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REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDELINES ON CHANGE NOTIFICATION/VARIATION OF REGISTERED MEDICAL DEVICES INCLUDING IN-VITRO DIAGNOSTICS

January 2022

Citation and address

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HPT/PER/GUD/055	GUIDELINES ON CHANGE NOTIFICATION FOR REGISTERED MEDICAL DEVICES INCLUDING IN-VITRO DIAGNOSTICS	Revision No. 0	Effective Date: 31/01/2022 Review Date: 21/10/2026

Prepared by Head, Medical Devices and Invitro Diagnostics

Sign.....

Date....10/ January / 2022.....

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Sign.....

Date....12th January 2022.....

Checked by Head, Quality Management

Sign.....

Date....14/01/2022.....

Authorized by Chief Executive Officer

Sign.....

Date.....

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I. ABBREVIATIONS

AE	Adverse Event
DPER	Department of Product Evaluation and Registration
FSCA	Field Safety Corrective Action
HPT	Health Product and Technology
MD	Medical Device
PER	Product Evaluation and Registration
PPB	Pharmacy and Poisons Board
IVD	In-Vitro Diagnostic
ISO	International Organization of Standards
GUD	Guideline

II. ACKNOWLEDGEMENTS

The Board acknowledges all the authors and contributors who contributed to the preparation of this document.

III. GLOSSARY OF TERMS

Accessory: An article that is intended specifically by its product owner to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended purpose. An accessory typically is intended to be used for one or more of the purposes as described in the definition of medical device and therefore should be considered a medical device

Control Mechanism: for the purpose of this guidance document, a means for verifying or checking that the specifications or outputs of the medical device meet a standard or predetermined result

Label: in relation to a health product or an active ingredient, means any written, printed or graphic representation that appears on or is attached to the health product or active ingredient or any part of its packaging, and includes any informational sheet or leaflet that accompanies the health product or active ingredient when it is being supplied

Intended Purpose/Intended Use: in relation to a medical device or its process or service, means the objective intended use or purpose, as reflected in the specifications, instructions and information

Operating Principle: For the purpose of this guidance document, the means by which a medical device produces or brings about a desired or appropriate effect

Product Owner: in relation to a health product, means a person who —

supplies the health product under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

Quality Management System: for the purpose of this guidance document, means certification to ISO 13485 or its equivalent

Applicant: in relation to a registered health product, means the person who applied for and obtained the registration of the health product under the *Act*

Indirect Contact: in relation to the nature of body contact of medical device, includes devices that contact the blood path at one point and serve as a

conduit for entry into the vascular system e.g., blood transfusion tubes, blood bags, etc.

Change Notification: a change or modifications in design, components, methods of manufacture or intended use made to a medical device including in-vitro diagnostic

1.0 PART ONE

1.1 INTRODUCTION

Medical devices are classified into four risk classes (A, B, C & D) based on the classification rules set out in the *Guideline for Submission of Documentation for Registration of Medical Devices and In-Vitro Diagnostics (IVDs)*. Class A represents the lowest risk medical devices and Class D represents the highest risk medical devices.

These guidelines to Change Notification are based on the principles of safety, quality and efficacy/performance of medical devices marketed in Kenya. Changes to a medical device can affect its safety, quality or efficacy/performance and must be approved prior to the modified device being marketed in Kenya, unless otherwise indicated.

1.1 LEGAL FRAMEWORK

The PPB is empowered under Section 3A(a) of the Pharmacy and Poisons Act ("the Act") to formulate guidelines for regulating the manufacture, import and export, distribution, sale and use of medical products including medical devices and IVDs.

The Pharmacy and Poisons Board will ensure that the change notification for a medical device application submitted for market authorization are complying with requirements as stipulated in the technical guidelines and in accordance with the relevant policies, laws, legal frameworks, guidelines, manuals and procedures existing in Kenya.

Further, the PPB is empowered under Section 3A of the Act grant or withdraw marketing authorization for medical devices and IVDs subject to appropriate conditions and revise such conditions for marketing authorization as necessary.

This guideline is intended to implement the requirements of the Act stipulated under Section 3B(2)(b) to ensure that all medicinal products manufactured in, imported into or exported from the country conform to prescribed standards of quality, safety and efficacy. In doing so, Section 3B(2)(i) of the Act requires the PPB to consider applications for approval and alterations of dossiers intended for use in marketing authorization of medicinal substances.

In performing its regulatory functions, the PPB is empowered under Section 3B92)(r) of the Act to collaborate with other national, regional and

international institutions on medical substances regulation. This enables the PPB to recognize and rely on registrations and certifications from notified bodies and listed reference regulatory authorities. The remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.

1.2 SCOPE

This guidance document applies to post approval changes of all medical devices including in-vitro diagnostics registered in Kenya. It sets out points for consideration by the applicant when a registered medical device is in the process of modification.

Owing to the various possible scenarios for changes made to a device, it is not the intention of this guidance document to describe every permutation and type of change that can occur.

This guidance document is also applicable to situations when a registered medical device undergoes any changes or proposed changes, including labelling changes, as a result of a reportable Adverse Event (AE) or an on-going Field Safety Corrective Action (FSCA).

1.3 How to use this guidance

When several simultaneous changes are being implemented on a registered medical device and IVD, hereafter referred to as 'device' in this guideline; this guidance document should be used to assess each change separately. If a Change Notification is required, the applicant shall describe how the modified device differs from the previously registered device (or device type).

Applicants are reminded that the determination of documents and the category of Change Notification (e.g. notification, technical) should be made in accordance to the set criteria in this guideline. Changes to accessories of registered medical devices will also come within the purview of this guideline.

Some changes that will **NOT** qualify for Change Notification and require the submission of a **NEW Pre-market** Product Registration include:

1. Change to the intended purpose of a registered medical device;
2. Change to the risk classification of a registered medical device;
3. Addition of model(s) that do not fulfil the grouping criteria, including permissible variants, reference to the guidance document on submission of documents for medical devices and IVDs on Grouping of Medical Devices for Product Registration;

4. Change to the medicinal substance in a device that incorporates a medicinal product in an ancillary role;
5. Addition of medical devices with device proprietary names different from the registered devices, into a device listing. Unless the devices with different proprietary names qualify to be listed together under one system, family or group in Pharmaceutical Regulatory Information Management Systems (PRIMS).

2.0 PART TWO:

2.1 CATEGORIES OF CHANGES

Changes to registered medical devices that require the submission of a change notification are classified into four categories namely:

a) **Technical Changes for Class C and D medical devices (Category 1**) affect the safety, quality or efficacy/performance of these medical devices. These require the Boards approval prior to implementation of the change(s) in Kenya

b) **Review Changes (Category 2)** (closed list of changes) for Class B medical devices affect the safety, quality or efficacy/performance of these medical devices. These require PPB's approval prior to implementation of the change(s) in Kenya and are as follows:

(i) Change(s) to indications for use of the registered medical device (except reduction of indications for use not arising due to device safety, quality or efficacy/performance concerns);

(ii) Addition of new model(s) to a registered medical device listing;

(iii) Removal and/or revision of warnings, precautions and contraindications;

(iv) Modification of approved method of use, including change from "Professional use only" to "Home use".

c) Notification Changes (Category 3) Notifications are changes that could have minimal or no adverse effects on the overall safety, efficacy/performance and quality of the medical device. Applicants must satisfy themselves that they meet all of the prescribed conditions for the change and submit all required documentation with the notification application. Such changes can be implemented immediately at the time of submission and they can be considered accepted if an objection is not issued by PPB within two (2) months of the date of acknowledgement of receipt of the application.

Notification changes are;

(i) Change to delete or remove device particulars which are approved by PPB;

(ii) All other changes which do not fall under Administrative, Technical or Review changes, unless specified under Changes that do not require submission of Change Notification section of the guideline.

If the change is in the context of or is a consequence of a reportable Adverse Events (AEs) or Field Safety Corrective Actions (FSCAs), implementation of such changes can only proceed after the FSCA/local AE cases have been

reported to National Pharmacovigilance Center, referenced in the PPB's Guideline on The Safety and Vigilance of Medical Products and Health Technologies.

Notification Changes may be bundled together and notified to the Board in one change notification application. Alternatively, such changes could also be submitted together with the next Review/Technical change of the registered device (whichever comes first). While bundling such changes, any such change shall be submitted within a maximum of 6 months from the time the product owner is aware of the change. In the interim, companies shall maintain relevant inventory records on file to ensure traceability of the changes as part of their QMS requirements. Bundled Notification Changes do not apply to Artificial Intelligence based devices, changes to the drug substance/medicinal product of combination products and AE/FSCA related changes.

NOTE: 'Notification' changes which are incorrectly classified will be rejected upon review and further supply of the affected device will be prohibited. Subsequent supply will be subject to approval of the change in the correct Change Notification category.

d) **Administrative Changes include**: Changes to the administrative documents and information submitted at the point of registration of the medical device. These require the Boards approval prior to implementation of the change(s) in Kenya

2.2 REQUIREMENTS FOR CHANGE NOTIFICATION

a) Registration holder is required to submit completed copies of the following documentation:

i. **Annex 1:** Change Notification Application form
ii. **Annex 2**: Medical Device Safety and Performance Declaration Template
iii. **Annex 3:** Summary Table of Change Notification.
iv. All supporting documents listed in Annex 1, Annex 2, and Annex 3
v. Updated Common Submission Dossier Template (CSDT).

Registration holders are reminded that the determination of documents required for change notification should be made with reference to all submitted changes, and not solely on one category of change.
Upon the successful submission of the Change Notification application on PRIMS, no further amendment of the application will be allowed unless otherwise advised by PPB.
An application for changes categorised as **'Technical Change'** or **'Review Change'** will be evaluated. An evaluation decision is made based on the outcome of the PPB's evaluation of the submitted information. The decision can be one of the following:

(i) The Change Notification is **approved** – where Authority assessed that the changes made to the registered medical device meet prevailing requirements of safety, quality and efficacy/performance for its intended purpose and may be registered for local supply;

or

(ii) The Change Notification is **not-approved** – where the response provided by the applicant fails to address the deficiencies highlighted during the input request, or failure to adhere to specified time as stated in input request or provide information requested for within reasonable timeframe, or where changes made to the registered medical device does not meet prevailing requirements of safety, quality or efficacy/performance for its intended purpose.

2.3 CHANGE NOTIFICATION FOR REVIEW CHANGES (CATEGORY 2)

Table 1:

Types of change	**Documents to be submitted**
1. Change in manufacturing facility, process and quality management system (QMS)	
(a) All changes to manufacturing and/or sterilisation facilities with no changes to the manufacturing and/or sterilisation processes. *Example: Change of manufacturing site.*	i) Revised QMS certificate(s) (if applicable); ii) Medical Device labelling stating changes for each amended section (if applicable); iii) Declaration that there is no change to manufacturing and sterilisation process; iv) Sterilisation validation report.
(b) All changes to manufacturing processes (including changes made to outsourced processes) that result in a change in specifications of a registered medical device. *Example:* *Change in the equipment used for cutting the result in the change in length of sutures.* *Moulding or cutting manufacturing process.*	. i) Revised QMS certificate(s) (if applicable); . ii) Summary of new manufacturing process; . iii) Validation report covering new processes; . iv) Pre-clinical studies (if applicable); . v) Software validation report (for software); . vi) Clinical safety report (for operating principles and design characteristics change) (if applicable); . vii) Risk analysis.
(c) All changes to sterilisation processes (including changes made to outsourced processes). *Example:* *Change in moist heat sterilisation parameters or change in*	. i) Sterilisation technique (certificate); . ii) Medical Device labelling stating changes for each amended section (if applicable); . iii) Sterilisation validation report (including the sterilisation protocol, sterilisation

sterilisation method from ethylene oxide to gamma radiation or change from batch release to parametric release.	standards applied, sterility assurance level, sterilisation revalidation report); . iv) QMS certificate(s).
2.Changes in design or specifications of a registered medical device	
(a) All changes to the control mechanisms, operating principles and/or design characteristics of a registered medical device. *Example:* *Change from a quantitative assay to a qualitative assay.* *Addition of a footswitch to an X-ray system that previously do not operate via a footswitch mechanism.*	. i) Revised QMS certificate(s) (if applicable) . ii) Pre-clinical studies; . iii) Risk analysis; . iv) Clinical studies (if applicable); . v) Medical Device labelling stating changes for each amended section (if applicable . vi) Software validation report (for software, if applicable); . vii) Detailed summary of software changes (for software, if applicable).
(b) Changes that only involves a design change that does not affect the safety or performance of the medical device (e.g. changes that improve the medical device ergonomics, aesthetic modification of the medical device).	. i) Revised QMS certificate(s) (if applicable); . ii) Risk analysis; . iii) Usability testing report (if applicable).
(c) All changes in specifications (including shelf life and stability) of a registered medical device.	• i) Revised QMS certificate(s) (if applicable); • ii) Pre-clinical studies (if applicable); • iii) Clinical safety report (if applicable); • iv) Risk analysis;

	• v) Medical Device labelling stating changes for each amended section (if applicable); • vi) Software validation report (for software, if applicable); • vii) Detailed summary of software changes (for software, if applicable).
(d) Change to software that affect safety and performance of the registered device such that the treatment or diagnosis of the patient is altered. *Example:* *Upgrade of software version changes the performance characteristics like specificity or sensitivity of the diagnostic medical device.*	. i) Revised QMS certificate(s) (if applicable); . ii) Risk analysis; . iii) Software validation report; . iv) Detailed summary of software changes.
3. Changes to materials in a general medical device	
(a) All changes to biological materials that involve a change in type, source, processing and/or supplier of cells, tissues and/or derivatives of animal, human, microbial or recombinant origin without a change in the intended purpose of the biological material. *Example:* *Change in source of hyaluronic acid from Streptococcus zooepidemicus to Streptococcus equi.*	. i) Revised QMS certificate(s) (if applicable); . ii) Pre-clinical studies, including biological safety data; . iii) Clinical safety report (if applicable); . iv) Information of sources/donors; . v) Risk analysis;

(b) All changes to materials or material formulation (of non-biological origin), including changes to medical device coating or surface modification techniques, that involve materials that make direct/indirect contact with body tissues and fluids, or are absorbed by the body. *Example:* *Replacement of catheter surface coating from PEBA to PEEK.*	. i) Revised QMS certificate(s) (if applicable); . ii) List of materials making direct/ indirect contact with human body; . iii) Pre-clinical studies; . iv) Clinical safety report (if applicable); . v) Risk analysis.

Types of change	**Documents to be submitted****
(c) All changes to materials that are used for shielding in medical devices emitting ionising radiation. *Example:* *Change in shielding material of X-ray system from lead to tungsten.*	. i) Revised QMS certificate(s) (if applicable); . ii) Information on radiation source; . iii) Information on materials for shielding of radiation; . iv) Radiation safety test/test report; . v) Risk analysis.
(d) All changes to the radiation source (e.g. radioisotopes).	. i) Revised QMS certificate(s) (if applicable); . ii) Information on radiation source; iii) Radiation safety test/test report; iv) Risk analysis.
4. Changes to materials in an in-vitro diagnostic (IVD) medical device	
(a) All changes to the radiation source (e.g. radioisotopes in radioimmunoassay).	. i) Revised QMS certificate(s) (if applicable); . ii) Pre-clinical performance evaluation data;

	. iii) Clinical performance evaluation data; . iv) Information on source of material; . v) Radiation safety test/test report; . vi) Risk analysis.
5.Changes to labelling of medical devices	
(a) All changes to the labelling of medical devices that involve addition, removal and/or revision of warnings, precautions and/or contraindications. *Example:* *Minor changes to clarify the existing wording of the warnings and precautions for a device may not trigger the need for approval. However, in the case where these changes add or remove a contraindication, or remove a warning or precaution, an endorsement by the MDA is required.*	. i) Revised QMS certificate(s) (if applicable); . ii) Description of the warnings, precautions and/or contraindications; . iii) Reasons for the revision of approved indications; . iv) Medical Device labelling for new medical device(s) stating changes for each amended section.
(b) Labelling changes that— . i) modify the approved method of use; OR . ii) involve a change from 'professional use only' to 'home use'.	. i) Revised QMS certificate(s) (if applicable); . ii) Preclinical Studies (if applicable); . iii) Clinical safety report (if applicable); . iv) Software validation report (for software); . v) Risk analysis; . vi) Medical Device labelling stating changes for each amended section.
6.Changes to registered medical devices registration information	

(a) If within the medical device grouping, the change only— i) involves the addition of new medical devices of the same	. i) Justification for addition of medical device(s) to be grouped within the registered medical device group; . ii) List of configurations of medical devices;

Types of change	**Documents to be submitted****
design, within the existing range of sizes already registered; OR ii) involves addition of a new medical device with design change that does not affect the safety or performance of the medical device (e.g. changes that improve medical device ergonomics, aesthetic modification of the medical device).	. iii) Regulatory approval documents from the recognised countries (if applicable); . iv) Medical Device information; . v) Medical Device labelling stating changes for each amended section; . vi) Declaration of conformity; . vii) Pre-clinical studies (where applicable); . viii) Software validation report (for software, if applicable); . ix) Manufacturing information (if applicable).
(b) If the change only involves an addition of active, with measuring function or sterile Class A medical device accessories that complement the registered medical device as a system.	. i) Declaration by registration holder to state - - the added models are class A sterile; - the name of the medical device affected; - the medical device identifier; - no change in manufacturer for the class A sterile medical device;

	- name and address for the manufacturing site(s) for class A sterile medical device; . ii) List of configurations of medical device; iii) Declaration of conformity; iv) Validation report and certificate.
c) All changes to medical device registration that involve an increase or reduction in the number of medical devices in a set grouping of a registered medical device.	. i) Declaration of conformity; . ii) Declaration from manufacturer to state that there is no change to medical device in all aspects, including intended use, technical specifications; . iii) List of configurations of medical devices; . iv) Device labelling stating changes for each amended section; . v) Description of the addition or reduction.
d) All changes to the medical device name and/or medical device identifier.	. i) Declaration of conformity; . ii) Declaration from manufacturer to state that there is no change to medical device in all aspects, including intended use, technical specifications; . iii) List of configurations of medical device; . iv) Device labelling stating changes for each amended section.

The guiding principles for identification of category 3 of various types of change to registered medical devices are presented in Table 2.

2.4 CHANGE CATEGORY FOR NOTIFICATION CHANGES (CATEGORY 3)
Table 2:

Types of change	**Documents to be submitted****
1.Change in manufacturing facility, process and quality management system (QMS)	
(a) All changes to certificates for manufacturing and sterilisation facilities that - . i) involves an update of certificate QMS validity date only OR; . ii) change in scope of the QMS certification which affect the registered medical device (that is not due to safety, and/or performance of the medical device) OR; . iii) involves a cancellation of QMS scope on the certificate for any of the multiple existing manufacturing facilities that is related to the registered medical device (that is not due to safety, and/or performance of the medical device), OR; . iv) involves the change in conformity assessment body with no change in scope of the certification OR; . v) involves the expansion of scope of the QMS certification which does not affect the registered medical device.	
2.Changes in design or specifications of a registered medical device	

All changes in software related to design or specifications of a registered medical device are in Category 1, (a) Unless the change only involves a change to software version number that does not affect safety or performance of the medical device, such as— • i) software changes solely to correct an inadvertent software error which does not add new functions, does not pose any safety risk and is intended to bring the system to its original specification; • ii) software changes which augment interfacing to other non-medical peripherals such as printers or VDUs and which has no diagnostic or therapeutic function; or • iii) software changes which only modify the appearance of the user interface with no risk to diagnostic or therapeutic function of the medical device.	. i) Software validation report. . ii) Detailed summary of software changes. The change notification for this item may be consolidated for a maximum period of 6 months.
3.Changes to labelling of medical devices	
(a) Where the change only involves a reduction of indications for use not arising due to medical device safety or performance concerns.	. i) Description of the new indications for use; . ii) Reasons for the reduction of approved indications; . iii) Medical Device labelling for new medical device(s) stating changes for each amended section.
(b) Labelling changes that only— i) involve the addition of Recognised Countries' approvals	i) Medical Device labelling stating

(e.g. CE marking).	changes for each amended section; ii) Valid certificates from relevant bodies (where applicable).
(c) Other labelling changes involving information in the labelling that does not fall under above (a) and (b).	i) Medical Device labelling stating changes for each amended section; ii) Details of changes and the reason for changes;

Types of change	**Documents to be submitted****
Rephrasing information/ Change in arrangement in IFU/ Change of colour/ font size/ location of information/ correction of spelling mistake or any administrative change (e.g. from Rd. to road), for example, do not required change notification. *Example:* *Minor changes to clarify the existing wording of the warnings, precautions, and/or how to use for a device in the IFU.*	iii) Documents supporting proposed changes detailed above (if applicable).
4.Changes to registered medical devices registration information	
(a) If the change only involves an addition of Class A medical device accessories that complement the registered medical device as a system or family.	. i) Declaration by registration holder to state - - the added models are class A non-sterile; - the name of the medical device affected;

	- the medical device identifier; - no change in manufacturer for the class A non-sterile medical device; - name and address for the manufacturing site(s) for class A non-sterile medical device; . ii) List of configurations of medical device; iii) Declaration of conformity.
b) All deletions of a medical device from medical device registration (for medical devices in grouping). *Example: The change only involves the reduction in the number of medical device in the grouping due to obsolescence and not due to safety or performance considerations.*	. i) Justification for deletion of medical device(s) to be grouped within the registered medical device; . ii) Declaration from manufacturer to state that there is no change to medical device in all aspects, including intended use, technical specifications; . iii) List of configurations of medical devices; . iv) Device labelling stating changes for each amended section.
c) All changes in the manufacturer information including changes in manufacturer's name and address (which is not the manufacturing site).	. i) Declaration of conformity; . ii) Declaration from manufacturer to state that they will undertake responsibility to provide post market support and

	assistance related to the medical devices already supplied under the former manufacturer's name (if applicable); iii) Medical Device labelling stating changes for each amended section.

Types of change	**Documents to be submitted****
d) A change in regulatory status on rejection or withdrawal in any recognised countries for any registered medical device.	. i) Existing regulatory approval; . ii) Documents from relevant regulatory authorities citing reason for the change in regulatory status; . iii) Reason for company to withdraw from regulatory authorities (if applicable).

2.5 APPLICATION PROCESS FOR CHANGE NOTIFICATION

Change Notification application for registered medical device may be grouped as follows;

(i) For changes within **one dossier** and involving listings of **a single risk class**: Multiple changes (Notification, Administrative, Review and Technical changes) will be considered in one CHANGE NOTIFICATION application if they are submitted together. Fees and assessment done will follow the highest change category in that application.

(ii) For changes in **two or more dossiers** involving listings of **a single risk class**:

(i) Applicants can submit one CHANGE NOTIFICATION application on PRIMS for:

(ii) identical administrative and notification changes to multiple listings, or

(iii) where the same new product is added, if the changes are submitted together. Non-identical changes in any one listing may result in the entire CHANGE NOTIFICATION application being rejected.

(i) Applicants can submit one CHANGE NOTIFICATION application for technical changes to the same medical device that is part of multiple device listings (as part of a FAMILY, SYSTEM, GROUP, TEST KIT). Product identifiers listed in each of the registered device listings selected must be the same.

(ii) Non-identical administrative changes and technical changes that do not fall under the categories above: Applicant to submit separate CHANGE NOTIFICATION application for each change on PRIMS.

(iii) **Identical changes** involving **Products of different risk classes** may be submitted in one CHANGE NOTIFICATION application only for the following categories of change.

a) Change in product owner
b) Change in manufacture and/or sterilisation site
c) Change only involves an update of QMS certificate validity date
d) Addition of identical Class A accessories

(iv) ***Identical changes*** *arising from open Field Safety Corrective Actions (**FSCAs**) or reportable Adverse Events (**AEs**) involving **listings of different risk classes,** please seek advice for applicable requirements prior to the submission of the application on PRIMS*

Please note that it is not possible to submit a new Change Notification application if there is a pending Change Notification application for the same product. The applicant has the option of either:

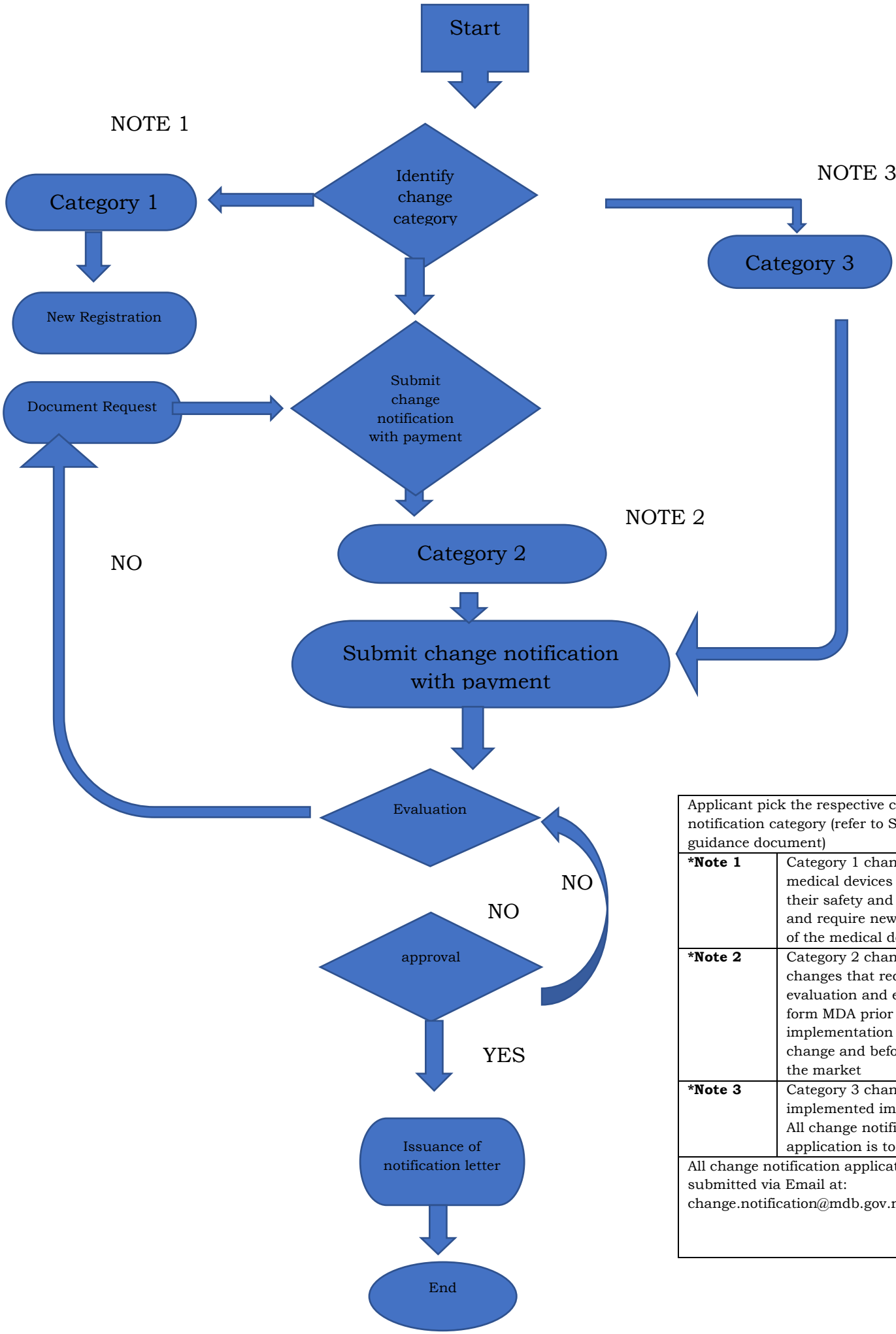
i) Withdrawing the pending Change Notification application and submitting a new change notification application, or
ii) Submitting a new change notification application once the pending change notification application is completed.

Single applications submitted with changes belonging to multiple categories (**Notifications, Administrative, Technical** and **Review** changes) shall be classified based on the most stringent category of change in that application and evaluated accordingly.

2.5.1 Application for Change Flowchart

The flowchart below describes the process for change notification. Applicants shall ensure that the change notification required documents are complete before submission. Incomplete submissions and untimely responses to queries will result in unnecessary delays to the review process and inevitably prolong the overall processing timeline.

If the application is a wrong category submission, the applicant needs to re-apply the change notification.



Applicant pick the respective change notification category (refer to Section 7 of guidance document)	
***Note 1**	Category 1 changes of medical devices that affect their safety and performance and require new registration of the medical device;
***Note 2**	Category 2 changes are changes that require evaluation and endorsement form MDA prior to implementation of the change and before placing in the market
***Note 3**	Category 3 changes may be implemented immediately. All change notification application is to be
All change notification application is to be submitted via Email at: change.notification@mdb.gov.my	

Changes to Medical Devices due to an Adverse Events (AE) and/or Field Safety Corrective Action (FSCA)

Changes to medical devices may arise from the occurrence of AEs or FSCAs. The proposed changes to the medical devices in these situations are intended to have an impact on the safety, quality and/or efficacy/performance of the medical device.

Documents and information to be submitted in support of proposed changes may include the following information:

(i) Product owner's Field Safety Notice (FSN) or
(ii) Product owner's Health Hazard Evaluation (HHE);
(iii) Product owner's Root Cause Analysis (RCA);
(iv) Product owner's Corrective and Preventive Action (CAPA) to reduce likelihood of recurrence of device issue;
(v) Product owner's CAPA effectiveness/ validation.

If there is no change to the aforementioned documents submitted under FSCA reporting, applicant is not required to re-submit them in the Change Notification application. The FSCA reference number should be provided as a Summary Table of Change Notification for reference. In situations where some of the above documents have yet to be submitted to PPB or where further information is required, PPB may request for them.

Determination of the appropriate change category for Change Notification applications submitted in the context of, or as a consequence of or arising from open reportable AEs or on-going FSCAs shall be based on the type of change

Changes submitted in the context of, or as a consequence of or arising from open reportable AEs or on-going FSCAs would require prior approval from PPB before implementation. This clause applies to all registered medical devices regardless of the category of change selected. Exception to this clause shall require the registrant to possess a written advice (e.g. acknowledgement email) from PPB that states otherwise.

2.6 CHANGES WHICH DO NOT REQUIRE SUBMISSION OF CHANGE NOTIFICATION

The following specified change(s) would not require the submission of Change Notification

(i) Labelling changes that only involve changes in layout, colour, font sizes and design, without change in prominence of precautions, warnings and contraindications.

(ii) Labelling changes that involve the addition and/or removal of languages not required by the Authority. Labelling changes that involve the addition/removal of reference agency approvals (e.g. CE Marking).

(iii) Labelling changes that involves the update of distributor information, and which does not affect the device listing information. Labelling changes that involves the addition/change or removal of barcodes, and which does not change the device listing information. Labelling changes that involve the addition of a Unique Device Identifier (UDI), and which does not change the device listing information. Labelling changes that involve the change in date format of an existing labelling date field (e.g. from MMYY to DDMMYY).

(iv) Change in regulatory status on rejection or withdrawal in any reference agencies for models registered on SMDR. Change involves only a design change that does not affect performance characteristics and/or specifications of the medical device (e.g. changes that improve ergonomics, aesthetic modifications)

(v) Raw material supplier changes (except medicinal substances and biological material suppliers) that do not change the registered medical device specifications. Change in scope of the quality management system (QMS) certification which does not affect the registered medical device.

(vi) Change in certification body with no change in scope of QMS certificate.

(vii) Class A Medical Devices and IVDs will require new submission whereas a change notification affecting the product performance, safety and quality is deemed necessary. Otherwise, Class A Medical Devices do not require submission of change of notification.

2.7 CHANGE NOTIFICATION FEES

All fees are **non-refundable** once the application has been submitted. Withdrawal or rejection of the application will result in **forfeiture** of the fees charged.

Notifications for Class A Medical Devices do not attract a fee.

The table below indicated the proposed charges for Change Notification:

Class of Medical Device	**Administrative** **In USD**	**Technical** **In USD**
Class A	**20**	**30**
Class B	**50**	**100**
Class C&D	**100**	**250**

3.0 REFERENCES/BIBLIOGRAPHY

1. *Global Harmonization Task Force (GHTF)-/SG1/N12:2000 Role of Standards in the Assessment of Medical Devices.*
2. *GHTF/SG1/N29:2005 Information Document Concerning the Definition of the Term 'Medical Device'.*
3. *GHTF/SG1/N40:2006 Principles of Conformity Assessment for Medical Devices.*
4. *GHTF/SG1/N41:2005 Essential Principles of Safety and Performance of Medical Device.*
5. *The Global Harmonization Task Force (GHTF)which is now The International Medical Devices Regulatory Forum (IMDRF)*
6. *Singapore Health Safety Authority (HSA) change notification for Medical Devices and IVDs*
7. *Medical Devices -ISO 13485 Standards-Quality Management Systems-Requirements for Regulatory purposes 2016*
8. *WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices (WHO Medical device technical series 2017.*
9. *Change Notification for Registered Medical Devices, Medical Devices Authority, Ministry of Health Malaysia, November, 2018*

4.0 CONTRIBUTORS

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5.0 ANNEXURES:

Annex 1: Change Notification Application form

(Medical Device is not a subject of an on-going Field Safety Corrective Action (FSCA) and conforms to Essential Principles for Safety and Performance)

[To be printed on Company Letterhead of applicant]

The Chief Executive Officer

Pharmacy and Poisons Board

P.O Box 27663-00506

Nairobi.

[Date]

Dear Sir/Madam,

I, *[name of Company]*, the Applicant of the medical device(s) stated below, hereby declare that the medical device(s) in this Change Notification application, is/are not a subject of an open reportable adverse event and/or an on- going field safety corrective action

It conforms(s) to the Essential Principles for Safety and Performance as laid out in the guidance for submission of medical devices This declaration shall apply to the following medical device(s)/IVD's:

[List containing product names of medical devices]

I, the Applicant, am aware that a false declaration is an offence and may result in the cancellation of registration of the above medical devices.

Yours Sincerely,

[Signature]

[Full Name and Title of Senior Company Official]

[Company stamp]

Annex 2: Medical Device Safety and Performance Declaration Template
[To be printed on Company Letterhead of the registration holder]

The Chief Executive Officer

Pharmacy and Poisons Board

P.O Box 27663-00506

Nairobi.

Dear Sir/Madam,

Declaration of Medical Device Safety and Performance on Change Notification

I, on behalf of *[company name],* the manufacturer of the medical device(s) stated below, hereby declare that the medical device(s) in this change notification,

is/are not a subject of a mandatory reportable incident and/or an ongoing field corrective action

conform(s) to the Essential Principles for Safety and Performance as per the statutory requirements of CAP 244 Laws of Kenya Pharmacy and Poisons Regulations of 2019.

This declaration shall apply to the following medical device(s):

[List containing medical devices names and registration submission ID]

Yours Faithfully,

[Signature] [Full Name and Title (Top Management Official)] [Company stamp]

Annex 3: Summary Table of changes

This annex provides guidelines on completing the Summary Table of Change Notification.

- (a) This summary table is to be completed and submitted for all change applications.
- (b) List the proposed changes, according to the "category of change", to the registered medical device(s) in the summary table below.
- All applicable types of changes are to be included; any change not specified in this table will not be included for the change notification.
- (c) Information to be included in the table is explained below:

. ii) **Present:** Please state clearly the current scope and aspects of the medical device to be changed.

. iii) **Proposed:** Please state clearly the proposed scope and aspects of change.

. iv) **Reason for change:** Please state clearly the rationale for the proposed scope and aspects of change.

v) **Status of proposed change in recognised countries:** Please state the reference agency status (approved/authorised for marketing) for these proposed changes.

(a) Type of changes	(b) Present	(c) Proposed	(d) Reason for change	(e) Status of proposed change in recognised countries
Type of change: *e.g. Change in material: Delivery tube material changed from polyvinyl chloride(PVC) to silicone*	*Delivery tube material: polyvinylchloride (PVC)* **Registration no:** **List of medical device** i) ii) iii)	*Delivery tube material: silicone*	*Improve patient safety by changing to DEHP-free tubing material*	*Australia TGA – pending* *EU Notified Body – approved/authorised for marketing* *Health Canada – not supplied* *US FDA – not supplied*

Category of change:				*Japan MHLW – not supplied*
Type of change: *e.g. Change in manufacturing facility* **Category of change:**	*Name and* *address current manufacturing facility A* *of* **Registration no:** **List of medical device** i) ii) iii)	_____ *Name and address of new manufacturing facility B*	*Reason for to move manufacturing activities from facility A to facility B*	*Australia TGA – pending* *EU Notified Body – approved/authorised for marketing* *Health Canada – not supplied* *US FDA – not supplied* *Japan MHLW – not supplied*

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