

## **PANDEMIC INFLUENZA PREPAREDNESS: SHARING OF INFLUENZA VIRUSES AND ACCESS TO VACCINES AND OTHER BENEFITS**

*Briefing Paper by Third World Network (11 January 2011)*

The issue of Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other benefits is listed as agenda item 4.1 in the upcoming 128<sup>th</sup> session of the Executive Board that will meet from 17-25 January 2011. [Note: As at 11 January no report on this issue is available on the website. ]

This note aims to highlight the historical context of the negotiations as well as points that should be stressed by civil society and member states during the meeting of the Executive Board.

### **Background in Brief**

The PIP negotiations followed the adoption of a resolution at 60<sup>th</sup> WHA in 2007: Resolution WHA60.28 titled “*Pandemic Influenza Preparedness: sharing of influenza viruses and access to vaccines and other benefits*”. The Resolution outlines a road map to revamp WHO’s virus sharing scheme to address its inequities.

World attention was focused on this issue in early 2007 when the then Indonesian Health Minister Siti Fadillah Supari publicly announced that her country would no longer provide avian flu viruses to the WHO “Global Influenza Surveillance Network” (GISN), as the scheme was unfair to the interests and needs of developing countries. Indonesia’s reluctance was not new as other affected countries had also previously either stalled or slowed down the sharing of viruses with the unjust system.<sup>1</sup>

Under the WHO scheme, affected countries sent flu virus samples to WHO's collaborating centres and essential regulatory laboratories, all of which are national institutions located in developed countries. These designated laboratories turn the viruses into candidate vaccine viruses, which are then passed to private sector entities for vaccine development using Material Transfer Agreements (MTAs).

Under the WHO's 2005 and 2006 guidelines, these WHO-linked centres are not suppose to pass on the viruses to third parties such as companies or to publish papers or make known the gene sequences of the viruses without the prior permission of the countries that had contributed the viruses. However, Indonesian officials discovered that their viruses were being used in activities such as patenting, commercial development and production of vaccines, and publication of research materials without their permission or even their knowledge. In addition, vaccines developed using the viruses were not affordable to developing countries that were affected by avian flu.

It also emerged that developed countries had already entered into advance purchase agreements to have vaccines delivered to them in the event of a pandemic. As there is only a limited amount that companies can produce in a year, stockpiling of vaccines by developed countries makes such vaccines unavailable to affected developing countries in times of a pandemic when demand will exceed the supply of vaccines. Vaccine development and production is also largely based in

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<sup>1</sup> See Martin Khor (18 February 2007), Indonesia's move on bird flu samples highlights key access issues at <http://www.twinside.org.sg/title2/avian.flu/news.stories/afns.001.htm>

developed countries, compounding the lack of access to affordable and timely supply of vaccines for developing countries.

Moreover, it was also revealed that there was a spike in the number of patent applications covering influenza virus (or parts of it, i.e. the genes and sequences), as well as vaccines, treatments and diagnostics. In a number of patent applications, companies and other institutions had made claims over viruses and their parts (genes/sequences) shared in good faith by affected countries such as Indonesia, Vietnam, China and Thailand with the GISN system.

Concerns about patenting have frequently been raised amongst the international community as a patent holder can deny others access to its patented subject matter during the protection period of at least 20 years as well as hinder scientific R&D.

Thus, out of the virus sharing system, one set of clear winners are the commercial vaccine developers which have already obtained many millions worth of contracts from the developed countries to supply vaccines, in addition to grants and subsidies for research and development activities. Developed countries are the other set of winners as they are able to pay for the high cost of stockpiling vaccines and to make advance orders for pandemic vaccines. Many other entities in those countries such as research institutes are also able to gain easy access to viruses and to then file patent claims over parts of the viruses in the hope of making some profit.

Meanwhile, developing countries in particular the affected countries, could face astronomical bills for the purchase of vaccines and other medical supplies, as well as difficulties in accessing such supplies, due to their limited availability. Technologies as well as know-how used in vaccine development and production (largely based in developed countries) are also protected by intellectual property rights creating more obstacles for developing countries that may seek to build their own production capacity.

All of these issues came to a head at the 60<sup>th</sup> World Health Assembly in 2007. Indonesia with the support of a group of more than 20 developing countries brought the issue of inequities in the existing system to the World Health Assembly and sought to revamp the system by putting forward a draft Resolution. The final product that emerged out of more than a week of intensive negotiations – WHA Resolution 60.28 titled “*Pandemic Influenza Preparedness: sharing of influenza viruses and access to vaccines and other benefits*” very importantly links the sharing of viruses to benefit sharing, despite attempts by several developed countries to downplay the role and rights of countries contributing the viruses.

The Resolution recognizes the sovereign right of States over their biological resources and the right to fair and equitable sharing of benefits arising from the use of the viruses. It signals the view of WHO members that the current practices of the WHO GISN do not bring about fair results, and that these practices need to be overhauled with transparent mechanisms to be put in place for fair and equitable benefit sharing.

A major part of the Resolution outlines processes for agreeing to terms and conditions for sharing of viruses between the originating countries, WHO Collaborating Centres and third parties, as well as for ensuring resulting fair and equitable sharing of benefits.

The Resolution set up an inter-disciplinary working group (IDWG) as well as an intergovernmental meeting (IGM). The IDWG met in Singapore on 31 July-4 August 2007 followed by the first IGM meeting on 21-23 November 2007. During the IGM, several

developing countries (Indonesia, Thailand and the Africa Group) also presented proposals on terms and conditions for virus and benefit sharing.

Other formal and informal meetings have since followed this IGM including resumed session of the IGM on 3-4 April 2008; 8-13 December 2008; 15-16 May 2009. The IGM ended in May 2009 and was followed up with an Open-Ended Working Group (OEWG) that met from 10-12 May 2010 and most recently from 13-17 December 2010.

During the negotiations, developing countries have been advocating for a sustainable solution, i.e. a framework that is transparent, fair and equitable to the needs of developing countries, and that does not put commercial interests and profits before the public health interests of WHO member states. In this regard many of the countries have been pushing for a “Standard Material Transfer Agreement (SMTA)” i.e. a contractual agreement to govern access and benefit sharing between the provider and the recipient, mandatory concrete benefit sharing and no intellectual property rights over the biological materials contributed to WHO, parts of those materials as well as over the products developed using such biological materials.

On the other hand, developed countries have been reluctant to have any mechanism or rules governing particularly the commercial entities for virus sharing and benefit sharing although the commercial entities profit from the viruses contributed to WHO. In fact, developed countries attempted in 2009 to terminate negotiations on influenza virus and benefit sharing.

The worldwide H1N1 flu panic in 2009 has once again made a strong case for the international community to work towards a sustainable solution that is fair and equitable to the needs and interests of all WHO member states. The H1N1 flu highlighted (as also seen during the H5N1 avian flu outbreak) the continuing inequities of the international health system that delivers diagnostics, vaccines and anti-virals to developed countries but that requires developing countries to rely on *ad hoc* solutions such as donations. Industry also gets access to viruses and reagents for vaccine production, without having to commit to any benefit sharing.

Thus the impetus for a transparent, fair and equitable sustainable framework for virus and benefit sharing remains strong. The question is as the negotiations proceed, whether the international community will be bold enough to put in place a solution that addresses the interests and needs of developing countries and prioritises public health over industry interests and profits.

### **Update on Status of Negotiations**

The last meeting of the OEWG was from 13-17 December. The report of the meeting can be found at [http://apps.who.int/gb/pip/pdf\\_files/OEWG2/A\\_PIP\\_OEWG\\_2-en.pdf](http://apps.who.int/gb/pip/pdf_files/OEWG2/A_PIP_OEWG_2-en.pdf). This report will be transmitted to the Executive Board. The basic negotiation documents are the Framework of PIP A62/5 Add 1 and the various forms of SMTAs found in A63/48. Both these documents are available at [http://apps.who.int/gb/pip/e/E\\_Pip\\_oewg2.html](http://apps.who.int/gb/pip/e/E_Pip_oewg2.html). Basically the contentious points during the negotiations were the following:-

(i) the definition/scope of PIP biological material: the developed countries want a limited definition that does not include the parts of the biological material e.g. the genes whereas the developing countries would like to see a more comprehensive definition that includes the parts of the biological material;

(ii) the form and nature of SMTA for transfers from countries to WHO linked centres and among the centres: Developed countries agree to a SMTA for transfer of influenza biological material to

a WHO linked centres however insist that such a SMTA should not contain dispute settlement provisions that refer to arbitration. Instead argue that disputes should be resolved by the Director General. Developing countries insist that a SMTA is a contractual agreement thus there must be proper dispute settlement provisions ie. that includes mediation and arbitration;

(iii) the form and nature of SMTA for transfers of influenza biological material to third parties i.e. to industry: Developed countries do not wish to see the industry having to be bound by any SMTA particularly if such an agreement includes terms and conditions on the use of influenza biological material as well as benefit sharing provisions. Developing countries wish to see a SMTA for the third parties i.e. that third parties have to sign if they wish to receive access to influenza biological materials held by WHO linked centres. Such a SMTA would then include terms and conditions for sharing of biological materials as well as obligate benefit sharing by third parties.

(iv) claims of intellectual property rights by WHO linked centres: Developed countries have been arguing that the recipients of influenza biological material even if they are WHO linked centres should be allowed to claim IPRs over the biological material received as well as over the products/processes developed using the biological material received. Developing countries have been arguing against this position stating that such claims are simply unacceptable. Certain centres are designated as WHO linked centres for purpose of pandemic preparedness and thus it is unacceptable that they are able to claim IPRs and assert exclusive rights over biological material received and the products developed. Allowing IPRs will undermine public health and trust in WHO.

(v) claims of intellectual property rights by the third parties (including the industry): Developed countries have been arguing that the recipients of influenza biological material that are third parties (i.e. not WHO labs) should be allowed to claims IPRs over the biological material received as well as over the products/processes developed using the biological material received. Some developing countries are pushing for no IPRs to be allowed to be claimed over the biological material received and parts thereof. With regard to products and processes there is a general push by developing countries that if IPR claims are allowed it should be on the understanding that royalty free licenses will be given to developing countries facilitated by WHO. These positions are supported on the basis that claims of IPRs over the biological materials are unethical and would hinder scientific innovation. Furthermore the materials are shared for pandemic preparedness purpose. With regard to IPR claims over the products and processes it is argued that the royalty free licenses is important to build the capacity of developing countries as well as to prepare for a pandemic.

According to the outcome of the December meeting, the next IGM will take place from 11-15 April 2011. In the inter-sessional period the Chairs of the Working Group will hold consultations with civil society as well as with the industry as well as key scientific institutions.

In the intersessional period, the co-chairs will continue with informal consultations with Member States. In addition informal consultations will be organized by Australia on the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity; Brazil on dispute resolution (SMTA inside the system); and India on definitions and use of terms.

The report also requests the Director-General to seek information from WIPO on PIP- related patents, including patent applications, in connection with the H5N1 virus and the pandemic (H1N1) 2009.

### **Key Points for Member states (MS)**

1. MS should highlight during the EB that the H5N1 and H1N1 crisis has shown the need for a equitable and transparent mechanism for pandemic preparedness that puts public health as a top priority over industry's profits.

2. To create a viable and sustainable system for pandemic preparedness, such a system must stress on sustainable forms of benefit sharing as ad hoc donations are unreliable solutions. This means that recipients of influenza biological materials must be asked to commit to benefit sharing on a mandatory basis. This is important to achieve public health objectives as well as to ensure compliance with international obligations under the Convention of Biological Diversity (CBD) to which almost all WHO member states (except for the US) are a party to. CBD requires that those that receive and use genetic resources must share benefit arising from the use of those resources.

2. In view of (1), MS need to point out that a contractual agreement (also known as Standard Material Transfer Agreement) between the provider of biological resource and the recipient of such resource seems to be the way forward in achieving concrete benefit sharing. It needs to be noted that MTAs have been used in the context of WHO for sharing of influenza biological material thus there is simply no reason now to object to the use of MTAs that are standardised in the transfer of influenza biological materials. SMTA must have a contractual binding effect, and contain terms and conditions on the use of influenza biological material as well as benefit sharing to be an effective solution.

3. Noting that influenza biological material are being shared for public health purposes in the context of a pandemic, claims of private intellectual property rights over the influenza biological resources or over the products/processes developed using such material should not be allowed by WHO linked centres or by third parties. If third parties (e.g. the industry) is allowed to claim IPRs over the products/processes developed using such material then royalty free licenses must be made available to developing countries.

4. The definition of PIP biological material in the Framework must include parts of the biological material in particular their genetic and other components and parts thereof, including genes (RNA and DNA), genes sequences and polynucleotides as well as the polypeptides they encode. It further includes sequence data.

5. The Co-chairs must allow civil society to make written submissions as many civil society organization may be unable to participate the inter-sessional consultations in person due to funding constraints.

### **Key actions by NGOs**

1. Need to highlight the problematic features of the current WHO influenza virus sharing system and to push for proper reform as mentioned above by: lobbying developing country governments to take a more active role in the negotiations; reaching out to the media; writing to WHO and to the Co-Chairs of the negotiations highlighting key points of reform; lobbying northern and southern governments to take the right position in negotiations.

2. NGO needs to participate either through written submission or in person in the inter-sessional consultation that will be undertaken by the co-chairs