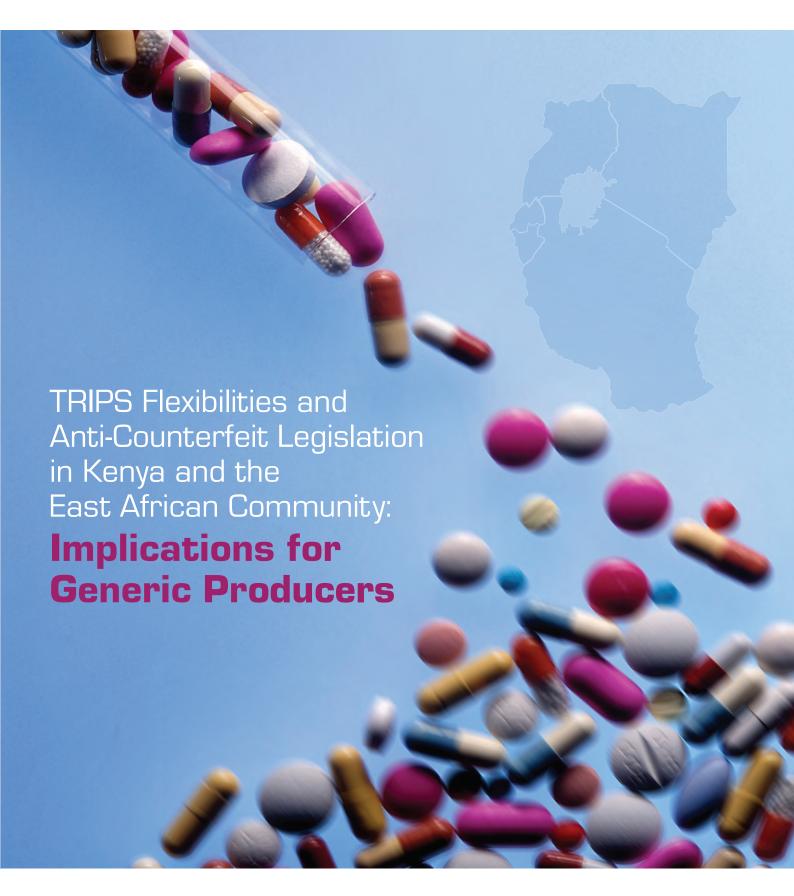
# UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION





#### UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT

# TRIPS Flexibilities and Anti-Counterfeit Legislation in Kenya and the East African Community: Implications for Generic Producers

An UNCTAD-UNIDO Discussion Paper



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### **Acronyms**

EAC East African Community

IP Intellectual Property

IPRs Intellectual Property Rights
LDCs Least-Developed Countries

KPSDS Kenya Pharmaceutical Sector Development Strategy

PPB Kenyan Pharmacy and Poisons Board

SFFC Spurious/Falsely-Labeled/Falsified/Counterfeit (medicines)

TRIPS Trade-Related Aspects of Intellectual Property Rights
UNCTAD United Nations Conference on Trade and Development
UNIDO United Nations Industrial Development Organization

WHO World Health Organization
WTO World Trade Organization

### **Overview of Policy Recommendations**

- Recommendation 1: In the course of the current revision of the Kenyan Anti-Counterfeit Act, the definition of "intellectual property rights" in Section 2 of the Act should be amended to only cover trademarks and copyrights and related rights. The Anti-Counterfeit Act should not apply to patents, in line with the minimum standards of the TRIPS Agreement and recent changes under Uganda's 2015 version of the Counterfeit Goods Bill.
- Recommendation 2: The definition of "counterfeiting" in Section 2 of the Act should be redrafted, following the definitions of "counterfeit trademark goods" and "pirated copyright goods" in Article 51 of the TRIPS Agreement. The new definition should not apply to foreign IP rights or to activities undertaken abroad, in line with the principle of territoriality that governs intellectual property law.
- Recommendation 3: From a public health perspective, the existing drug regulatory laws appear sufficient to address the mislabeling of drugs that creates confusion about quality or other drug characteristics. There is no need to expand the scope of the Anti-Counterfeit Act to cover issues of product quality. Efforts should focus on upgrading the drug regulator's capacity to enforce quality standards under domestic regulatory laws.

# **Background**

The United Nations Conference on Trade and Development (UNCTAD) and the United Nations Industrial Development Organization (UNIDO) collaborate on a global project to strengthen pharmaceutical production in developing countries and least-developed countries (LDCs). Within this context, UNCTAD assists in the implementation of flexibilities in intellectual property (IP) rights available under the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The full use of TRIPS flexibilities to protect public health, and, in particular, to provide access to medicines for all, is a target under Sustainable Development Goal 3 ("Ensure healthy lives and promote well-being for all at all ages").

The availability of TRIPS flexibilities creates the legal space for the production of generic medicines, and may thus provide important incentives for foreign generic firms to invest in a country's domestic pharmaceutical sector. UNCTAD considers the use of TRIPS flexibilities as an important element to promote generic pharmaceutical investment and domestic

<sup>&</sup>lt;sup>1</sup> See SDG 3 Target: "Support the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all."

enterprise development under sustainable investment policy frameworks.<sup>2</sup> In order for such frameworks to be coherent and effective, policy makers should avoid discrepancies between the use of TRIPS flexibilities, the enforcement of intellectual property rights (IPRs), and domestic laws and policies on drug regulation. This paper aims to make a contribution to the ongoing debate in Kenya and the East African Community (EAC) about substandard drugs, access to medicines, local pharmaceutical production, and the role of IPRs enforcement and drug regulatory laws.

# Introduction: Substandard Drugs, Access to Quality Medicines and Local Pharmaceutical Production

The World Health Organization (WHO) and other public health-oriented organizations regularly report on the gravity of the problem of substandard drugs in African countries, especially in disease areas most relevant to the African continent. According to a WHO report, one third of 306 antimalarial medicines collected and tested in six African countries in 2011 failed to meet international quality standards.<sup>3</sup> Surveyed countries included East African nations such as Ethiopia, Kenya and Tanzania. While imported medicines from well-established foreign manufacturers performed well in this regard,<sup>4</sup> prices for these medicines are often out of reach for developing countries' public health systems.

High medicine prices may be partly explained by the fact that many drugs are protected by IPRs such as patents, which exclude generic competition for the duration of the patent. IPRs may provide important incentives for innovation in the pharmaceutical sector. On the other hand, they may create obstacles to future innovation and impediments to the diffusion of both knowledge and research results. In addition IPRs may contribute to high prices that reduce access to needed medicines. Experts have highlighted that exclusive rights are one of the important factors influencing the prices of pharmaceutical products. This premise was also acknowledged in the WTO Declaration on the TRIPS Agreement and Public Health, whose paragraph 3 states:

<sup>&</sup>lt;sup>2</sup> For more information on UNCTAD's Investment Policy Framework for Sustainable Development (IPFSD), see <a href="http://unctad.org/en/Pages/DIAE/International%20Investment%20Agreements%20(IIA)/IIA-IPFSD.aspx">http://unctad.org/en/Pages/DIAE/International%20Investment%20Agreements%20(IIA)/IIA-IPFSD.aspx</a> (visited 4/12/2015).

<sup>&</sup>lt;sup>3</sup> See WHO, "Survey of the quality of selected antimalarial medicines circulating in six countries of sub-Saharan Africa", 2011. Available at <a href="http://www.who.int/medicines/publications/qamsareport/en/">http://www.who.int/medicines/publications/qamsareport/en/</a> (visited 4/12/2015).

<sup>4</sup> Ibid

<sup>&</sup>lt;sup>5</sup> See, e.g., J. Straus, "The Impact of the New World Order on Economic Development: The Role of the Intellectual Property Rights System", *European Review*, Vol. 15, Issue 01, 2007, pp. 47 ff., referring also to other sectors of industry.

<sup>&</sup>lt;sup>6</sup> See, e.g., C. Correa, "Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?", in *International Public Goods and Transfer of Technology under A Globalized Intellectual Property Regime*, editors K. Maskus and J.H. Reichman, Cambridge University Press, 2005, pp. 227 ff (229–32); J.H. Reichman, R. Cooper Dreyfuss, "Harmonization Without Consensus: Critical Reflections on Drafting A Substantive Patent Law Treaty", *Duke Law Journal*, 2007, pp. 85 ff.

<sup>&</sup>lt;sup>7</sup> See Commission on Intellectual Property Rights, "Integrating Intellectual Property Rights and Development Policy", London, 2002, p. 36 (available at <a href="www.iprcommission.org/graphic/documents/final\_report.htm">www.iprcommission.org/graphic/documents/final\_report.htm</a>; visited 20/04/15).

"We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices."

In order to avoid dependence on high-priced patented medicines, African developing countries have for some time relied on the importation of generic medicines from India, especially in the areas of HIV/AIDS and malaria. Until 2005, India benefited from a WTO waiver not to implement pharmaceutical product patents. However, since 2005, the Indian patent office has granted numerous patents on medicines that otherwise would be available in more affordable generic versions. This begs the questions for how long Indian generic firms will still be available to serve as the "pharmacy of the developing world" and to what extent African countries should seek to promote domestic production of quality essential medicines in areas such as HIV/AIDS and malaria, as a matter of health security. In this context, the African Union and the EAC have shown considerable commitment to establish local pharmaceutical production in African countries, through the Pharmaceutical Manufacturing Plan for Africa<sup>9</sup> and its East African regional instrument, the Regional Pharmaceutical Manufacturing Plan of Action.<sup>10</sup>

Quality upgrading of domestic pharmaceutical producers is an essential element of countries' efforts to promote access to affordable and quality medicines. In Kenya, the Kenya Pharmaceutical Sector Development Strategy (KPSDS) and the Kenya GMP Roadmap illustrate the Government's commitment in this regard. In addition, the Kenyan Pharmacy and Poisons Board (PPB) ensures through testing the safety, efficacy and quality of drugs in the Kenyan market.

While these efforts address directly the issue of drug quality, there have also been initiatives at both the EAC and Partner States' levels, including Kenya, which claim to address the issue of substandard drug quality through a new set of rules on the enforcement of IPRs. This approach has been based on the perception that makers of substandard medicines use without authorization well-reputed pharmaceutical firms' trademarks to sell their insufficient, often dangerous products in the market. The enforcement of trademark rights, according to this approach, would thus indirectly benefit public health.

This indirect approach has caused considerable concern in Kenya and elsewhere, as "anti-counterfeit" initiatives could - if misguided - potentially affect activities by the local generic industry. This paper expresses the view that legitimate concerns about IPR enforcement should be addressed in harmony with national policy objectives such as the promotion of local pharmaceutical production, and should not intimidate local producers. The paper will first seek to clarify the distinctions between substandard, counterfeit and generic drugs to enable an informed discussion of the relevant Kenyan and other EAC Partner States' legislations. It will then provide an overview of what is considered "counterfeiting" at the multilateral level (i.e. TRIPS Agreement), and subsequently address the situation in Kenya and the EAC.

<sup>&</sup>lt;sup>8</sup> Declaration on the TRIPS Agreement and Public Health, WTO document WT/MIN(01)/DEC/W/2, of 14 November 2001. Available at: http://www.who.int/medicines/areas/policy/tripshealth.pdf (visited 20/04/2015).

<sup>&</sup>lt;sup>9</sup> See http://apps.who.int/medicinedocs/documents/s20186en/s20186en.pdf (visited 20/04/2015).

<sup>10</sup> See

 $<sup>\</sup>frac{http://feapm.com/fileadmin/user\_upload/documents/EAC\_Regional\_Pharmaceutical\_Manufacturing\_Plan\_of\_A\_ction.pdf \ (visited 20/04/2015).$ 

As the paper will show, some of the EAC Partner States are in the process of adopting, at the regional and/or the national level, specific anti-counterfeiting legislation that to some extent exceeds minimum standards established under the TRIPS Agreement. At the same time, the EAC and its Partner States have been pro-actively pursuing policies of implementing public health-related TRIPS flexibilities in their domestic IP legislation, which are at least partly affected by "TRIPS-Plus" obligations in the area of IP rights enforcement. The present paper illustrates the need for policy coherence between the areas of IPRs, trade, and public health.

# Substandard vs Counterfeit vs Generic Drugs - a Distinction

There appears to be considerable confusion about the definitions of substandard, counterfeit and generic drugs and how these differ from each other. Multilateral and national rules treat each of these categories differently, and this understanding should also inform the ongoing debate in the EAC and its Partner States. Table 1 seeks to illustrate the differences between these terms.

Table 1: Substandard vs counterfeit vs generic medicines

-	- · ·	**	
Issues	Description	Key concerns	Relevant legal
			framework
(1) Substandard	Deficiencies in	Affect patients'	Drug regulatory
drugs	quality, efficacy or	health.	laws.
	safety.	Public health	
		concern.	
(2) Counterfeit	Mislabeled products;	Confusion about the	Domestic IP laws;
drugs	Not necessarily of	origin of the product.	TRIPS Agreement
	substandard quality.	Concern to	remedies;
		trademark holder.	Domestic drug
		Concern also to	regulatory laws.
		public health: Risk	
		of concealed	
		substandard drugs.	
(3) Generic	Not protected by a	There could be	For IPR
drugs	patent;	attempts to benefit	compatibility:
	Copies of patented	from the	domestic IPR laws;
	originator products;	unauthorized use of	For safety, efficacy,
	May only be	generic producers'	quality: domestic
	marketed upon	trademarks (i.e.	drug regulatory laws.
	patent expiry or	counterfeits).	
	patent invalidation	,	
	by a patent office or		
	court;		
	May be of good or of		
	substandard quality;		
	May be marketed		
	under their own		
	trademark ("branded		
	generic").		
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Source: UNCTAD.

An important concern relates to the mislabeling of substandard drugs, resulting in a mix of scenarios (1) and (2), above. Besides the public health concern, this could equally present an intellectual property issue, provided the mislabeling creates confusion among the public about the origin of the drugs. If, by contrast, the created confusion relates to the quality, safety and efficacy of the product, intellectual property (i.e. trademark protection) is not the main issue.

# The Multilateral Level: "Counterfeiting" under the TRIPS Agreement

The TRIPS Agreement links the notion of counterfeiting with one particular category of IPRs, i.e. trademarks. Footnote 14 to Article 51 of the TRIPS Agreement provides the following:

"counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;

The characterization of a product as a "counterfeit trademark good" will trigger the application of criminal procedures and penalties at least in cases of "willful trademark counterfeiting" (or copyright piracy on a commercial scale), according to Article 61 of the TRIPS Agreement.

The above definition contains at least two important limitations: (1) it does not apply to other categories of IPRs, such as patents; (2) it only applies to special cases of trademark infringement, i.e. where an unauthorized party uses a sign identical to the protected sign or at least so similar that it cannot be distinguished from it. This implies intent to deceive consumers on the part of the unauthorized party, as opposed to cases of unintentional trademark infringement, where one trademark is confusingly similar to another, but remains distinguishable. In the area of pharmaceuticals, where trademarks are often - against expressed WHO recommendations - based on the drug's international non-proprietary name (INN), such confusingly similar trademarks may occur quite often and may also constitute cases of ordinary trademark infringement. They are, however, excluded from the specific definition of "counterfeit trademark goods."

The exclusion of patents and ordinary cases of trademark infringement under TRIPS corresponds to the legal situation in many developed countries, where only civil remedies such as injunctions and claims to compensation (damages) are available in those cases. <sup>11</sup> The rationale behind this approach lies in the fact that unlike in cases of intentional trademark infringements, it is much more difficult for users and developers of technology to understand the scope of a registered patent. Many patent claims have to be clarified by the courts. A producer of medicines may not even be aware that certain of its activities such as

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<sup>&</sup>lt;sup>11</sup> See UNCTAD-ICTSCD Resource Book on TRIPS and Development, Cambridge University Press, 2005, p. 621, specifically referring to the United States. Available at <a href="http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm">http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm</a> (visited 20/04/2015).

commercially-oriented research and development (R&D) may infringe someone else's patent. In developing countries, much technology development is done by "inventing around" existing patents. This means that many technology developers are constantly at risk of committing patent infringement. As outlined above, a comparable risk exists for users of pharmaceutical trademarks, where the use of the INN may often result in confusingly similar trademarks and thus trademark infringement.

By excluding cases of patent and ordinary trademark infringement from the definition of "counterfeit trademark goods," the TRIPS Agreement ensures that criminal sanctions will not apply to these cases. While patent and trademark holders need to be able to defend their rights in cases of patent and ordinary trademark infringement, many developed countries consider it disproportionate to apply criminal sanctions, as such infringements may frequently arise in the course of trade and the undertaking of R&D. Criminal sanctions may have a chilling effect on these activities, which are normally considered beneficial to society.

## The Kenyan Anti-Counterfeit Act

A potential chilling effect on generic activities has been a point of concern in Kenya. The 2008 national Anti-Counterfeit Act in its pre-2012 version contained language that could be misunderstood and misinterpreted by judges, resulting in the application of criminal sanctions to cases of potential patent infringement that occurs in the context of generic activities. In addition, it is questionable to what extent remedies related to IP infringement constitute an effective tool to (indirectly) address problems of substandard drug quality. It may be assumed that sales of substandard drugs can be promoted through the unauthorized use of someone else's trademark by taking advantage of the sign's reputation. But even quality drugs could benefit from the unauthorized use of a well-reputed trademark. Trademark enforcement would be needed in this case, but this would not address any public health concern.

This paper expresses the view that from a public health perspective, the main concern with drug mislabeling should be about cases where such mislabeling creates confusion about a product's quality or standard, rather than the product's source or origin, as under trademark enforcement legislation. To the extent that the quality, safety and efficacy of a drug are in question, remedial action should be taken by drug regulatory agencies, not IP owners and an anti-counterfeit agency.

This differentiation between IP-related remedies on the one hand and health-oriented measures on the other hand was also stressed by the Kenyan High Court in its judgment of 20 April 2012, in which it declared parts of the Anti-Counterfeit Act unconstitutional for potential violations of the rights to life, human dignity and health and requested the Kenyan legislator to amend the Act: 12

"Clearly, as the above provisions [i.e. Sections 32-34 of the Kenyan Anti-Counterfeit Act on seizure & detention of suspect goods] show, the tenor and object of the Act is to protect the intellectual property rights of individuals. [...] Had the primary

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<sup>&</sup>lt;sup>12</sup> Judgment of the High Court of Kenya in *Patricia Asero Ochieng, Maurine Atieno and Joseph Munyi v The Republic*, 20 April 2012 [hereinafter Kenyan High Court decision].

intention been to safeguard consumers from counterfeit medicine, then the Act should have laid greater emphasis on standards and quality."<sup>13</sup>

The Court requested the Kenyan legislator to amend the Act. Importantly, the Kenyan law has provided a template for anti-counterfeit draft legislation in other EAC Partner States and the EAC Secretariat.

## Overview: Anti-Counterfeit Legislation in the EAC

In 2010, the EAC Secretariat made available to Partner States <sup>14</sup> an EAC Anti-Counterfeit Bill as drafted pursuant to a consultancy by two Nairobi-based law firms. The 2010 version received comments from Partner States' governments and underwent a number of minor modifications. Consultations between the EAC Secretariat and Partner States then proceeded on the basis of the 2011 version of the Bill. <sup>15</sup> In April 2015, however, the EAC Council of Ministers decided to discontinue the enactment of a separate law on anti-counterfeiting and instead placed draft provisions on counterfeiting within an amendment to the 2006 EAC Competition Act. The amendment applies anti-counterfeiting measures to protect trademarks and copyright, but not patents.

The EAC Competition Authority will have the power to harmonize the national legal frameworks on counterfeiting and piracy in the region. Partner States will be obliged to establish or designate an institution responsible for anti-counterfeit matters, and to enact laws prohibiting the manufacturing or production, the possession or control in the course of trade, the sale, hire, barter or exchange, or the distribution of counterfeit goods for trade. They should also prohibit the importation into, the transit through, transshipment or export from a Partner State. As a safeguard for access to medicines, the amendment provides that its provisions shall not be construed as prohibiting the manufacture, importation, sale or dealing in medicinal products generally known as generic medicines provided such medicines are not counterfeit goods. <sup>16</sup>

In Uganda, as of March 2015, the latest version of the Counterfeit Goods Bill was with Cabinet after a number of changes made by the Parliament. <sup>17</sup> Local civil society and the Ministry of Industry, Trade and Cooperatives played an important role in amending a previous version from 2009 to better reflect concerns related to public health and generic competition.

Tanzania adopted the Merchandise Marks Regulations in 2008, which contain provisions on counterfeiting. <sup>18</sup> Patent legislation in Tanzania is divided between Tanzania-Mainland and the island of Zanzibar. In an effort to implement TRIPS Agreement public health-related flexibilities, Tanzania-Zanzibar adopted the 2008 Patents Act, which in cases of patent

<sup>&</sup>lt;sup>13</sup> Kenyan High Court decision, paragraph 82.

<sup>&</sup>lt;sup>14</sup> Partner States of the EAC are Burundi, Kenya, Rwanda, Uganda, and the United Republic of Tanzania.

<sup>&</sup>lt;sup>15</sup> Version 080411 of 2011.

<sup>&</sup>lt;sup>16</sup> See the EAC Competition Act Amendment Bill, 2014, paragraphs 5 and 34 F (on file with the author).

<sup>&</sup>lt;sup>17</sup> Personal communication to UNCTAD from the Ugandan Ministry of Industry, Trade and Cooperatives, March 2015.

<sup>&</sup>lt;sup>18</sup> See August N. Mrema, "Recent Legislative Changes in Trademark Law in Tanzania", at http://www.mkono.com/pdf/Inta%20paper%202009-Final%20doc.pdf (visited 3/12/2015).

infringement and counterfeit trademarked goods provides for remedies comparable to TRIPS Agreement minimum standards. Tanzania-Mainland still relies on the pre-TRIPS Patents Act of 1995.

#### The Definition of "Counterfeiting"

The Kenyan Anti-Counterfeit Act in Section 2 states that:

"Counterfeiting" means taking the following actions without the authority of the owner of [the] intellectual property right subsisting in Kenya or elsewhere in respect of protected goods—

- (a) the manufacture, production, packaging, re-packaging, labelling or making, whether in Kenya or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods;
- (b) the manufacture, production or making, whether in Kenya or elsewhere, the subject matter of that intellectual property, or a colourable imitation thereof so that the other goods are calculated to be confused with or to be taken as being the protected goods of the said owner or any goods manufactured, produced or made under his licence;

[...<sup>\*</sup>

(d) in relation to medicine[s], the deliberate and fraudulent mislabelling of [a] medicine with respect to identity or source, whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging; Provided that nothing in this paragraph shall derogate from the existing provisions under the Industrial Property Act.

Paragraph (d) on medicines was not part of the original draft provision. It was added to respond to concerns voiced about the impact the definition especially in paragraph (a) may have on the legitimate generic production of medicines. The chapeau to the provision establishes that the authorization from the IPR holder shall be the key criterion for determining counterfeiting, and paragraph (a) *inter alia* refers to the manufacture of goods that are substantially similar copies of protected goods. This could encompass the production of generics, especially as Section 2 provides that the notion of "intellectual property rights" includes "any right protected under the Industrial Property Act, 2001" (i.e. especially patents).

It is obvious that without the subsequently added paragraph (d), the broad definition of "counterfeiting" particularly in paragraph (a) would have encompassed activities by generic producers that do not necessarily meet the patent right holder's approval. Such activities could relate to the use of the regulatory review exception for early generic market entry and especially the marketing of generic copies during the patent term in cases where the generic producer has reason to believe that the right holder's patent is weak and may be challenged in infringement litigation. Consequently, generic producers engaged in these legitimate activities would have been exposed to criminal sanctions, which are triggered by activities that meet the definition of "counterfeiting" (see section on applicable remedies below for details).

Paragraph (d) of the above-quoted Kenyan definition of "counterfeiting" was drafted along the lines of the WHO's definition of spurious/falsely-labelled/ falsified/counterfeit (SFFC) medicines. <sup>19</sup> Its relationship with paragraph (a) of the provision is not obvious. In particular, it is unclear to what extent the unauthorized manufacture of copies of protected goods may still apply to generic producers' activities, or whether paragraph (d) excludes paragraph (a) in the context of medicines. This ambiguity may have been the result of hasty drafting. In any

<sup>&</sup>lt;sup>19</sup> See http://www.who.int/mediacentre/factsheets/fs275/en/ (visited 04/03/2015).

case, it was criticized by the Kenyan High Court in its 20 April 2012 decision as not providing a sufficient safeguard for the right to life, dignity and health against IP enforcement actions targeting generic medicines.<sup>20</sup> The Court drew the conclusion that Section 2 of the Anti-Counterfeit Act threatens to violate the petitioners' right to life, human dignity and health as provided under Kenya's Constitution.<sup>21</sup>

The March 2015 version of the Ugandan Counterfeit Goods Bill removed patents from its scope of application, thereby addressing concerns that legitimate generic trade could be qualified and sanctioned as "counterfeiting." Under the older, i.e. 2009 version of the Bill, the definition of "counterfeiting" was essentially a copy of the Kenyan definition, stating that:

"Counterfeiting" means without the authority of the owner of any intellectual property right subsisting in Uganda in respect of protected goods –

The manufacturing, producing, packaging, repackaging, labelling or making, whether in Uganda or outside Uganda, of any goods by which those protected goods are imitated in such manner and to such a degree that those other goods are identical to or substantially similar to protected goods; [...]

(c) In the case of medicines, *includes* the deliberate and fraudulent mislabelling of medicines with respect to identity or source, whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging. [emphasis added]

As in the case of the Kenyan definition, the relationship between paragraph (a) and the specific paragraph on medicines was unclear. In the case of Uganda, the situation was made even more difficult by the use of the term "includes" (see italics in the above text), which is not used in the Kenyan provision. This could have been misunderstood as implying that paragraph (a) regarding manufacturing activities still applied in addition to paragraph (c), thus qualifying generic producers' activities as counterfeiting.<sup>22</sup> The criticism advanced by the Kenyan High Court (see above) applied to an even greater extent to this Ugandan draft provision. As in Kenya, the definition of "intellectual property rights" in the Ugandan Bill also included patents, thus potentially targeting generic pharmaceutical production activities. Finally, the Tanzanian 2008 Merchandise Marks Regulations have also raised concern as to potentially creating confusion between legitimate generic activities and IP infringement.<sup>23</sup>

A striking feature in the Kenyan definition of "counterfeiting" is the extra-territorial application of IPRs existing in Kenya to activities occurring in third countries. According to the original drafting of the definition of "counterfeiting" in Kenya, an IPR holder in Kenya could have qualified manufacturing activities in a third country, such as for instance India, where its product enjoys no IPR protection, as "counterfeiting." Domestic subsidiaries of these foreign manufacturers operating in Kenya would potentially have been exposed to sanctions related to "counterfeiting", such as criminal remedies (fines and imprisonment). Considering the important presence of particularly Indian generic investors in the EAC

<sup>&</sup>lt;sup>20</sup> Kenyan High Court decision, p. 44/para. 84.

<sup>&</sup>lt;sup>21</sup> Ibid, para. 87.

<sup>&</sup>lt;sup>22</sup> See UNCTAD-ICTSD, "Development Dimensions of Intellectual Property in Uganda: Transfer of Technology, Access to Medicines and Textbooks", available at <a href="http://unctad.org/en/docs/diaepcb200913">http://unctad.org/en/docs/diaepcb200913</a> en.pdf (visited 20/04/2015), p. 53 [hereinafter UNCTAD, DDIP Uganda].

<sup>&</sup>lt;sup>23</sup> See reference in WTO, WIPO, WHO, "Promoting Access to Medical Technologies and Innovation. Intersections between public health, intellectual property and trade", Geneva 2013, p. 185 (Box 4.19.). Available at <a href="https://www.wto.org/english/res">https://www.wto.org/english/res</a> e/booksp e/pamtiwhowipowtoweb13 e.pdf (visited 3/12/2015).

<sup>&</sup>lt;sup>24</sup> This shows the importance of the (subsequent) introduction of the specific proviso on medicines, as quoted above.

Partner States,<sup>25</sup> this could have a serious impact on decisions related to foreign investment in EAC Partner States.

Finally, a unique issue under Kenyan legislation is the application of Kenyan IP enforcement to protect foreign IP rights. Section 2 of the Anti-Counterfeit Act defines "counterfeiting" as taking certain actions without the authority of the owner of the IP rights subsisting in Kenya or elsewhere. The idea of enforcing foreign IP rights is in contradiction to the principle of territoriality that underlies IP law. This principle makes particular sense in the area of IP enforcement. Foreign rights holders would otherwise be entitled to claim enforcement of their foreign rights even if they do not meet the substantive requirements of protection under Kenyan IP laws. This would disregard the balance of interest between the protection of exclusive rights and the contribution that the IP owner should make to society. In practical terms, it would be very difficult for Kenyan authorities to know if certain rights not protected domestically are protected abroad. In addition, importers and consumers that rely on the fact that certain products are unprotected in Kenya may find themselves subject to IP enforcement because of foreign rights that they were unaware of. The need to respect the principle of territoriality should be reflected in an amendment to the current definition of "counterfeiting" in the Kenyan Anti-Counterfeit Act, as suggested below (Recommendation 2).

#### Applicable Remedies in Case of Patent and Trademark Infringement

#### Kenya, Uganda, Tanzania

Under the Kenyan Anti-Counterfeit Act and the Ugandan Counterfeit Goods Bill, the application of remedies such as criminal sanctions and border measures entirely depends on the qualification of an activity as "counterfeiting." Based on the specific proviso on medicines in the definition of "counterfeiting" in the Kenyan law, it should be argued that none of the available remedies apply to generic drugs, as these do not imply any "deliberate and fraudulent mislabeling". On the other hand, the unclear interpretation of this definition as observed by the Kenyan High Court (and the even greater uncertainty in the 2009 Ugandan bill, see above) could encourage some holders of pharmaceutical patents to claim unauthorized production and labeling activities as falling under the term of "counterfeiting." Such uncertainty could potentially generate a chilling effect on generic production activities. It is important to note that the 2015 version of the Ugandan Bill has addressed this problem by removing patents from its scope of application.

Criminal sanctions under the Kenyan law range from certain fines to imprisonment of up to 15 years in case of a secondary or subsequent conviction. Sanctioned activities not only encompass any domestic activities undertaken in the course of trade, but equally imported, exported, transited or transshipped products. The reference to the "course of trade" in this regard illustrates that the intention behind these laws is IP protection, rather than the control of substandard medicines.

<sup>27</sup> See Section 32 of the Kenyan Anti-Counterfeit Act.

<sup>&</sup>lt;sup>25</sup> For example, the Indian pharmaceutical firm Cipla in a joint venture with Uganda's Quality Chemicals formulates anti-retroviral drugs at a site near Kampala (see UNCTAD, DDIP Uganda, pp. 6/7).

<sup>&</sup>lt;sup>26</sup> See Section 35(1) of the Kenyan Anti-Counterfeit Act.

While transits and transshipments may thus give rise to criminal sanctions, the Kenyan law does not provide for border measures in these cases. Seizures and detentions of counterfeit products are only provided in the case of importation.<sup>28</sup>

Tanzania-Zanzibar in 2008 adopted the new Patents Act, which provides only civil remedies in all cases of patent infringement.<sup>29</sup> The Act provides for border measures only in case of "counterfeit trademark goods" within the meaning of Article 51 of the TRIPS Agreement. By contrast, Tanzania-Mainland relies on the 1995 Patents Act, which does not provide for specific border measures. It mandates, inter alia, for a maximum term of imprisonment of five years in cases of intentional patent infringement.<sup>30</sup> It also provides, however, for the possibility to seek declarations of non-infringement, which would benefit generic producers.<sup>31</sup>

In Uganda, general patent law provides no criminal sanctions in the case of intentional patent infringement.<sup>32</sup> Generic producers may therefore consider, at any time during the patent term, challenging a pharmaceutical patent by means of invoking its invalidity in the course of patent infringement litigation.

- **Recommendation 1:** In the course of the current revision of the Kenyan Anti-Counterfeit Act, the definition of "intellectual property rights" in Section 2 of the Act should be amended to only cover trademarks as well as copyrights and related rights. The Anti-Counterfeit Act should not apply to patents, in line with the minimum standards of the TRIPS Agreement and recent changes under Uganda's 2015 version of the Counterfeit Goods Bill.
- Recommendation 2: The definition of "counterfeiting" in Section 2 of the Act should be redrafted, following the definitions of "counterfeit trademark goods" and "pirated copyright goods" in Article 51 of the TRIPS Agreement. The new definition should not apply to foreign IP rights or to activities undertaken abroad, in line with the principle of territoriality that governs intellectual property law.

# **Drug Regulation in Kenya**

The above anti-counterfeit initiatives could be supported by the argument that they target the mislabeling of products, which in many cases may be used by the producers of low quality drugs to take advantage of the good reputation of a trademark. As outlined above, however, public confusion about drug quality is primarily a public health issue and should primarily be dealt with by the drug regulator. Accordingly, Sections 9 and 10 of the Kenyan Food, Drug and Chemical Substances Act provide for the following:

<sup>&</sup>lt;sup>28</sup> Section 34(1) of the Kenyan Anti-Counterfeit Act.

<sup>&</sup>lt;sup>29</sup> See Sections 73, 82, 84, 85 of the 2008 Zanzibar Patents Act.

<sup>&</sup>lt;sup>30</sup> See Section 70 of the 1995 Patents Act.

<sup>&</sup>lt;sup>31</sup> See ibid, Section 68. The Kenyan Patents Act provides a similar remedy.

<sup>&</sup>lt;sup>32</sup> Both the 1993 Patents Act and the 2009 Industrial Property Bill only foresee civil remedies to address patent infringements.

#### Deception

**9.** Any person who labels, packages, treats, processes, sells or advertises any drug in contravention of any regulations made under this Act, or in a manner that is false, misleading or deceptive as regards its character, constitution, value, potency, quality, composition, merit or safety, shall be guilty of an offence.

#### Standards of drugs

- **10.** (1) Where a standard has been prescribed for a drug, any person who labels, packages, sells or advertises any substance in such a manner that it is likely to be mistaken for that drug shall be guilty of an offence unless the substance is the drug in question and complies with the prescribed standard.
- (2) Where a standard has not been prescribed for a drug but a standard for the drug is contained in any of the publications specified in the Schedule, any person who labels, packages, sells or advertises any other substance or article in such a manner that it is likely to be mistaken for such drug shall be guilty of an offence.
- (3) Any person who labels, packages, sells or advertises any drug for which no standard has been prescribed, or for which no standard is contained in any of the publications specified in the Schedule, shall be guilty of an offence unless such drug—
- (a) is in accordance with the professed standard under which it is labelled, packaged, sold or advertised; and
- (b) does not resemble, in a manner likely to deceive, any drug for which a standard has been prescribed or which is contained in any of the publications specified in the Schedule.

These provisions directly address the mislabeling of drugs, where such mislabeling creates confusion among patients about the quality of the labeled medicine. This is a direct public health concern, as quality is what matters in this context. By contrast, the anti-counterfeit laws discussed above only address the mislabeling of products with respect to the source or identity of the product. This does not directly address quality, but relies on the traditional trademark concept of indicating the source of the product. This is not a public health concern, as mislabeling with respect to identity or source may include medicines with the correct ingredients, according to the above definition in the Kenyan Anti-Counterfeit Act and according to a WHO definition. <sup>33</sup> In order to respond to this shortcoming in the Anti-Counterfeit Act, the Anti-Counterfeit Agency has suggested extending the scope of the Act to cover issues of drug quality. <sup>34</sup> In light of the existing regulatory laws as cited above as well as the existing Kenyan consumer rights legislation, and in light of the existing responsibility of the PPB to address quality issues, however, such an extension of the Anti-Counterfeit Act appears inappropriate. As compared to an IP enforcement agency, the drug regulator is much better placed to evaluate misleading information on the quality of a drug.

Recommendation 3: From a public health perspective, the existing drug regulatory laws appear sufficient to address the mislabeling of drugs that creates confusion about quality or other drug characteristics. There is no need to expand the scope of the Anti-Counterfeit Act to cover issues of product quality. Efforts should focus on upgrading the drug regulator's capacities to enforce quality standards under domestic regulatory laws.

From an intellectual property perspective, however, there is a need to assist the trademark holder in enforcing its rights, provided the mislabeling creates public confusion about the

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<sup>&</sup>lt;sup>33</sup> See http://www.who.int/mediacentre/factsheets/fs275/en/ (visited 20/04/2015).

<sup>&</sup>lt;sup>34</sup> Oral communication from the representative of the Anti-Counterfeit Agency at the UNCTAD High Level Capacity Building Workshop on 12 March 2015.

origin of the product. In this respect, the first concern is to prevent the registration of a drug that displays a trademark without the right holder's authorization. This is addressed under Section 3.2.2.7.1.1 of the Kenyan Drug Registration Guidelines to Submission of Applications, according to which the PPB when registering a medicine will examine if a drug displays a name, package or label that bears close resemblance to an already registered product, as follows:

#### 3.2.2.7.1.1 Labelling of the primary packaging

The applicant shall ensure that the primary (immediate) packaging of the product is labelled according to the law applicable in Kenya. The following minimum information shall be required in English on the label of the immediate packaging:

- (a) brand name where appropriate
- (b) International non-proprietary name/generic name
- (c) Pharmaceutical dosage form, quantity of active ingredient per dosage unit
- (d) total contents of container
- (e) date of manufacture
- (f) date of expiry
- (g) batch number
- (h) specific storage conditions
- (i) name and full location address of manufacturer

Any drug product whose name, package or label bears close resemblance to an already registered product, or is likely to be mistaken for such a registered product, shall not be considered for registration. Disputes regarding trademark infringements not identified by PPB at the time of registration or amendment shall be the responsibility of the applicants. If however, valid safety concerns are identified, the new applicant shall be advised to make appropriate amendments.

There is thus no need for any additional remedies to prevent the registration of medicines bearing unauthorized labels. This being said, Kenyan drug regulation does not provide for any civil or criminal remedies to enforce trademark protection. This is an intellectual property concern addressed under the Kenyan Trade Marks Act (2007). In addition, the Anti-Counterfeit Act in Part IV provides for a number of measures that may be necessary to carry out inspection of suspect goods and premises, including the seizure and storage of suspected counterfeit goods.

#### **Conclusions**

The above analysis has sought to provide an overview of tools to address the problem of mislabeling of substandard medicines. Two main approaches were identified: (1) the enforcement of IPRs, especially trademarks, which is based on a creation of consumer/patient confusion about the **source/origin** of a labeled medicine; and (2) the use of drug regulation, which sanctions the creation of consumer/patient confusion about the **quality** of a labeled medicine. Only the latter approach is directly concerned with patients' health and thus appears to be the more appropriate tool to address the problem at issue.

Kenyan regulatory laws include sufficient remedies to enforce quality standards and to prevent the registration of medicines bearing labels that mislead patients as to the characteristics of a drug. Thus, an extension of the Anti-Counterfeit Act to drug quality issues appears inappropriate and not necessary. The Act should be limited to counterfeit trademarks and copyrights in line with Article 51 of the TRIPS Agreement. Any reference to patents

should be removed to avoid misunderstanding and potential application of criminal sanctions to generic manufacturers. This would be incoherent with other policy developments in Kenya and the EAC, where remarkable efforts have been made to prepare a policy environment that is conducive to local generic production, related investment and trade within the EAC. This was done mainly by agreeing on regional harmonization of drug regulation, phasing out tariffs on pharmaceutical products among Partner States, designing public procurement regimes that take account of industrial policy objectives, <sup>35</sup> and adopting common approaches to the implementation of TRIPS flexibilities. <sup>36</sup>

IP enforcement provisions that go beyond the minimum standards of the TRIPS Agreement may deter foreign generic investment, which over the past years has made important contributions to the building of pharmaceutical capacities in EAC Partner States. Maintaining the appropriate balance between the use of IP flexibilities, IPR enforcement and drug regulation is an essential element of a country's sustainable pharmaceutical investment framework.

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<sup>&</sup>lt;sup>35</sup> For the case of Uganda, see UNCTAD, DDIP Uganda, p. 34.

<sup>&</sup>lt;sup>36</sup> In 2011, EAC Health Ministers adopted two important, but non-binding instruments regarding the interface of IP and public health: (1) the "EAC Regional Intellectual Property Policy on the Utilisation of Public Health Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation"; and (2) the "EAC Regional Protocol on Public Health Related WTO-TRIPS Flexibilities".

## **Annex:** Workshop Program





#### **ROK-UNCTAD High-Level Capacity Building Workshop**

Policy Coherence for Local Pharmaceutical Production and Access to Medicines in Kenya

In partnership with the Ministry of Health, the Ministry of Foreign Affairs and International Trade and the Ministry of Industrialization and Enterprise Development of Kenya and the World Health Organization

Nairobi, Kenya, Hotel Intercontinental 11-13 March 2015

This workshop is part of a series of workshops being held under the European Union-funded Project on "Improving access to medical products in developing countries through capacity building for local production and related technology transfer."

The objective of the capacity-building workshop is to enable national stakeholders to make a contribution to the development of a national framework for improved access to medicines through domestic manufacturing. The workshop will seek to identify essential cross-cutting linkages between domestic policies related to industry, trade and health.

Discussions will be geared toward the elaboration of an action plan to address specific gaps in policy coherence. The target audience will comprise policy makers from relevant ministries, domestic pharmaceutical firms, civil society and academia.<sup>37</sup>

<sup>&</sup>lt;sup>37</sup> For more details, please contact:

Christoph Spennemann, UNCTAD. Tel: 41 (0) 22 917 59 99. E-Mail: <u>Christoph.Spennemann@unctad.org</u> or Padmashree Gehl Sampath, UNCTAD. Tel: 41 (0) 22 9174446. E-mail: Padmashree.gehl.sampath@unctad.org

# **Capacity Building Workshop**

# Policy Coherence for Local Pharmaceutical Production and Access to Medicines in Kenya

Nairobi, Kenya, Hotel Intercontinental 11-13 March 2015

### Programme

11 March 2015: Morning Session			
08:30 - 09:00	Registration of Participants		
	Chairs: Dr. Kipkerich Koskei, Chief Pharmacist and Registrar of the Pharmacy and Poisons Board, Kenya; Dr. Padmashree Gehl Sampath, Chief, Technology and		
	eport Series, Division for Technology and	,	
09:00 - 09:50	Welcome Remarks	Dr. Padmashree Gehl Sampath, Chief, Technology and Innovation Report Series, Division for Technology and Logistics, UNCTAD	
		Dr. Kipkerich Koskei, Chief Pharmacist and Registrar of the Pharmacy and Poisons Board, Kenya	
	Remarks	EU Country Representative (tbc)	
		WHO Country Representative (tbc)	
		Principal Secretary, Ministry of Foreign Affairs and International Trade, Kenya	
		Principal Secretary, Ministry of Industrialization and Enterprise Development, Kenya	
	Keynote address	Principal Secretary, Ministry of Health, Kenya	
09:50 – 10:15	Coffee Break	, ,	
11 March 2015: Introductory Session			
Chair: Representative, Ministry of Health			
10:15 – 10:45	Local Pharmaceutical Manufacturing for Access to Medical Products: Developing a Framework to Improve Public Health	Mr. Ermias Biadgleng, Legal Expert, Intellectual Property Unit, UNCTAD	
10:45-11:15	Regional Initiatives: The Regional Pharmaceutical Manufacturing Plan of	Ms. Jennifer A. Gache, Senior Industrial Engineer,	

	Action of the EAC (EAC-RPMPOA)	Industrial Davidsonment	
	Action of the EAC (EAC-RPWIFOA)	Industrial Development Department, EAC Secretariat	
11:15-11:45	Overview of Kenya Pharmaceutical	Dr. Wilberforce Wanyanga,	
11.13-11.43	Sector Development Strategy	National Pharmaceutical	
	(KPSDS)	Expert, UNIDO	
11:45 –	Q&A	All participants	
12:15	Q&A	An participants	
12:15 –	Lunch Bre		
13:30	Lunch Bre	сак	
11 March 201	15: Afternoon Session - The Interface b Policies in Kenya	petween Industrial and Health	
Chair: Padmas	shree Gehl Sampath		
13:30- 14:00	The Role of Industrial Policy in the	Dr. Padmashree Gehl	
	Context of Local Pharmaceutical Manufacturing	Sampath, UNCTAD	
14:00-14:30	Implementation of the KPSDS:	Mr. George Makateto,	
	Opportunities and Challenges	Ministry of Industrialization	
14:30 - 15:00	Drug Regulation and Local	Dr. Fred Siyoi, Asstistant	
	Pharmaceutical Manufacturing	Registrar, Pharmacy and	
		Poisons Board (PPB)	
15:00 - 15:30	Implementation of the KPSDS:	Mr. Palu Dhanani, Director,	
	views from local manufacturers	Federation of Kenya	
		Pharmaceutical	
1	G 20 D 1	Manufacturers	
15:30-15:45	Coffee Break	D W. 1D D (1D)	
15:45 – 16:15		Dr. Vimal P. Patel, Director,	
	Pharmaceutical Manufacturing: Views from Local Manufacturers	Cosmos Pharmaceuticals	
16:15 – 16:45		Discussion facilitated by Dr.	
10.13 – 10.43	Health Policy Aspects of Local Production of Pharmaceuticals:	Padmashree Gehl Sampath,	
	Contribution of the health	UNCTAD	
	system to choice of medicine	ONCIAD	
	for local production.		
	<ul> <li>Health products retailing and</li> </ul>		
	supply chain.		
16:45-17:15	Q&A	All participants	
17:30- 19:30	Cocktail Reception		
12 March 201	15: Morning Session - Science, Innovat	ion, Intellectual Property and	
	Investment		
Chairs: Dr. M	oses Makayoto, Head, Chief Research So	cientist, Kenya Industrial	
Research and Development Institute (KIRDI);			
Christoph Spennemann, Legal Expert, Intellectual Property Unit, UNCTAD			
09:00- 09:30	Science, Innovation and Technology	Dr. Padmashree Gehl	
	Framework Setting for Kenya	Sampath, UNCTAD.	
09:30 -	Science, Technology and Innovation	Ms. Ingrid Wekesa, Head,	
10:00	in Kenya: The Need for a Common	Chemical Engineering	

	Framework	Division, KIRDI	
10:00 -	Medical Research & Development in	Dr. Robert Karanja, Research	
10:30	Kenya: The University - Industry	Scientist, Villgro Kenya and	
10.50	Linkage	formerly Kenya Medical	
	Dilikuge	Research Institute (KEMRI)	
10:30 -	Tea/Coffee	research institute (IEE/III)	
10:45	100/ 001100		
10:45 -	Q&A	All participants	
11:15			
11:15 -	Intellectual Property: Generic	Mr. Christoph Spennemann,	
11:35	Pharmaceuticals Manufacturing and	UNCTAD	
	Access to Medicine		
11:35 -	Kenya's IP Regime: Incentives for	Mr. Misati Mboi, Senior	
12:00	Local Pharmaceutical Manufacturing	Patent Examiner, Kenya	
		Industrial Property Institute	
		(KIPI)	
12:00-12:30	Q&A	All participants	
12:30-13:30	Lunch Bre	eak	
1	2 March 2015: Afternoon Session - IP,	Trade and Tariffs	
	sentative, Ministry of Foreign Affairs and	1	
13:30- 14:00	TRIPS Flexibilities and Anti-	Mr. Christoph Spennemann,	
	Counterfeit Legislation: Implications	UNCTAD	
	for Generic Producers		
14:00 -	The Revision of the Kenyan Anti-	Mr. Abdikadir Hussein	
14:30	Counterfeit Act	Mohamed, Assistant Director,	
		Enforcement and	
		Prosecutions, Kenyan Anti-	
14:30 -	Q&A	Counterfeit Agency All participants	
15:00	Q&A	All participants	
15:00 –	Tea/Coffee		
15:15	Tea/Correc		
15:15- 15:45	Trade Rules, Procurement and Local	Mr. Ermias Biadgleng,	
13.13 13.13	Pharmaceutical Manufacturing	UNCTAD	
15:45 -	Kenya's Trade Regime: Tariffs and	Representative, Kenyan	
16:15	Customs Procedure for Local	Revenue Authority (tbc)	
	Pharmaceutical Industry		
16:15- 16:45	Kenya's Trade Regime: Views from	Mr. Rohin Vora, Director,	
	the Industry	Regal Pharmaceuticals	
16:45-17:15	Q&A	All participants	
13 March 2015: Morning Session			
09:00-11:00	Interactive Group Discussion	Facilitators:	
	(preferably in 3 groups)	- Dr. Padmashree Gehl	
Tea/coffee	Participants engage in an exercise to	Sampath,	
in parallel	identify:	- Mr. Christoph	
1	- specific linkages and gaps	Spennemann,	
	important for promotion of	- Mr. Ermias	
L		1	

#### TRIPS Flexibilities and Anti-Counterfeit Legislation in Kenya and the EAC: Implications for Generic Producers

	access to medicine through	Biadgleng
	local production in Kenya;	
	- a list of desired key	
	intervention areas by policy	
	and regulatory agencies;	
	<ul> <li>role of manufacturers.</li> </ul>	
11:00 -	Presentation of the Results of Group	Group Coordinators
11:45	Discussion	
11:45- 12:45	The Way Forward: Key Issues and	Discussion facilitated by Dr.
	Areas for Intervention to Strengthen	Padmashree Gehl Sampath,
	Local Coordination	UNCTAD
12:45-14:00	Lunch Break	
14:00- 14:30	Closing of Workshop	UNCTAD/WHO/Ministry of
		Health/Ministry of Foreign
		Affairs and International
		Trade/EU/EAC

# **National Policy Makers: Consultation**

11 March 2015: Closed Dialogue		
10:15-12:15	Dedicated Session on Assessment of Policy Coherence Issues for Local Production and Other Means to Improve Access to Medicines in Kenya	UNCTAD and representatives of key government agencies

