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REPUBLIC OF KENYA

Ministry of Health

PHARMACY AND POISONS BOARD

GUIDELINES FOR THE ESTABLISHMENT OF QUALIFIED PERSONS FOR PHARMACOVIGILANCE

JANUARY 2023

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For clarifications, comments, or suggestions, please contact:

The Chief Executive Officer

Pharmacy and Poisons Board

P.O. Box 27663-00506, Nairobi

Telephone: 0709 770 100, 0795 734 049

Email: info@pharmacyboardkenya.org, pv@pharmacyboardkenya.org

Website: www.pharmacyboardkenya.org

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Prepared by Principal Regulatory Officer

Name..... Dr Nambwa Pamela .....

Sign..... .....

Date..... 17/01/2023 .....

Reviewed by Director

Name..... DR AHMED I. MOHAMED .....

Sign..... .....

Date..... 19/01/2023 .....

Checked by HQM

Name..... Immaculate Naibei .....

Sign..... .....

Date..... 19/01/2023 .....

Authorized by Chief Executive Officer

Name..... DR FRED MOIN SIYOI .....

Sign..... .....

Date..... 19/1/2023 .....

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Abbreviations and Acronyms

ADE	Adverse drug Event
FDA	Food and Drugs Authority
GVP	Good Pharmacovigilance Practice
MAH	Market Authorization Holder
MIPV	Medicines Information and Pharmacovigilance
PBRER	Periodic Benefit Risk Evaluation Report
PPB	Pharmacy and Poisons Board
PSMF	Pharmacovigilance System Master File
PSUR	Periodic Safety Update Report
QMS	Quality Management Systems
QPPV	Qualified Persons for Pharmacovigilance
SPC	Summary of Product Characteristics

Glossary of terms

Term	Definition
Adverse Events	Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment.
Adverse Drug Reaction	A response to a medicinal product which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological conditions.
The Board	The Pharmacy and Poisons Board
Distributor	An agent who supplies goods to retailers.
Focal person for Pharmacovigilance	An individual responsible for monitoring safety of their marketed products
Health Technologies	Application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives.
International Conference for Harmonization	Technical requirements for registration of pharmaceuticals for human use.
Local Technical representative	A person or company appointed by the manufacturer or the Marketing Authorization Holders to import, receive as donation, distribute or sell a medicinal product in Kenya.
Manufacturer	A person or a body who sells a product under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person or the body, and who is responsible for designing, manufacturing, assembling, processing, labeling, packaging, refurbishing or modifying the product, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.
Marketing Authorization Holder	A person or company authorized by the Board to manufacture, import, receive as donation, distribute or sell a medicinal product in Kenya.
Health Products	Any products used to diagnose, treat or care for patients.

Periodic Benefit-Risk Evaluation Report	An update of the worldwide marketing experience of a medicinal product at defined times with focus on formal evaluation of benefit in special populations at defined times during the post-registration period.
Periodic Safety Update Report	A regular update of the world-wide safety experience of a medicinal product at defined times during post-registration period.
Pharmacovigilance	The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.
Qualified Person for pharmacovigilance	An individual appointed by a Marketing Authorization Holder (MAH) as the main person responsible for ensuring that the company (the MAH) meets its legal obligations for monitoring the safety and quality of the product marketed in Kenya.
Risk Management Plan	A systematic approach and set of Pharmacovigilance activities and interventions designed to identify, characterize, prevent or minimize risks relating to medicinal products, and the assessment of the effectiveness of those interventions and how these risks will be communicated to the Board and the general population.
Urgent Safety Restriction	an interim change, due to new information having a bearing on the safe use of the medicinal product, to the product information concerning particularly one or more of the following items in the summary of product characteristics: the indications, posology, contraindications, special warnings and special precautions for use and undesirable effects. In rare cases the changes may also relate to quality problems requiring a change of the SmPC labeling or Package Leaflet.

Acknowledgment

The Pharmacy and Poisons Board acknowledges the contribution of the following in the research and compilation of these guidelines from the Ministry of Health, our stakeholders, and Partners.

We take this early opportunity to thank all the pharmaceutical manufacturers, distributors, retailers, and respondents who offered their valuable contributions to the development and editing of this guideline.

Preface

The Pharmacy and Poisons Board (PPB) is the authority mandated, by Cap 244 of the Laws of Kenya, to regulate the Practice of Pharmacy and the manufacture and trade of drugs and poisons.

The Pharmaceutical Industry has seen rapid growth since the enactment of the Act. Despite the obvious benefits of Health Products and Technologies, they are known to have a possibility of causing adverse events, which can be serious or even fatal. The safety and quality of these Health Products and Technologies must continuously be monitored by key players in the industry to ensure patient's safety.

In order to continuously monitor the quality and safety of the marketed products in Kenya, the Pharmacy and Poisons Board has been actively involved in designing tools and guidelines for the detection and reporting of suspected quality and safety issues related.

In order to engage and involve the Pharmaceutical Industry this document has been developed to provide guidance for the establishment of Qualified Persons for Pharmacovigilance (QPPV) by Market Authorization Holders in order to enhance the safety monitoring of their products.

This is the second edition of QPPV guideline and we undertake to continuously review it and incorporate up-to-date practices, as may be necessary for our setting, hence feel free to send us your feedback.

Dr. Ahmed Mohammed

Director, Health Products and Technologies

Foreword

Medical Products and Health Technologies have significant benefits to our lives and lead to a significant reduction in morbidity and mortality. However, even though their beneficial effects cannot be over-emphasized, they have the potential for producing adverse or unwanted events no matter how skillfully they are used.

The Pharmacy and Poisons Board, the National Regulatory Authority in Kenya, has been implementing strategies aimed at ensuring that products used in Kenya are safe, efficacious, of good quality, and are supplied and handled by qualified personnel. Safety and efficacy surveillance of Health Products and Technologies by Market Authorization Holders has in the past not been emphasized. To address this, the Pharmacy and Poisons Board has developed Guidelines for the establishment of qualified persons for Pharmacovigilance (QPPV). The QPPV is necessary to ensure that MAH is actively involved in the monitoring of the safety and quality of Medical Products and Health Technologies.

This document sets out to guide Market Authorization Holders on the operations of the QPPV. All MAHs are encouraged to actively participate in pharmacovigilance to monitor and report all quality and safety related to their Health Products and Health Technologies to help safeguard the health of all Kenyans

Dr. F. M. Siyoi,

Chief Executive Officer, Pharmacy and Poisons Board

Executive summary

The Pharmacy and Poisons Board as the National Medicines Regulatory Authority in Kenya has the responsibility of ensuring the quality, safety and efficacy of Health Products and Health Technologies. This guideline describes the obligations of the Marketing Authorization Holder to set up a pharmacovigilance system master file through the establishment of qualified persons for pharmacovigilance in order to ensure they collect, collate and evaluate information about suspected adverse reactions and quality problems of products it puts into the Kenyan market. These guidelines apply to all entities that have the authorization to put Health Products and Health Technologies into the Kenyan market.

MAH shall be required to have a QPPV person at his disposal who shall meet specific required qualifications as stipulated in the guideline. The QPPV shall be the contact person between the Board and MAH and hence shall perform all the roles of a QPPV. From time to time, as shall be stipulated in the Good Pharmacovigilance Practice Guidelines, the Board shall carry out pharmacovigilance inspections at the MAH offices and at the outsourced offices in order to ensure compliance with the law and this Guideline.

Regulatory sanctions shall be applied to the MAH, local representative, manufacturer, and/or the QPPV in the case of non-compliance to the regulations in these guidelines.

The sanctions shall depend on whether the non-compliance shall be critical, major, or minor.

This guideline should be read and used alongside the Guidelines on the Safety and Vigilance of Health Products and Technologies and the Pharmacovigilance and Post Marketing Surveillance Rules 2022

1. Introduction

1.1. Background

The World Health Organization defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problem. The ultimate goal of pharmacovigilance is to improve the safe and rational use of Health Products and Technologies, thereby improving patient care and protecting the health of the public.

The Pharmacy and Poisons Board as the National Regulatory Authority in Kenya has the responsibility of ensuring the quality, safety, and efficacy of HPTs. Marketing Authorization Holders/Manufacturers as owners of these products in Kenya have the responsibility of ensuring that their products in the Kenyan market meet the highest standard of quality, safety, and efficacy. The Marketing Authorization Holders/Manufacturers shall be responsible for the products they import for as long as they are in the Kenyan market.

This guideline describes the obligations of the Marketing Authorization Holders to set up a pharmacovigilance system master file through the establishment of qualified persons for pharmacovigilance in order to ensure they collect, collate and evaluate information about suspected adverse reactions and quality problems of products it puts into the Kenyan market. The ultimate goal is to ensure that HPTs available on the Kenyan market are safe, efficacious, of good quality, and continue to provide a satisfactory benefit-risk balance.

These guidelines have been adapted mainly from the European Medicines Agency's Guidelines for Good Pharmacovigilance Practices (GVP), which

currently provide the most comprehensive description of best practices in safety monitoring and reporting for marketing authorization holders. Regionally adaptations include the Ghana FDA guidelines for the establishment of QPPV.

The guidelines provide detailed guidance for marketing authorization holders on establishing and maintaining a pharmacovigilance system including its quality management system, pharmacovigilance system master file, adverse reaction reporting, risk management, post-authorization safety studies, risk communication, and pharmacovigilance audit.

This document is to be used in conjunction with other existing relevant Health Products and Health Technologies guidelines and policies in the country. The requirements outlined herein are to be considered general guides, to be adapted to ensure the marketing authorization holder achieves compliance with regulatory objectives.

These guidelines are hereby promulgated for information, guidance and strict compliance by the Pharmaceutical Industry including local representatives appointed by Marketing Authorization Holders/Manufacturers whose products have been given marketing authorization in Kenya on the requirements and responsibilities of Qualified Person for Pharmacovigilance, especially when dealing with post marketed medicines safety and quality related issues.

1.2. Legal framework

The regulation for the conduct of pharmacovigilance activities is governed according to Pharmacy and Poisons Act, Cap 244 Laws of Kenya Subsidiary Legislation, Pharmacy, and Poisons (PV/PMS) Rules 2022 charted out in the mission “to protect the health of the public by regulating the profession of pharmacy and ensuring quality, safety and efficacy of Health Products and Technologies.”

1.3. Scope

These guidelines apply to all entities that have the authorization to place a product (HPT) in the Kenyan market. The marketing authorization holders include but are not limited to Pharmacy and Poisons Board (PPB) license holders, individuals, public and private institutions, local and international manufacturers, importers/parallel importers, and donors of Health Products and Technologies. These guidelines apply to all products registered in the country.

2. Requirements

2.1. General Requirements

The Marketing Authorization Holder (MAH) shall permanently and continuously have at his/her disposal an appropriately qualified person responsible for Pharmacovigilance (QPPV) residing in Kenya.

The MAH shall:

a. Ensure provision of training in Pharmacovigilance to the QPPV
b. Ensure that the QPPV has sufficient authority to:
    i. Implement pharmacovigilance activities as listed in section 5.1
    ii. Participate in Risk Management Planning when necessary
    iii. Participate in the preparation of regulatory action in emerging safety concerns e.g., variations, urgent safety restrictions, and, as appropriate, communication to Patients and Healthcare Professionals.
    iv. Influence the performance of the quality system and the pharmacovigilance activities of the marketing authorization holder.
    v. Information to be submitted to the Board by the MAH.

c. Ensure that there are appropriate processes, resources, communication mechanisms, and access to all relevant information for the fulfillment of the QPPV's responsibilities and tasks.
d. Have written a contract with the QPPV.

The MAH shall submit the following information, via an official letter, to the Board relating to the QPPV:

i. Curriculum Vitae including key information on the job description of the QPPV, contact details including but not limited to the name, telephone, fax and email, postal and official working address as well as emergency contact details.
ii. Description of the responsibilities guaranteeing that the QPPV has sufficient authority over the pharmacovigilance system in order to promote, maintain and improve compliance including the reporting structure.
iii. Details of backup arrangements to apply in the absence of the qualified person responsible for pharmacovigilance; and
iv. A list of tasks that have been delegated by the qualified person for pharmacovigilance and to whom these tasks have been delegated.

Any change or update to the above shall be communicated to the Board within 30 calendar days.

2.2. Specific Requirements

2.2.1. Qualifications of QPPV

a. The qualified person for pharmacovigilance (QPPV) shall have minimum
requirement of a Bachelor's Degree in Pharmacy, with additional certificate/diploma/fellowship or postgraduate training in good pharmacovigilance practices (GVP) from institutions recognized by Pharmacy and Poisons Board.
b. The qualified person responsible for Pharmacovigilance shall in addition receive a mandatory refresher GVP training facilitated by the MAH in accredited/recognized institutions by the Board.
c. The refresher training shall be carried out at least once in two years and evidence of the same submitted to the Board upon request or during audits/inspections.
d. Have knowledge of applicable Kenyan safety monitoring legislation

and guidelines and international standards for good pharmacovigilance practices.

e. Demonstrate GVP knowledge in the implementation of activities stipulated in the MAHs pharmacovigilance system master file.
f. The QPPV shall have a current letter of designation from the Pharmacy and Poisons Board as the QPPV pharmacist and must produce the same at the time of pharmacovigilance inspections.
g. The QPPV shall be qualified by pertinent training or experience relevant to their assigned responsibilities.

3. Back-up QPPV

There shall be backup procedures in the case of the absence of the QPPV and shall be accessible through the QPPV's contact details.

i. The QPPV shall ensure that the backup person has all the necessary information to fulfill the role.
ii. A backup QPPV shall meet all the requirements of a QPPV.
iii. The backup QPPV shall receive pharmacovigilance training appropriate for his/her roles.
iv. In addition to the above, the backup QPPV shall have knowledge of applicable Kenyan safety monitoring legislation and guidelines and international standards for Pharmacovigilance and also demonstrate (e.g., through qualifications and training) that he/she has knowledge of the key pharmacovigilance activities performed as part of the MAH's pharmacovigilance system and how to implement them.
v. Back-up QPPV shall also reside in Kenya.

4. Roles and Responsibilities

4.1. Qualified Persons for Pharmacovigilance (QPPV)

The qualified person responsible for pharmacovigilance shall be available at all times at the marketing authorization holder or local technical representative when needed and be responsible for;

a) The maintenance of the marketing authorization holder's pharmacovigilance system master file and therefore shall have sufficient authority to influence the performance of the quality system and the good pharmacovigilance standards and to promote, maintain and improve compliance with the legal requirements. Hence, the QPPV shall have access to the pharmacovigilance system master file (PSMF) at all times.
b) Having oversight over the functioning of the pharmacovigilance system in all relevant aspects including quality management system (e.g., standard operating procedures, contractual arrangements, database operations, compliance data regarding quality, completeness, and timeliness of expedited reporting and submission of periodic update reports, audit reports and training of personnel in relation to pharmacovigilance).
c) The QPPV shall 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.
d) Preparing, reviewing, and implementing company SOPs for PV activities in the country.
e) The QPPV shall 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. The QPPV shall also be informed of significant changes that are made to the database (e.g., changes that could have an impact on pharmacovigilance activities).
f) The QPPV may delegate specific tasks, under supervision, to appropriately qualified and trained individuals, for example, acting as safety experts for certain products, provided that the QPPV maintains system oversight and overview of the safety profiles of all products. Such delegation shall be documented.
g) Establishing and maintaining a system that ensures that information about all suspected adverse drug reactions/events (or spontaneous

post-marketing events), which are reported to the personnel of the marketing authorization holder, including to medical representatives, is collected, collated, processed, and evaluated and forwarded to the Board in line with the timelines stipulated by the Board.

h) Preparing and submitting the following to the Board through established channels:
   i. Adverse Events to Health Products and Health Technologies.
   ii. Periodic Safety Update Reports and Periodic Benefit-Risk Evaluation Reports (PSUR/PBRER).
   iii. Company-sponsored post-registration safety and efficacy study reports.
   iv. Risk Management Plans (RMPs).
   v. Ongoing pharmacovigilance evaluation during the post-registration period. The report shall be submitted to PPB as soon as possible after the evaluation.

i) Ensuring 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.

j) Overseeing the safety profiles of the company's marketed products and any emerging safety concerns.

k) Ensuring 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.

l) Ensuring that all personnel involved in pharmacovigilance activities are aware of the principles of pharmacovigilance that affect them, and all personnel shall receive relevant training.

m) Ensuring that competent persons are appointed to carry out their duties and functions in their absence.

n) Ensuring that Qualified health care professional possessing adequate experience and education (e.g., QPPV and medical affairs staff), shall be available to evaluate information in respect of potential ADEs, assesses

the seriousness, expectedness, and reportability of ADEs, and determine if the ADE report qualifies for expedited reporting.

o) Ensuring that training is provided prior to the implementation of new or revised procedures. Records of training shall be maintained.
p) Have oversight of the PMS activities of the MAHs products registered in the country.
q) Act on MAH's behalf including liaising with the Board.

4.2. Focal persons for Pharmacovigilance (FPPV)

The FPPV is an individual responsible for monitoring the safety of their marketed products at the distributor level. They shall be responsible for:

a) Preparing, reviewing, and implementing company SOPs for PV activities in the company.
b) When required by NRA, FPPV shall obtain this information from QPPV.
c) Establishing and maintaining a system that ensures that information about all suspected adverse drug reactions/events (or spontaneous post-marketing events) are reported to the Pharmacy and Poisons Board through the established channels.
d) Overseeing the safety profiles of the company's marketed products and any emerging safety concerns.
e) Ensuring that all personnel involved in pharmacovigilance activities are aware of the principles of pharmacovigilance that affect them, and all personnel receive relevant training.

5. Outsourcing of QPPV

The Marketing Authorization Holders/Manufacturers can outsource the services of QPPV. Under such an arrangement, the following conditions apply;

i. All the provisions in this guideline including the QPPV being a resident in Kenya, be accredited and recognized by the Pharmacy and Poisons Board.

ii. If the QPPV is employed by a third party, even if the usual working address is an office of the marketing authorization holder, this shall be indicated and the name of the company the QPPV works for provided.

iii. The Marketing Authorization Holder shall nevertheless retain the full responsibility for the completeness and accuracy of the pharmacovigilance system master file. The ultimate responsibility for the fulfillment of all pharmacovigilance tasks and responsibilities as well as the quality and integrity of the pharmacovigilance system always remain with the Marketing Authorization Holder.

iv. In addition, the outsourcing company shall supply the Board with a copy of the contract with the outsourced company clearly indicating the roles and responsibilities of each party.

v. A description of the subcontracted activities and/or services shall be included in the pharmacovigilance system master file (PSMF) and a list of the subcontracts shall be included in an annex to the PSMF, specifying the product(s) organization may be subject to inspection at the discretion of the PPB.

vi. The QPPV working at the outsourced companies shall supply the Board with a valid annual practice license.

vii. The outsourcing services shall be limited to not more than 5 companies per nominated QPPV.

6. Timelines for safety reporting and pharmacovigilance Inspections

Please refer to the provisions of the ***Guidelines on the Safety and Vigilance of Health products and Technologies 2023*** *(https://web.pharmacyboardkenya.org/legal-provisions-guidelines-procedures/).*

7. Sanctions & Infringements Actions

The following regulatory sanctions shall be applied to the MAH, local representative, manufacturer, and/or the QPPV in the case of non-compliance to the regulations in these guidelines. They shall be informed of non-compliance and advised on how this can be remedied. The sanctions shall

depend on the classification of the non-compliance as being critical, major, or minor.

a) **Critical (CR):** a deficiency in one or more pharmacovigilance processes or practices that represents a serious violation of applicable legislative requirements and /or guidance and/or leads to a seriously deficient pharmacovigilance system with a high level of risk to animal or public health.

b) **Major (MA):** a non-critical deficiency in the pharmacovigilance system, practices, or processes that represents a violation of applicable legislative requirements and/or guidance and could potentially adversely influence or pose a risk to animal or public health.

c) Minor (MI): a deficiency in the pharmacovigilance system, practices, or processes that represents a deviation from applicable legislative requirements and/or guidance and would not be expected to adversely affect or pose a risk to animal or public health**.**

8. Examples of offenses

Classification	Offense	Sanction
Critical	● Important safety warning omitted ● QPPV Non-compliance ● Failure to operate a comprehensive pharmacovigilance system	1. Product recall 2. Suspension or revocation of MAH licensure 3. Early re-inspection (within 12 months) 4. Making public list of shame/blacklisting 5. Urgent safety restriction 6. Delay in approval of MA applications 7. Variation of MAH
Major	● Repeat findings due to failure of MAH to adequately implement previous CAPA ● Previous findings not adequately and promptly addressed and have potential to develop into critical finding	1. Administrative fines 2. Non-compliance statement- 3. Infringement notice

	• Change in prescribing information without filing for variation	
Minor	• Delays or non-submission of safety reports (PSUR/PBRERS)	1. Warning letters: The board may issue a formal warning reminding the MAH, local representative, manufacturer and/or the QPPV of their pharmacovigilance regulatory obligations 2. Delays in approvals of retention of products

9. Implementation Timeline

Existing Marketing Authorization Holders/Manufacturers, local technical representatives, and distributors have six (6) months from the effective date to be fully compliant with this guideline.

10. References

1. Guideline on Good Pharmacovigilance Practices (GVP) European Medicines Agency, EMA/816573/2011 Rev April 2013
2. Health Products and Food Branch Inspectorate Good Pharmacovigilance Practices (GVP) Guidelines GUI-0102
3. Ghana Food and Drugs Authority Guidelines for Selection of Qualified Persons for Pharmacovigilance
4. National Agency for Food and Drug Administration and Control (NAFDAC),
5. Good Pharmacovigilance Practice Guideline 2016.
6. Guidelines on the Safety and Vigilance of Medical Products and Health Technologies 2019
7. Pharmacy and Poisons Rules (Pharmacovigilance and Post Marketing Surveillance) Rules 2022

11. Revision History

Pharmacy and Poisons Board	**Revision history**		**PPB/HPT/PDS/VMS/GUD/006**
Revision #	**Date**	**Section (s)**	**Description of change**
1.	05/11/2022	Definition of terms	Introduced definitions for distributor and focal persons for pharmacovigilance Changed the term medical products to health products to align with the current term used
1.	05/11/2022	The legal framework	Introduced the provisions of the newly gazetted PV/PMS rules and regulations, 2022
1.	05/11/2022	Scope	Changed from criteria that had previously been indicated to all products marketed in the country
1.	05/11/2022	Qualifications of QPPV	The requirement of having a master's degree in pharmacoepidemiology and pharmacovigilance within 5 years from designation has been expunged The requirement to have a valid QPPV practice license replaced with a letter of designation as QPPV from PPB after his/her nomination by MAHs
1.	05/11/2022	Specific requirements	A section on requirements for a backup QPPV has been introduced with emphasis that the QPPV shall also reside in Kenya
1.	05/11/2022	Role and responsibilities of QPPV	Expunged the word establishing under bullet 1 to only have maintain the PSMF as the establishment is the role of MAH Added that QPPV shall act on MAH's behalf including liaising with the Board Introduced the Roles and responsibilities of the appointed focal persons for PV (FPPV)
1.	05/11/2022	Outsourcing of QPPV	Introduction of limitation to the number of outsourcing services "the outsourcing services shall be limited to not more than 5 companies per a nominated QPPV"
1.	05/11/2022	Timelines for safety reporting	Expunged and the section reference the main PV guideline (hyperlink for the revised guideline to be inserted)

Pharmacy and Poisons Board	**Revision history**		**PPB/HPT/PDS/VMS/GUD/006**
1.	05/11/2022	Pharmacovigilance inspections	Expunged section references the main PV guideline (hyperlink for the revised guideline to be inserted)
1.	05/11/2022	Sanction	Critical section - an example of offenses has been added and under its sanctions, the timeline to re-inspection is clarified, and also delay in the approval of MA applications added Major sections, 2 new examples added

12. List of contributors

The Pharmacy and Poisons Board acknowledges the immense contribution of the following for their research, compilation, and commitment to developing this guideline.

Dr. Fred M. Siyoi	Chief Executive Officer
Dr. Christabel Khaemba	Head, Pharmacovigilance
Dr. Edward Abwao	U.S. Pharmacopeial Convention
Dr. Pamela Nambwa	Pharmacovigilance
Dr. Martha Mandale	Pharmacovigilance
Dr. Ronald Inyangala	Pharmacy Practice
Mr. George Muthuri	QMS
Dr. Stephen Kimathi	Ministry of Health
Ms. Mary Njeri	Ministry of Health

Reviewers

Dr. Kariuki Gachoki	Deputy Director, Product Safety
Dr. Wanga Karim	Head, Post Market Surveillance

REPUBLIC OF KENYA

Ministry of Health

PHARMACY AND POISONS BOARD

P. O. Box 27663 - 00506 Lenana Road Opposite Russian Embassy, Nairobi
Tel: +254 709 770 100, +254 795 734 049
Website: www.pharmacyboardkenya.org
Email: info@pharmacyboardkenya.org, pv@pharmacyboardkenya.org