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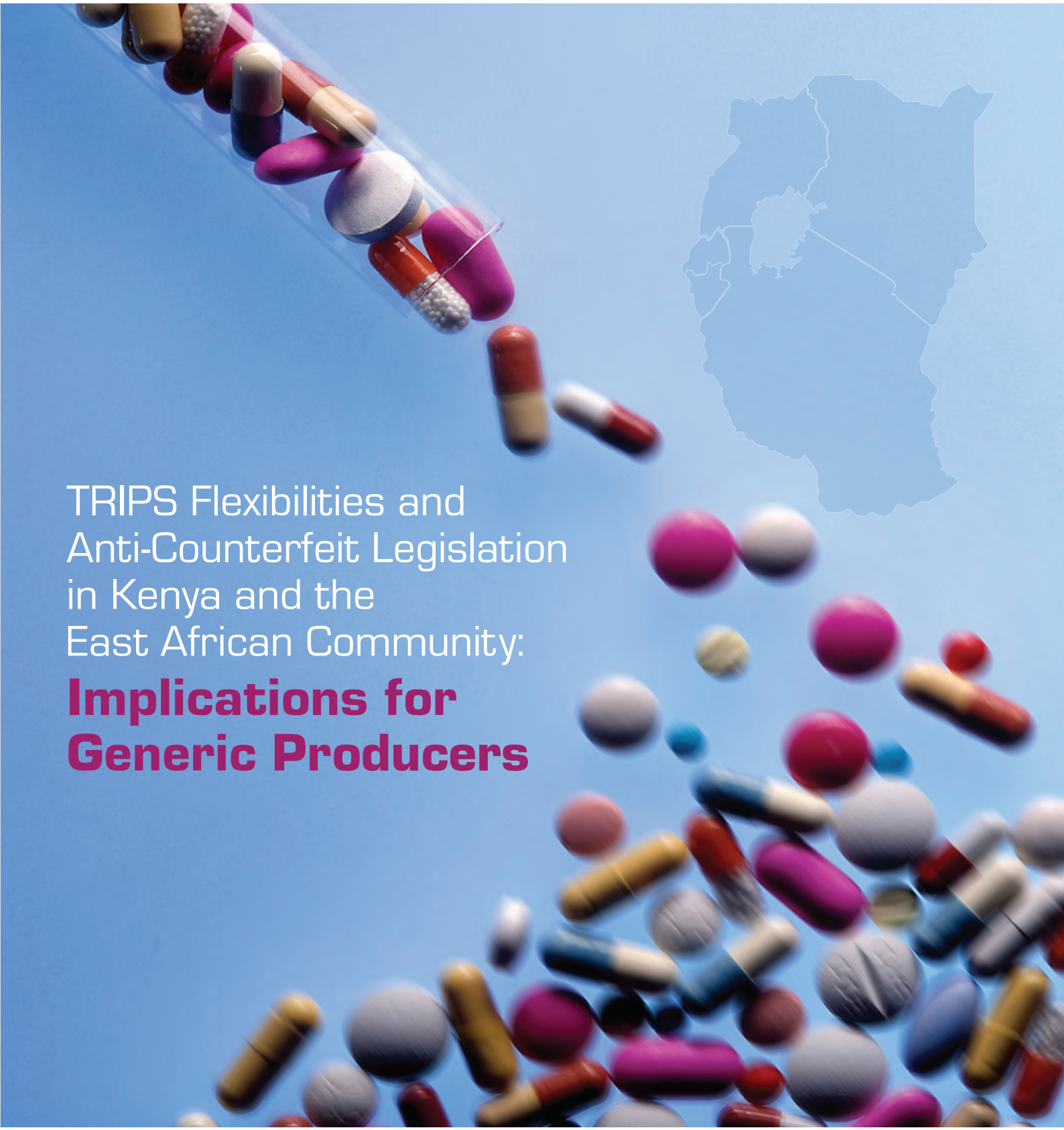

TRIPS Flexibilities and Anti-Counterfeit Legislation in Kenya and the East African Community: **Implications for Generic Producers**

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

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A first draft of this paper was presented to stakeholders at the UNCTAD High Level Capacity Building Workshop on Policy Coherence for Local Pharmaceutical Production and Access to Medicines in Kenya in Nairobi on 12 March 2015. The workshop program is annexed to this paper. This final version takes account of views expressed by stakeholders in the context of the Workshop.

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").[1]

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

[1] 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.[2] 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.[3] 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,[4] 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.[5] 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.[6] Experts have highlighted that exclusive rights are one of the important factors influencing the prices of pharmaceutical products.[7] This premise was also acknowledged in the WTO Declaration on the TRIPS Agreement and Public Health, whose paragraph 3 states:

[2] For more information on UNCTAD's Investment Policy Framework for Sustainable Development (IPFSD),