

# HEALTH DIPLOMACY MONITOR

SPECIAL ISSUE: UN SUMMIT ON THE MILLENNIUM DEVELOPMENT GOALS

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## Health Diplomacy Monitor

The Health Diplomacy Monitor aims to report and inform readers about key international negotiations currently underway which have a significant impact on global health. The objective is to "level the playing field" by increasing transparency and making information about the issues and proposals being discussed more readily available.

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## A WORD FROM THE EDITORS

Since their adoption at the United Nations in 2000, the Millennium Development Goals (MDGs) have become central to international development efforts, mobilizing and shaping resource allocation, and guiding the actions of donor and recipient governments, development institutions, and non-governmental actors. Three of the MDGs focus on health: child health (MDG 4), maternal health (MDG 5), and HIV/AIDS, malaria and other diseases (MDG 6). The eight MDGs also include commitments to poverty reduction, access to education, gender equality, environmental sustainability, and the establishment of a global partnership for development. For each of the MDGs, the international community committed to specific targets by 2015.

However, if current trends are maintained, the majority of these MDG targets will not be met. To accelerate progress, the United Nations will host a High Level Meeting from 20-22 September, during the General Assembly. This meeting presents a critical moment for international leaders to reflect on impediments to achieving the MDG targets and to develop a strategy to overcome these

obstacles. Keeping the Promise – United to Achieve the Millennium Development Goals, the Summit outcome document, will outline the commitments – both actions as well as resources - that UN member states will undertake to meet the MDGs by 2015.

In advance of the Summit, this issue of the Health Diplomacy Monitor examines the contentious debates, key issues, and regional dimensions of international negotiations on the health related MDGs.

The Summit may be the turning point for the MDGs, resulting in renewed international commitment and effort. However, it occurs while the international economy struggles to avert a global economic downturn. Securing sufficient resources, from donors as well as recipient countries, to achieve the MDGs is a key component of the preparations for the Summit. However, as Adam Kamradt-Scott points out, the economic crisis has also sharpened the focus on the efficient use of resources, which includes enhancing the accountability of both donors and recipient countries.

Efficiency is a particularly salient theme for the health-related MDGs given the interconnectedness of efforts needed to meet health targets. Mark Pearcey examines the main components of the proposed Joint Action Plan for Women and Children, while Bente Molenaar analyses the debate surrounding the proposed expansion of the Global Fund’s mandate to include maternal and child health. Both proposals prioritize the efficient and accountable use of resources. During the Vienna International AIDS Conference held in July, researchers examined how to enhance the efficiency of the global AIDS response, including the importance of targeting interventions to those most at risk. Tammy MacLean outlines this research, and discusses how it may be reflected in the Summit outcome document.

In their effort to meet the MDGs, various regions face different priorities and challenges. Adam Kamradt-Scott examines how Asian-Pacific countries are faring regarding the health MDGs, while Rangarirai Machedmedze assesses the challenges faced by Sub-Saharan African countries. Although progress has been slowest in Africa, regional institutions, such as the African Union are taking concrete measures to scale up efforts to meet the MDGs, whereas institutions in Asia (APEC and ASEAN) have only recently focused on health. Both authors highlight the perils of current methodologies for measuring progress on the MDGs, with data aggregated at the national level hiding dramatic inequalities within countries.

In the last year, the debate over how to address the threat of counterfeit drugs without undermining access to generic medicines has been raised in many forums. Ensuring developing countries have access to generics is critical for the achievement of the health-related MDGs. Through his examination of the counterfeit issue,

Rangarirai Machedmedze shows how actors are utilizing health diplomacy in various forums – international as well as domestic - to address and resolve this debate.

All eyes will be on New York from 20-22 September to examine if and how the international community rises to the challenge of meeting the MDGs. The Health Diplomacy Monitor will also be closely watching the negotiations and the Summit, and we look forward to providing you with follow-up reporting for the next issue.

Chantal Blouin and Val Percival  
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## ACHIEVING THE HEALTH-RELATED MDGs: PREPARATION FOR THE UN HIGH LEVEL MEETING

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### BACKGROUND

#### THE ISSUE

The 2015 deadline for achieving the Millennium Development Goals (MDGs) is fast approaching. Recent events, such as the global financial crisis, have hampered international efforts, and without immediate and significant commitments, it is unlikely that the MDG targets will be met by 2015.

#### GLOBAL HEALTH IMPACT

Three of the eight MDGs are explicitly concerned with human health, setting objectives for reducing child mortality (MDG 4), improving maternal health (MDG 5), and combating HIV/AIDS, malaria and other diseases (MDG 6). Between 1990 and 2008, there has been a marked improvement in all health indicators related to

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these targets, but progress varies within and between countries, and across regions.

The Role of Diplomacy: Diplomacy is critical to ensuring the MDGs are achieved. Recently, a series of international meetings such as the G8 and G20 meetings highlighted the need for further efforts to encourage the allocation of new resources, and to foster greater political commitment for achieving the various targets. The UN High-Level Meeting in September, and the commitments made by all countries in the outcome document *Keeping the Promise: United to Achieve the Millennium Development Goals*, will signal whether that political commitment exists.

#### INTRODUCTION

From 20-22 September, Heads of State, Ministers, and senior officials will meet in New York to examine the progress that has been made towards achieving the Millennium Development Goals (MDGs). With the 2015 deadline now less than five years away, concerns are mounting that some of the various targets will not be met.

Several progress-monitoring events have been held in recent years to raise the profile of the MDGs, and to engender further political commitment and financial resources for their achievement. Earlier this year, the United Nations (UN) Secretary-General, Ban Ki-Moon, released his *Keeping the Promise* report, in which he outlined an action plan for accelerating progress on the MDGs.[1] In addition, the UN Development Program (UNDP) released its latest assessment on MDG progress, noting that the resources and know-how for achieving the MDGs currently exist, but that “dramatically faster progress,” is needed if the 2015 deadline is to be met.[2, 3] The June G8 and G20 meetings held in Canada reviewed these documents, and participants of both groups reaffirmed their commitment to achieving the MDGs by 2015. [4, 5] Recognizing that progress on maternal and child health (MNCH) targets has been particularly slow, the G8 members launched the Muskoka Initiative, pledging an additional US\$5 billion in new funding to meet MDGs 4 and 5.[4]

In late June, the UN Secretary-General also announced the formation of the MDG Advocacy Group. The Group, which comprises 21 eminent persons, and is co-chaired by Rwandan President Paul Kagame and by Spanish Prime Minister José Luis Rodríguez Zapatero, aims to galvanize further international support

in the lead up to, and beyond, the High Level Meeting in September. When introducing the Group, UN Secretary-General Ki-Moon observed: “We need to emerge from the September Millennium Development Goals summit with concrete national action plans for realizing the Goals. These advocates can help us get there” [6]. To that end, each of the members of the Advocacy Group have been assigned one or more specific MDGs to promote.[7]

#### THE SEPTEMBER SUMMIT

The aim of the September High Level Plenary Meeting is to finalize an “action-orientated outcome document,” that seeks to identify various interventions and initiatives to achieve the MDGs by 2015. The Summit will comprise six plenary meetings and six roundtable sessions over three days.[8].

Negotiations regarding the content and scope of the outcome document commenced in April 2010, with delegations being asked to consider key themes that included: what the overall message of the document should be; how to structure any proposed action plans; how to clearly define the interventions required; and how to reflect the need to revisit policies and financial support to meet the 2015 deadline.[9] Official delegations of member states were invited to attend two informal hearings in late April and mid-May, to provide their initial input into the draft text of the outcome document.

A zero-draft of the outcome document, entitled *Keeping the Promise: United to Achieve the Millennium Development Goals*, was released on 31 May, and provided the framework for negotiations among member states.[10] The outcome document is structured in two parts: the preamble discusses the synergies between the various MDGs and reference ongoing international efforts, while the operational paragraphs commit the international community to specific action on each MDG and outline reporting requirements. After negotiations among member states, the outcome document grew from 14-pages to a compilation text of over 80-pages, and negotiations will likely continue until the eve of the Summit.

In light of the proliferation of global health initiatives, as well as the cross-cutting importance of public health to many of the MDGs, the operational paragraphs contain a section entitled *Promoting Global Public Health For All*. While still under negotiation, this section commits the international community to support country-led

efforts to strengthen national health systems, integrate the delivery of health services, address human resources challenges and access essential medicines. It also references the importance of public-private partnership and the promotion of research and development.[10]

Civil society organizations, non-governmental organizations (NGOs) and private sector organizations contributed their perspectives on the zero draft at a special informal hearing held in mid-June, 2010. Over 335 organizations were represented at the hearing.[11] In addition, many member states also consult national civil society organizations during the negotiation process.

Considerable attention is expected to be given to the issue of official development assistance (ODA). Greater emphasis is expected to be placed on “value for money” initiatives, due to the reduction in ODA following the global financial crisis. In a statement provided to the Health Diplomacy Monitor, the UK Department for International Development (DFID) noted: “Financing remains an important element to securing further progress. However, DFID will not be measuring success solely in terms of financial sums committed. A hope is for the event to have an action-oriented outcome which also takes account of results based policy commitments from both donors and developing countries. Accountability for financial commitments is also an issue where progress is necessary. We will be working with a range of partners – government, private sector and civil society – to develop plans to ensure that commitments are realized.”[12]

The ongoing divide between the perspectives of high-income “donor” countries and the G77 countries has appeared during the negotiations on the outcome-document. Donor countries stress the need for “mutual accountability,” in the allocation of funding to support the MDGs, while the G77 underscore that more resources are needed to meet the MDGs. Leaders attending the September meeting from low and middle-income countries will be encouraged to take on a greater share of the responsibility, in addition to making new commitments, to fast-track their countries’ efforts for achieving the MDGs.

## CONCLUSION

2010 marks the 10-year anniversary of the MDGs, and less than five years remain until the deadline for their achievement. The September High Level Plenary meeting is crucial: unless current efforts are intensified

and a clear plan is developed that takes into account the progress made to date and how to move forward, it is highly unlikely that the MDG targets will be met by 2015. As Jeffrey Sachs, Professor of Health Policy and Management at Columbia’s School of Public Health and a member of the MDG Advocacy Group summarized, the UN MDG Summit is arguably, “the last chance for the world to get it right” [13].

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# ASIAN PERSPECTIVES: THE HEALTH-RELATED MDGs AND THE UN HIGH LEVEL SUMMIT

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## BACKGROUND

### THE ISSUE

A number of Asian countries have made considerable progress over the past ten years to improve outcomes in maternal and child health (MNCH), and in combating infectious diseases such as HIV/AIDS, malaria and tuberculosis. However, this progress has not been uniform, varying considerably both within and between countries. Moreover, progress has often been contingent upon external aid and technical expertise. Next to Africa, Asia faces some of the toughest challenges in achieving the MDGs. Unless current efforts are intensified, and additional financial support is obtained from other Asian countries and the wider international community, several low-income Asian countries will likely not meet the 2015 MDG targets.

### GLOBAL HEALTH IMPACT

Asian countries collectively comprise approximately two-thirds of the global population. India and China have populations in excess of one billion, together accounting for approximately one-third of the world's total population. Without further progress on the MDGs in Asia, it is therefore highly unlikely that the targets will be met at a global level.

### THE ROLE OF DIPLOMACY

Diplomacy has been, and will continue to be, critical to mobilize the requisite financial resources and political will to achieve the MDGs. For Asian countries, the MDG Summit will be important to re-affirm previous commitments, and for those countries reliant on foreign aid, to obtain new resources. Key Asian countries, such as China, Indonesia and India, have emerged as important voices in international health negotiations. Their ability to shape the outcome document will provide a measure of their current level of diplomatic influence, and, arguably, will be important for the development of a realistic international consensus on how to achieve the MDGs.

### INTRODUCTION

When viewed as a whole, Asian countries have made considerable progress on the health-related MDGs. Without exception, in each of the 19 indices that are currently being used to assess progress, Asia has witnessed overall development. Indeed, even when China and India

are excluded from the statistics, the general picture is one of marked improvement.[1]

At the same time, the results are often not as positive for individual countries. According to the latest World Health Organization (WHO) statistics, maternal mortality in Cambodia is estimated at 540 women per 100,000 births [2] – virtually double the estimate for South-East Asia as a whole.[3] Maternal mortality in Nepal at 840 deaths per 100,000 births contrasts sharply to Japan's 6 fatalities per 100,000.[2] Likewise, while the under-five mortality rate is estimated to be 3 deaths per 1,000 children in Singapore, in Lao People's Democratic Republic (Lao PDR) this number is estimated to be 61.[2] Access to antiretroviral therapy (ART) is similarly skewed, as the regional average for ART in Southern Asia is 31%, [3] but Bangladesh currently covers around 7%, and Sri Lanka approximately 14% of their affected populations.[2]

### FOREIGN AID & HEALTH SECTOR EXPENDITURE

As these figures reveal, a clear divide exists between high- and low-income countries in Asia. For low-income countries, foreign aid makes up a significant share of their health sector expenditure. According to the latest statistics, whereas Viet Nam, Lao PDR and the Philippines have successfully decreased their reliance upon external assistance for healthcare, Cambodia, Indonesia, Myanmar, Nepal, and Thailand have become more reliant since 2000. The extent to which these countries depend upon foreign aid varies considerably, ranging from 0.3% (Thailand) to 17.8% (Nepal);[2] however, the overall trend for the majority of low-income Asian countries is one of increasing dependence. If low-income countries are expected to increase domestic health sector expenditures to meet their MDG targets, such foreign-aid dependence will be problematic, particularly if donor countries' reduce their official development assistance (ODA).

### HEALTH DISPARITIES WITHIN ASIAN COUNTRIES

As much as disparities exist between countries, they also exist within countries. As the most recent regional assessment on MDG progress has indicated, within-country disparity is particularly evident when examining under-five mortality rates (MDG 4). While as a whole, Asian countries have recently lowered these mortality levels, disparity within countries has increased, particularly between rural and urban areas.[4] The most striking example is Viet Nam where the rural rate of child mortality is virtually twice that of the urban rate.[4] Bangladesh,[5]

Cambodia, Indonesia and Nepal also have experienced similar, albeit smaller, increases in rural/urban disparity. While access to health care services is an important determinant of the health outcomes of children under five, other important factors include household wealth and gender.[4]

#### ISSUES FOR ASIAN COUNTRIES HEADING INTO THE MDG SUMMIT

At least three key areas are expected to be of high importance for Asian countries entering the MDG Summit talks:

1) Secure new financial commitments, particularly for primary healthcare and child and maternal health programs: Given the extent to which some Asian countries rely on foreign aid to support national healthcare expenditure, one of the critical issues in the upcoming Summit will be the level of new financial and/or in-kind technical support that countries obtain and how such support is allocated.[7] A small number of low-income countries, such as Viet Nam, have received considerable foreign investment in specific areas (e.g. pandemic influenza preparedness), which has allowed them to be more discerning in the aid packages and preconditions they accept. For the majority of other countries, overseas investment remains a necessary mainstay of domestic health expenditure.

2) Ensure the action-plan is not just donor-driven and meets the needs of Asian countries: While considerable funding has been previously allocated to areas such as HIV/AIDS,[7] other areas such as child and maternal health programs have not received the necessary attention or resources.[8] To overcome this issue, the international community currently emphasizes the need for country-led health planning. However, for the MDGs to be met at both the national and sub-national levels, country led plans must identify and work to rectify regional disparities such as the inequitable access to services between rural and urban areas.[8]

3) Closer regional cooperation: In the last decade, countries such as India and China have transitioned from being recipients of foreign aid to becoming donors. [9] Their focus has been on regions such as Africa, with donor resources primarily targeted at the energy sector. [9] However, potential exists for these two countries to join together with other Asian donor countries, such as Japan and Singapore, to build stronger regional capacity in health.

Regional organizations such as the Association of South-East Asian Nations (ASEAN) and the Asia-Pacific Economic Cooperation (APEC) are playing a more significant role in health matters, particularly in regional pandemic preparedness.[10] In more recent years though, the work of these organizations has been expanding beyond pandemics to focus on other transnational health issues. ASEAN and the WHO's Western Pacific Regional Office recently signed a Memorandum of Understanding to jointly host regional health discussions.[11] However, ASEAN is perceived as not yet having the necessary technical and human resource capabilities to meaningfully contribute to resolving the region's health challenges.[12] Discussions on health issues within these organizations may sensitize the region's foreign and economic policy decision makers on the importance of health; highlight the need for and the efficacy of regional cooperation on health issues; and, potentially have a spill-over effect into other multilateral forums. The negotiations on the MDG Outcome Document may provide an important signal of the formation of Asian alliances, as well as the strength of regional powerhouses, India and China.

#### CONCLUSION

Asian countries face a number of challenges not only to meet their MDG targets, but also in how they approach the upcoming Summit. Securing financial assistance will be a strong focus of negotiators, but beyond the MDG Summit, greater effort is required to promote closer regional integration and cooperation in health.

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## AFRICAN PERSPECTIVES: THE HEALTH RELATED MDGs AND THE UN HIGH LEVEL SUMMIT

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### BACKGROUND

#### THE ISSUE

The special needs of Africa must be given high priority at the Millennium Development Goal Summit (the Summit) in New York from 20-22 September. Without swift action by African leaders, as well as by international donors, countries in Sub-Saharan Africa will not reach the health-related Millennium Development Goals (MDGs) by 2015.

#### GLOBAL HEALTH IMPACT

Sub-Saharan Africa remains far from meeting the targets set out in the MDGs for child health (MDG 4); maternal health (MDG 5); and HIV, malaria and other diseases (MDG 6). It is clear what African states and international donors have to do: build strong health systems that integrate the delivery of health care services; secure adequate and sustainable financing for these health services; and build effective African-led governance of these systems and services. Without strong and robust action,

preventable illness and death will continue to be a reality for too many Africans.

### THE ROLE OF DIPLOMACY

To ensure that Africa receives the resources and technical assistance needed to support country-level action on the health-related MDGs, African leaders must ensure that the perspectives and needs of Africans are heard at the Summit and reflected in its Outcome Document.

### INTRODUCTION

#### THE CHALLENGE OF THE MDGs IN AFRICA

While outcomes related to HIV/AIDS, malaria and child health have improved in Sub-Saharan Africa, if current trends are maintained, the region will not meet the health-related MDGs by 2015.

#### MDG 4: REDUCE CHILD MORTALITY

Sub-Saharan Africa has the world's highest rate of child mortality, with one in seven children dying before their fifth birthday.[1] The region has witnessed a 22% decline in the under-5 mortality rate since 1990,[1] although significant variation exists between countries. Moreover, population growth has resulted in an increase in the absolute number of child deaths – from 4 million in 1990 to 4.4 million in 2008.[1] Infant mortality rates are estimated at 82 per 1,000 live births. Although the rate has declined since 1990, 17 of the 20 countries with the highest infant mortality rates are African.[2]

#### MDG 5: IMPROVE MATERNAL HEALTH

Maternal mortality "is the health indicator that shows the widest gaps between rich and poor, both between and within countries." [2] While data is scarce, WHO estimates that 900 women die per 100 000 live births in Africa.[3] The entire region, with the exception of Namibia, is identified by the UN as experiencing high or very high maternal mortality.[4]

#### MDG 6: COMBAT HIV/AIDS, MALARIA AND OTHER DISEASES

Sub-Saharan Africa remains the region most affected by the HIV/AIDS epidemic. In 2008, the region accounted for over two thirds (22.4 million) of all people living with HIV worldwide, and nearly three-quarters of AIDS-related deaths. An estimated 1.9 million people in the region were newly infected. There are some positive signs: the rate of new HIV infections has slowly declined, and 44% of adults and children in need of antiretroviral

therapy had access to treatment, up from 2 % five years earlier.[5] Efforts to combat malaria have progressed: the use of insecticide treated bed nets by children in 26 African countries rose from 2% in 2000 to 22% in 2008.[1]

Advocates warn that this MDG data is aggregated at the national level, and the UN has no provision for disaggregation of country-level data to assess sub-national progress on the MDGs. Data therefore does not capture the stark inequalities “among different socio-economic, ethnic, racial and cultural groups within countries.”[6] In addition, the World Bank has noted, “uniform goals like reducing infant mortality by two-thirds, maternal mortality by three-quarters—can underestimate progress in poor countries. Why? Because the greater the distance to the goals from low starting points in poor countries, the greater the improvement needed to reach the targets.”[7]

#### **ACTION BY AFRICANS TO ADDRESS THE MDGs**

Various stakeholders, from states to civil society organizations, agree that country- and community-led responses are critical for progress toward the MDGs. Health systems must provide universal access to integrated health care services, with an emphasis on primary health care.[8] Additional financing must be secured to strengthen health systems, to attract and retain more health workers, and to enhance access to essential medicines.

Through regional economic organizations and the African Union (AU), African countries have developed several strategies to improve the health of people on the continent.

As part of its efforts to scale up progress towards the MDGs, the AU endorsed the Maputo Plan of Action on Sexual and Reproductive Health and Rights in 2006.[9] The objective of the Maputo Plan is to ensure sexual and reproductive health rights are prioritized in government policies; ensure that health system strengthening addresses reproductive issues; increase the availability of sexual and reproductive health supplies; and build long-term health infrastructure. Significant progress has been made, including the development of Maternal and Newborn Health Road Maps by 22 countries. Linkages between sexual and reproductive health and HIV/AIDS have been established; family planning implemented and expanded; and laws passed to protect women against violence and to criminalize harmful practices against women. [10]

The AU's African Health Strategy 2007-2015 proposes to strengthen health systems through increased access to resources, better health policies and stronger management. The strategy states that this will contribute to equity through a system that reaches the poor and those most in need of health care.[11] Other African health strategies include the AU's 2005 Gaborone Declaration on universal access to HIV prevention, treatment and care;[12] the Abuja Declarations, the second one (2001) committing African states to allocate 15% of their national budgets to health; the WHO Regional Committee for Africa resolution on achieving the MDGs passed in 2005; and the 2008 Ouagadougou Declaration on Primary Health Care and Health Systems in Africa.

The theme of the 2010 AU summit, held in July in Kampala, was “Maternal, infant and child health and development in Africa.” The summit passed a number of resolutions, including a renewal of the second Abuja Declaration's commitment to allocate 15% of domestic budgets to health; and CARMMA- the Campaign for the Accelerated Reduction of Maternal Mortality in Africa.[13]

The success of the Global Fund demonstrates what can be accomplished with a combination of resources, technical assistance, a strong relationship with partner countries and civil society. As a result, the AU called upon the Global Fund to expand its mandate to include maternal and child health.[13]

The AU and its member states must go beyond rhetoric to implement the promises set out in their declarations and produce tangible results. For example, the Global Fund has reported that as of 2007, out of 52 African countries (no data was available for Somalia), only three (Botswana, Djibouti, and Rwanda) had met the 15% target for health budgets, while three more (Liberia, Malawi and Burkina Faso) surpassed this target.[14,15] While mobilizing domestic resources for health is challenging, it is crucial for both sustainability and accountability.

#### **AFRICAN PREPARATIONS FOR THE MDG SUMMIT**

The draft Outcome Document, Keeping the Promise – United to Achieve the Millennium Development Goals for the MDG summit in New York includes a paragraph on Africa, stating: “We recognize that Africa as a whole is lagging behind on many of the Millennium Development Goals and has special needs as a continent not on track to achieve the Millennium Development Goals.

Progress has been made in some African countries but the poorest ones remain a grave concern, especially in the wake of the hard hitting financial and economic crisis. We note that while aid to Africa has increased in recent years, it still lags far behind commitments made and we strongly call for the early delivery of these commitments.”[16]

The Summit is a critical moment for Africa, yet African countries have not yet developed a clear strategy on their priorities for the Summit. African states must press the international community to go beyond rhetoric to real action.

African states should emphasize the critical importance of local level interventions. They also need to address the debates regarding MDG assessments. Are MDGs aspirational or hard targets? Should states be judged on whether the targets are met? Is it the rate of progress, or the likelihood of achieving the targets that should be evaluated? Some advocates conclude that: “the metric for measuring progress is the rate of progress, not the likelihood of achieving the target;”[18] a metric they argue would place more pressure on governments to do more.[17,18]

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THE JOINT ACTION PLAN FOR  
WOMEN AND CHILDREN'S HEALTH

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**BACKGROUND**

**THE ISSUE**

Without immediate and dramatic progress, the fourth Millennium Development Goal (MDG), to reduce child mortality, and the fifth MDG, to improve **MATERNAL**

health, will not be met.[1] While weak national health systems and lack of access to health care are key causes of maternal and child mortality,[1] insufficient donor resources and poor coordination are also to blame.[2]

In a bid to accelerate progress on MDGs 4 and 5, UN Secretary General Ban Ki-Moon announced the development of a Joint Action Plan for Women's and Children's Health (the Plan).[2] According to Ki-Moon, the Plan will prompt "decisive and concerted action" on maternal and child health at the UN High Level Summit on the Millennium Development Goals.[2,3] A consultation draft, Investing in our Common Future: Joint Action Plan for Women's and Children's Health, has been circulated for comment.[4] The final version will be released at the High Level Summit.

#### GLOBAL HEALTH IMPACT

Child mortality rates have improved slightly, but 9 million children under the age of five continue to die each year.[5] Two-thirds die from preventable causes and 40% of these deaths occur in the first month of life.[6] While maternal mortality fell at an annual rate of 1.3% from 1990–2008, a 5.5% decline is needed to meet the MDG target.[6] For every woman that dies during pregnancy or childbirth, 20 more will suffer injuries, infection and/or disability.[6] Sub-Saharan Africa and South Asia account for 82% of maternal, newborn and child deaths.[1]

#### ROLE OF DIPLOMACY

Concerted diplomatic action is needed to generate new funds and enhance donor coordination and accountability mechanisms. The UN hopes that Heads of State and senior officials participating in the Summit will show the political will to address these institutional and coordination barriers, and provide sufficient financial resources to meet the MDG targets. Support for the Joint Action Plan will be an important signal of this political will.

#### WHAT IS THE JOINT ACTION PLAN?

The Plan builds on The Global Consensus for Maternal, Newborn and Child Health, which "highlights the need to align actions in politics, finance, and delivery around a cohesive set of policies and priority interventions." [4] While the Plan aims to mobilize resources for the health MDGs, it is also a framework that will enable multilateral agencies, bilateral donors, national governments and global health institutions to improve the performance of development assistance. The Plan focuses on four

areas:

- Global health interventions need to build on **country-led health plans**;
- Efforts to **strengthen health systems** are essential to improving the health of women and children throughout all stages of their lives;
- Health programs and approaches for the health related NGOs must be mutually reinforcing and support the **integrated delivery of health care services**; and,
- **Coordinated global research and innovation** must develop new medical innovations and improve the delivery of health services for women and children.[4]

#### INVESTMENTS IN CHILD AND MATERNAL HEALTH: MORE MONEY, MORE ACCOUNTABILITY

Between 2003 and 2007, donor support for maternal, newborn and child health increased by nearly 100%, to \$4 billion per year.[1] However, the annual funding gap remains at \$20 billion.[1] Researchers argue that closing this gap could save approximately 1 million women, 4.5 million newborns and 6.5 million children (aged 1 month to 5 years) by 2015.[1]

To fill the funding gap, the Plan will work to 1) ensure that donors fulfill their existing commitments, 2) use resources more efficiently, and 3) advocate for more finances for women's and children's health. The Plan calls on partners to raise an additional US\$15 billion in annual contributions.[4] Funding partners include developed and developing states, and a cross-section of civil society organizations (philanthropic agencies, research institutions and advocacy networks). Investments in maternal and child health have benefits beyond improving health. Interventions for women and children are cost effective, helping to reduce poverty and stimulate the economy through a more productive workforce. Four working groups have been developed:

- 1) *filling the financing gap, led by the World Bank;*
- 2) *building an accountability framework, led by Canada, Rwanda and WHO;*
- 3) *advocacy and social mobilization, led by the United Nations Foundation, the Partnership for Maternal, Newborn and Child Health and ONE International; and,*
- 4) *the role of innovation, led by Norway and Johnson & Johnson.[7]*

The accountability framework will monitor donor funds on an annual basis to ensure a collective and coordinated approach, tracking progress across core indicators, to provide data to partners on best practices and to develop consensus on common challenges.[4] “The accountability framework will track the policy, program and financial commitments of all stakeholders involved in implementing the Joint Action Plan, and show how these commitments contribute to improvements in women’s and children’s health at the local, national and global levels.”[4]

#### **GOVERNMENT SUPPORT, CIVIL SOCIETY CAUTION**

Norway has been a driving force of the Plan, and argues that it is essential for the successful achievement of MDGs 4 and 5. Prime Minister Jens Stoltenberg stated, “We cannot accept the fact that women continue to die in childbirth and that children continue to die from easily preventable causes. Now we must mobilize the necessary resources and know-how to save the lives of women and children and make sure we can achieve the Millennium Development Goals.”[7] At UNICEF’s annual Executive Board, held 1-4 June 2010, Norway’s UN Ambassador, Morten Wetland, urged other countries to raise their level of support for maternal and child health by supporting the Joint Action Plan.[8]

Canada, who recently championed the G8’s Maternal Newborn and Child Health Initiative, and is taking a lead role in the Plan’s Tracking and Accountability Working Group – also voiced its support and pledged to ensure that the G8 Initiative contributes to the Joint Action Plan.[7] The G8 Initiative hopes to raise US\$5 billion for health services over a five year period, with an additional US\$ 2.3 billion provided by six developed countries and two foundations.[9]

The United States is also supportive, with US Secretary of Health, Kathleen Sebelius stating “A cornerstone of the Obama Administration’s Global Health initiative is women and girl-centered programming that acknowledges women are the gateway to their communities.”[7] The US Strategy for meeting the MDGs repeats many of the same themes as the Joint Action Plan, including the need to leverage innovation, invest in sustainability, track development outcomes, and enhance the principles and practice of accountability.[10]

In July 2010, the African Union passed a number

of resolutions supportive of the goals of the Joint Action Plan, including a renewed commitment to the Abuja Declaration, which commits member governments to allocate 15% of their national budgets, excluding donor funds, to health. They also launched CARMMA- the Campaign for the Accelerated Reduction of Maternal Mortality in Africa.[11]

However, the lack of a human-rights framework concerns civil society groups. On 30 June 2010, a group of nine civil society members released a statement arguing that the multiple barriers to healthcare services for women are linked to the failure of states to guarantee non-discrimination, equal access to care, and the human right to life and health. For them, “The draft Joint Action Plan does not reflect this reality and does not adequately reflect states’ obligations to realize the right to health and other human rights of women and girls. We believe that a human rights-centered approach to strategies, policies and programmes aimed at realizing the MDGs will enhance their effectiveness.”[12]

#### **NEXT STEPS**

The Plan will be launched at the MDG High Level Summit. The current negotiating text for the Outcome Document includes a reference to the Joint Action Plan, and repeats many of the themes of country led efforts, health system strengthening, integrated delivery of health services, and accountability. During the lead-up to the Summit, the UN Secretary General will seek new financial commitments required to fully implement the Plan.[12] While few donations for the Plan have been announced, advocates hope that donors will announce new funding at the Summit. Private foundations will also be an important source of funds for the Plan. At the annual Women Deliver Conference (held 7-9 June 2010), the Gates Foundation announced that it would commit US\$1.5 billion for to maternal and child health over the next five years. These funds will be administered through the Foundation’s global health program.[13]

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## HIV AND THE MDG OUTCOME DOCUMENT: WILL THE 2010 INTERNATIONAL AIDS CONFERENCE HAVE AN IMPACT?

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### BACKGROUND

#### THE ISSUE

In July, the global health community gathered at the 18th International AIDS Conference in Vienna, Austria. This year's conference was particularly noteworthy as 2010 marks the deadline set by UN member-states in the 2006 High Level Political Declaration to achieve "as close as possible to" universal access to HIV/AIDS prevention,

treatment and care. [1] Millennium Development Goal (MDG) 6 to combat HIV/AIDS, malaria and other diseases, includes two HIV-related targets: to provide universal access to treatment by 2010 and to halt and reverse the spread of HIV/AIDS by 2015. [2]

While over five million people worldwide have access to antiretroviral therapy (ART), an estimated 10 million are still in need. [3] ARTs can successfully halt disease progression and prevent transmission, yet only two people receive treatment for every five newly infected. [4] Access to comprehensive, evidence-based services to prevent new infections is problematic in many parts of the world. Globally, more than 80% of people most at risk of contracting HIV lack access to prevention services. [5]

### GLOBAL HEALTH IMPACT

HIV remains the world's deadliest infectious disease, responsible for over 2 million deaths and 2.7 million new infections each year. [3] Worldwide, there are 33.4 million people living with HIV/AIDS, with 22.4 million in sub-Saharan Africa. While the HIV epidemic appears to have stabilized, albeit at unacceptably high prevalence levels, Eastern Europe and Central Asia have high rates of new infections, particularly among injecting drug users. Globally, an estimated 2.1 million children live with HIV and over 50% of HIV positive adults are women. [6]

### THE ROLE OF DIPLOMACY

While the International AIDS Conference is not a negotiating forum, the conference sets the tone and the agenda for future multilateral and bilateral discussions and negotiations on HIV/AIDS, including this September's UN High Level Meeting on the MDGs in New York.

### WHY IS THE INTERNATIONAL AIDS CONFERENCE IMPORTANT?

The International AIDS Conference has become the largest global public health gathering, and remains critical to assess progress, disseminate new research, and advocate for continued political support to combat HIV/AIDS. This year, over 20,000 scientists, health personnel, donors and advocates from 197 countries examined the current global AIDS response, shared scientific developments and reviewed lessons learned. Below, we examine three areas of focus at the conference and their relationship to the MDG Summit: HIV and Drug Use; Violence against Women and HIV; and Global Coordination in the Fight Against HIV/AIDS.

donors and advocates from 197 countries examined the current global AIDS response, shared scientific developments and reviewed lessons learned. Below, we examine three areas of focus at the conference and their relationship to the MDG Summit: HIV and Drug Use; Violence against Women and HIV; and Global Coordination in the Fight Against HIV/AIDS.

#### **POLITICAL WILL NEEDED TO EXPAND HIV PREVENTION AMONG INJECTING DRUG USERS**

Advocates and scientists alike expressed serious concern over the criminalization of drug-use and the failure to address the growing AIDS epidemic among injecting drug users (IDUs). Illicit drug use is a key driver of the epidemic, particularly in Eastern Europe and parts of Asia, and current estimates indicate that one-third of new HIV infections outside of sub-Saharan Africa occur among IDUs. [3] Anti-drug laws are not only unsuccessful, [7] they undermine efforts to prevent, diagnose and treat HIV/AIDS among IDUs. [8]

Researchers presented scientific evidence that harm reduction techniques, including Needle and Syringe Programs, Opioid Replacement Therapy and Supervised Injection Sites can effectively prevent HIV transmission among IDUs. [9] Condom distribution, voluntary HIV counseling and testing, and targeted information and education were also promoted as effective prevention tools for IDUs. Overcoming stigma and discrimination towards drug-use, especially among law enforcement agencies and the health sector, is critical to translate policy into action and to enable drug users to access harm reduction programs.

At the conference, researchers and advocates launched “The Vienna Declaration,” which calls for a review of the effectiveness of current drug policies and the implementation of science-based public health approaches to address individual and community harm stemming from drug use. The Declaration also promotes the decriminalization of drug users, the scaling-up of evidence-based treatment options, and the abolishment of compulsory treatment centers. The Declaration was drafted by global leaders in medicine, public health and public policy, and signed by over 16,000 individuals, including former Presidents Fernando Henrique Cardoso (Brazil) and Ernesto Zedillo (Mexico), as well as the Global Fund’s Michel Kazatchkine. Advocates hope the declaration will prompt a redirection of the financial resources currently spent on the war against drugs towards interventions sup-

ported by public health evidence. [10]

While research shows the effectiveness of harm reduction policies in preventing the spread of HIV, international norms on harm reduction have remained static since the 2001 UN Declaration of Commitment on HIV/AIDS. These norms recognize the importance of “sterile injecting equipment; harm-reduction efforts related to drug use [1, 11]” in the fight against HIV, but do not urge states to fully adopt evidence-based harm reduction programs. In many countries, the criminalization of drug use makes harm reduction programs impossible. The ‘Zero Draft’ version of the MDG Outcome Document did not reference harm reduction [12]. Subsequent drafts have simply reiterated these norms without strengthening the references to harm reduction initially adopted in 2001, or urging states to adopt harm reduction.

#### **TACKLING HIV/AIDS BY ADDRESSING VIOLENCE AGAINST WOMEN**

Violence against Women and Girls (VAWG) is another key driver of the epidemic. According to one expert, “If we don’t address the issue of gender and HIV/AIDS, we’ll continue to mop the floor without fixing the tap.” [13] Women often surpass men in HIV prevalence rates, particularly in sub-Saharan Africa, where an estimated 12 million women are living with HIV/AIDS, compared with only 8.3 million men. [14] The relationship between HIV and VAWG is mutually reinforcing: VAWG increases the risk of HIV, while HIV increases the risk of VAWG.

When women and girls have unequal access to education, economic opportunities, property rights, and legal protection, particularly protection of their sexual and reproductive rights, dependence on their male partners increases. The inability of women to access and control HIV prevention means that many women are unable to negotiate safe-sex. [15] This vulnerability is exacerbated by aggressive male behavior and the preference for multiple partners in some societies. [14] HIV also increases the risk of VAWG. Women living with HIV in many countries face higher rates of intimate partner abuse and social rejection, as well as structural violence, including obligatory HIV testing, and forced sterilization and abortions. [16]

Conference delegates advocated for a range of actions to mitigate the HIV-VAWG relationship. This involves tackling gender inequality by challenging social

norms and attitudes that condone violence, and ensuring that gender is considered and incorporated into all aspects of HIV programming. Gender-disaggregated data and further research are also necessary to improve the AIDS response for women and girls. [13]

Such research includes the development of safe and effective microbicides. Globally, an estimated 70% of women experience coercion during their first sexual encounter, hampering their ability to negotiate safe-sex. [15] Microbicides could become a crucial tool for women to reduce their risks of contracting HIV. While previous microbicide trials have shown disappointing results, the conference highlighted the results of the recent Tenofovir gel trial in South Africa. The Tenofovir microbicide prevented HIV infection among 39% of study participants. While promising, researchers cautioned that further trials are needed to confirm the results and improve its efficacy. [17] If successfully developed, the Tenofovir microbicide could prevent more than 1.3 million new HIV infections and 800,000 deaths over the next 20 years in South Africa alone. [18]

International negotiations on HIV have recognized the role of gender inequality and violence against women. In 2006, the UN pledged: “to eliminate gender inequalities, gender-based abuse and violence... [to] ensure that women can exercise their right to have control over, and decide freely and responsibly on, matters related to their sexuality in order to increase their ability to protect themselves from HIV infection, including their sexual and reproductive health, free of coercion, discrimination and violence.” [1] Yet, without stronger language, specific targets, and research on female-controlled prevention tools, these norms will not be realized in many countries. The current ‘Zero Draft’ version of the outcome document mentions the empowerment of women and ‘sexual reproductive health, repeating agreed language, but does not fully address the role played by VAWG in the HIV epidemic, nor the role of female controlled prevention. [12]

#### **FUTURE DIRECTIONS: INCREASING EFFICIENCY AND EFFECTIVENESS OF THE GLOBAL AIDS RESPONSE**

Given the impact of the global financial crisis on the ability to achieve MDG 6 targets [3], ambassadors from the President’s Emergency Plan for AIDS Relief (PEPFAR) and UNAIDS argued for more effective and efficient AIDS programming. PEPFAR announced a new three-pronged approach: continued strengthen-

ing of country-led program ownership and management; integration of vertical HIV programming into the national health system; and scaling-up of prevention efforts among entire families. [19] UNAIDS will work to simplify and reduce the cost of AIDS treatment and diagnostics, and mobilize community involvement to improve access to care. [3]

Many advocates accused USAID/PEPFAR and other donors of neglecting AIDS in favor of other global health priorities. While enhanced efficiency is critical for universal access, more funding is also needed to address the significant gap in treatment coverage, and to sustain current treatment programs. As noted by former US President Bill Clinton in Vienna, “we cannot get to the end of this epidemic without both more money and real changes in the way we spend it.” [20]

The ‘Zero Draft’ MDG Outcome Document references the need for “new strategic coalitions to strengthen and leverage the synergistic linkages between HIV and other health and development initiatives,” [12] while subsequent negotiated drafts include reference to national health and social systems, and the use of HIV platforms as a foundation for the expansion of health service delivery.

HIV researchers and advocates will closely scrutinize the MDG Summit to assess how these research findings are integrated into international action, and to evaluate how the international community will sustain and enhance the global response to HIV/AIDS.

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# THE GLOBAL FUND AND THE MDGs: MOVING TOWARDS A GLOBAL FUND FOR HEALTH?

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## Background

### The Issue

Since its creation as a public/private partnership in 2002, the Global Fund to Fight AIDS, Tuberculosis (TB) and Malaria has become the main source of funding for these three diseases in developing countries. Given the success of the Global Fund and the approaching 2015 deadline for reaching the Millennium Development Goals (MDGs), researchers, global health advocates and the African Union have called for an expansion of the Global Fund's mandate to include all the health-related MDGs.

**Global Health Impact:** Since 2002, the Global Fund has spent US\$ 19.3 billion, funding more than 572 programs in 144 countries.[1] The Fund estimates that every day its programs "save at least 3,600 lives, prevent thousands of new infections and alleviate untold suffering." [2] Advocates hope that with an expanded mandate, the Fund would be similarly successful at improving maternal and child health outcomes.

**The Role of Diplomacy:** The G8 spearheaded the establishment of the Global Fund in 2001, and diplomacy continues to play a key role in the mandate and funding of the organization. The Fund's Board, which discusses the scope of programming and approves grants, includes both donor and recipient countries, as well as representatives from non-governmental organizations, the private sector (including businesses and foundations) and affected communities. From 4-5 October, donors will meet in New York at a pledging conference to discuss the replenishment of the Fund. Full replenishment will be a critical prerequisite for any expanded Global Fund mandate.

## INTRODUCTION

The Global Fund has significantly contributed to meeting the targets set out in MDG 6 on HIV/AIDS, malaria and other diseases. In an editorial in The Guardian Online, Jeffrey Sachs notes that the work of the Global Fund is, "arguably the most successful innovation in foreign assistance over the past decade." [3]

Sachs argues that the Global Fund should be

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transformed into a Global Health Fund, focusing on all the health related MDGs.[3] The Lancet echoes this call: “Having proven itself these past 8 years and given the importance of coherence in global health policy making, in our view it is time for the Global Fund to [expand its mandate].”[4] The African Union also urged the Global Fund to “create a new window to fund maternal, newborn and child health.”[5]

This call for an expanded mandate has prompted a number of questions. First, would a Global Health Fund be the best vehicle to achieve the health related MDGs? Second, is the success of the Global Fund linked to its clear and focused mandate? Would broadening the mandate undermine future success? And third, will donors provide more resources, or simply ask the Fund to accomplish more with constant levels of funding? The Fund is in the midst of its third replenishment round, and donors have not been forthcoming in providing resources to allow the Global Fund to reach its funding target.

#### **THE GLOBAL FUND’S MANDATE**

The 2015 deadline for reaching the MDGs is approaching, and the rapid progress required to meet the MDG targets remains elusive. Progress in the areas of improving maternal health (MDG 5) and reducing childhood mortality (MDG 4) has been particularly slow.[6]

Although the current mandate of the Global Fund does not explicitly include maternal and child health or health systems, it does support health system strengthening in the context of its programs on HIV/AIDS, tuberculosis and malaria. In addition, programs supported by the Fund have also specifically contributed to improving child and maternal health.[7]

The Global Fund is also developing a joint health systems funding platform with GAVI and the World Bank, in collaboration with WHO. A recent Board decision: “affirms the critical importance of strong health systems to achieve the Global Fund’s mandate to fight AIDS, tuberculosis and malaria.”[8]

Jeffrey Sachs argues that the Global Fund could do even more. If health interventions addressed the interconnectedness of all the health MDGs, primarily through the scaling up of primary health care services, maternal and child health outcomes will improve, and developing countries will be closer to meeting MDG 4 and 5.

According to Sachs, the Global Fund is the institution best placed to address this interconnectedness and fund the scaling up of health services.[3]

Others fear that expanding the Global Fund’s mandate would entail significant re-organization and restructuring, possibly undermining the Fund’s current success. The Global Fund is not an implementing agency, but rather an instrument to channel funds to HIV/AIDS, TB and malaria programs. Partnerships with local experts, as well as multilateral and development agencies, and the provision of technical support is at the core of the Fund’s approach. The design facilitates the ‘raise it, spend it, prove it’ method, with an emphasis on specific evidence-based interventions and the delivery of tangible results. With a broader mandate, the Global Fund would need time and resources to adapt the structures and policies of the Fund to the complex task of health systems development.[7]

The agenda of the Global Fund’s April Board Meeting included the item “Optimizing Synergies with Maternal and Child Health”. [8] In preparation for this discussion, the Global Fund’s Policy and Strategy Committee assessed its current contribution to MDGs 4 and 5. The Committee’s report highlights that HIV/AIDS, TB and malaria place a heavy burden on the health of women and children, and that these three diseases indirectly cause a significant share of maternal deaths. The Committee argues that the Fund is already contributing to achieving MDGs 4 and 5 through:

- *Increased health spending at the macro level;*
- *Support to gender equality and creating an enabling environment for women and girls;*
- *Support to health interventions that impact the health of women and children; and,*
- *Programs which strengthen health systems to improve health outcomes generally.*[9]

At the April Board Meeting, members requested the Secretariat to: “review and elaborate the potential options and their implications for enhancing the contributions of the Global Fund to MCH [maternal and child health], recognizing the urgent need for additional and sufficient financing for MCH as well as for AIDS, tuberculosis and malaria, and explore how this will impact on existing Global Fund policies, partnerships, resource mobilization, procedures, and operations”[8] The Secretariat will report

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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# HEALTH DIPLOMACY MONITOR

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