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REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

PROPOSED FRAMEWORK FOR REGULATION OF PARALLEL IMPORTATION OF MEDICINAL SUBSTANCES IN KENYA

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This framework represents the current thinking of the Pharmacy and Poisons Board regarding Parallel Importation of medicinal substances. It does not create of confer any rights for or any persons. It does not bind Pharmacy and Poisons Board or the Public. An Alternative approach may be used if such approach satisfies the requirements of application laws and regulations on parallel importation.

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PARALLEL IMPORTATION OF MEDICINAL SUBSTANCES

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Preface

The content of this framework has been created by a number of factors relating to pharmaceutical supply chain security concerns and lack of implementation of Parallel Importation Guidelines, 2008.

Parallel importation refers to the importation of a medicinal substance by an importer outside the manufacturer's or its licensed distributor's formal channels. The regulation of parallel importation of trade marked medicinal substance is a contentious issue involving conflicting principles and policies that need careful balancing and periodic review to ensure that the regulation continues to serve the public interest. The practice of parallel importation globally has raised controversial debates between the stakeholders. Arguments for and against seem to continue to be released in the press by both parties.

It is unfortunate that stakeholders and policy arguments have focused on the economic issues of parallel imports rather than a critical analysis of the value of parallel imports to patients in a broader context. There is need to comprehensive examine the concept of parallel importation of medicinal substances to determine its cost benefits analysis to patients. Thus Pharmacy and Poisons Board has developed this framework as the basis for regulation of parallel imports.

Legal framework

Pharmacy and Poisons Board is empowered by section 44(1) of the Pharmacy and Poisons Act, Chapter 244 Laws of Kenya to regulate medicinal substances imported into Kenya. Pharmacy and Poisons Board had the responsibility for determining whether or not a medicinal substance offered for importation is in compliance with or in violation of the Pharmacy and Poisons Act. Legal notice 192 of 2010 required the regulation of parallel imported medicinal substances in Kenya.

Abbreviations

PPB: Pharmacy and Poisons Board
CAP 244: Chapter 244 Laws of Kenya
API: Active Pharmaceutical Ingredient
GMP: Good Manufacturing Practices
PIMS: Parallel Imported Medicinal Substance
SRA: Stringent Drug Regulatory Authority
ICH: International Conference on Harmonization

Definitions:

For the purpose of this framework the following acronyms and definitions are used:

Trademark owner means the manufacturer, marketing authorization holder, local technical representative or authorized distributor of a medicinal substance.

Medicinal substance as defined in CAP 244 means any medicine, product, article, or substance, which is claimed to be useful for any of the following purposes:

(a) Preventing or interfering with the normal operation of a physiological function whether permanently or temporarily and whether by way of terminating, reducing, postponing or increasing or accelerating the operation of the function in human beings or animals;
(b) Treating, preventing or alleviating disease or symptoms of disease;
(c) Diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;

Arbitrage is a practice in economics and finance of taking advantage of a price difference between two or more markets to capitalize upon the imbalance so as to gain profit from the difference in the market prices.

Source country means the country from which the parallel imported product is imported.

Parallel importer means a person or company engaged in the activities of parallel importation.

Parallel imported medicinal substance means a medicinal substance authorized in another country imported by parallel importation.

Parallel importation means the importation from another recognized country of a medicinal substance, which is already authorized on the Kenyan market, by an importer other than the authorized importer and appointed by the marketing authorization holder of the medicinal substance on the Kenyan market.

Kenyan-marketed medicinal substance means the medicinal substance for which a marketing authorization has been granted in Kenya, with which the parallel imported medicinal product is compared.

Stringent Drug Regulatory Authority (SRA): A National medicines regulatory authority that has strict, precise, exact with effective and well-functioning regulatory systems i.e. members of the International Conference on Harmonization (ICH) as specified on www.ich.org

Scope

The scope of this proposed framework is applicable to parallel importation of medicinal substances as defined above. It does not cover the following categories of medicinal substances commonly confused to be parallel imports:

- Importation of non-registered patented medicinal substance for compassionate use.
- Importation of an orphan medicinal substance.
- Importation for non-registered medicinal substance for named patient use and hospitals.

Introduction

Medicinal substances form a major part of an effective healthcare system whose main objective is provision to the public access to essential medicinal substances that are of **good quality, safe, efficacious** and **are economically affordable** as captured by the Kenya National Pharmaceutical Policy (KNPP), sessional paper no. 4 of 2012. Access to essential medicinal substances becomes critical given that majority of our population live below poverty line. Parallel importation is one of the means of enhancing access to essential medicinal substances and control spiraling costs of healthcare associated with medicinal substances in Kenya.

The regulation of parallel importation of trade marked medicinal substance (Grey Market) has long been a contentious issue involving conflicting principles and policies that need careful balancing and periodic review to ensure that the regulation continues to serve the public interest. There is need to comprehensive examine the concept of parallel importation of trade marked medicinal substance to determine its cost benefits analysis to patients.

Brief History of Parallel importation in Kenya

Branded products dominate the pharmaceutical industry in Kenya. The price of medicinal substances in Kenya is significantly expensive in comparison to the price of the same products other countries. This created press wars before 2005 among various stakeholders arguing for or against parallel importation. In 2006, a task force was formed with a mandate to do the following:

- To streamline the practice of parallel importation among the various stakeholders for the benefit of the public.
- To create peace and harmony among the Pharmaceutical Industry stakeholders for or against parallel importation.
- To encourage growth and development of the Pharmaceutical Industry in Kenya.
- To explore the various laws that deal with trade in Pharmaceuticals in Kenya which include: Intellectual Property Act, The Pharmacy and Poisons Act, Cap 244, and, WTO Articles including TRIPs and TRIPs Flexibilities.

In 2008, the taskforce developed a guideline that gave specific registration requirements for parallel imported medicinal substances and also contained obligations of the Drug Regulatory Authorities of the exporting countries. The Pharmacy and Poisons Board did not operationalize the guideline 2008 because of the contentious issues raised soon after its release. Between 2008 and 2013 Pharmacy and Poisons issued import permits in the interest of public for specific products on a case-by-case basis. This led to significant prices reduction to some products that has been verified by Pharmacy and Poisons Board. There were concerns raised by stakeholders against parallel importation regarding issuance of permits without lack of proper regulatory framework.

In 2014, the issue of parallel importation was reignited again because stakeholders against parallel importation wanted operationalization of 2008 guidelines. Again this led to press wars regarding parallel importation. In 2015, parallel importation became a political issue among Pharmaceutical Society of Kenya stakeholders.

Parallel importation of trademark medicinal substances

Parallel Importation of medicinal substances is a consequence of price differential of **identical medicinal substances** between Kenya and other countries i.e. arbitrage of trademark medicinal sustances. It often arises when an importer purchases a medicinal substance at a lower price in another country and transports it for resale in Kenya where it is expensive, and sells it in Kenya at a lower price than the trademark owner. Thus parallel-imported medicinal substance in Kenyan market competes with a similar product that is marketed by the trademark owner. Parallel importation promotes competition and access to essential medicinal substances that will in turn help patients. Parallel importation of medicinal substances occurs when there is collaboration between:

1) A licensed pharmaceutical wholesaler who holds stock of a parallel-imported medicinal substance at a lower price in another country and
2) A Parallel importer in Kenya who has an approval to import the medicinal substance as a parallel import.

It must be emphasized that parallel imported medicinal substances are "genuine" products regardless of where they are initially placed on the market. Parallel imported medicinal substances are **not counterfeit medicines** i.e. medicinal substances deliberately and fraudulently mislabeled with respect to identity and/or source. Thus stakeholders are encouraged to be vigilant and report any suspicious or suspected counterfeit medicinal substance to Anti Counterfeit Agency for appropriate action.

The stakeholders involved with this practice have highlighted the need for regulation of parallel importation of medicinal substances because of the following reasons:

- Price differential: The price of medicinal substances in Kenya is significantly expensive in comparison to the price of the same products other countries because of lack of price regulation in Kenya. The high cost of medicinal substances hampers access to critical essential medicinal substances to deserving patients.
- Lack of regulation poses public health risk to patients that can expose them substandard medicines in the market.
- Lack of regulation is affecting compliance of stakeholders to the established medicine regulatory system in the country.
- There is need to strengthen the current legal and regulatory situation applicable to parallel imports.
- There is need to increase the levels of information available to stakeholders to enable them make informed opinion.

The stakeholders in favor of parallel importation have highlighted issues that can be summarized as follows:

- Direct reduction in branded medicines price because parallel importers do not incur any marketing and distribution expenses.
- Parallel importation provides savings to patients by;
  - Providing patients with lower prices for the same medicinal substances;
  - Making medicinal substances more accessible to lower-income individuals, and;
- Parallel importation provides a mechanism for pharmaceutical price arbitrage in Kenya.

The stakeholders against parallel importation have highlighted issues that can be summarized as follows:

- The benefit added goes largely to intermediary traders and parallel importers not the patients.
- The practice exploits the inefficiencies caused by lack of pharmaceutical price regulation and reimbursement system in Kenya
- Parallel importation creates additional regulatory cost and burden both to regulatory authorities and original trademark owner.
- Parallel importation complicates the already highly complex pharmaceutical supply chain.
- The practice of repackaging and relabeling undermines supply chain security is a potential conduit for entry of Substandard/spurious/falsely-labeled/falsified/ counterfeit medicinal substances into the legitimate pharmaceutical supply chain.
- Parallel Importation leads to product shortages in the exporting national market, which undermines the requirement for ensuring continuous global pharmaceutical supply.
- Reduced profitability of original trademark owner affects research and development programs for innovation.
- The practice can be legally circumvented because the original trademark owner can claim that parallel imports as illegal imports or counterfeit products.
- The issue of medicines and patient safety because parallel imported medicinal substances are first sold to wholesalers and distributors that may not be as reliable as the original trademark owner.

The key milestones achieved with regard to parallel importation of medicinal substances in Kenya include the following:

- Pharmacy and Poisons Board must regulate parallel importation of medicinal substances.
- Pharmacy and Poisons Board should develop and operationalize a guideline for regulation of parallel imported of medicinal substances.
- All parallel imported medicinal substances must have package insert and patient information leaflet that is in English.
- Parallel imported medicinal substances must have a certificate of analysis when quantities reach a certain minimum per annum.
- Parallel importer must submit quarterly reports to Pharmacy and Poisons Board for all batch numbers of parallel-imported medicinal substances.
- Parallel importer must take full responsibility of quality, efficacy, safety and security of parallel-imported medicinal substance. This is not the responsibility of the trademark owner.
- Parallel importer must comply with Good Distribution (GDP) and other standards prescribed by the Pharmacy and Poisons Board.
- Parallel Importer must pay requisite medicinal substance applicable fees determined by the Pharmacy and Poisons Board.

Contentious Issues from Parallel Importation Guidelines, 2008

The table below highlights contentious issues from Parallel Importation guidelines developed in 2008 that require further stakeholder consultation

Contentious Issue	Concerned Stakeholder	Reason for Objection
1. Any person or company registered by the Pharmacy and Poisons Board, other than Trademark owner may parallel import a medicinal substance.	Trademark owner or local technical representative	Proponents of Parallel Importation are avoiding the normal medicine registration system and are avoiding proper regulatory oversight.
2. Trademark owner shall not be entitled to prevent parallel import a medicinal substance.	Trademark owner or local technical representative	Unethical trade practices by proponents of Parallel Importation
3. Conditions for Re-Packaging and Re-Labelling of Parallel Imported Medicines to include the words 'Parallel Imported Medicine; or the abbreviation "PIM" on the label of each distributed pack	Trademark owner or local technical representative	Potential conduit for entry of Substandard/spurious/falsely-labeled/falsified/ counterfeit of product into the supply chain by re-packer, wholesaler or traders.
4. No Cost benefit to patients	Trademark owner or local technical representative	The current practice by proponents of Parallel Importation does not improve access to medicines availed the patients.
5. Consent from Trademark owner or local technical representative before parallel importation	Proponents of Parallel Importation	Trademark owner or local technical representative will not grant consent to proponents of parallel importation.
6. Technical barriers to trade by Trademark owner or local technical representative before parallel importation	Proponents of Parallel Importation	They include stability studies, requirements for comparative dissolution and labeling parallel imports differently.
7. Submission of evidence of registration for parallel-imported medicinal substance	Proponents of Parallel Importation	Trademark owner or local technical representative will not grant evidence of registration to proponents of parallel importation.
8. Providing intent information to trademark owner 30 days before parallel importation.	Proponents of Parallel Importation	Trademark owner or local technical representative require this information to block proponents of parallel importation.
9. Prohibition of re-exports any parallel imported medicinal substance.	Trademark owner or local technical representative	Unfair trade practices by Trademark owner or local technical representative
10. Record Maintenance: The need for the parallel importer to submit to the local trademark owner all batch numbers of medicines parallel imported every quarterly.	Trademark owner or local technical representative	Trademark owner or local technical representative require this information to block proponents of parallel importation.
11. Condemnation of parallel imported medicinal substances as counterfeit and illegal imports	Trademark owner or local technical representative	Unfair trade practices by Trademark owner or local technical representative

Proposed Framework for Regulation of Parallel Importation.

In view of the above, the following is proposed as a framework for regulation of Parallel Importation of medicinal substances in Kenya.

1) A person or company that wishes to parallel-import a medicinal substance **MUST** be registered with Pharmacy and Poisons Board as a **Parallel Importer.** The requirements are the same as those for other importers or wholesalers.

2) All Parallel-Imported medicinal substance **must match** the registered reference medicinal substance already available and registered in Kenya in terms of the **formulation, proprietary name, packaging, strength, labelling, quality, efficacy and safety standards.** In addition, biological products must have same **purity and potency** as the reference biological medicinal substance**.** The parallel-imported medicinal substance must have the same active substance(s), the same pharmaceutical form and be identical to, or have no significant therapeutic difference from, the Kenyan-market medicinal substance.

3) Any Parallel-imported medicinal substance **must be** registered in Kenya. The conditions of authorization of a parallel imported medicinal substance (PIMS):
   - The medicinal substance must have a current, full marketing authorization at the time of submission or, if not authorized, it must have been withdrawn from Kenyan market for commercial reasons.
   - Parallel importer shall provide a justification of the basis on which the applicant makes a presumption of essential similarity between the parallel imported medicinal substance and the Kenyan-marketed product.
   - Parallel Importer shall comply with regulatory requirements set out by the Directorate of Product Evaluation and Registration.
   - Parallel Importer shall pay requisite applicable regulatory fees for a medicinal substance.

4) Parallel importer is restricted to parallel-import a particular medicinal substance from a **named source, supplier and country of origin**. The parallel imported medicinal substance **must** meet the following sourcing criteria;
   - Parallel importation of medicinal substances must be released from areas regarded as Stringent Drug Regulatory Authority (SRA) i.e. from countries participating in the International Conference on Harmonization (ICH).
   - The parallel-imported medicinal substance must have a current, full marketing authorization in the country of origin.

5) The parallel importer must notify the board on changes of the address of the named source, manufacturer or its representative. The requirements for variation must follow applicable variations guidelines developed by the Directorate of Product Evaluation and Registration.

6) The parallel importer must obtain an import permit for importation of medicinal substance to be parallel imported.
7) Parallel importer should submit a copy of authorization or registration of their supplier from issuing national medicines regulatory authority.

8) Parallel-Imported medicinal substance should be accompanied with a certificate of analysis from the manufacturer if quantities imported exceed 1000 Units per annum.

9) Parallel Importer should ensure that the package insert, patient information leaflet and labelling of the product is in English.

10) Parallel Importer shall pay requisite medicinal substance applicable regulatory fees determined by the board.

Obligations of Parallel Importer

- **Understand of Supplier of Parallel-Imported medicinal substance:**
  - Parallel importer must declare their supplier, location, contacts of each of parallel imported medicinal substance to Pharmacy and Poisons Board.
  - **Full responsibility** of quality, efficacy, safety, potency, and security of parallel-imported medicinal substance lies on the Parallel importer.

- **Compliance with Good Distribution Practice (GDP) standards.**
  - Parallel importer must ensure that the storage conditions, GDP and GMP are observed during transport and distribution, e.g. cold chain requirements.
  - Parallel importer must have standard operating procedures (SOPs) for GDP and must comply with Pharmacy and Poisons Board guidelines on GDP.
  - Parallel importer is responsible for recall and destruction of their parallel imported medicinal substance(s) incase of quality, safety or efficacy issues as per Pharmacy and Poisons Board guidelines.

- **Cost benefit declaration**: Parallel importer is must declare the cost benefit of the medicinal substance to the public. The declaration should meet the following conditions:
  - The market price must be significantly cheaper (at least 20% cheaper) than the current market price being sold by the trademark owner in Kenya.
  - The price at which the parallel imported medicinal substance will be availed in Kenya and the cost to the patient.
  - Non-reduction in cost for parallel imported medicines will lead to cancellation of parallel import licence. Thus it is the obligation of a parallel importer to ensure that patients are not exploited in the supply chain.
- **Record Maintenance:**
  - Parallel importer must track all batches imported in the market and must have documented recall and pharmacovigilance procedures.
  - Parallel importer must maintain records of all batches imported either in file or electronically that should available for audit by the Pharmacy and Poisons Board.
  - Parallel importer must submit to the Board all the batches of parallel-Imported medicinal substance imported every quarter.

Obligations of Trademark Owner

- Provide intelligence support to Pharmacy and Poisons Board on suspicious or suspected poor quality, unsafe parallel-imported medicinal substance.

Conditions for revocation of a Parallel Importation License

The Pharmacy and Poisons Board will revoke a parallel importation license of a parallel importer when evidence of non-compliance is documented in the following circumstances;

- Importation of parallel-imported medicinal substance from undisclosed source, supplier and country of origin.
- Failure to show or declare cost benefit to Pharmacy and Poisons Board.
- Inappropriate labeling of the parallel imported medicinal substance

- Failure to maintain records for all parallel imported medicinal substances
- Failure to submit records of all parallel imported products every quarter to PPB
- Failure to comply with Pharmacy and Poisons Board GDP requirements and other applicable regulations.

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Annexes: to be added later

Application forms to be developed

Revision History

Revision No:	Date	Author	Section(s) revised	Description of change	Approvals
0	10 Sep, 2015	Anthony Toroitich	Proposed Framework for Regulation of Parallel Importation and Conditions for revocation	-	Draft
1	11 Sep, 2015	Anthony Toroitich	Proposed Framework for Regulation of Parallel Importation and Conditions for revocation	Comments from internal stakeholders	Draft

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