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Republic of Kenya

Ministry of Health

PHARMACY AND POISONS BOARD

STRATEGIES FOR CLEARING BACKLOG OF MARKETING AUTHORIZATION APPLICATIONS

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HPT/PER/GUD/050	**Strategies For Clearing Backlog of Marketing Authorization Applications**	**Revision No. 0**	**Effective Date:** 31/01 /2022 **Review Date:** 01/12/2026

Prepared by Deputy Director, Product Evaluation and Registration

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Date.....20/01/2022.....

Reviewed by Director, Health Products and Technologies

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Date.....21/01/2022.....

Authorized by CEO

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ABBREVIATIONS AND ACRONYMS

API- Active Pharmaceutical ingredient

QC- Quality Control

CPP-Certificate of pharmaceutical product

CTD- Common Technical Document

DMF-Drug Master File

EMA-European Medicines Agency

FPP- Finished Pharmaceutical Product

GMP- Good Manufacturing Practices

GUD- Guidelines

PPB- Pharmacy and Poisons Board

NRA- National Regulatory Authority

SRA-Stringent Regulatory Authority

TGA-Therapeutic Goods Administration

US FDA- United States Food & Drug Authority

WHO-World Health Organization

HPTs- Health Product and Technologies

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1.0 GLOSSARY

Abridged Procedure: Regulatory procedures facilitated by reliance, whereby a regulatory decision is solely or partially based on application of reliance. It is expected that use of reliance in these pathways will save resources and time as compared with standard pathways, while ensuring that the standards of regulatory oversight are maintained

Backlog: An accumulation of unevaluated applications for Marketing Authorizations of HPTs beyond 24 months post submission and payment.

Opt-in- Choose to participate in the registration process.

Opt-out- Choose to discontinue from the registration process.

Reliance: The act whereby a National Regulatory Authority in one jurisdiction may take into account or give significant weight to work performed by another regulator or other trusted institution in reaching its own decision

Recognition: Acceptance of the regulatory decision of another regulator or trusted institution. Recognition should be based on evidence that the regulatory requirements of the reference regulatory authority are sufficient to meet the regulatory requirements of the relying authority. Recognition may be unilateral or mutual and may, in the latter case, be the subject of a mutual recognition agreement.

Rejection: The act of declining dossier application due to gross deficiencies in the data submitted.

2.0 INTRODUCTION

2.1 BACKGROUND

The Pharmacy and Poisons Board on a daily basis receives a number of new applications for marketing authorization of Health Products and Technologies. However, the Board, just like any NRA in low to middle income country, does not have sufficient capacity in terms of expertise and financial resources to fulfil core regulatory function of timely marketing authorization of HPTs. Timely review of applications for marketing authorization have a direct bearing on access to HPTs and consequently impact on public health.

Due to the increasing number of medicine applications being received, it has become necessary for Pharmacy and Poisons Board to come up with mechanisms to clear its applications for marketing authorization backlog. PPB needs to develop a detailed strategy to clear the backlog of marketing authorization applications for Health products including human medicines, medical devices, nutritional supplements and borderline products which are yet to receive final approval or verdict.

Given the magnitude of pending marketing applications for health products and technologies that dates back to 2015 and beyond, if PPB maintains the current capacity and current processes, it would take several years to clear the backlog – assuming no new applications are received.

The Strategies for clearing backlog of applications for marketing authorizations provide mechanisms that can be used by Pharmacy and Poisons Board to clear pending backlog.

2.2 LEGAL FRAMEWORK

The Pharmacy and Poisons Act, Cap 244, mandates the Pharmacy and Poisons Board to, among others, set standards to ensure high level of public health protection by ensuring access to quality, safe, efficacious and affordable health products and technologies. The Act promotes the

functioning of the internal market with emphasis on timely marketing authorization of HPT as the main principle.

PPB as per service charter of 2018 committed to evaluate HPT applications for marketing authorizations within 2 years for foreign Human medicines and …… months for those that are locally manufactured however, this timeline if ever is rarely met due to several factors. Inability of the Board to keep service charter timelines can lead to among other effects poor customer satisfaction and loss of faith in the regulatory process.

It is important to note that backlog is not just an administrative challenge but represents a public health crisis

The Board therefore should come up with innovative ways to rapidly clear the backlog in marketing authorization of HPTs applications.

2.3 SCOPE

This strategy is applicable to the backlog of new applications for marketing authorization of Health Products and Technologies regulated by Pharmacy and Poisons Board.

3.0 BACKLOG CLEARANCE PROCESS MAPPING

The process mapping will be required to define timelines and key enablers for marketing authorization, namely GMP and QC analysis assessments. To do this PPB will need to undertake the following:

a) Identify the number of applications which have pending inspection of manufacturing sites.
b) Identify applications where no assessment has been done after 24 months of receiving application.
c) Identify number of applications awaiting submission of quality control and analysis documents.
d) Identify number of applications awaiting responses from the applicants for marketing authorization.

4.0 IDENTIFICATION OF HPTs THAT HAVE PASSED THE STIPULATED TIMELINE FOR REGISTRATION

The identified data of products will be categorized as Generics, New chemical entity, locally manufactured etc.

5.0 SETTING OF TARGETS FOR BACKLOG CLEARANCE

Facilitate how to address the backlog with the help of marketing authorization holders, and devise a workplan to prioritise applications for review.

Provide a program for addressing the implementation and clearance of the backlog

The regulatory effort in the assessment of backlog applications should commensurate with the level of risk of the product.

The use of facilitated regulatory pathways should be considered in order to ensure the effective allocation of limited resources

Joint review initiatives should be. Used for assessment of backlog applications by including officers from other departments of the board to support the products evaluation and registration department

Set targets for addressing pending GMP assessments, quality control testing and number of applications awaiting responses from the applicants

Appoint a focal person responsible for addressing backlog

6.0 BACKLOG CLEARANCE STRATEGIES

The following strategies can be used by Pharmacy and Poisons Board to clear backlog of marketing authorization applications;

6.1 Reduce number of applications requiring evaluations by

a) Eliminating old applications. All applications for registration that are at least 5 years old, industry will need to 'opt-in' for applications submitted in 2015 or earlier. These older applications are more likely to be out-of-date / in an old format, of less commercial interest to industry, and / or of less importance to public health. The Industry should be requested to notify PPB of their intention to 'opt-in' using a survey template. If no 'opt-in' is received, these older new registration applications will be eliminated from the backlog.

b) Rejecting all poor-quality applications that do not have the necessary modules/ sections or those that are not in the standard format.

6.2 Use of new Models of evaluation e.g. If different FPP manufacturers have submitted applications whose API manufacturers and source are common and DMFs have been submitted at the Board, reviewed and accepted, such applications should follow a separate pathway such that focus is only on the FPP section.

6.3 Segment and prioritise all applications by public health need and public health risk will determine the evaluation pathway. This will be based upon the type of application and complexity of evaluation required in addition to the level of prior scrutiny by recognized regulators.

6.4 Use of Reliance Pathways to facilitate regulatory decisions:

a. Recognition procedures: Products that have been evaluated by stringent regulatory authorities such as US FDA; EMA;

Japan MHLW; Swiss Medic; Health Canada; Australia TGA, and United Kingdom MHRA, the Board to formalize different processes to operationalize these reliance models. Examples: EMA Article 58, WHO prequalification, Swiss medic MAGHP.

b. **Verification review procedure:** Verification review is used to reduce duplication of effort by agreeing that the importing country will allow certain products to be marketed locally once they have been authorized by one or more SRAs (Stringent Regulatory Authorities). Review on the basis of CPPs, GMP certificates, and/or the assessment reports of reference authorities.

c. **Abridged review procedure:** Relies on assessments of data that have been already reviewed and approved by SRAs but includes an abridged independent review of a certain part of the dossier relevant to use under local conditions. This review could be of the Module 3 of the CTD, GMP inspections reports, and CPPs from reference authorities. Examples of this procedure come from Costa Rica, Mexico, Indonesia, Panama, Singapore, and Taiwan.

Implementation of these strategy will be accompanied by a renewed level of operational excellence, including:

a) Streamlined processes – upfront administrative and technical screening, batch processing by API, top-down summary-enabled approach to full reviews

b) Optimal staffing – with a dedicated backlog clearance team (separate to 'business as usual') and new positions such as Application Managers who will have end-to-end responsibility for an application's progress

c) Digitally empowered approach to evaluation – all re-submitted / updated applications to be in eCTD or e resubmission format

d) Improved transparency and accountability

e) Effective change management

6.5 Use of fast track procedures for expedited Regulatory Pathways for Medicines Targeting Unmet Medical Need

a. **Expedited review:** PPB can speed up the review of certain products to enable faster approval as has been done in authorities such as from Brazil, China, Egypt, Saudi Arabia, Singapore, Indonesia, South Korea, and Israel.

b. **Expedited submission (rolling submissions):** Information and data-packages can be submitted and reviewed as they become available. This has been done by authorities such as South Korea.

c. **Expedited development:** Earlier submission and approval with a data set which may be less complete than from a standard development program (e.g., surrogate endpoints, phase 2 data only). This has been done in authorities such as Brazil, South Korea, and Taiwan.

6.6 Use of Donor Agencies

Donor agencies willing to offer technical and / or financial support in HPTs evaluation should be approached. The support in terms of expertise or funding of evaluation budget elements can go a long way in speeding up the rate of backlog clearance.

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