(n) carry out the recall within the time frame specified in the recall guidelines prescribed by the Board and as applicable to each class of defect.

Establishment of the Technical Working Group.

19. (1) The Board shall establish a working group to be known as the National Pharmacovigilance and Post-Marketing Surveillance Technical Working Group.

(2) The Technical Working Group shall comprise of the following members—

(a) one representative from the Directorate of Pharmaceutical Services, Ministry of Health who shall be the chair of the technical working group;

(b) two representatives from the Board's department responsible for Pharmacovigilance and Post Market Surveillance who shall be the secretariat;

(c) one representative from each of the Ministry of Health's Public Health Programs;

(d) one representative from Kenya Medical Supplies Authority;

(e) one representative from Mission for Essential drugs and supplies;

(f) two representatives from the National Quality Control Laboratory;

(g) one representative from teaching institutions offering programs in pharmacovigilance and post market surveillance;

(h) one representative from research institution relevant for pharmacovigilance and post market surveillance;

(i) one representative from Council of Governors;

(j) one representative from county governments with experience in pharmacovigilance and post market surveillance; and

(k) other members who shall be co-opted on ad hoc basis.

(3) The National Pharmacovigilance and Post-marketing surveillance Technical Working Group shall—

(a) provide technical guidance on the design, development and implementation of pharmacovigilance and post-marketing quality surveillance guidelines in Kenya including post-marketing quality surveillance forms and procedures;

(b) oversee the development and implementation of pharmacovigilance and post marketing surveillance strategies;

(c) provide technical guidance for the implementation of pharmacovigilance and post-marketing quality surveillance activities to ensure quality, safe and efficacious medical products and health technologies;

(d) provide technical assistance and guidance on the development of databases and information sharing system on quality profiles of medical products and health technologies;

(e) identify the logistical and resources needs for the implementation of pharmacovigilance and post-marketing quality surveillance activities;

(f) provide a forum for private and public sector groups to consider and recommend policy direction on pharmacovigilance and post marketing surveillance program in Kenya;

(g) participate in the review of training and sensitization materials for health care workers;

(h) provide a platform for the development, review and approval of pharmacovigilance and post-marketing quality surveillance messages for the health care workers and the general public;

(i) mobilize partners and advocate for funds for pharmacovigilance and post marketing surveillance research and surveys;

(j) provide a platform for the review and dissemination of reports on status of pharmacovigilance and post-marketing quality surveillance in Kenya ; and

(k) provide a platform for mutual information sharing on risk communication among the Hospital Medicines and Therapeutic Committees.

Manufacture of health product technologies.

20. (1) A person shall not manufacture, import, export, supply, possess or offer for sale falsified medical product or health technology.

(2) A falsified medical product shall include—

(a) a product which is deliberately or fraudulently mislabelled with respect to its identity;

(b) a product manufactured under a name which belongs to another product;

(c) the label or container bears the name of an individual or a company which is fictitious or does not exist and purports to be the manufacturer of the medical product;

(d) it has been substituted wholly or in part by any other medicinal substance;

(e) it purports to be a product of a manufacturer of whom it is not truly theirs;

(f) it is a medical product which or the container or labelling of which, without authorization, bears;

(g) the trademark, trade name or any other identifying mark, imprint, or device; or

(h) the likeness of manufacturer of medical product, processor, packer or distributor, other than the person who in fact manufactured, processed, packed, or distributed the medical product and which thereby falsely purports or is represented to be the product of or to have been packed or distributed by the other product manufacturer, processor, packer or distributor.

Surveillance system.

21. The National Post-marketing quality surveillance system established under 5 (1) shall comprise of the—

(a) the national reporting system for substandard and falsified products;

(b) the National Pharmacovigilance and Post-marketing Surveillance Technical Working Group; and

(c) the quality control testing laboratories.

Post-marketing surveillance approaches.

22. (1) The Board shall in order to ensure effective post-marketing surveillance of health products and technologies undertake—

(a) active Post-marketing quality surveillance; and

(b) proactive Post-marketing quality surveillance.

(2) In order to undertake effective active post-marketing quality surveillance, the Board shall—

(a) establish a national reporting system for suspected substandard and falsified medical products and health technologies;

(b) ensure the reporting system shall be both electronic and manual; and

(c) establish a system of investigating and review of reports on substandard and falsified medical products and health technologies and subsequent implementation of regulatory actions.

(3) The Board shall ensure that the system established under paragraph (2)(c) can support simplified reporting, search analysis, tracking and improved data quality.

(4) In order to undertake effective proactive post-marketing quality surveillance, the Board shall—

(a) carry out routine scientific, systematic, structured, risk based quality surveys to cover expanded scope of medical products and health technologies; and

(b) apply findings from post-marketing quality surveys to implement regulatory actions.

Roles of patients and the public.

23. Any patient or member of the public shall be required to—

(a) report any suspected substandard and falsified medical product dispensed to them to a healthcare provider or the nearest health facility or directly to the Board through email, telephone, walk in, or electronic reporting system;

(b) submit samples of suspected substandard and falsified products to a healthcare provider, or to the nearest healthcare facility or to the Board offices where applicable;

(c) report any deviations in handling and storage requirements to the Board;

(d) comply with regulatory actions in collaboration with the Board, including quarantine or recall of medical products; and

(e) support, detect and report suspected substandard and falsified medical products health technologies and submit the reports to the Board through the electronic reporting system or manual reports and copy to County Vigilance Focal Person.

Role of health care providers.

24. In order to facilitate post-marketing surveillance, every health care provider shall—

(a) report any suspected substandard and falsified health product and technologies they may be aware of to the County Vigilance focal person or directly to the Board through email, telephone, walk in, or electronic reporting system;

(b) submit samples of suspected substandard and falsified products to a healthcare provider or to the nearest healthcare facility or to the Board offices where applicable;

(c) report any deviations in handling and storage requirements to the Board;

(d) implement regulatory actions in collaboration with the Board, such regulatory actions include quarantine, recall and withdrawal of health products and technologies;

(e) detect and report suspected substandard and falsified health products and technologies and submit the reports to the Board through the electronic reporting system and copy to County Vigilance Focal Person; and

(f) submit reports on antimicrobial use and consumption to the Board.

Role of market authorization holders.

25. (1) A market authorization holder shall ensure that his or her products meet the quality, safety and efficacy at all times while the product is on the Kenyan market.

(2) A market authorization holder shall share data on quality surveillance detected and any local reports on quality of medical products which are brought to their attention, whether reported spontaneously by healthcare professionals, consumers or occurring in the context of market surveillance study, with the Board within seventy-two hours of receipt of the data or report.

(3) Where, in the event of reporting referred in subrule (1), and where cases of quality defect have high public health impact, a market authorization holder shall—

(a) implement directives of the Board on investigations of quality of the health products and technologies as well as implementation of regulatory actions;

(b) collaborate with the Board by providing any information or data on quality of their products when required to do so by the Board;

(c) inform the Board about product deterioration or detection of substandard and falsified products within twenty-four hours, from the time the information becomes available;

(d) establish an emergency plan to ensure effective implementation of recalls or withdrawals of products with voluntary or statutory recalls;

(e) ensure effective and efficient recall action or withdrawal of medical products where applicable;

(f) notify the Board, within seven days, of any quality defects or regulatory actions affecting their products in other markets, other than Kenya, by submitting a report on products similar to those circulating in Kenya including the impact of such quality defects and regulatory actions on the quality of products circulating in Kenya;

(g) submit data on antimicrobials supplied to the market on quarterly basis, or when required by the Board; and

(h) in cases of quality defects or problems with use of medical devices (including in-vitro diagnostics—

(i) follow corrective actions or preventive actions procedures under the manufacturer 's or distributor's quality management system;

(ii) inform the users about the problem of the medical device (including in-vitro diagnostic);

(iii) make corrections to the device or in-vitro diagnostics; and

(iv) removal i.e., recall the medical device (including in-vitro diagnostics) from the market where applicable;

(i) notify the Board where the following actions need to be taken as regards medical devices (including in-vitro diagnostics)—

(i) correcting product on the market;

(ii) removing product from the market; or

(iii) issuance of field safety corrective action;

(iv) issuance of field safety notice;

(v) advising users of an issue with a medical device.

(4) All the requirements applying to market authorization holders shall apply to parallel importers.

Role of manufacturers.

26. A manufacturer shall for the purposes of post-marketing surveillance—

(a) cooperate with the Board on matters of investigations on quality defects of medical products including among others—

(i) carrying out internal investigations and preparing root cause analysis reports, submitting the reports to the Board;

(ii) submitting data or information as required by Board and implementation of the proposed corrective and preventive actions; and

(iii) updating the board on implementation of and participating in special Good Manufacturing Practice inspections by the Board to investigate quality defects;

(b) submit a root cause investigation report to the Board within two weeks from the date of receipt of the request from the Board;

(c) inform the Board, following detection of non-compliance during manufacturing for a product that is already in the Kenya market, within seventy-two hours after the information becomes available;

(d) implement directives of the Board on investigations of quality of the products and implementation of regulatory actions;

(e) submit data on antimicrobials supplied to the market on quarterly basis, or when required by the Board;

(f) notify the Board where the following actions need to be taken as regards medical devices (including in-vitro diagnostics)—

(i) correcting product on the market;

(ii) removing product from the market;

(iii) issuance of field safety corrective action; or

(iv) issuance of field safety notice;

(g) in cases of quality defects or problems with use of medical devices (including in-vitro diagnostics);

(h) follow corrective actions or preventive actions procedures under the manufacturer's or distributor's quality management system;

(i) inform the users about the problem of the medical device (including in-vitro diagnostic); and

(j) make corrections to the device (including in-vitro diagnostic) and recall the medical device (including in-vitro diagnostic) from the market where applicable.

The Quality Control Testing Laboratory.

27. The Quality Control Testing Laboratory shall for the purposes of post-marketing surveillance—

(a) test health products and technologies on request of the Board or any other entity;

(b) prescribe testing methods, standards or specifications based on internationally acceptable standards including pharmacopeia standards;

(c) issue Certificates of Analysis on each sample tested to the clients in the format developed by the Board;

(d) participate in development and review of post-marketing surveillance protocols;

(e) train staff from the Board and other staff on MiniLab activities; and

(f) participate in the activities of the National Pharmacovigilance and Post-marketing Surveillance Technical Working Group.

Role of wholesale dealers.

28. The Wholesale dealers shall—

(a) participate in matters of investigations on quality defects of health products and technologies;

(b) submit data on antimicrobials supplied to the market on quarterly basis, or when required by the Board;

(c) notify the Board where the following actions need to be taken as regards medical devices, including in-vitro diagnostics—

(i) correcting product on the market;

(ii) removing product from the market; or

(iii) issuance of field safety corrective action;

(iv) issuance of field safety notice;

(v) advising users of an issue with a medical device;

(d) in cases of quality defects or problems with use of medical devices (including in-vitro diagnostics)—

(i) follow corrective actions or preventive actions procedures under the manufacturer's or distributor's quality management system;

(ii) inform the users about the problem of the medical device (including in-vitro diagnostic;

(iii) make corrections to the device or including in-vitro diagnostics; and

(iv) removal i.e., recall the medical device (including in-vitro diagnostics) from the market where applicable.

Role of the central procurement agencies.

29. The central procurement agencies shall in order to support post-marketing surveillance—

(a) participate in the activities of the National Pharmacovigilance and Post-marketing Surveillance Technical Working Group;

(b) participate in investigations on quality defects of medical products;

(c) share post-marketing quality surveillance data, and any local reports on quality of medical products which are brought to their attention, whether reported spontaneously by healthcare professionals or consumers or occurring in the context of market surveillance study, with the Board within seventy-two hours of receipt of the data or report and immediately in cases where the quality defect has high public health impact.

Role of the Board.

30. The Board shall for the purposes of post-marketing—

(a) receive and review reports on suspected poor quality medical products from healthcare providers, County vigilance focal persons, public, Central procurement agencies, market authorization holders and manufacturers;

(b) investigate suspected sub-standard and falsified medical products and health technologies;

(c) implement risk based expanded post-marketing quality surveys to cover broad category of products;

(d) implement, oversee and enforce regulatory actions including quarantine, recalls, suspension of marketing authorization and suspension of manufacturing licenses;

(e) provide feedback to reporters of poor-quality medical products on completion of the investigation report;

(f) disseminate findings from post-market surveillance activities to all relevant stakeholders;

(g) establish the Quality, Safety and Efficacy Committee which shall be responsible for the review of investigation reports and findings of post-market surveillance activities and make recommendations for appropriate regulatory actions;

(h) establish mechanisms for the coordination, communication and involvement of all relevant stakeholders and various departments or units within the Board in post-marketing surveillance programs;

(i) establish and provide secretariat to the National Pharmacovigilance and Post-Marketing Surveillance Technical Working Group;

(j) conduct advocacy, training, education and sensitization on post-marketing surveillance related activities;

(k) develop and disseminate information, education and communication materials;

(l) carry out communication to healthcare providers and the public on market surveillance related activities;

(m) maintain database on antimicrobial consumption in Kenya;

(n) maintain a rapid alert list;

(o) notify other National Regulatory Authorities and the World Health Organization on falsified products, where appropriate;

(p) participate in the World Health Organisation member state mechanism on substandard and falsified products;

(q) carry out routine analysis of quality data to inform regulatory actions and policy decisions;

(r) rely on and recognize regulatory decisions related to quality, safety and efficacy of medical products and health technologies that are made in other jurisdictions, where the Board considers it applicable to Kenya; and

(s) partner with stakeholders on post marketing surveillance activities as and when needed.

(t) receive and evaluate field safety corrective actions for medical devices (including in-vitro diagnostics);

(u) monitor implementation of field safety corrective actions for medical devices (including in-vitro diagnostics);

(v) collaborate with regional and international organizations on matters of quality, safety and efficacy of health products and technologies;

(w) collaborate with Ministry of Health to establish and implement a system for reporting on antimicrobial use and consumption by healthcare providers, importers, marketing authorization holders and local manufacturers of antimicrobial agents.

Rapid alert system.

31. (1) The Board shall establish a rapid alert system designed to ensure a timely, proportionate, accurate and consistent response to health events arising from sub-standard and falsified medical products which represent a significant threat to health and safety of the public.

(2) The Rapid alert system shall be applied to transmit alerts on quality, safety and efficacy of medical products and health technologies, alerts which cannot permit any delay.

(3) The Rapid alert system shall be triggered after new information on public health is received from any source, reviewed and validated and determined that the quality defect presents critical risk to public health.

(4) Pursuant to these Rules, the sources of information may include—

(a) market authorisation holder;

(b) patients or members of the public;

(c) media;

(d) healthcare providers;

(e) manufacturers;

(f) central procurement agencies; and

(g) other National Regulatory Authorities, Literature review or international organizations like the World Health Organization.

(5) A rapid alert notification shall include—

(a) quality defects and medical device deficiencies identified by the Board that requires urgent regulatory actions including Class I recalls, product withdrawal and product quarantine;

(b) quality defects for medical products of high public health impact including, among others, vaccines, parenteral formulations, male latex condoms, female condoms, surgical gloves, sutures;

(c) World Health Organisation alerts of finished products and Active Pharmaceutical Ingredients regarding safety issues;

(d) follow up actions on rapid alert notification;

(6) The Board may issue further guidance on the rapid alert system.

PART IV —GENERAL PROVISIONS

Offences.

32. A marketing authorisation holder, local technical representative or parallel importer or health care provider who—

(a) omits important safety warning;

(b) fails to report serious adverse reaction or event;

(c) delays or fails to submit safety reports to the Board; or

(d) fails to comply with the requirements of these Rules;

commits an offence and shall be liable, upon conviction to the penalty set out in section 51 of the Act.

Pharmacovigilanc Assessment and Inspections.

33. (1) The Board shall carry out pharmacovigilance audits and good pharmacovigilance practices inspections on manufacturers, marketing authorization holders, local technical representatives, parallel importers, distributors and any outsourced persons or companies in order to ensure compliance with good pharmacovigilance practice and these Rules.

(2) The Board shall conduct routine inspections every three years and may conduct frequent inspections on a case-to-case basis depending on other considerations such as risk-based inspections.

(3) Upon completion of the inspection under this regulation, the Board shall issue a certificate of good pharmacovigilance practices, in the Form set out in the Schedule, to manufacturers, marketing authorization holders, local technical representatives, parallel importers and outsourced persons or companies who have complied with the inspection.

(4) The Board shall periodically conduct pharmacovigilance assessments for the public health programs, health facilities, marketing authorization holders and central procurement agencies using such tools as the Board may determine from time to time.

Safety studies.

34. For a period of three years or such other period as may be determined by the Board, after the initial placing of a product in the Kenyan market, the Board may request that the marketing authorization holder to arrange for specific pharmacovigilance data to be collected from targeted groups of population or under specific conditions.

International collaboration for pharmacovigilanc activities.

35. The Board shall work closely with other regulatory authorities at regional and international level, development partners and the World Health Organisation for purposes of sharing information on safety issues and anticipated regulatory action.

Reliance.

36. The Board shall consider and rely on pharmacovigilance decisions from other competent national, regional and international regulatory authorities, where necessary.

SCHEDULE: (r.33(3)

CERTIFICATE OF GOOD PHARMACOVIGILANCE PRACTICES

Pharmacy and Poisons Board	CERTIFICATE OF COMPLIANCE WITH GVP	FOM023/VMS/SOP/021
		Rev No: 0

Certificate of Compliance Form: FOM023/VMS/SOP/021

On the basis of the inspection carried out on [date] _____ we certify that the company/entity indicated on this certificate:

Name of company/entity: .....

Postal address: .....

Physical address (building, road/street, City/town): .....

.....

complies with Good Pharmacovigilance Practices in Kenya.

This certificate remains valid until [date] _____. It becomes invalid if areas certified herewith are changed or if the company/entity is no longer considered to be in compliance with GVP.

Date:

Note:

1. This certificate certifies the status of the company/entity listed in the certificate
2. This certificate shall remain valid for a period of 3 years from the date of issue, but can be revoked at any time if there is evidence that the company/entity no longer complies with the current PPB Pharmacovigilance regulations.

Pharmacy and Poisons Board	NOTICE OF CONCERN LETTER	FOM024/VMS/SOP/021
		Rev No

Notice of concern Letter Form: FOM024/VMS/SOP/021

Ref No.....

RE: NON- COMPLIANCE WITH GOOD PHARMACOVIGILANCE PRACTICES

On basis of the inspection carried out on (Dates of inspection) ..... we certify that at the time of inspection (Name of the company/entity inspected) ....., located at (Physical address of the company/entity) ....., DID NOT Comply with current Good Pharmacovigilance Practices for all the activities undertaken at the site.

You may however apply for re-inspection of the facility once corrective actions contained in the report attached to this letter have been addressed. The inspection however will not be undertaken earlier than six months from the date of this letter.

Thank you for your cooperation in this matter.

Made on the 8th June, 2022.

MUTAHI KAGWE,
Cabinet Secretary for Health.