

# HEALTH DIPLOMACY MONITOR

vol 2: issue 2  
April 2011

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## A WORD FROM THE EDITOR

Preparing for the World Health Assembly (WHA) is the focus of many health diplomats in the coming month. The health ministers, who will meet in Geneva from May 15 to 25, 2011 in Geneva, have indeed a very full agenda. Several articles in the current issue of the Health Diplomacy Monitor focus on agenda items of the Assembly. Ranga Machedze provides an update on the debates in Sub-Saharan Africa around counterfeit drugs (WHA Agenda item 13.7) which has risen to a higher profile since the creation of a working group at the last WHA. Adam Karamdt-Scott summarizes the preliminary findings of the independent committee that reviewed the implementation of the International Health Regulations (IHR) and the role of the WHO during the H1N1 epidemics (WHA Agenda item 13.2). I prepared an article on the preparations for the High-Level meeting

on non-communicable diseases which will take place at the UN General Assembly in September in New York; the WHO being the lead UN agency preparing for this summit, the Assembly will be an opportunity to take stock and progress toward consensus for the Summit (WHA Agenda item 13.12). Priyanka Kanth presents five resolutions related to the health system strengthening which were introduced at the WHO's Executive Board and will be debated at the WHA.

We should note that articles in previous issues of the Monitor can also provide policymakers and stakeholders with useful briefing material when preparing for the Assembly. The last issue (Volume 2, Number 1) covered the discussions around the financing of the WHO (Agenda item 11), the draft WHO HIV/AIDS strategy (Agenda item 13.6), the selection process for the WHO Director General (Agenda item 18.6), and pandemic influenza

## 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.

PUBLISHED BY THE  
CENTRE FOR TRADE  
POLICY & LAW

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Global Health Diplomacy Network

Since the launch of the Monitor last year, we have sought to expand our coverage to reflect the diversity of health-related issues being negotiated in diplomatic circles. Health and security is one area where we wish to bring information and analysis to the forefront; two members of our advisory board contribute to this effort. First, in an editorial article on the role of health in peacebuilding, Egbert Sondorp and Olga Bornemisza argue that, "...health professionals working in conflict-affected and fragile states may increasingly be confronted with dilemmas emanating from tensions between their primary motivation to improve health in the most equitable way, and the stabilisation and state building goals of their sponsors." Henceforth, they recommend that guidelines be developed for health professionals working in such environments. In a second article on health and security on humanitarian emergencies, Val Percival explains that humanitarian decision making is opaque and operating on several levels of diplomacy. She reports on the discussions which took place at the Humanitarian Action Summit in March, where participants expressed frustration that humanitarian actors are often unable to influence the political decisions that shape humanitarian engagement. Facilitating engagement in the decision-making process surrounding particular humanitarian emergencies by increasing information about them will be one goal of the Monitor in the coming year.

Rene Loewenson's contribution focuses on the debate as to how to improve access to quality medicine in Sub-Saharan Africa. The discussions, which are taking place at the WTO TRIPs Council, are related to intellectual property issues such as fair access to and benefit from the genetic resources, which can be the basis for new treatment. Broader considerations regarding the production and regulatory capacity of African countries in the pharmaceutical sector have arisen. Indeed, the African Union has called for a plan to increase research

and manufacturing capacity; however, the World Bank has challenged whether this approach makes sense from an economic and public health perspective.

Finally, Adam Karamdt-Scott looks at the health consequences of the natural disaster that recently afflicted Japan and the role that the Asia-Pacific Economic Cooperation (APEC) could play to accompany Japan in this time of crisis.

The next issue of the Monitor will be published after the WHA; it will review the main outcomes of the meeting and report on other fora where global health challenges are being addressed. Your suggestions as to what negotiations and discussions should be the focus of our future work are always appreciated.

Chantal Blouin

## EDITORIAL

### HEALTH IN PEACE-BUILDING: THE NEED TO DEVELOP GUIDELINES FOR HEALTH PROFESSIONALS Egbert Sondorp and Olga Bornemisza

Linking health to foreign policy is a relatively new phenomenon. At least three different ways in which these two topics have been linked can be identified. The first is around the effects of emerging communicable diseases on state stability and state relations. For instance, during the 1990's, HIV/AIDS was thought to lead to state destabilisation and even collapse, resulting in national and regional security risks. More recently, there have been fears that newly emerging diseases like SARS and avian influenza may lead to strained foreign policy relations at regional or global levels. A second link is the pursuance of global health goals through foreign policy diplomacy, usually referred to as Global Health Diplomacy. One example of this is the development of the International

Published by the Centre for Trade Policy and Law  
1125 Colonel By Drive | Ottawa, Ontario | K1S 5B6 | [www.ctpl.ca](http://www.ctpl.ca)  
t: 613-520-6696 | f: 613-520-3981  
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ISSN 1923-5631

Health Regulations (IHR). A third link is the use of health as a tool of foreign policy, a topic which to date has received less attention. While this approach is being increasingly promoted in a number of different ways, the evidence-base remains weak and the risks of unwanted side-effects are poorly understood. We will describe a number of ways in which health is used as a foreign policy tool, and highlight how this may cause dilemmas for health professionals working in highly politicised contexts.

#### THE USE OF HEALTH FOR PEACE-BUILDING

Broadly, there are three different ways that health can be used as a tool of foreign policy, all of which share the desire to use health for peace-building purposes.

First, there are health and peace activities often referred to as Health as a Bridge for Peace initiatives [1]. These aim to use the relatively neutral and super-ordinate goal of health care to bring opposing parties together to promote reconciliation and peace. While successful examples are rare and causality and impact are notoriously difficult to measure, the idea continues to have resonance for many health professionals [2].

Second is the use of health care by the military to win “hearts and minds.” This may range from creating goodwill in a specific area by providing health care as a way to protect the armed forces, to counter-insurgency operations where health care is used to engage with certain communities of interest [3]. Here, health care is very obviously used for political purposes to “win the peace.” While such peace-building may be fully endorsed by the international community, the use of health care is essentially political and is not primarily focused on improving health outcomes within a population.

The third instance emanates from mainly Western donor countries which are investigating how developmental processes and the delivery of basic services, including health care, can contribute to state-building and state stabilization, both of which have peace at the centre of their conceptualization [4]. They argue that health and other basic services play a role, as their delivery enhances state legitimacy and therefore stability [5]. These ideas are influenced, in part, by the overall securitization of development aid. The events of September 11, 2001 brought development back into the security sphere, where development aid was seen as subsidiary, and a tool to stabilize states and enhance global security. This was done under the rubric of the “new security agenda” [6] – a construct that defines security narrowly in terms of terrorism, weapons of mass destruction (WMD) and organized crime as the main threats to global security. Development has been combined with diplomacy and defence to become

the “3Ds” of foreign policy and security.

This state-building role for health is something that health professionals are increasingly being confronted with, especially in situations where a new fledgling government, supported by the international community, is confronted by a potential or real insurgency. For example, health reconstruction is often accompanied by rhetoric stating that health should be part of the peace dividend, contribute to stabilisation and legitimisation of a new government, and contribute to improved governance and state building. While most will agree that state-building, stability, and good governance are important as they are pre-requisites for sustained health improvements, tensions can arise when trying to both rebuild the health care system according to the public health principles of access and equity, while at the same time explicitly contributing to peace and state-building.

#### IMPLICATIONS FOR HEALTH PROFESSIONALS

Health as a Bridge to Peace initiatives are usually initiated by health professionals themselves, driven in part by those who see themselves as peace advocates. Peace is widely seen as beneficial to health, as peace promotes health through increased prosperity, and results in improvements to a range of social determinants of health, including a revitalised health care system [7]. Common critiques are that health and peace initiatives have to prioritize health and peace objectives (with one, usually health, superseding the other) and that health professionals often struggle to design programs with an effective peace-building element [8]. More fundamental is the inherent tension in the concept - it aims to use the ‘neutral’ space health provides, but at the same time places health in the political, peace-building sphere, which means it becomes politicised.

“Hearts and minds” activities may range from running a mobile clinic to counter-insurgency operations and the broader concept of medical diplomacy [9]. These activities are primarily run by military medics, but more sophisticated counter-insurgency operations will involve civilian health professionals as well. Military doctors may be motivated by humanitarian, human rights and medical ethics to assist individual civilian patients, but are subject to the broader political motives of the country they serve. Most will be aware of the dilemmas that come with serving in an army and being a doctor bound to medical ethics. Civilian health professionals who serve, for instance, as medical staff of NGOs in the context of highly politicised, “3D” operations, may be less aware of potential dilemmas or the way to deal with them.

The use of health care to contribute to stabilization and

state building may carry a number of risks, from a public health 'health for health' perspective. These range from raising expectations among the population that cannot be met, the use of inappropriate technology, a focus on treatment rather than prevention, and the undermining of government-led reconstruction of affordable health services. Another important risk is the inequitable allocation of funds to countries, or areas within countries, that are of specific concern to foreign policymakers [10].

Overall, health professionals working in conflict-affected and fragile states may increasingly be confronted with dilemmas emanating from tensions between their primary motivation to improve health in the most equitable way and the stabilisation and state building goals of their sponsors. For instance, in the current climate, a health professional working to address the obvious health needs of the Afghan population will almost inevitably be part of efforts to legitimise a possibly illegitimate regime.

Humanitarian workers have their humanitarian principles of neutrality, impartiality, and independence to guide them when confronted with similar dilemmas. While these principles may not provide ready-made solutions, they form a framework that helps them to think, discuss, and develop practical solutions [11][12]. For health professionals working in a more developmental context where the humanitarian principles do not apply, there does not seem to be an alternative framework to guide thinking about the politicisation of health. Increased awareness amongst health professionals that health is being used as a foreign policy tool, and is therefore politicised, may be needed. A framework that can guide individuals and organisations in how to deal with the dilemmas that emerge in these situations may help guard against the overt politicisation of health, and the many risks this entails.

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## PROTECTION OF GENERIC DRUGS REMAINS TOP PRIORITY FOR AFRICAN COUNTRIES



Photo: CTV News

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### BACKGROUND

#### THE ISSUE

Discussions on counterfeit medicines at the World Health Organisation (WHO) have become very controversial and polarised. In particular, there has been no consensus on the definition of counterfeit medicines, first devised by the WHO in 1992, and revised by the International Medical Products Anti-counterfeiting Taskforce (IMPACT) in 2008 [1]. The issue of counterfeit medicines has included the concept of copying – which has a specific meaning in relation to intellectual property – with issues related to the quality, safety, and efficacy of medicines. African countries, in particular, have raised concerns that the current definition might erode the gains the countries have made in accessing legitimate generic drugs of assured quality to mitigate various public health problems afflicting their countries. Other large developing countries had problems with having a definition in the first place, making the discussions extremely difficult to reconcile.

## GLOBAL HEALTH IMPACT

The failure by WHO member states to come up with a standard and universally acceptable definition of counterfeit medicines poses some challenges nationally, regionally, and internationally with regards to curbing the proliferation of substandard products, while also making sure that generic drugs are available and moving smoothly between and across countries. The members are in agreement that falsified medicines are a threat for global public health, but most delegates—including African ambassadors to the UN in Geneva—lament that the solution cannot be dominated by intellectual property rights enforcement issues. According to the WHO, the problem of counterfeit drugs exists 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.” [2] The Economist notes that “... studies of anti-infective treatments in Africa and South-East Asia have found that perhaps 15-30% are fakes. The UN estimates that roughly half of the anti-malarial drugs sold in Africa—worth some \$438m a year—are counterfeits.” [3]

## THE ROLE OF DIPLOMACY

Resolution WHA63(10) on substandard/spurious/falsely-labelled/falsified/counterfeit medical products of the Sixty-third World Health Assembly in May 2010 established a working group to review the WHO policy with regard to counterfeit, falsified, and substandard medicines, and its relationship with IMPACT, a task force that it launched in 2006 “to build coordinated networks across and between countries in order to halt the production, trading and selling of counterfeit medicines.” The taskforce is a partnership comprised of all the major anti-counterfeiting players, including international organizations, non-governmental organizations, enforcement agencies, pharmaceutical manufacturers’ associations, and drug regulatory authorities. [1] In that decision, the Director-General of the WHO was requested to convene and facilitate the work of the working group. The group has only met once over three days at the end of February 2011, and the sharp differences among the members have not yielded concrete results. The next WHA meeting is only a month away, yet no agreement on major issues has been reached.

## INTRODUCTION

The February 28-2 March 2011 meeting of the WHO working group on substandard/spurious/falsely-labelled/falsified/counterfeit medical products was convened amid sharp differences and divergent views among the countries. The African Group, coordinated by Rwanda, has joined hands with other countries, particularly developed countries, on the need for quality and safe drugs to be available in their

countries. In particular, the group has emphasised the fact that there are very weak pharmaceutical regulatory frameworks in Africa and the proliferation of the movement of substandard and falsified drugs was a cause for concern. [4] For example, according to a new WHO report on a survey of the quality of anti-malaria drugs, almost 30% of anti-malarial medicines collected from Cameroon, Ethiopia, Ghana, Kenya, Nigeria and the United Republic of Tanzania failed to meet international quality standards.” [5]

However, the availability of safe drugs, according to some African delegates, was not supposed to be hampered by intellectual property rights issues as they are not supposed to be discussed under the mandate of the working group established. At the same time, the definition of counterfeit medicines should be restricted to cover substandard drugs and not extend to affect generic medicines that are legally produced although they are a copy of the branded and patented drugs.

At a training meeting of health officials from Eastern and Southern Africa on global health diplomacy issues in Nairobi, Kenya from 14-18 March 2011, several delegates expressed the need to protect generic drugs from being labelled counterfeit and falsified medicines. One delegate from Zimbabwe implored other African countries to keep a watchful eye on the developments around the issue saying this is one of the top priority issues for Africa at the forthcoming WHA.[6]

## THE NEGOTIATIONS

Although the working group has only met once, it has provided countries with an opportunity to discuss the core issues. There are limited fora, providing African countries opportunities to discuss and consult on the issues of counterfeit drugs. One such forum is the Malabo (Equatorial Guinea) meeting of the WHO regional Task Force on 2 September 2010. Despite the lack of progress at the international level, the regional meeting has recommended, among other things, various interventions and controls by member states to deal with the aforementioned challenges.[7] The Southern African Development Community (SADC) has put in place a Health Protocol and a regional policy that also consider the issue of counterfeit and substandard drugs. [8] In east Africa, for example, the region has been working towards revising their laws to tackle the problem of counterfeits.

Despite the existence of these initiatives, especially at the regional level, the negotiations at the international level have not been conclusive as member states have proffered divergent views especially on the extent and scope of the WHO policy on counterfeits. “Some countries strongly contend that counterfeiting is principally an issue

of intellectual property, and expressed their concern that the WHO, by using the term 'counterfeit' and providing the secretariat for IMPACT, was becoming involved in the enforcement of privately owned intellectual property rights without the endorsement of all member states in the WHA." [1] They argued that the WHO should only look at issues related to combating the growth of the substandard drugs "industry" to protect public health. An African delegate who was involved in the negotiations stated privately that there was a need for a clear distinction between intellectual property and the work that IMPACT was doing and its relationship with the WHO. He said the fact that the WHO was now defacto working on intellectual property issues when the resolution did not mandate it, raised more questions than answers.

Although there was no concrete agreement, the member states discussed the future role of the WHO with regards to substandard, spurious, falsely labelled, falsified and/or counterfeit medical products to concern three main issues: information and awareness creation, norms and standards and technical support to countries.[9]

On the WHO's relationship with IMPACT, African delegates are of mixed views. Some support the work IMPACT is doing, but several others are not satisfied with the taskforce and have been suggesting discontinuing engagement. This is one area where there was no agreement as various member states had views ranging from continued engagement with IMPACT to disengagement and putting in place a moratorium until the working group has fully assessed the activities.

#### ANTI-COUNTERFEITING LEGISLATION

At another level, a number of countries mostly from Europe and North America are finalising the Anti-counterfeiting Trade Agreement (ACTA) that would apply new, stricter legal and enforcement standards to the trade in informational goods. No sub-Saharan African countries are involved in these negotiations as they fear the new standards would extend far beyond those required by the World Trade Organisation agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs). Only Morocco in North Africa is involved in the negotiations. The other governments involved in the negotiations of this agreement are that of the United States, the European Commission, Japan, Switzerland, Australia, New Zealand, South Korea, Canada, and Mexico. The issues under discussion here are mostly intellectual property related. African countries have no interest in dealing with IP issues when discussing counterfeit matters hence their non participation. They feel this is adequately dealt with by the WTO under the TRIPs agreement.

#### THE WAY FORWARD

Member states are still miles apart from reaching a conclusion especially on the separation of intellectual property issues from the problem of substandard, spurious, falsely labeled, falsified and/or counterfeit medical products. The countries are all dissatisfied with the lack of progress. The WHA meeting in Geneva in May provides another opportunity for countries to close ranks and ensure there is agreement to protect public health through availability and accessibility of affordable and safe and quality drugs. African countries are the most affected in terms of availability of affordable drugs and the proliferation of substandard drugs. This is an opportunity for them to protect their interests by defending the gains they have made with regards to generic drugs and also advancing strong regulatory practices to ensure safe and quality drugs.

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# DRAFT REPORT RELEASED ON WHO HANDLING OF H1N1 FLU PANDEMIC AND IMPLEMENTATION OF IHR



Photo: cbc.ca

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## BACKGROUND

### THE ISSUE

The IHR Review Committee has released their preliminary report on the World Health Organization's (WHO) handling of the 2009 H1N1 influenza pandemic. The report outlines a series of wide-ranging recommendations, identifying in frank and clear terms where the WHO needs to adjust its policies and procedures to better respond to future public health emergencies. The report also evaluates several allegations of misconduct and criticisms that the WHO Secretariat over-reacted to the spread of the H1N1 influenza virus, finding that while practices need to be improved, no wrongdoing actually occurred. The final report will be submitted to the 64th World Health Assembly in May 2011, but questions have already been raised over the extent to which the Committee's recommendations will be implemented.

### GLOBAL HEALTH IMPACT

The IHR Review Committee's recommendations include several practical measures that, if implemented by Member States and the WHO Secretariat, have the potential to significantly enhance the international community's ability to respond effectively to public health emergencies of international concern. The report makes a strong case to expedite technical capacity building both within the WHO and Member States, and for more open and transparent procedures when responding to future public health crises.

### THE ROLE OF DIPLOMACY:

Political commitment at the highest level, accompanied by a significant injection of financial resources to support new training and technical capacity building programs, will be required to implement the IHR Review Committee's findings in full. The discussions and negotiations at the 64th World Health Assembly will therefore be critical to achieving any lasting change in the international community's public health response capacity.

## BACKGROUND

In January 2010, the Executive Board of the World Health Organization (WHO) endorsed a proposal by the WHO Director-General, Dr Margaret Chan, to commission an independent review of the activation of the International Health Regulations (2005) and the organization's response to the 2009 H1N1 influenza pandemic. Following the Executive Board's approval, the Director-General appointed 29 representatives to serve on the IHR Review Committee. The 29 members of the Review Committee were drawn from the IHR Roster of Experts, which is a list of specialists previously nominated by Member States for their expertise in international communicable disease outbreak and control. The Review Committee was tasked with three responsibilities:

1. to assess the functioning of the International Health Regulations (2005) in relation to the current pandemic (H1N1) 2009 and other public health events;
2. to review the scope, appropriateness, effectiveness, and responsiveness of global actions as well as the role of the WHO Secretariat in supporting pandemic preparedness, alert and response in relation to the pandemic;
3. based on the above, to identify and review the major lessons learned from the global response to the current pandemic and to recommend actions to be taken by Member States and the Director-General to strengthen the preparedness and response to potential future influenza pandemics and other public health emergencies [1].

The first meeting of the Review Committee was held at the WHO headquarters in Geneva from April 12-14, 2010, and an initial report was submitted and noted by the 63rd World Health Assembly (WHA) in May 2010 [2]. A further three meetings were held between April 2010 and March 2011. A preview report was released in March 2011, and a final report will be submitted to the 64th WHA in May 2011 [3].

### THE IHR REVIEW COMMITTEE'S PREVIEW REPORT

In their preview report, the IHR Review Committee has outlined three "Summary" or overarching conclusions, and each conclusion is then expanded upon and accompanied by a number of key recommendations and their rationales. The content of the report is both clear and engaging, outlining several of the key criticisms of the WHO Secretariat in relation to its management of the 2009 H1N1 influenza pandemic such as the decision to amend the definition of a pandemic, the openness and transparency of the IHR Emergency Committee, and the operationalization of the International Health Regulations (2005) [4]. It is in this regard that the report offers an open and frank account of what the WHO Secretariat has done well, where it needs to improve, and where Member States should now concentrate their efforts.

For example, the Review Committee has acknowledged and openly discussed in their report the criticism that arose regarding the WHO Secretariat's decision to keep the identities of the IHR Emergency Committee members confidential throughout the 2009 H1N1 influenza pandemic. The IHR Emergency Committee was responsible for advising the Director-General on whether the organization should declare Phase 6 (e.g. a full-scale pandemic). The decision to keep the Committee members' identities confidential, along with suspected conflicts of interest with the pharmaceutical industry and the withdrawal of online documents (without explanation) that stipulated severity was a key factor in determining a pandemic, contributed to accusations of misconduct and prompted a number of external investigations [5]. These issues have been openly discussed in the IHR Review Committee's report, and several remedial action points have been identified for the WHO Secretariat to implement in order to prevent a repeat of similar issues arising in the future.

Likewise, one of the key issues identified by the IHR Review Committee is the WHO Secretariat's inability to manage a sustained global public health emergency. The Committee noted, "[the] WHO's internal response capacities to health emergencies are geared towards relatively short-term, geographically focal events, a type that WHO confronts many times each year. By contrast, the pandemic required a worldwide response lasting one to two years" [6]. To address this weakness, the Committee has recommended the organization establish an event management structure, train additional staff in emergency management, adjust internal policies to permit these staff support a prolonged response, and ensure that the physical and social needs of staff managing such an event are catered for (Recommendation 5).

In addition, the IHR Review Committee has also argued that Member States need to address, as a matter of some urgency, their strategies for building and maintaining the IHR core capacity requirements (Recommendation 1). Under the terms of the IHR, governments have until mid-2012 to ensure they meet the minimum requirements for disease surveillance, verification, and response, to prevent disease outbreaks from spreading internationally [7]. In their report, the IHR Review Committee has identified, however, that the international community is currently "ill-prepared to respond to a severe influenza pandemic or to any similarly global, sustained, and threatening public health emergency" (Summary Conclusion 3). To that end, the IHR Review Committee have outlined a series of measures for the WHO and Member States to consider, including:

- enlisting the support of various agencies and organizations willing to provide assistance to countries in building their core capacities (Recommendation 1);
- expanding a "global, public health reserve corps" of public health experts to render technical assistance (Recommendation 12);
- establishing a contingency fund of US\$100 million to support surge capacity when confronted with an international public health emergency (Recommendation 13);
- reach consensus on the influenza virus-sharing and other benefits negotiations (Recommendation 14); and,
- implement a comprehensive influenza research program (Recommendation 15).

In this regard, the IHR Review Committee has attempted to provide a series of methodical and measured solutions to the issues/areas of concern they identified.

#### NEXT STEPS

The fourth and final meeting of the IHR Review Committee was held in Geneva between March 28-30, 2011. From this meeting, the final report of the Committee will be tabled at the 64th World Health Assembly in mid-May 2011 for Member States' attention [8]. Ultimately, it remains to be seen how many of the Review Committee's recommendations will be acted upon. This is due to the fact that a number of the suggested actions – such as Recommendation 4 that advocates Member States should ensure IHR National Focal Points possess "the authority, resources, procedures, knowledge and training to communicate with all levels of their governments and on behalf of their governments as necessary" – overlooks the fact that it may be in Member States' interests to maintain the status quo. Added to this, given that the WHO is facing significant financial constraints in the next budgetary period [9], it remains to be seen how much capacity the WHO Secretariat will have to implement the IHR Review Committee's recommendations. Given, however, that considerable consensus exists amongst Member States regarding the WHO's global health security role and function [10], it can be anticipated that the IHR Review Committee's report will attract considerable political interest, and that pressure will be brought to bear on the WHO Director-General to implement the Committee's recommendations in full.

The WHO's Director-General, Margaret Chan, has already indicated, however, that implementing the Review Committee's recommendations in full will present a challenge for her organization. In her opening remarks at the fourth meeting of the IHR Review Committee, Dr Chan stated, "Some of your recommendations will be far easier to implement than others, as has been mentioned

by some Member States. In general, changes in policies, practices, and priorities that fall entirely within the purview of WHO and its governing bodies are comparatively easy to implement, though the amount of time needed for full implementation will vary, as will resource needs” [8]. But Dr Chan was also keen to stress that “More difficult to address are weaknesses in the pandemic response that lie outside the direct authority and beyond the direct influence of WHO. These are weaknesses that arise from larger systemic difficulties” [8]. It can already be seen, therefore, that implementing the IHR Review Committee’s recommendations will not be a straightforward process. Ultimately, the extent and speed with which any reforms are undertaken now rests with Member States at the World Health Assembly in May.

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## UN HIGH-LEVEL MEETING ON NON-COMMUNICABLE DISEASES



Photo: cigarbrandsinfo.blog.com

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#### BACKGROUND

##### THE ISSUE

The UN General Assembly will hold a High-Level meeting on non-communicable diseases (NCDs) in New York on September 19-20, 2011. This is the first time that the world’s leaders will convene to discuss concerted actions to address the challenges posed by NCDs, and only the second time that the UN General Assembly focuses on global health, following its Special Session on HIV/AIDS in 2001.

Member states, international organizations, civil society and business are now engaged in discussions as to what commitments should be included in the outcome document that will be agreed upon at the Summit. The WHO has undertaken consultations with Member States through its regional offices and with non-state actors through ad hoc informal dialogues.

Prevention and control of NCDs have risen on the global health agenda not only because of the increasingly heavy global disease burden associated with them, but also because of a greater attention given to the economic impact of NCDs. For instance, in its annual report on global risks, the World Economic Forum highlighted chronic diseases as one of the key risks to the global economy. The economic risks are not only caused by rising healthcare costs, but even more so by the productivity losses associated to death, disability, and work absence caused by NCDs.[1]

##### GLOBAL HEALTH IMPACT

NCDs, mainly cardiovascular diseases, cancers, chronic respiratory diseases and diabetes are the world’s biggest killers, causing an estimated 35 million deaths each year—60% of all deaths globally—with 80% in low- and middle-income countries.[2] These diseases are preventable. Up to 80% of heart disease, stroke, and type 2 diabetes, and over a third of cancers could be prevented by eliminating shared risk factors, mainly tobacco use, unhealthy diet, physical inactivity and the harmful use of alcohol.

##### THE ROLE OF DIPLOMACY

In the last years, there has been growing interest in

designing concerted actions to address NCDs. In 2008, the World Health Assembly (WHA) endorsed the Action Plan for the Global Strategy for the Prevention and Control of Non-communicable Diseases [2]. The Global Strategy was adopted in 2000 and covers surveillance, prevention and treatment of NCDs, stressing the importance of multi-sectoral actions to address the main risk factors leading to preventable deaths and diseases. [3] The resolution on the marketing of food and non-alcoholic beverages to children adopted at the WHA in 2010 is an example of recommended actions coming from the Global Strategy.[4] In the resolution proposed by CARICOM and adopted last September at the UN General Assembly to convene the Summit, governments expressed their conviction that there is urgent need “to undertake multilateral efforts at the highest political level to address the rising prevalence, morbidity, and mortality of non-communicable diseases worldwide and to raise the priority accorded to non-communicable diseases in development cooperation”. [5] The outcome document that will be adopted by leaders at the High-level meeting brings this challenge beyond the traditional health forum in order to receive this higher level of attention from political actors.

#### CONSULTATIONS TO DATE

Mr. Raymond Wolfe, Permanent Representative of Jamaica in New York and Ms. Sylvie Lucas, Permanent Representative of Luxembourg in New York, have been appointed by the UN membership to serve as co-facilitators to lead informal consultations and drafting of the outcome document. It is expected that a first draft of the document will be ready for the end of June. Meanwhile, the World Health Organisation has been taking the lead to organize formal consultations with Member States. With the UN Department of Economic and Social Affairs (UNDESA) and the Government of Norway, it convenes a regional consultation for Europe in Oslo in November 2010. Since then, the WHO's regional offices have been holding regional consultations with Member States in Mexico (PAHO), Jakarta (SEARO), Seoul (WPRO) and Brazzaville (AFRO). It also held an informal dialogue with civil society and the private sector in Geneva on November 1, 2010.

#### ISSUE BEING DISCUSSED AND PROPOSALS PUT FORWARD

Three main issues are emerging in the on-going discussions as to what should be included in the outcome document. First, consultations highlighted the importance of including measurable targets in the document; the power of specific targets and indicators to mobilize action and ensure accountability is seen as a key lesson of the Millennium Development Goals (MDGs). For instance, including actionable targets related to the implementation of the

Framework Convention on Tobacco Control has been proposed during the EURO consultations [6]. Similarly, the Ministerial Declaration adopted in Mexico by the PAHO members called upon the WHO to develop specific targets against which progress in prevention and control of NCDs can be measured, with a view of their future inclusion in the MDGs. [7]

The NCD Alliance, a coalition of the four international federations of NGOs working on cancer, diabetes, heart and lung diseases, with the Lancet NCD Action group, an informal network of researchers, practitioners, and civil society organizations have proposed potential targets with a view to reduce NCD death rates by 2% per year. [8,11] Focusing on the most cost effective interventions, their first target is to achieve, by 2040, a reduction of tobacco use to a level where less than 5% of the world population will be using tobacco. They also suggests that governments commit to reduce salt intake to 5g/day per person by 2025, to eliminate the marketing of foods high in saturated and trans fats, salt, and refined sugars by 2016, and ensure universal access to essential drugs such as insulin, anti-hypertensives, and aspirin by 2015.[8,11]

The second issue emerging is the capacity of the High-level meeting to mobilize financing for prevention and treatment of NCDs globally. Less than 3% of development assistance for health was allocated to address NCDs in 2007, despite the fact they represent a large part of the burden of diseases.[9] However, given the financial crisis and its fiscal consequences, some have expressed strong doubts about the capacity to attract significant resources for NCDs.[10] Civil society organizations have estimated that financing the priority intervention would require \$9 billion annually,[11] but none of the reports and declarations coming out of the consultations up to now have mentioned specific global financial commitments. For instance, the Jakarta Declaration coming out from the WHO consultation in South-East Asia has focused on domestic resources mobilization and called upon governments and parliaments to “increase overall budgetary allocations for health and especially budgets for combating NCDs.”[12] Similarly, the first draft of the Declaration circulated in advance of the WHO Ministerial meeting to take place in Moscow at the end of the April mentions the importance of investigating innovative financing mechanisms to mobilize resources for NCD prevention and control.[13] The cost-saving nature of preventing NCDs is not very explicitly promoted in these documents, even though such arguments can strongly resonate with the Ministers for Finance which have to face increasingly high price tags for NCDs treatment in their country. This is especially the case for interventions such as reduction of tobacco use and salt consumption reduction, which are less costly and offer large health and economic benefits.[11]

Given the need for multi-sectoral actions to prevent NCDs, the implementation of UN commitments will require innovative whole-of-society approaches; a better integration of business actors, especially from the food and beverages industry, in the policy process is perceived as a key element for successful collective action.[14] However, analysts observe that the main obstacle to improve private sector engagement is “to find an institutional platform that is trusted by all stakeholders. With the WHO taking the lead within the UN on organizing the September meeting, there is distrust on both sides as to whether a meaningful dialogue can take place.”[10] Some of the existing preparatory documents mention the need for collaborative partnerships with the private sector,[7] but do not propose what forms such collaboration should take. On the other hand, the NCD Alliance’s proposals include the creation of a “Stop NCDs partnership” and of a high-level commission to monitor the implementation of the Summit’s commitment which would include private sector’s participation.

In addition to these three main issues, the discussions around the Summit have also raised questions about the scope of the initiative. Some would like to expand it to include mental health and injuries. However, such expansion beyond the four “big killers” could dilute the focus and reduce impact.[10] Another issue raised has been the risk of focusing on vertical interventions and the need to adopt a health system approach, as it is increasingly been advocated to address infectious diseases. Finally, it remains to be seen whether leaders, presidents, and prime ministers will actually attend the Summit or send their representatives to New York to represent their country.

#### NEXT STEPS

The negotiations and discussions around the preparation of the outcome document for the High-level meeting on NCDs will continue in a variety of fora in the coming months. The WHO is convening a Ministerial meeting on NCDs on April 28-29, 2011 hosted by the Government of Russia in Moscow.[13] The Ministerial meeting will be preceded by a one day NCD Global forum (April 27, 2011) where non-state actors will be able to share their views. The Summit is also on the agenda of the 64th World Health Assembly which will take place on May 16-25, 2011, in Geneva. The Assembly will consider, among other things, a resolution proposed, but not adopted, at the Executive Board of the WHO in January; the resolution was put forward by Barbados with New Zealand, Norway, Russia and Trinidad\Tobago. [14] On June 16, 2011 the UN is holding civil society hearings in New York. Meanwhile, the co-facilitators from Jamaica and Luxembourg will

continue their informal consultations with missions in New York to have a draft document at the end of the June to be negotiated and revised until the Summit in September.

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# OPTIONS FOR SUSTAINABLE ACCESS TO MEDICINES IN AFRICA: MOVING BEYOND TRIP'S FLEXIBILITY TOWARD LOCAL PRODUCTION CAPACITY



Photo: Medics Sans Frontieres

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## BACKGROUND

### THE ISSUE

The 2001 Doha Declaration on the Trade-related aspects of Intellectual Property Rights Agreement (TRIPs) and Public Health provided a number of flexibilities that affirm the right of governments to grant compulsory licences for local, foreign, or non-state production or procurement of essential medicines as required to respond to national emergency or public health crisis. A further provision in 2003 allowed countries to export medicines to countries lacking manufacturing capacity if the latter had issued a compulsory licence for these medicines. In 2010 and 2011, WTO members have been reviewing the implementation of the flexibilities in the WTO TRIPs Council, for their formal adoption at the World Trade Organisation by December 2011. Additionally, the WHO, WTO, and WIPO have been exploring the intellectual property policies, procurement and competition policies, tariffs, and regulatory aspects of ensuring quality, safe and efficacious medicines [19]. The debates at the March 2011 WTO TRIPs council meeting and in other international fora indicate that, further to the 2001 flexibilities, developing countries are seeking fair use and benefit from the genetic resources and traditional knowledge used in the development of new medicines, and technology transfer and financing measures that will strengthen their own production capacities.

### GLOBAL HEALTH IMPACT

While there has been progress since 1999, when 90% of all medicines were consumed by 15% of people living in high-income countries[17], by 2004, over 80% of the global pharmaceutical market remained in North America, Europe and Japan[8]. The consumer market has expanded in Africa, but only three of the 56 countries in the continent (South Africa, Nigeria, and Tanzania) make up 36% of the market for HIV/AIDS, malaria, and tuberculosis (TB) medicines. Further, a third of the African market is shared among 48 countries in the continent[1]. Given the high burdens of communicable and non communicable

diseases, current consumption patterns tend to reflect purchasing power, rather than need. At the same time, the recent focus on drugs for neglected diseases has benefitted from increased funding, and new products being developed and marketed, raising challenges for under-resourced regulators to assess and register these products for African use[6].

### THE ROLE OF DIPLOMACY

African countries can negotiate the implementation of a widening array of options to improve implementation of TRIPs flexibilities and to strengthen access to quality medicines. In so doing, they balance measures for more immediate improvements in access and affordability against longer term, possibly more sustainable, developmental measures for strengthening local capacity to produce and register quality medicines, including new medicines. This widens the scope of global policy debates on access to medicines to include technology transfer as well as the issue of fair use and benefit from genetic resources and traditional knowledge applied to the development of new medicines and vaccines.

### INTRODUCTION

Developing countries have raised concerns about the adequacy of and barriers to implementation of the current provisions of the 2001 Doha Declaration. Few countries have formally provided the TRIPs Council with information on their priority needs for technical and financial cooperation to facilitate implementation [14]. However, observers have noted that countries often lack the domestic capacities that support implementation, and have faced trade and investment pressures not to use the flexibilities[13]. Developing countries themselves have raised questions in the TRIPs Council about the extent to which exporters are facilitating technology transfer and ensuring that the generic medicines supplied are safe and effective [14].

### THE MALARIA EXAMPLE

Artemisinin-based combination therapy (ACT), i.e. artemisinin and one other anti-malarial drug, is the only current recommended first line malaria treatment in most parts of Africa. Countries need thus to ensure access, availability, affordability, efficacy and drug quality, while avoiding drug resistance and ensuring adherence to ACT treatment[5][2].

A WHO report released on 25 February 2011 revealed that a third of the 306 anti-malarial medicines collected and tested from six African countries failed to meet international quality standards, due to an insufficient or absent active pharmaceutical ingredient (API) [11]. An

earlier 2010 WHO study concluded that 90% of sub-Saharan African Medicine Regulatory Authorities (MRAs) lacked the resources or capacities to adequately carry out regulatory functions, including ensuring drug efficacy [18].

As a global response, WHO has prequalified AIDS, TB, and artemisinin-containing malaria drugs and manufacturers that meet their quality assessments[16]. Since 2005, the Global Fund for AIDS, TB and Malaria (GFATM) has required recipients to use WHO-prequalified products. Quality failure rates were less than four percent for WHO-prequalified medicines in the six African countries surveyed above[18]. WHO also works with national MRAs, quality-control laboratories, and manufacturers in developing countries to improve market surveillance and enhance quality assurance systems. In addition to this prequalification programme support, there are other options that countries may negotiate to support registration of efficacious medicines. These include the European Commission support to developing country MRA decisions on registration with a scientific assessment of the dossier for those medicinal products used outside the European Union [12]. They can also use twinned reviews, where developing country MRAs assess a pharmaceutical dossier in consultation with a reviewer from a well-resourced MRA; or parallel reviews, where an independent review by a developed country MRA is provided to the developing country MRA.

#### WIDER CONCERNS ON PRODUCTION CAPACITIES

African countries have a widening array of options to improve regulatory approval and registration of new products in Africa, since prequalification has improved quality and lowered the monitored price cost of anti-malarials. However, these options partially, but not fully address African concerns. In particular, they do not address concerns about transfer of technology and strengthening local industrial capacity. Few of the pharmaceutical plants on the continent have been prequalified by the WHO [1]. None of the manufacturing facilities were reported in 2009 to have been prequalified for anti-malarials. Further, linking funding to prequalification would have primarily benefited exporters from outside the continent. Limited funding creates additional constraints to local production. These constraints include low purchasing power, and lack of access to credit, export, and tax incentives or infrastructural support [1][10]. One local producer in Uganda told leading medical journal *The Lancet* that while support to Indian manufacturers from their governments reduces prices of their products, “our [Ugandan] government does not subsidise us, so our products look more expensive...The environment is hostile”[3].

Nevertheless, local production has risen on the global agenda, thanks to the TRIPs flexibilities and the pressure from countries in the south that have advanced their own local pharmaceutical industries[4][16]. Health ministries argue that local production decreases transport costs, increases expertise, reduces difficulties in the use of TRIPs flexibilities, and cuts dependence on foreign suppliers. African leaders see it as a means to provide local jobs, retain taxes, and improve paths to more endogenous and sustainable economic development[4]. The African Union (AU) has called for a plan of action to facilitate increased drug research and manufacturing in the region[1][4]. There is debate around this choice, however. A 2003 World Bank review concluded that local production makes little economic or public health sense in countries where technical expertise, raw materials, active ingredients, quality standards, production and laboratory equipment all need to be imported, and where the industry is unreliable [9][4]. Nevertheless, the World Bank also recognised that a national industry is a significant asset in achieving treatment goals, and, “...more important than potentially slightly higher costs per unit”(quoted in[4]). At the 2007 G8 meeting, members committed to support capacities for local production, while India, Brazil, Germany, and other countries are supporting local production initiatives in African countries[4].

A number of policy options are emerging in support of local production. One of these options is to build partnership, including south-south public and private sector partnerships, noted above. Another is for regional level production agreements to concentrate the demand of various countries, generating economies of scale, better use of installed capacities, greater possibilities of local supply of active ingredients and other raw materials, and strengthening negotiating positions on prices [12]. This calls for political agreement across countries on production, taxes and tariffs, medicines registration, and regulation. Using TRIPs flexibilities at the regional level raises additional issues of harmonising different national legal patent provisions, as not all may be LDCs.

Regional economic communities with legally enforceable mandates such as the Southern African Development Community (SADC) and the East African Community (EAC) have, however, begun to address these issues through pharmaceutical plans that include regional interactions to strengthen member state MRAs, pool procurement, harmonize essential medicine lists, and the harmonization of drug evaluation, registration, and monitoring requirements. These regional arrangements offer a platform to establish reference production prices, review import taxes, and provide longer term options for

drug purchasing under agreed price conditions that can stimulate investment in local production [12].

#### DEEPER AND WIDER CONCERNS ON PUBLIC HEALTH AND TRIP'S

Advancing sustainable availability of quality drugs calls for a synergy between national, regional, and global level policies and negotiations across a number of platforms, and between short and longer term agendas. It is not surprising therefore that the debate has deepened and widened since 2001, extending to discussions about longer term, fair, and sustainable control over the means to secure quality drug availability. This includes, for example, ensuring that the genetic resources and traditional knowledge from developing countries used in developing new medicines and vaccines are fairly and equitably shared, including through technology transfer. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization adopted by the Conference of the Parties (COP) to the UN Convention on Biological Diversity in October 2010, extends a 1993 United Nations treaty declaring that nations have sovereign rights to the biological materials within their territory. Those materials—which include plants, microbes, and other living things—have been a rich source for today's medicines, including the Artemisinin discussed above. They also have an important role in the development of new drugs and vaccines for neglected diseases. African and other source countries of biological materials may negotiate with industry, under "fair benefit sharing," for the technological, capacity building, or financial resources that would support the local production and regulation of quality drugs.

#### NEXT STEPS

A review of implementation of existing flexibilities takes place annually in the TRIP's Council in October. The regional communities offer a platform to monitor and report on implementation of the flexibilities and of measures, such as those raised in this paper, for production and registration of and access to quality medicines. Benchmarks of progress would include issues such as whether any African producers are prequalified for production of anti-malarials. Meanwhile, debates on the wider issues of benefits sharing are continuing at the TRIP's council (next meeting in June 7-8, 2011). In March 2011, there was a call at the TRIP's Council for a review of the provisions of Article 27.3(b) of TRIP's, to take account of the Nagoya protocol. Bolivia proposed that Article 27.3(b) be amended to prohibit all forms of patenting of life. Several member states, including Brazil, India, China, Peru, Angola (on behalf of the LDCs), South Africa, Indonesia, Colombia, Turkey, Ecuador, and Kenya

called for amendment of TRIP's to require all patent applicants to disclose the origin of genetic resources and associated traditional knowledge, which would make the voluntary provisions of the Nagoya Protocol binding. Other members of the council, including Canada and Australia, opposed use of the TRIP's for this purpose [14].

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## JAPAN'S NATURAL DISASTER AND GLOBAL HEALTH: THE ROLE OF APEC IN MOUNTING EFFECTIVE RESPONSES



Photo: Mirror News

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### BACKGROUND

#### THE ISSUE

The earthquake and tsunami that struck Japan on March 11, 2011, will have a number of direct and indirect impacts on human health across the region. Already there has been a tragic loss of human life, and the potential for new outbreaks of disease combined with the possibility of radiation exposure following the explosions at the Fukushima Daiichi nuclear plant remain significant challenges. Moreover, the effects on Japan's economy are also likely to be considerable in the short- to medium-term. Effective and coordinated international cooperation will be critical in assisting Japan recover, and regional organisations such as the Asia-Pacific Economic Cooperation (APEC) have a key role to play in coordinating recovery efforts.

#### GLOBAL HEALTH IMPACT

Aside from the profound adverse health consequences for Japan's population, as the region's leading economy and one of the Asia's largest contributors of overseas development assistance (ODA), it is quite likely that Japan's disaster will have wider implications for the region's health, particularly if there is a significant contraction in the Japanese economy. Added to this, there remains a very significant risk that radiation leakage from the damaged nuclear reactor may further contaminate the environment,[1] which may lead to further adverse health consequences.

#### THE ROLE OF DIPLOMACY

Diplomacy will be critical to ensuring that the international community's response to Japan's disaster is swift, effective, and does not contribute to further harm. Given its traditional participation in regional economic matters, APEC is arguably one of the key forums through which the international community could channel assistance. This assistance may take the form of coordinating direct financial aid or promoting policies aimed at assisting Japan's economic recovery. The 2011 APEC is currently being hosted by the United States, and senior officials are due to meet in their second round of talks from May 7 – 21, 2011.

### BACKGROUND

On March 11, 2011, an earthquake measuring 9.0-magnitude occurred off the eastern seaboard of Japan. The earthquake prompted a massive tsunami that struck the eastern coast of Japan, completely destroying several communities and devastating a number of others. At the time of writing, some 10,901 people are confirmed dead with a further 17,000 still missing.[1] The earthquake and tsunami also caused significant damage to Japan's Fukushima Daiichi nuclear reactor power plant, prompting a number of explosions and raising the possibility of a nuclear meltdown. While Japan's military has been mobilised to help conduct the search for survivors and recover bodies, Japan's nuclear agency has been working frantically to stabilize the Fukushima plant to prevent further radiation leakage.

Given the extent of devastation, it is likely that the recovery and clean-up efforts will take months, if not years, to re-build the towns and communities that have been destroyed and deal with the aftermath of the nuclear accident [2]. In the meantime, survivors are confronted with the very real prospect of disease outbreaks. A risk assessment completed by the Japan Infectious Disease Surveillance Centre (IDSC) and the National Institute of Infectious Diseases (NIID) in the immediate aftermath of the quake has identified a high risk of acute respiratory and diarrhoeal diseases, as well as vaccine-preventable diseases such as tetanus and measles. [3] In addition, concern exists over radiation exposure following the nuclear reactor plant explosions.[1] While Japanese authorities have responded quickly to protect the local population against radiation exposure, were the Fukushima Daiichi nuclear reactor situation to worsen, this may have regional implications for human health.

Of equal concern is the impact this event will have on the Japanese economy in the short- to medium-term [4]. Traditionally, natural disasters only tend to have a minimal impact on stock markets,[5] but as Koetsu Aizawa, an economics professor at Saitama University, recently noted, "...[p]eople might see an already weakened Japan, overshadowed by a growing China, getting dealt the finishing blow from this quake." [4] Indeed, coming after more than two decades of reduced economic growth, some analysts are predicting that Japan's Gross Domestic Product (GDP) may decline as much as 1 percent in 2011 as a consequence of this latest disaster.[6] In such an environment, it is conceivable that the Japanese government may be forced to reconsider reducing its current ODA budget, which between 2009 and 2010 had already suffered a 5.7 reduction. [7] As Japan is one of

the region's largest contributors of foreign assistance, and as reported in a previous issue of this publication, a large supporter of the health-related Millennium Development Goals in particular.[8] further cutbacks in Japanese aid may have serious consequences for the region's health. In this context, it will be important for the international community to assist Japan in implementing measures to reduce its debt (currently estimated to be in excess of 200 percent of GDP [6]) and boost its productivity.

## APEC 2011

APEC was established in 1989 to further economic growth for the Asia-Pacific region by reducing tariffs and trade barriers. Over the past two decades, the organization has progressively expanded its initial focus to include other issue areas beyond trade liberalization such as the environment, education, intellectual property, energy, infrastructure, gender issues, and more recently, health (notably pandemic preparedness) [10,11]. As a result, APEC is subsequently becoming viewed as "the premier forum for facilitating economic growth, cooperation, trade and investment in the Asia-Pacific region." [9]

The institution functions on the basis of open dialogue and consensus building, agreeing to non-binding commitments and maintaining "equal respect for the views of all participants." [9] Agreements are brokered each year via a series of senior officials meetings (SOM), ministerial meetings (e.g. finance ministers), and issue-specific technical working groups where draft commitments are negotiated. The draft agreements are then presented to heads of state and representatives of the 21 Member Economies at the annual "Leaders Week" meeting where formal consent is given. Each year Member Economies rotate hosting APEC, and in 2011, the host country is the United States of America.

The first SOM for APEC 2011 was held in Washington, D.C., officially between February 27 and March 12, 2011, and drew together government officials from the organization's 21 Member Economies. Importantly, however, the core senior officials' meeting was held on the last two days of the meeting between March 11 and 12, 2011, which coincided with the Japanese earthquake and tsunami. The key agenda items for this latter part of the meeting included reviewing a number of technical working group reports, as well as measures to strengthen regional economic integration, promoting "green growth" clean energy, advancing regulatory cooperation, and the reform of APEC. [12] One of the working group reports reviewed by the SOM was on the recently created Emergency Preparedness Working Group (EPWG) that has been tasked with "strengthening business resilience and the

participation of the business sector" in relation to natural disasters such as earthquakes. [13]

However, officially, little attention appears to have been paid to Japan's tragedy within the context of the first SOM, even though the crisis had just occurred. The agenda was not amended, nor was any provision officially made for discussing how APEC may respond to the crisis or assist its Member Economies to respond. The chair of the first SOM, Michael Froman, did express his condolences to the Japanese people on behalf of the United States as host country of APEC 2011 [15] and a statement was later released by the APEC Secretariat expressing its sympathy over the tragedy. [16] However, based on the fact that the organization's Member Economies later demonstrated their willingness to provide financial aid directly to Japan or via the Association of South East Asian Nations (ASEAN), [17] it would appear at this time that APEC has been effectively sidelined.

The decision by the organization's Member Economies to work outside APEC is understandable to the extent that the organization primary function is to promote economic growth and prosperity. [18] APEC has also played a role in strengthening emergency preparedness throughout the region, but importantly, the organization's mandate does not extend to conducting emergency relief operations. [19] Nonetheless, no provision was made throughout the first SOM to discuss the economic implications of Japan's disaster. This could be explained by the fact that the disaster had only just occurred, and the agenda for the first SOM had been negotiated some months in advance.

## NEXT STEPS – SOM 2

The second round of the APEC 2011 SOM is due to be held in Big Sky, Montana, from May 7 to 21, 2011, and will engage both APEC and government senior officials in a number of working groups and various sub-fora. Two key meetings within this next round of talks will be the Trade Ministers' and Small and Medium Enterprise Ministers' meetings. Importantly, however, the agendas for these meetings have not yet been set, nor has any indication been given publicly as to how, or even whether APEC will be responding further to this crisis. For regional organisations such as APEC and ASEAN though, Japan's disaster presents a unique opportunity to demonstrate their relevance and capacity to respond effectively. As the premier economic forum that has also displayed a keen interest in emergency preparedness and recovery, and improving health indicators across the entire Asia-Pacific region, APEC arguably has a key role to play in assisting Japan's economic recovery and preventing long-term adverse health consequences that

## HEALTH DIPLOMACY AND HUMANITARIAN EMERGENCIES: DEBATES AT THE HARVARD HUMANITARIAN ACTION SUMMIT



Photo: Harvard Humanitarian Initiative

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may arise from such events. While intergovernmental fora do contain inherent limitations that often prevent them from responding as rapidly as individual governments, it is equally the case that such forums can provide unparalleled normative leadership, serving as a catalyst to inspire their membership to commit more resources and provide more technical assistance than they might do otherwise. It is in this regard that the next SOM will prove a key test for APEC in demonstrating how rapidly it can respond to the needs of one of its Member Economies in crisis.

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### BACKGROUND

#### THE ISSUE

High levels of civilian morbidity and mortality, caused by either natural disasters or violent conflict, characterize humanitarian emergencies. The international community, in the form of multilateral agencies and transnational non-governmental organizations, often leads the response to these crises, particularly in states with weak domestic capacity. International engagement is governed by global norms and international humanitarian law, which include principles outlined in United Nations General Assembly Resolutions, agreements reached in multilateral forums such as the Inter-Agency Standing Committee, and the Geneva Conventions which apply to humanitarian action in war-torn countries.

Despite the high profile of many humanitarian emergencies, the role of health diplomacy in shaping humanitarian engagement has not yet been analyzed.

#### GLOBAL HEALTH IMPACT

The health effects of conflict and natural disasters vary in intensity and severity according to the local context. The health of the civilian population is often the first casualty of conflict, and natural disasters can have a devastating and indiscriminate impact on population health.

As of November 2010, the United Nations Office for the Coordination of Humanitarian Assistance (UN OCHA) estimated that 49 million people required humanitarian assistance.[1] In 2009, over 15 billion USD was dispersed in humanitarian assistance; governments contributed 11 billion USD while private contributions totalled 4.1 billion USD.[2] Health assistance accounts for approximately ten percent of humanitarian funding.[2]

While few humanitarian emergencies have an impact on "global health," the response to these emergencies is global in nature. Natural disasters frequently overwhelm the state, particularly in countries with low capacity. Conflicts either implicate the state, or reflect its fragility. As a result, multilateral agencies and international non-governmental

organizations provide direct health assistance to reduce mortality and morbidity of the civilian population.

#### THE ROLE OF DIPLOMACY

Humanitarian action, including the provision of health assistance, is characterized by multiple levels of diplomacy. Negotiations determine the amount of assistance, how that assistance is delivered, what actors are engaged in delivering that assistance, and how to access crises-affected populations. This diplomacy takes place in multilateral, bilateral, and local settings, and involves state as well as non-state actors. As a result of this complexity, humanitarian decision-making is not very transparent. Further analysis is needed to examine diplomacy among the various actors engaged in the delivery of humanitarian assistance, how humanitarian norms govern these interactions, and how these negotiations affect humanitarian assistance.

#### INTRODUCTION

Humanitarian emergencies capture the public's attention. Television images and newspaper stories convey scenes of innocent civilians affected by violence, the devastating and indiscriminate impact of natural disasters, and the life-saving interventions of international non-governmental organizations.

Behind these images lies a complex array of multilateral agencies, transnational non-governmental organizations, donor governments, and national-level agencies. While international norms provide general guidance on both political and technical aspects of humanitarian assistance, much remains open to negotiation.

Multiple actors engage in health diplomacy at various levels during humanitarian operations. At the global level, diplomacy plays a role in determining the allocation and scale of resources as well as the technical components of health interventions. Locally, negotiations determine how assistance is coordinated, the engagement of the military, and the role of national governments and other national stakeholders.

#### HARVARD HUMANITARIAN ACTION SUMMIT

The Harvard Humanitarian Initiative held its Humanitarian Action Summit from March 4-6, 2011. The Summit attracts practitioners currently active in humanitarian settings, researchers, as well as government officials engaged in humanitarian response.

Harvard Humanitarian Initiative's Summit is driven by the need to unpack the complexity of the response to humanitarian crises, recognizing the importance of collaboration to professionalize and improve that response. Taking place every two years, the Summit is

a unique conference, combining expert presentations on key challenges facing humanitarian action with the creation of working groups where participants collaborate to share and develop solutions to overcome those challenges. Working groups continue their activities between Summits, facilitating ongoing collaboration and professional development among Summit participants, with the objective of further building the evidence-base for humanitarian action.

Contemporary debates in humanitarian assistance include if and how humanitarian action is compromised by the changing nature of conflict; the relationship between humanitarian actors and the military; if and how early recovery can build local resilience and national capacities; how to deliver assistance in urban settings; and how to improve and enhance the professionalization of humanitarian action given the diversity of sectors and actors engaged in humanitarian action. The Summit's Working Groups directly address these debates.

#### THE WORKING GROUPS

A working group on Professionalizing the Humanitarian Response has been active for several years, and Peter Walker and Karen Hein presented the work of the group to date. They argued that to enhance humanitarian professionalism, an individual accreditation system was needed to develop a global association of committed, accredited individuals with basic competencies.

The working group on NGO Security and Staff Protection examines the perception of increased risk for humanitarian workers, acknowledging that while some deaths and injuries are a result of deliberate targeting, others were the result of humanitarian workers being bystanders in dangerous contexts. The working group will continue to analyze mechanisms to compile and share security information, and examine variance in casualty rates across organizations and humanitarian settings.

The Urbanization and Humanitarian Emergencies group examines how to effectively address the needs of the humanitarian population in urban environments. Cities present many challenges to humanitarian response – including security, how to identify and differentiate the humanitarian population from the host population, the generally poor living conditions in many urban areas, and how existing humanitarian norms and standards can be translated for urban areas. This group is adapting the Sphere Guidelines to urban settings as well as systematically examining the coordination and security challenges of working in these environments.

The group on Field Level Coordination Among Civilian

and Military Humanitarian Actors works to identify and describe effective coordination techniques. They will examine how to institutionalize best practices while recognizing the constraints of the constant turnover of military staff and humanitarian personnel. The working group on Humanitarian Technologies, Crisis Mapping and Challenges in Information Management discusses how to harness the use of these technologies in the humanitarian response.

The group on Surgical Issues in the Humanitarian Space outlined the critical need for surgical expertise in humanitarian settings, but noted that the majority of surgical needs are a result of non-conflict related causes. To examine the role of Mental and Psychosocial Support in Crisis and Conflict, another working group examines and identifies key knowledge gaps. Their work is guided by the principle of no mental health survey without service and no service without a survey.

The Summit also announced the formation of future Working Groups, including a group on Post Conflict Health System Reconstruction, which will examine if and how humanitarian actors can better support national capacities and interface with the local health system. Another group will focus on Clinical Care in the Field, examining how to improve the effectiveness of the clinical component of the health response.

In addition to the Working Groups, the Summit also featured two notable plenary speakers. Honourable Lieutenant General (retired) Romeo Dallaire, currently a Canadian Senator and advocate for child soldiers, spoke of the complexity of the overall response to conflicts, referencing his experiences in Rwanda. Paul Farmer examined the case of Haiti, reflected on his experiences as one of the founders of Partners in Health, and spoke of the need for humanitarian actors to have a more sustained presence in the country to build national capacity.

#### ENGAGING AND INFLUENCING DIPLOMATIC PROCESSES

Throughout the course of the Summit, participants expressed frustration that humanitarian actors are often unable to influence the political decisions that shape humanitarian engagement. While the Harvard Humanitarian Initiative's Working Groups can develop guidelines and best practices, the pathways to translate this guidance into action at the international level remain unclear.

Humanitarian actors have been important participants in global processes surrounding technical norms, such as the Sphere Standards. However, humanitarians actors point to critical decisions on humanitarian action that are

made in diplomatic forums that are out of their reach, lack transparency, and are not subject to appropriate scrutiny or input from those engaged in the humanitarian response.

More research needs to be done on health diplomacy in humanitarian operations to determine the key decision making forums, the actors who make these decisions, and the information that shapes the decision making process. Over the next few years, the Health Diplomacy Monitor hopes to shed a light on diplomacy in humanitarian action. We will examine negotiations in humanitarian forums, as well as decision-making processes surrounding particular humanitarian emergencies. We will also continue monitoring important conferences, such as the Harvard Humanitarian Action Summit, to gauge if and how the concerns of those on the frontlines of humanitarian action are being addressed on the international stage.

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# HEALTH SYSTEMS STRENGTHENING: FIVE RESOLUTIONS TO BE CONSIDERED AT THE WHA



Photo: vision2020.org

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## BACKGROUND

### THE ISSUE

The recent past has seen a shift from vertical programs to a growing focus on strengthening national health systems. This shift is reflected in the various topics and resolutions brought to the table by member states at the World Health Organisations (WHO), notably at the 128th Executive Board meeting of the WHO, held in January 2011. Under Agenda item 4.5, “Health Systems Strengthening,” we saw the significant engagement and involvement of the member states, in terms of statements and in the formulation of five separate resolutions in a proactive, results-oriented manner, where countries voiced the major concerns they face. These resolutions will be forwarded to the World Health Assembly in May 2011, for consideration and adoption.

### GLOBAL HEALTH IMPACT

As highlighted in the Report prepared by the WHO from the Executive Board meeting, “a large proportion of the population worldwide remains deprived of access to care, while 150 million people face catastrophic expenditures and 100 million are thrust into poverty because of direct out-of-pocket payments for services and medicines”[1]. “At its broadest, health system strengthening (HSS) can be defined as any array of initiatives and strategies that improves one or more of the functions of the health system and that leads to better health through improvements in access, coverage, quality, or efficiency.”[12] More specifically, health system strengthening incorporates all of the essential building blocks that ensure provision of care to a nation’s population, such as existence of adequate health personnel, medical education, infrastructures, access to health commodities (drugs, vaccines and other equipment); service delivery components; sustained financing for health; health information and monitoring systems including production, analysis, dissemination of timely information; and finally and most importantly, leadership, governance and ownership, which related to “strategic policy frameworks ... combined with effective oversight, coalition-building, regulation, attention to system-design and accountability” [13].

## THE ROLE OF DIPLOMACY

Health-system strengthening has been a key area of focus for member states of the WHO and work in previous years has concentrated on various aspects of this, such as the World Health Report on Primary Health Care in 2008,[2] the World Health Report on Health System Financing in 2010,[3] and the Report of the Committee on Social Determinants of Health, 2008.[4] The topic of health system strengthening was on the Agenda of the 128th Executive Board meeting of the WHO in January 2011.

These discussions also occurred at the regional level, and the “WHO regional committees at their sessions in 2010 called on countries to strengthen health systems on the basis of the values of primary health-care, and identified the need to tackle the determinants of health through a multi-sectoral approach, making services more responsive, addressing universal coverage and strengthening health-service delivery at the district level. Resolutions requested the Regional Directors to work more proactively than before with Member States in the development or renewal of comprehensive policies, strategies and plans to improve health outcomes.”[5]

## INTRODUCTION

During the meeting of the Executive Board in January, Member states of the WHO reported various progresses made at national and regional levels in strengthening their health systems. These included adoption of universal coverage policies, training of health personnel, and most importantly, political commitment to abide by the principles of the Paris Declaration on Aid Effectiveness, people-centered primary care delivery and “Health in all policies.” Various resolutions were put forward by member states, as summarised below:

### STRENGTHENING NATIONAL POLICY DIALOGUE TO BUILD MORE ROBUST HEALTH POLICIES, STRATEGIES AND PLANS

India, believing that a robust health system is a must for achieving the Millenium Development Goals (MGDs), highlighted the imperative need to make policy changes and bring in reforms to respond to health challenges. To this end, India proposed a resolution on heightening policy dialogue as a way of ensuring robust health systems. [6] It highlighted that there is a lack of analysis on how developing countries can fulfill their responsibilities on health systems strengthening, and noted movement of health personnel to donor-driven programmes. Since 2005, India’s National Rural Health Mission is working to ensure access to the majority of its population living in the rural area, in conjunction with efforts to produce more skilled labor and provide more generic medicines.

The resolution urges member states to focus on a variety of ways of engaging various stakeholders, public and private, national, subnational, and international in formulating their national health policies, in addition to aligning them to the principles of universal coverage, people-centered primary care, and health in all policies. It also urges countries to align vertical programmes into their national policies and regularly monitor progress, ensuring ownership especially in light of a country's overall development and political agenda. It requests the Director-General to "renew the Organization's emphasis on its role at the country level as a facilitator of inclusive policy dialogue around national health policies, strategies and plans... [to ensure] continued technical input for conducting the planning process,... foster cross-country and regional learning and cooperation."

#### STRENGTHENING NURSING AND MIDWIFERY

Secondly, Burundi and Kenya tabled a resolution on "Strengthening nursing and midwifery". [7] Burundi noted that improving health systems, means undertaking health prevention, treatment, and rehabilitation within primary health care. To ensure this, it is of utmost importance to secure and strengthen midwifery and nursing services, especially for mother and child health. In most developing countries, local communities count on midwives not only for newborns but also for the care of children as they grow up. Health personnel that are trained in Africa need to be retained as the existing phenomena of brain drain makes the health systems of these countries even weaker. The resolution therefore emphasizes the importance of maternal and child care. The resolution calls on countries to adopt recommendations of the WHO Global Code of Practice on the International Recruitment of Health Personnel, [8] to collaborate at the regional levels to counteract brain-drain phenomena, and to strengthen "regulatory processes which govern [these] professions," amongst others. In addition, the resolution requests the Director-General to "strengthen [the] WHO's capacity for development and implementation of effective nursing and midwifery policy programmes through continued investment and appointment of professional nurses and midwives to specialist posts in the WHO Secretariat at the headquarters and regional posts" along with other requests for the provision of technical support and collecting evidence on the role and responsibilities of nurses and midwives within national and sub-national health policies.

#### STRENGTHENING NATIONAL HEALTH EMERGENCIES AND DISASTER MANAGEMENT CAPACITIES AND RESILIENCE OF HEALTH SYSTEMS

Chile, along with Guatemala, and with the support of all

South-American countries, put forward a third resolution on "Strengthening national health emergency and disaster management capacities and resilience of health systems." [9] In light of various natural catastrophes, Chile noted the need to prepare for 'various types of events, some of them being serious disasters'. They noted, in their statement to the EB, on the issue of health system strengthening, that the "proposed draft resolution does not deal with the humanitarian response but with what needs to be done in building national health capacities, to deal with disaster management." In the resolution, Chile calls for strengthened cooperation bilaterally, regionally, and globally, and calls for lessons learned and asks the Director-General to provide the necessary technical support to build up capacities on the national level.

Chile made reference and showed appreciation for the work that has been done by WHO/PAHO in building up capacities on the national and regional level. Chile seeks to build regional alliances and share lessons learned. They call on the WHO to support countries in developing risk measurement systems and developing solutions for risk management. The resolution also calls on member states, donors and other stakeholders to expand their support for developing these capacities in coping with disasters. In response to the tabled resolution, China noted that it is also regularly struck by disasters and thus attaches great importance to emergency response. China offered to share its experience and knowledge on this issue with member states and notes the importance of capacity-building in health system strengthening. China calls on the WHO to give more attention and input to disaster-related health emergency response. Brazil corroborated the need for having such in-built expertise in health systems of countries prone to natural disaster, making an example of its own recent floods, where in Rio de Janeiro itself more than 700 people died and many are still missing.

#### HEALTH WORKFORCE STRENGTHENING

Thirdly, Japan and Norway tabled a resolution on "Health workforce strengthening." [10] Japan welcomed the World Health Report, 2010.[3] During its statement at the Executive Board, Norway noted the "increasingly global nature of the labor market, which has increased the flow of health workers from South to North." It expressed the hope that the WHO Global Code of Practice on the International Recruitment of Health Personnel,[8] adopted last May at the WHA, will hopefully mitigate effects on national health systems. However, it notes the need to address the fundamental issues on health workers. With regards to health systems strengthening, Norway urges to scale up health workforce education and distribution of health

workers that yields the best possible health outcomes for all member states. It calls on the WHO for a comprehensive mandate that reflects the complexity of the subject. They also hope that the draft they put forward together with Japan, will, together with the Global Code of Practice on the International Recruitment of Health Personnel [8] provide the WHO with a strengthened mandate to address the global health workforce challenges. Japan reiterated the points made by Norway.

#### SUSTAINABLE HEALTH FINANCING STRUCTURES AND UNIVERSAL COVERAGE

Finally, Germany, the European Union and Switzerland put forward a resolution on “Sustainable Health Financing Structures and Universal Coverage”. [11] The resolution builds on the 2010 World Health Report [3] and urges member states to ensure health-financing systems that are in line with global aims and efforts to ensure equitable universal health-care. Switzerland noted its engagement in social health protection through many bilateral agreements. Switzerland emphasized that it can learn from international experience to improve its national health system, an approach that is exactly in line with the draft resolution proposed by India. The resolution also calls on donor countries and recipient countries to align their work and objectives to the Paris Declaration on Aid Effectiveness and frames the issue of health system financing through a human rights lens of access to health. It requests the Director-General to, amongst other commitments, work “closely with other UN organizations, international development partners, foundations, academia and civil society organizations, in fostering efforts towards achieving universal coverage... [and] prepare a plan of action for WHO to support member states in realizing universal coverage as envisaged by the World Health Report 2010.”

#### NEXT STEPS:

These five resolutions will be discussed and negotiated at the sixty-fourth World Health Assembly between 16-24 May 2011. These resolutions will be considered under the agenda item 13.4 entitled ‘Health system strengthening’.

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# HEALTH DIPLOMACY MONITOR

The Monitor is a publication of the Centre for Trade Policy and Law, a research centre affiliated with the Norman Paterson School of International Affairs, co-sponsored by Carleton University and the University of Ottawa, in Canada. The Monitor is published five times of year, free of charge.

The Monitor is affiliated with the Global Health Diplomacy Network (GHD-Net), a group of research institutions and practitioners seeking to improve the quality of negotiations which have significant impacts on global health. The Monitor is available on the GHD-Net website at: [www.GHD-NET.org](http://www.GHD-NET.org).

The Health Diplomacy Monitor is made possible in 2010-2011 thanks to the financial support of the Rockefeller Foundation. The editor would also like to acknowledge the in-kind contributions of the London School of Hygiene and Tropical Medicine, Global Health Programme of the Graduate Institute and Global Health Europe.



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