FOREWORD
The Pharmaceutical Industry plays an important role in the provision of health care in Kenya. Trade in pharmaceuticals also accounts for a substantial portion of the country’s Gross Domestic Product.

Over the last couple of years, there has been a considerable concern among the stakeholders of this industry on the issue of Parallel Importation and Illegal Trade in Pharmaceuticals. Previous stakeholders’ meetings had addressed this issue without any tangible results. It is against this backdrop that the Registrar of the Pharmacy and Poisons Board appointed members of the Board Secretariat under the chairmanship of Dr. Ronald Inyangala to hold consultative meetings with representatives of Kenya Association of Pharmaceutical Industries (KAPI) and Kenya Pharmaceutical Distributors’ Association (KPDA) to delve further into these practices. Later, it was deemed necessary to include representatives from Pharmaceutical Society of Kenya (PSK) and Kenya Pharmaceutical Association (KPA) so as to harness valuable input from Pharmaceutical Professional bodies and to make the consultation all inclusive.

The Consultative meetings were carried out under the following Terms of Reference:

- To determine whether the current Rules under the Pharmacy and Poisons Act, cap 244 allow for Parallel Importation and Control of Illegal Trade in Pharmaceuticals.
- To study the Industrial Property Act, as it relates to Parallel Importation and Control of Illegal Trade in Pharmaceuticals.
- To examine the Trade Related Aspects of Intellectual Property Rights (TRIPs) and the subsequent TRIPs Flexibilities with respect to Parallel Importation and Control of Illegal Trade in Pharmaceuticals.
- To establish the effect of Parallel Importation of Pharmaceuticals on access to health services by the general public.
- To find out whether Parallel Importation of Pharmaceuticals facilitates the influx of Counterfeits.
- To establish the impact of Parallel Importation of Pharmaceuticals on the process of Drug Registration.
- To make recommendations towards policy formulation for improvement of practices in the Pharmaceutical Industry and access to health services.

The committee has now finalized its tasks as per the terms of Reference and hereby submits its report.

Dr. R. M. Inyangala

HEAD, TRADE AFFAIRS AND POST MARKET SURVEILLANCE, PPB
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ACKNOWLEDGEMENTS
The task force accomplished its tasks due to the input of a cross section of individuals. We appreciate that the Director of Medical Services Dr. James Nyikal and the Registrar of the Pharmacy and Poisons Board Dr. Fred Siyoi supported us morally during the stakeholders’ meetings and personally found time to attend some of the meetings. Special thanks go to Dr. Ronald Inyangala for effective and efficient convening and chairing of all sessions.

We are grateful to the following for their active and resourceful participation during the meetings:
Prof. Isaac Kibwage – Chairman, PSK
Dr. Anastasia Nyalita – Board Member, PPB
Dr. Wilfred Ochieng’ – PPB
Dr. Andrew Chemwolo – PPB
Mr. Walter Okok – Chairman, KAPI
Dr. John Munyu – KAPI
Mr. Mainil Shah – KAPI
Mr. Mohamood Mohammed – KAPI
Dr. Kamau – KPDA
Dr. Ndirangu – KPDA
Eng Kiarie and KEBS Team
KRA Team

Finally, we cannot forget the sub-committee that met and worked on this report:
Dr. Ronald Inyangala – Chairman
Dr. William Mwatu - KAPI
Dr. Jesse Mukuria - KPDA
Dr. Kamamia wa Murichu - KPDA
Dr. Joseph Yano - PPB
Dr. Pius Wanjala - PPB
Dr. John Munyu - KAPI
Mr. John Sabaya - KPA
Dr. Kariuki Gachoki - Secretary

ABBREVIATIONS

<table>
<thead>
<tr>
<th>Board</th>
<th>Description</th>
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<tbody>
<tr>
<td>PPB</td>
<td>Pharmacy and Poisons Board</td>
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<tr>
<td>KAPI</td>
<td>Pharmacy and Poisons Board</td>
</tr>
<tr>
<td>KPDA</td>
<td>Kenya Association of Pharmaceutical Industries</td>
</tr>
<tr>
<td>KPA</td>
<td>Kenya Pharmaceutical Distributors Association</td>
</tr>
<tr>
<td>PSK</td>
<td>Kenya Pharmaceutical Association</td>
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<tr>
<td>TRIPS</td>
<td>Pharmaceutical Society of Kenya</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<td>WTO</td>
<td>World Trade Organization</td>
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INTRODUCTION

The importance of the Pharmaceutical Industry in the provision of Health care Services in Kenya cannot be overemphasized. The nature and extent of the burden of disease amongst the poor population is a critical concern to the nation.

Intellectual Property Laws and specifically Patent Laws are national laws effective within national territories. It is important to appreciate that International Treaties, particularly TRIPs and TRIPs Flexibilities have achieved substantial international harmonization of principles. Member countries of WTO are obliged to subscribe to various WTO Articles and to provisions of the TRIPs and its flexibilities. TRIPs provide that patents should be available in all fields of technology and empower the patent owner with exclusive rights to enjoy monopoly over the exploitation and use of the patented product(s) or technology. Others are prevented from making, using, offering for sale or importing the patented product(s) or technology unless with authorization from the patent holder.

TRIPs also provide for circumstances in which limitations or exceptions may be introduced or measures adopted restricting the rights of the patent holder. TRIPs has inbuilt flexibilities that can be used by countries to structure their patent regimes to take into account their national interests. Flexibilities can be used to control the impact of patent on access to medicines as follows:

1. Early entry of generics of the patented product into the market.
2. Voluntary and compulsory licensing for manufacture of the patented product.
3. Governmental use orders
4. Exhaustion of Rights nationally and internationally

Countries could use the appropriate combination of flexibilities to improve the access of citizens to medicines. It is a matter of national laws that stipulate the domestic position regarding exhaustion of Rights internationally and the legitimacy of Parallel Importation of Pharmaceutical Products. Exhaustion of Patent Rights is provided for in Section 58(2) of the Industrial Property (IP) Act: ‘The Rights under the patent shall not extend to acts
in respect of Articles which have been put on the market in Kenya or in any other country or imported into Kenya.” The Pharmacy and Poisons Act, cap 244 is not consistent with the IP Act section 58(2) because it has no provisions for exhaustion of Rights internationally. In that respect, the Pharmacy and Poisons Act, cap 244 does not provide for Parallel Importation of Pharmaceutical Products.

It is noteworthy that Pharmaceutical Counterfeits are a major problem in most countries Kenya being one of them. Counterfeits have a major adverse impact on public health. This problem is more pronounced in a situation where the manufacture, importation, distribution, supply and sell of medicines are less regulated and enforcement is weak. In Kenya, this is evident at the Ports of Entry (common with briefcase suppliers) and in the numerous outlets run by quacks. The Pharmacy and Poisons Act, cap 244 is silent on Counterfeits and the draft Counterfeit Bill is yet to be legislated.

Parallel Importation can be healthy and meaningful if it enables greater access to medicine by the public. However, in the absence of a strong regulatory framework, this trade practice can facilitate an influx of Counterfeits and may lead to unethical trade practices.

**PROBLEM STATEMENT**

The problem is that the Pharmaceutical Industry is dominated by the Agents of the branded products under the auspices of KAPI and the Kenyan public has suffered from harmful monopolistic effects such as high prices and limited supplies. KPDA represents a group of Practitioners set on exploiting Section 58(2) of the IP Act through Parallel Importation to trade in branded pharmaceuticals put into the national market by KAPI. This situation not only precipitated acrimony and press wars, but also, threatened to create anarchy in the Pharmaceutical Industry and the smooth provision of Health Services to the public. This task force was formed and given the mandate to address this problem.
JUSTIFICATION OF THE TASK FORCE
This task force was necessitated by the fact that access to affordable Health care is a critical issue at the heart of any nation. As such, the problem statement called for:

- The need to streamline the practice of the various players in the supply of pharmaceuticals for the benefit of the public.
- Create peace and harmony among the practitioners in the Pharmaceutical Industry.
- Encourage growth and development of the Pharmaceutical Industry.
- To restore public confidence in the Pharmaceutical Industry.

SCOPE OF THE TASK FORCE
- Explore the various laws that deal with trade in Pharmaceuticals in Kenya which include: IP Act, The Pharmacy and Poisons Act, cap 244, and, WTO Articles including TRIPs and TRIPs Flexibilities.
- To examine the activities of KAPI and KPDA
- To make recommendations on the way forward

METHODOLOGY
A total of nineteen participants from KAPI, KPDA, PPB Secretariat, PSK and KPA were involved in Focused Group Discussions. Consultative discussions were carried out in nine sessions at the Pharmacy and Poisons Board. Conclusions were based on the discussions. The following reference materials informed and enriched the group discussions: The Industrial Property Act; the Pharmacy and Poisons Act, cap 244; Public Health Act, Cap 242; TRIPs and TRIPs Flexibilities; The Trade Marks Laws; and, the Counterfeit Draft Bill. The minutes for the proceedings of the meetings are annexed at the end of this report.
FINDINGS

- The Pharmacy and Poisons Act, cap 244 does not allow for Parallel Importation but carries provisions for control of Illegal Trade in Pharmaceuticals.
- The Industrial Property Act allows Parallel Importation of Pharmaceuticals but does not have specific provisions for control of illegal trade and Counterfeits.
- The Trade Related Aspects of Intellectual Property Rights (TRIPs) and the subsequent TRIPs Flexibilities if domesticated through local laws allow for Parallel Importation but does not address control of Illegal Trade in Pharmaceuticals.
- Parallel Importation of Pharmaceuticals as practiced then did not improve access to medicines by the general public.
- Cases were cited where Parallel Importation of Pharmaceuticals had facilitated the influx of Counterfeits.
- Parallel Importation of Pharmaceuticals as practiced impacted negatively on the process of Drug Registration.

RECOMMENDATIONS

1. The Pharmacy and Poisons Board should be strengthened in the following areas to better regulate the Pharmaceutical Industry to ensure a level playing field and minimize illegal trade in pharmaceuticals and inflow of counterfeits:
   - Drug Registration
   - Inspectorate
   - Trade
   - Post Market Surveillance
   - Medicines Information
2. All parallel imported products should be registered by the importers with the Pharmacy and Poisons Board so as to guarantee traceability.
3. Guidelines should be developed by the Pharmacy and Poisons Board giving specific registration requirements for parallel imported products and should also contain obligations of the Drug Regulatory Authorities of the exporting countries.

4. The government should develop a pricing policy for parallel imported products to encourage competition and ensure access to medicines by the general public.

5. The inspectorate Department at the Pharmacy and Poisons Board should be strengthened to effectively man the ports of entry in collaboration with other arms of government.

6. The Pharmacy and Poisons Act, Cap 244 should be reviewed to accommodate Parallel Importation in line with IP Act and TRIPs and TRIPs flexibilities.

7. The Ministry of Health should liaise with the Ministry of Trade and Industry and the attorney General’s office to have the draft Counterfeit Bill enacted soon.

8. Pharmaceutical companies should be encouraged to have multiple agencies to market their products in the country to foster competition and bring the prices down.

**CONCLUSION**

There is a future for Parallel Importation in Kenya. There is no doubt that this practice can be of utmost benefit to Kenyans. However, the emerging challenges call for co-operation among all the stakeholders. The government shoulders the greatest responsibility of establishing a legal framework that will spell out the rights and obligations of Parallel Importers.
DECLARATION

We the following undersigned members of the Task Force do hereby declare that the facts, findings and recommendations in this report do represent what was agreed on during our deliberations and discussions.

Dr. Ronald Inyangala ________________________________

Dr. William Mwatu ________________________________

Dr. Jesse Mukuria ________________________________

Dr. Kamamia wa Murichu ________________________________

Dr. Joseph Yano ________________________________

Dr. Pius Wanjala ________________________________

Dr. John Munyu ________________________________

Mr. John Sabaya ________________________________

Dr. Kariuki Gachoki ________________________________