

on their review at the 14th Policy and Strategy Committee meeting, which will be held 25-26 October, prior to the 22nd Board meeting in December.[8]

FUNDING THE GLOBAL FUND

Replenishment of the Global Fund remains uncertain. The pledging conference for the third replenishment round is set to take place in October following the MDG Summit, and will have a significant impact on the Global Fund's future work. The Global Fund is facing a potential resource shortfall, as many countries have not yet made pledges, or articulated their future willingness to replenish it.

G8 members are critical supporters of the Global Fund. This year's G8 Communiqué states: "We will support country-led efforts to achieve this objective by making the third voluntary replenishment conference of the Global Fund to Fight AIDS, TB and Malaria in October 2010 a success. We encourage other national and private sector donors to provide financial support for the Global Fund." [10] Previous G8 communiqués, such as the St. Petersburg 2006 and Heiligendamm 2007, have contained stronger language, clearly committing G8 countries to provide resources for the replenishment of the Fund.

In a speech given to the Canadian HIV/AIDS Legal Network in June of this year, Michel Kazatchkine, the Executive Director of the Global Fund, outlined what could be achieved based on three different funding scenarios. At the low end, with US\$13 billion for three years (2011-2013), the Fund could continue to support program implementation, but: "we would not be able to continue scaling up programs at the same level as in recent years." In Kazatchkine's estimation, if US\$20 billion was available: "we could come close to, reach or even exceed the health-related Millennium Development Goals." [11]

NEXT STEPS

Supporters of an expanded mandate believe that the Global Fund is well-placed to take on a larger role. However, money will determine how much the Fund can accomplish. Before further discussion about an expanded mandate, donors will have to step up and make their pledges at the third replenishment round meeting in October. Before taking the radical step of expanding the mandate of the organization, the Fund is exploring how it can contribute better to maternal and child health and health systems within the existing framework.

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GENERIC VS. COUNTERFEIT DRUGS: DYNAMIC MULTI-SITE DIPLOMACY

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BACKGROUND

THE ISSUE

The failure to establish an internationally recognized and universally accepted definition of counterfeit drugs has contributed to confusion between counterfeits and generics, led to a number of controversial drug seizures, and generated intense debate in international negotiations. Developing countries as well as advocates for expanded access to medicine are concerned that this lack of clarity will limit access to generic drugs.

GLOBAL HEALTH IMPACT

Generic drugs are legitimate medicines. They are typically more affordable than brand name medicines and are critically important for improving access to essential, lifesaving treatment in both developed and developing countries.[1] In contrast, counterfeit drugs, designed to look authentic, threaten the health of people around the world. Their origin, content and efficacy are unknown, and some counterfeits may contain harmful, toxic ingredients.[2]

THE ROLE OF DIPLOMACY

Coordinated and multi-faceted diplomatic efforts are needed to establish an internationally recognized definition of counterfeit drugs and to ensure the threat of counterfeits is addressed without compromising the accessibility of generic medicines. International discussion and debate on counterfeit medicines takes place in various multilateral forums, including the World Health Organization (WHO), the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO), the UN Office on Drugs and Crime (UNODC), as well as in regional and bilateral dialogues. Strong differences of opinion between the developed and developing world are hampering efforts to reach consensus, heightening the diplomatic challenge.

INTRODUCTION

Recent seizures of drug shipments, where officials claimed generic drugs were counterfeit, as well as efforts to adopt and enforce anti-counterfeit legislation in domestic laws as well as in bilateral and multilateral agreements, have sparked concern that efforts to control counterfeits are a smokescreen to curb the sale of generics.

Generic drugs are defined as “pharmaceutical drugs which are manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights.”[3] Because they are more affordable than brand-name medicines, generic drugs allow more people, especially the poor, to access essential treatment.

The World Health Organization (WHO) defines counterfeit drugs as “medicines that are deliberately and fraudulently mislabeled with respect to identity and/or source.”[2] Counterfeit drugs are comprised of random mixtures of ingredients, including inactive, ineffective and

potentially harmful components. Many counterfeits look similar to genuine products, deceiving both health professionals and patients. In almost every case, the source of a counterfeit medicine is unknown, and its content is unreliable.

WHO notes that counterfeit drugs can be found in “both developed and developing countries, but the true extent of the problem is not really known since no global study has been carried out.”[3] Between January 1999 and October 2000, WHO received 46 reports of counterfeit drugs from 20 countries; 60% of these reported counterfeits were found in the developing world. The counterfeits were being sold as antibiotics, hormones, analgesics, steroids and antihistamines. While more international study is needed, these reports clearly indicate a problem exists.[4]

The debate on the distinction between generic and counterfeit drugs is taking place in several forums. Three specific examples of international diplomacy surrounding the counterfeit debate are provided below.

THE EUROPEAN UNION (EU) SEIZURE OF GENERIC DRUGS

The EU’s drug seizures in the Netherlands and Germany fuelled the ongoing controversy over intellectual property (IP) and generic drugs. Regulations to enforce European IP rules allow EU customs officials to seize medicines suspected of violating EU patent and trademark rules. In 2008 and 2009, the Netherlands and Germany seized generic drugs that were legal in both the originating country, India, and in the destination countries, Brazil and Nigeria. But the EU alleged that the drugs breached IP rules in the countries of transit (Netherlands and Germany).[5]

In response, Brazil and India have launched a trade dispute at the World Trade Organization (WTO) against the EU and the Netherlands.[6]. The first step of the dispute settlement process is currently underway, with Brazil and India formally requesting bilateral consultations with the EU and the Netherlands on this issue.

This trade dispute provided momentum for the establishment of an inter-governmental working group on counterfeit medical products at the WHO. At the 63rd World Health Assembly (WHA), held in May 2010, member states could not agree on the best approach to address counterfeit drugs. Instead, they formed a WHO working group to examine WHO’s role in “ensuring avail-

availability of good-quality, safe, efficacious and affordable medicine; its relationship with the International Medical Products Anti-Counterfeiting Taskforce (IMPACT); and its role in prevention and control of substandard/spurious/falsely-labelled/falsified/counterfeit medical products.”[7, 8]

ANTI-COUNTERFEITING TRADE AGREEMENT (ACTA)

Australia, Canada, the EU with its 27 member states, Japan, Mexico, Morocco, New Zealand, Republic of Korea, Singapore, Switzerland and the United States are negotiating ACTA. Its objective is to establish international standards to more effectively and efficiently enforce IP rights and address counterfeiting and piracy. The proposed agreement establishes best practices, as well as a legal framework, for IP enforcement.[9] The draft negotiating text of this agreement has been released, which includes bracketed text for language still under negotiation.[9, 10]

ACTA is a non-sectoral agreement, and does not specifically address or mention counterfeit medicines. Negotiators argue that it will work to address the problem of counterfeit drugs by “establishing international standards for trademark enforcement.” Negotiators rejected the proposal to remove medicines from the scope of the agreement because “removing pharmaceuticals would result in lower sectoral enforcement standards.”[11]

Yet advocates caution that these new standards would extend far beyond the WTO TRIPS Agreement and harm the trade in generic medicines. Oxfam spokesperson Rohit Malpani stated that “Negotiating countries are cynically using legitimate fears of counterfeit medicines to exert greater control over the trade in generic medicines to poor countries. ACTA is proposing a new, expanded framework of intellectual property protections on behalf of multinational drug companies which will be combined with border measures to stifle the trade in legitimate, generic medicines. This will mean that poor people will be denied legitimate and life saving generic medicines.”[12] Oxfam also cautions that ACTA may create legal liability for suppliers of active pharmaceutical ingredients – going beyond trade measures to threaten the supply of generic medicines.

In a joint statement on the 10th Round of Negotiations (16-20 August), negotiators tried to address this concern: “While ACTA aims to establish effective

enforcement standards for existing intellectual property rights, it is not intended to include new intellectual property rights or to enlarge or diminish existing intellectual property rights.”[13]

However, apart from Morocco, no African countries are involved in the ACTA negotiations. Brazil, a key international player on the access to medicines issue, is also not a party to the talks. The draft agreement proposes the creation of an ACTA Secretariat, which would have no representation from or accountability to the world’s poorest countries.[12] Many African states and civil society groups are therefore concerned that agreement will not be in the best interests of Africa. Moreover, with the recent seizures of legitimate generic drugs, many developing states and access to medicine advocates fear that this agreement may impact the availability and accessibility of drugs, especially in poor countries.[14]

NATIONAL LEGISLATION IN EAST AFRICA

In an effort to stop the spread of substandard and fake drugs, some African countries have recently revised their intellectual property laws to include anti-counterfeit measures. These new laws have been heavily criticized as being TRIPS plus, and causing confusion over the distinction between counterfeit and generic drugs.

For example, Kenya passed its Anti Counterfeit Act in 2008. This law defines counterfeiting as “taking the following actions without the authority of the owner of any intellectual property right subsisting in Kenya or elsewhere in respect of protected goods, (such as) the manufacture, production, packaging, re-packaging, labeling 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.”[15] The law does not distinguish medicines from these other goods.[16]

In Kenya, generic drugs account for 90% of available medicines.[17] Three people living with HIV successfully challenged the Anti-Counterfeit Act in the Constitutional Court of Kenya. They argued the Act threatened the importation or manufacturing of cheap generic medicines and therefore denied Kenyans their constitutional right to life. The judge ruled that the Act confused counterfeit and generic medicines, and suspended the ability of the Anti-Counterfeit Agency to interfere with the

the import and distribution of generic medicines in Kenya. [17]

CONCLUSION

The debate over the impact of anti-counterfeit measures on access to essential medicines is taking place in other forums. The UN Office on Drugs and Crime is strengthening efforts to address counterfeit medicines within the context of its work on transnational organized crime,[18] and the World Intellectual Property Organization (WIPO) is acting as an advisor to bilateral and multilateral discussions on counterfeiting and piracy.

Anti-counterfeit measures are also being integrated into bilateral trade agreements. Oxfam argues that the EU is aggressively seeking to extend TRIPS plus provisions by “exporting its IP enforcement measures through [Free Trade Agreements] with developing countries.”[3] Most African civil society organizations have bemoaned the current negotiations between the EU and African countries on economic partnership agreements that may enforce TRIPs-plus provisions in free trade agreements.

The counterfeit debate will undoubtedly be raised in the context of the MDG High Level Summit to be held in New York 20-22 September. The draft Outcome Document, *Keeping the Promise: United to Achieve the Millennium Development Goals*, encourages “all States to apply measures and procedures for enforcing intellectual property rights in such a manner as to avoid creating barriers to the legitimate trade of medicines and to provide for safeguards against the abuse of such measures and procedures.”[19] The final version of the Outcome Document will be scrutinized by developing states and access to medicines advocates to ensure it supports, rather than undermines, trade of and access to generic medicines throughout the developing world.

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