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# Levelling the playing field? Sharing of influenza viruses and access to vaccines and other benefits

Nicole Jefferies\*

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*With the adoption of the Pandemic Influenza Preparedness Framework, including its annexes, by the 64th World Health Assembly, this article investigates the disproportionate burden of risk and benefits between resource-poor countries in the developing South and resource-rich industrialised developed nations of the North in the World Health Organisation's Standard Material Transfer Agreement (SMTA) for accessing and sharing influenza viruses. It concludes that the countries of the South have a unique opportunity to level the playing field through providing timely and affordable access to life-saving vaccine and meaningful benefit-sharing that will deliver technology and economic development. Importantly, the article also demonstrates that SMTAs are not merely a redirection of existing resources from North to South but offer a solution to the ongoing shortage of pandemic influenza vaccine by enabling the South to access technology necessary for sustainable vaccine production and thus increasing global vaccine capacity.*

## INTRODUCTION

For over 50 years member states of the World Health Organisation (WHO) have voluntarily contributed influenza specimens for antigenic and genetic analyses<sup>1</sup> in order to isolate potential pandemic influenza strains and to facilitate the development of vaccines. In January 2007 Indonesia announced its controversial decision to withdraw its vital influenza A H5N1 (avian influenza) virus samples from the WHO influenza monitoring and virus-sharing system.<sup>2</sup> This move subsequently led to a platform for significant reform.<sup>3</sup> Indonesia objected to the disproportionate burden of risk and benefits between North-South members, particularly where virus seeds resulted in high-cost patented vaccines that were unavailable or unattainable by them or their counterparts in the South.<sup>4</sup>

Indonesia's argument for transparency and more equitable practices within the WHO virus-sharing network was validated during the 2009 H1N1 (swine influenza) pandemic. While Mexico and the United States found themselves equally at the epicentre of a swine flu outbreak, the

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<sup>1</sup> World Health Organisation, *World Health Report 2007 – Learning Lessons – Thinking Ahead*, Ch 4, p 45, [http://www.who.int/whr/2007/07\\_chap4\\_en.pdf](http://www.who.int/whr/2007/07_chap4_en.pdf) viewed 10 August 2012.

<sup>2</sup> Sedyaningsih E et al, "Towards Mutual Trust, Transparency and Equity in Virus Sharing Mechanism: The Avian Influenza Case of Indonesia" (2008) 37 *Annals Academy of Medicine Singapore* 482.

<sup>3</sup> Sedyaningsih et al, n 2 at 482, 486; Fidler D, "Influenza Virus Samples, International Law and Global Health Diplomacy" (2008) 14 (1) *Emerging Infectious Diseases* 88.

<sup>4</sup> Supari SF, *Statement of the Minister of Health of the Republic of Indonesia at the 62nd World Health Assembly* (Geneva, 19 May 2009), <http://www.kemlu.go.id/jenen/Lists/Statement/Attachments/86/Statementmenkes.pdf> viewed 10 August 2012; Bennett B and Carney T, "Review Paper: Pandemic Preparedness in Asia: A Role for Law and Ethics?" (2011) 23 *Asia Pacific Journal of Public Health* 419 at 425; Sedyaningsih et al, n 2 at 486; Vezzani S, "Preliminary Remarks on the Envisaged World Health Organisation Pandemic Influenza Preparedness Framework for the Sharing of Viruses and Access to Vaccines and Other Benefits" (2010) 13 *Journal of World Intellectual Property* 675 at 678; Abbott FM, "An International Legal Framework for the Sharing of Pathogens: Issues and Challenges", Issue Paper commissioned by the International Centre for Trade and International Development's *Programme on Intellectual Property Rights and Sustainable Development* (2010) p 1, <http://www.ictsd.org/downloads/2011/12/an-international-legal-framework-for-the-sharing-of-pathogens.pdf> viewed 10 August 2012.

United States secured vaccine via pre-emptive purchase agreement with major pharmaceutical companies.<sup>5</sup> The United States' access to pandemic influenza vaccine ahead of Mexico demonstrated there was insufficient global manufacturing capacity especially in the South and, where "demand outstrips supply, the factor most likely to determine who might secure treatments would be price".<sup>6</sup>

WHO members of the South demanded transparent, fair and equitable sharing of vaccines and benefits if the WHO virus-sharing system was to remain a viable global tool in the fight against pandemic influenza.<sup>7</sup> Addressing the concerns raised by Indonesia and other nations of the South, the World Health Organisation Intergovernmental Meeting on Pandemic Influenza Preparedness (WHO IGM-PIP) presented a new framework and draft resolution to the 64th World Health Assembly (WHA) in 2011.<sup>8</sup> This innovative proposal includes Standard Material Transfer Agreements (SMTAs) that will enable the South to contract with entities receiving pandemic influenza biological material and not only guarantee access to influenza vaccine but potentially to intellectual property previously protected by patents.<sup>9</sup>

The first part of this article describes the mechanisms utilised by the WHO in its monitoring and control of potential human pandemic influenza virus specimens and is followed a description of the circumstances whereby reform of the global influenza surveillance network came to the forefront of global health politics and the WHO institutional forum as a place for its resolution. The next part discusses the *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits* (Framework) in the context of the SMTAs that govern the transfer of virus specimens and benefits. The implications of mutually agreed terms are analysed to reveal the potential benefits for the South in the fight for access to influenza vaccine and other benefits during a pandemic. The dispute resolution provision is contrasted with the World Trade Organisation (WTO) dispute resolution mechanism to highlight the minimal repercussions for breaches. A case study of the 2009 swine flu pandemic that struck North and South America follows. Mexico's inability to secure timely access to vaccine while Americans received vaccination via stockpiles and priority pre-ordered purchases reinforced Indonesia's call for equitable access to vaccines. The final part of the article concludes that the SMTA 2 provides the South with a unique opportunity to level the playing field through access to life-saving vaccine and meaningful benefit-sharing that will deliver technology and economic development. Importantly, for the first time, private agreements between the South and pharmaceutical manufacturers will assist the South to avoid ad hoc strategies and in its place develop sustainable domestic vaccine production.

## WORLD HEALTH ORGANISATION MECHANISMS FOR INFLUENZA VIRUS SHARING

The World Health Organisation is the "directing and coordinating authority on international health within the United Nations" system'.<sup>10</sup> The WHO's membership consists of 193 countries and two

<sup>5</sup> Butler D, "US Ramps Up Swine Flu Protection" (2009) 543 *Nature News*, <http://www.nature.com.libraryproxy.griffith.edu.au/news/2009/090603/full/news.2009.543.html> viewed 25 August 2011; Hayden EC, "Avian Influenza Aided Readiness for Swine Flu" (2009) 459 *Nature News* 756, <http://www.nature.com.libraryproxy.griffith.edu.au/news/2009/090610/full/459756a.html> viewed 25 August 2011; Butler D, "Vaccine Decisions Loom for New Flu Strain" (2009) 459 *Nature News* 144, <http://www.nature.com.libraryproxy.griffith.edu.au/news/2009/090512/full/459144a.html> viewed 26 August 2011.

<sup>6</sup> Elbe S, "Haggling Over Viruses: The Downside Risks of Securitized Infectious Disease" (2010) 25 *Health Planning and Policy* 476 at 480.

<sup>7</sup> World Health Organisation, *Interim Statement of the Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccine and Other Benefits*, [http://www.apps.who.int/gb/pip/pdf\\_files/IGM\\_PIP-IntStatement-en.pdf](http://www.apps.who.int/gb/pip/pdf_files/IGM_PIP-IntStatement-en.pdf) viewed 10 August 2011; Shashikant S, "WHA Avian Flu Decision Links Sharing of Virus and Benefits", *Third World Network Info Services on Intellectual Property Issues* (29 May 2009), <http://www.twinside.org.sg/title2/intellectual-property/info.service/twn.ipr.info.050709.htm> viewed 4 September 2011.

<sup>8</sup> World Health Organisation, n 7.

<sup>9</sup> See terms of the Pandemic Influenza Preparedness Framework: Annex 2 SMTA, World Health Organisation, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits. Report by the Open-ended Working Group of Member States on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits* (A64/8, 2011).

<sup>10</sup> World Health Organisation, *Working for Health: An Introduction to the World Health Organisation* (2007) p 2,

associates who work together with non-government organisations, donors and United Nations agencies to tackle public health issues, support research and produce health guidelines and standards.<sup>11</sup> In the interests of global health, the WHO has various schemes for analysing virus strains, increasing vaccine production capacity and disseminating information.<sup>12</sup> The principal and longest-running mechanism for the monitoring and control of influenza virus specimens is the WHO's global surveillance network.<sup>13</sup>

### Global Influenza Surveillance Network

The Global Influenza Surveillance Network (GISN) was established in 1952 to advise member states on issues related to influenza.<sup>14</sup> The only worldwide monitoring system, GISN is based upon voluntary contributions by member states to National Influenza Centres (NICs) and WHO Collaborating Centres (WHO CCs).<sup>15</sup> One hundred and thirty-eight institutions recognised as NICs sample patients and submit viruses to any of the six WHO CCs for antigenic and genetic analyses.<sup>16</sup> The network serves as a global alert mechanism for potential pandemic influenza viruses, and recommends control measures and content of influenza vaccines.<sup>17</sup> With the adoption of the Pandemic Influenza Preparedness Framework in 2011, the GISN was renamed the Global Influenza Surveillance and Response System (GISRS).<sup>18</sup>

### Strategic Advisory Group of Experts

In addition to surveillance, the WHO relies upon the Strategic Advisory Group of Experts (SAGE) on Immunization for advice on vaccine and immunisations.<sup>19</sup> Specialised SAGE Working Groups prepare evidence-based reviews and develop options for recommendations<sup>20</sup> on seasonal influenza vaccines in addition to H1N1 and H5N1 vaccines.<sup>21</sup>

In 2007, SAGE recommended that the WHO stockpile influenza A (H5N1) vaccine on the rationale that such stockpiles are an intervention tool for global benefit and should be available to countries lacking production capacity or ability to amass national stockpiles.<sup>22</sup> To address the challenge of increasing the supply of global pandemic influenza vaccine, a Global Action Plan was developed by the WHO.<sup>23</sup>

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[http://www.who.int/about/brochure\\_en.pdf](http://www.who.int/about/brochure_en.pdf) viewed 10 September 2011.

<sup>11</sup> World Health Organisation, n 10, p 2.

<sup>12</sup> Wyman O, *Options for the Design and Financing of an H5N1 Vaccine Stockpile: Key Findings and Study Methodology* (Bill and Melinda Gates Foundation, 2009) p 3, [http://www.who.int/influenza/preparedness/pandemic/H5N1\\_Stockpile\\_Design\\_Feb2009.pdf](http://www.who.int/influenza/preparedness/pandemic/H5N1_Stockpile_Design_Feb2009.pdf) viewed 2 September 2011.

<sup>13</sup> World Health Organisation, *Global Influenza and Surveillance Response System (GISRS)*, [http://www.who.int/influenza/gisrs\\_laboratory/en](http://www.who.int/influenza/gisrs_laboratory/en) viewed 22 September 2011.

<sup>14</sup> World Health Organisation, n 13.

<sup>15</sup> World Health Organisation, *National Influenza Centres*, [http://www.who.int/influenza/gisrs\\_laboratory/national\\_influenza\\_centres/en](http://www.who.int/influenza/gisrs_laboratory/national_influenza_centres/en) viewed 10 August 2012.

<sup>16</sup> World Health Organisation, n 15.

<sup>17</sup> World Health Organisation, n 13.

<sup>18</sup> World Health Organisation, n 13.

<sup>19</sup> World Health Organisation, *Strategic Advisory Group of Experts (SAGE) on Immunization*, <http://www.who.int/immunization/sage/en> viewed 2 September 2011.

<sup>20</sup> World Health Organisation, *Purpose, Structure and Functioning of the Strategic Advisory Group of Experts on Immunization (SAGE) Working Groups*, [http://www.who.int/immunization/sage/SAGE\\_Working\\_Groups\\_general\\_information.pdf](http://www.who.int/immunization/sage/SAGE_Working_Groups_general_information.pdf) viewed 2 September 2011.

<sup>21</sup> See generally World Health Organisation, *SAGE Working Group on H5N1 Influenza Vaccine November 2008 to November 2010*, [http://www.who.int/immunization/sage/sage\\_wg\\_H5N1\\_oct08/en/index.html](http://www.who.int/immunization/sage/sage_wg_H5N1_oct08/en/index.html) viewed 2 September 2011; World Health Organisation, *Ad Hoc Policy Advisory SAGE Working Group on Influenza A (H1N1) Vaccines* (18 May 2009), [http://www.who.int/csr/resources/publications/swineflu/TC\\_report\\_2009\\_05\\_14.pdf](http://www.who.int/csr/resources/publications/swineflu/TC_report_2009_05_14.pdf) viewed 2 September 2011.

<sup>22</sup> World Health Organisation, *Experts Recommend WHO Stockpile up to 150 Million Doses of Avian Flu Vaccine* (16 November 2007), [http://www.who.int/immunization/sage/SAGE\\_note\\_19\\_11\\_07.pdf](http://www.who.int/immunization/sage/SAGE_note_19_11_07.pdf) viewed 2 September 2011; Wyman, n 12, p 3; Murray CJ et al, "Estimation of Potential Global Pandemic Influenza Mortality on the Basis of Vital Registry Data from the

## Global Pandemic Influenza Action Plan to Increase Vaccine Supply

In May 2006, the WHO adopted the Global Pandemic Influenza Action Plan to Increase Vaccine Supply (GAP)<sup>24</sup> after key stakeholders were consulted to identify solutions to close the supply-demand gap in influenza vaccine.<sup>25</sup> An advisory group of North and South representatives was convened to oversee the implementation of the plan and to update it as necessary. In achieving their main objective to increase influenza vaccine production and surge capacity,<sup>26</sup> three main approaches were identified:

- to increase seasonal vaccinations as a way to boost production capacity;
- to increase vaccine production capacity for pandemic vaccines; and
- to promote further research and development, including new technologies for faster production of pandemic vaccines.<sup>27</sup>

Local production of influenza vaccine was identified by the WHO as a means to redress the concentration of manufacturers based within the North and to “ensure greater equity in the deployment of scarce resources” during the initial phase of an influenza pandemic.<sup>28</sup> Therefore, in an effort to strengthen technical capacity, a pilot program was initiated with six developing country manufacturers to receive WHO technology transfer grants for the production of seasonal and pandemic influenza vaccine.<sup>29</sup> WHO pandemic influenza progress reports have reiterated that “[e]ffective technology transfer is arguably the most effective route for developing countries to secure sustainable access to quality influenza vaccination technology”.<sup>30</sup> The major barrier to implementation of the program was the identification of manufacturing partners prepared to transfer technology.<sup>31</sup>

## Pandemic Influenza Preparedness IGM and OEWG: Resolution WHA60.28

Formal recognition of the link between influenza virus-sharing and access by the South to vaccines and benefits occurred in May 2007, with the adoption of resolution WHA60.28 by the World Health Assembly.<sup>32</sup> The content of the resolution was not without controversy, as member states became deadlocked over the inclusion of the principles and language of the *Convention on Biological Diversity*.<sup>33</sup> Some member states debated the recognition of “sovereign rights” over PIP material<sup>34</sup> and the use of terms such as “ownership” and “prior informed consent”.<sup>35</sup>

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1918-20 Pandemic: A Quantitative Analysis” (2006) *Lancet* 2211, [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(06\)69895-4/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(06)69895-4/fulltext) viewed 2 September 2011.

<sup>23</sup> World Health Organisation, *The Global Action Plan to Increase Supply of Pandemic Influenza Vaccines: Report of the Second Meeting of the Advisory Group* (WHO/IVB/09.07, Pune, Maharashtra, India, 2009) p 1, [http://www.whqlibdoc.who.int/hq/2009/WHO\\_IVB\\_09.07\\_eng.pdf](http://www.whqlibdoc.who.int/hq/2009/WHO_IVB_09.07_eng.pdf) viewed 24 September 2011.

<sup>24</sup> GAP was developed for implementation by the global community: World Health Organisation, *Global Pandemic Influenza Action Plan to Increase Vaccine Supply: Progress Report 2006-2008* (WHO/IVB.09.05, 2009) p 42.

<sup>25</sup> Key stakeholders from national vaccination programs, national regulatory authorities, vaccine manufacturers and the research community were invited: World Health Organisation, *Global Pandemic Action Plan to Increase Vaccine Supply* (WHO/IVB/06.13, 2006), Executive Summary, <http://www.who.int/vaccines-documents/DocsPDF06/863.pdf> viewed 2 September 2011.

<sup>26</sup> World Health Organisation, n 25, p 3.

<sup>27</sup> World Health Organisation, n 25, Executive Summary.

<sup>28</sup> World Health Organisation, n 24, p 36.

<sup>29</sup> Included in the pilot was the government-owned Indonesian company BioFarma Persero and Mexico’s Birmex: World Health Organisation, n 24, pp 36-39.

<sup>30</sup> World Health Organisation, n 24, p 36; World Health Organisation, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits. Report by the Director-General (A/PIP/IGM/13, 2009)* p 48, [http://www.apps.who.int/gb/pip/pdf\\_files/PIP\\_IGM\\_13-en.pdf](http://www.apps.who.int/gb/pip/pdf_files/PIP_IGM_13-en.pdf) viewed 27 July 2011.

<sup>31</sup> World Health Organisation, n 24, p 39.

<sup>32</sup> World Health Organisation, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits* (WHA60.28, 2007), [http://www.apps.who.int/gb/ebwha/pdf\\_files/WHA60/A60\\_R28-en.pdf](http://www.apps.who.int/gb/ebwha/pdf_files/WHA60/A60_R28-en.pdf) viewed 27 July 2011.

<sup>33</sup> *Convention on Biological Diversity [1993] ATS 32*; Shashikant, n 7.

Indonesia, as a representative of over 20 co-sponsors, proposed that the North should allow technology transfer, access to vaccines and medical products in exchange for virus samples being placed in the public domain.<sup>36</sup> The United States delegation refused to adopt the language of ownership and was criticised for contending that countries of origin should waive any right to ownership while maintaining that intellectual property rights attached to vaccines and technology.<sup>37</sup> The same delegation stated that all members had a responsibility to share data and virus samples without precondition.<sup>38</sup> The United States expressed the view that the withholding of samples not only threatened global public health but also constituted a violation of members' obligation to adhere to the *International Health Regulations 2005*.<sup>39</sup>

The final resolution may not have included all proposals put forward during its eight-day drafting but it did recognise that the practices of the GISN were not transparent and resulted in the unfair distribution of benefits.<sup>40</sup> The WHO Director-General was requested to identify frameworks and mechanisms "that aim to ensure fair and equitable sharing of benefits" with particular attention to "the specific needs of developing countries".<sup>41</sup> As part of achieving these objectives, the Director-General was to convene an interdisciplinary working group and an intergovernmental meeting, thus ensuring that the link between virus sharing and equitable access to influenza vaccine remained "prominent on the global health agenda for the foreseeable future".<sup>42</sup>

Reaffirming resolution WHA60.28, the Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccine and Other Benefits (IGM-PIP) acknowledged an urgent need for effective international mechanisms to enable equitable access to and the sharing of benefits derived from influenza vaccines.<sup>43</sup> Two immediate measures were agreed to in order to deliver transparency. These were a new traceability and advisory mechanism.<sup>44</sup>

An advisory group appointed by the Director-General will "monitor, provide guidance and assess" the system while the traceability mechanism will electronically track influenza A (H5N1) and other potential human virus specimens submitted within the GISRS.<sup>45</sup> This interim system, "providing full disclosure of information on transfer and movement of virus[es]",<sup>46</sup> became operational in January 2008.<sup>47</sup>

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<sup>34</sup> For the purposes of the Framework and SMTAs this includes human clinical specimens, virus isolates and modified viruses, but excludes materials shared for non-commercial public health uses.

<sup>35</sup> Shashikant, n 7.

<sup>36</sup> Shashikant, n 7.

<sup>37</sup> Shashikant, n 7.

<sup>38</sup> "United States Delegate Statement on Pandemic-Influenza Preparedness: Sharing of Influenza Vaccines and Access to Vaccines and Other Benefits", cited in Fidler, n 3.

<sup>39</sup> "United States Delegate Statement on Pandemic-Influenza Preparedness: Sharing of Influenza Vaccines and Access to Vaccines and Other Benefits", cited in Fidler, n 3.

<sup>40</sup> See Indonesia's reaction in January 2007 as described below; Shashikant, n 7.

<sup>41</sup> World Health Organisation, n 32.

<sup>42</sup> Fidler, n 3.

<sup>43</sup> World Health Organisation, *Interim Statement of the Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccine and Other Benefits*, [http://www.apps.who.int/gb/pip/pdf\\_files/IGM\\_PIP-IntStatement-en.pdf](http://www.apps.who.int/gb/pip/pdf_files/IGM_PIP-IntStatement-en.pdf) viewed 1 September 2011.

<sup>44</sup> World Health Organisation, n 43.

<sup>45</sup> World Health Organisation, n 43; World Health Organisation, n 9, p 12, cl 5.3 Traceability and reporting mechanism.

<sup>46</sup> World Health Organisation, n 43.

<sup>47</sup> World Health Organisation, *Follow-up Action on Pending Issues and Selected Regional Committee Resolutions/Decisions for the Last Three Years: Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits* (Regional Office of Southeast Asia Committee document at the Sixty-second Regional Committee Session, Kathmandu, Nepal, 2009).

Following lengthy negotiations, the IGM-PIP agreed to proceed as an Open-ended Working Group.<sup>48</sup> In 2011, the Pandemic Influenza Preparedness-Open-ended Working Group (PIP-OEWG) presented the Pandemic Influenza Preparedness Framework to the 64th World Health Assembly for its consideration and adoption.<sup>49</sup> The content of this Framework, specifically the Standard Material Transfer Agreement (SMTA 2), is significant as a tool to solve the challenges of sharing on an equal footing between contributors of viruses and manufacturers of influenza vaccines.<sup>50</sup> Thus the overarching objective for the South entering into contractual agreements via a SMTA 2 is to rebalance the disproportionate burden of risk and benefits associated with pandemic influenza viruses and vaccines which currently exists between the North and South.

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

From July 2005 to December 2007 the highest reported cases of human H5N1 emerged out of Indonesia.<sup>51</sup> During this period Indonesia voluntarily submitted clinical specimens to participating WHO international laboratories for diagnostic assessment.<sup>52</sup> This changed in January 2007 when Indonesia stopped sharing samples as part of a demand for reform of existing WHO practices of virus sharing.<sup>53</sup> Indonesia raised two fundamental problems with the WHO virus-sharing system:<sup>54</sup>

- the use of virus samples “outside of the contemplation of the providing countries”; and
- the conditions of access to research and development technology and vaccines and treatments.<sup>55</sup>

Indonesia’s withdrawal was precipitated by Australian pharmaceutical company CSL’s planned development of a H5N1 vaccine based upon an Indonesian virus seed made available by the WHO network.<sup>56</sup> For Indonesia, the circumstances by which a pharmaceutical manufacturer could obtain free influenza samples upon which patented products were produced for profit exposed the inequity and unfairness of the virus-sharing system as it currently stood.<sup>57</sup> Indonesia questioned the legitimacy of the GISN, and declared a lack of trust in the WHO mechanisms that failed to adequately compensate developing countries for the benefits accruing from high-cost patented vaccines.<sup>58</sup>

During Indonesia’s period of withdrawal from the GISN system, H5N1 human cases continued to be confirmed in-country by Indonesian laboratories.<sup>59</sup> Indonesia’s position at the centre of the avian flu outbreak and the potential for virus mutation to human-to-human transmission meant their

<sup>48</sup> World Health Organisation, n 43.

<sup>49</sup> Sixty-fourth World Health Assembly, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits* (WHA64.5, 2011).

<sup>50</sup> World Health Organisation, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits. Report by the Director-General* (EB128/4, 2011), [http://www.apps.who.int/gb/ebwha/pdf\\_files/EB128/B128\\_4-en.pdf](http://www.apps.who.int/gb/ebwha/pdf_files/EB128/B128_4-en.pdf) viewed 1 September 2011.

<sup>51</sup> Sedyaningsih et al, n 2 at 482.

<sup>52</sup> Sedyaningsih et al, n 2 at 482.

<sup>53</sup> Sedyaningsih et al, n 2 at 482, 486.

<sup>54</sup> Abbott, n 4, p 1.

<sup>55</sup> Abbott, n 4, p 1.

<sup>56</sup> Aglionby J and Jack A, “Indonesia Accuses WHO of Misusing Flu Sample H5N1 Vaccine”, *Financial Times* (8 February 2007) p 9; Sedyaningsih et al, n 2 at 486; Fidler n 3.

<sup>57</sup> Sedyaningsih et al, n 2 at 486.

<sup>58</sup> Bennett and Carney, n 4 at 425; Sedyaningsih et al, n 2 at 486; Vezzani, n 4 at 678; Fidler D, “Negotiating Equitable Access to Influenza Vaccines: Global Health Diplomacy and the Controversies Surrounding Avian Influenza H5N1 and Pandemic H1N1” (2010) 7(5) *PLoS Med*, e1000247, DOI: 10.1371/journal.pmed.1000247, <http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.1000247> viewed 28 August 2011.

<sup>59</sup> Sedyaningsih et al, n 2 at 486.

cooperation with the virus tracking system was deemed critical for all member states.<sup>60</sup> Indonesian Health Minister, Dr Siti Fadilah Supari, said Indonesia would not share virus samples “as long as the WHO ran an unfair system”.<sup>61</sup>

It was Indonesia’s “willingness to leverage control over virus samples which provoked more multilateral responses”<sup>62</sup> than any of the previous WHO directed actions.<sup>63</sup> Alarm among the global health community with Indonesia’s continued withholding of genetic data caused the WHO to enter into a two-day crisis meeting in Jakarta to rectify the situation with urgency.<sup>64</sup> But by November 2007 the WHO Intergovernmental Meeting had still failed to reach consensus on the terms and conditions of a new virus- and benefit-sharing system.<sup>65</sup> In April 2011 the PIP-OEWG reconvened in Geneva under the co-chairs of Mexico and Norway, to finalise the Framework, including the SMTAs.<sup>66</sup>

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

The Indonesia controversy sparked lengthy negotiations between North and South WHO member states to develop a new global access Framework for the transparent, fair and equitable sharing of vaccines, access and other benefits.<sup>67</sup> Ensuring shared access to influenza viruses and vaccines is dealt with in the Pandemic Influenza Preparedness Framework via legally binding agreements between member contributors, the WHO, laboratories and industry.<sup>68</sup> Through a reformed system, the sharing of influenza viruses of pandemic potential and access to vaccines and sharing of other benefits is proposed to be on an equal footing for all member states.<sup>69</sup>

The new Framework has several objectives, including improving and strengthening member states’ influenza preparedness and response to an influenza pandemic.<sup>70</sup> This is to be achieved by improving and strengthening the WHO global influenza surveillance and response system.<sup>71</sup> The World Health Assembly and the Director-General will oversee the implementation and promotion of the Framework, while an independent Advisory Group will provide evidence-based reporting, advice and recommendations regarding the functioning of the Framework.<sup>72</sup>

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<sup>60</sup> Fidler, n 3; Abbott, n 4, p 1.

<sup>61</sup> “Stakeholders Want Virus-sharing Deal to Benefit RI”, *Jakarta Post* (22 June 2011), <http://www.thejakartapost.com/news/2011/06/22/stakeholders-want-virus-sharing-deal-benefit-ri.html> viewed 10 August 2012.

<sup>62</sup> Fidler, n 3.

<sup>63</sup> For example, see World Health Organisation, n 25; World Health Organisation, *Avian and Pandemic Influenza: Developments, Response and Follow-up, and Application of International Health Regulations (2005). Best Practice for Sharing Influenza Viruses and Sequence Data, Report by the Secretariat* (EB120/INF.DOC./3, 2007), [http://www.apps.who.int/gb/ebwha/pdf\\_files/EB120/b120\\_id3-en.pdf](http://www.apps.who.int/gb/ebwha/pdf_files/EB120/b120_id3-en.pdf) viewed 3 September 2011; Elbe, n 6, refers to Indonesia’s “valuable” submissions as a diplomatic bargaining chip for negotiating.

<sup>64</sup> MacKenzie D, “Indonesia Resumes Sharing Bird Flu Samples”, *New Scientist* (2007), <http://www.newscientist.com/article/dn11474-indonesia-resumes-sharing-bird-flu-virus-samples.html> viewed 4 September 2011; Fidler, n 3.

<sup>65</sup> Nebehay S, “WHO Fails to Reach Deal on Sharing Bird Flu Virus”, *Reuters* (24 November 2007), <http://www.in.reuters.com/article/2007/11/23/us-birdflu-who-failure-idINL2346900820071123> viewed 2 September 2011; Third World Network, “North’s Positions Hindering Pandemic Preparedness Progress”, *Third World Network Info Services on Intellectual Property Issues* (1 February 2011), [http://www.twinside.org.sg/title2/intellectual\\_property/info.service/2011/ipr.info.110201.htm](http://www.twinside.org.sg/title2/intellectual_property/info.service/2011/ipr.info.110201.htm) viewed 15 September 2011.

<sup>66</sup> World Health Organisation, n 9.

<sup>67</sup> World Health Organisation, n 32.

<sup>68</sup> International Centre for Trade and Sustainable Development, “WHO Reaches Virus Sharing Agreement After Four-Year Debate” (2011) 15 *Intellectual Property Programme*, <http://www.ictsd.org/i/news/bridgesweekly/105606> viewed 5 September 2011; World Health Organisation, n 9, p 6 (PP4).

<sup>69</sup> World Health Organisation, n 9, p 6 (PP3).

<sup>70</sup> World Health Organisation, n 9, pp 7-8.

<sup>71</sup> World Health Organisation, n 9, p 7.

<sup>72</sup> World Health Organisation, n 9 at cl 7, Governance and review.



## **Pandemic influenza preparedness (PIP) benefit-sharing system**

The Framework outlines the operation of the PIP benefit-sharing system. This system will operate to provide surveillance, risk assessment, early warning information and, where appropriate, pandemic preparedness capacity-building for all countries.<sup>73</sup> In addition, the benefit-sharing system specifically aims to assist developing countries that lack capacity to produce or access influenza vaccines.<sup>74</sup>

Key elements of the system include calling upon member states to urge pandemic influenza vaccine manufacturers to set aside some portions of vaccine for stockpiling by developing countries.<sup>75</sup> The Director-General is to continue to seek contributions from agencies, donors, institutions, pharmaceutical manufacturers and other entities for antiviral medicines and associated equipment for a WHO antiviral stockpile.<sup>76</sup>

Aside from vaccine stockpiling, member states are asked to work together to ensure adequate quantities of vaccine are made available to the South at the same time as the North on the basis of public health risk and needs and at tiered prices.<sup>77</sup> Member states are called upon to urge vaccine producers to consider the vulnerability of the least developed South when implementing tiered pricing.<sup>78</sup> Further, member states should urge influenza vaccine manufacturers to make specific efforts to transfer technologies to “empower developing countries” to study and manufacture influenza vaccines.<sup>79</sup> Donations and in-kind contributions as well as technology transfer are specifically dealt with in the Standard Material Transfer Agreements annexed to the Framework.

### **Framework Standard Material Transfer Agreements**

The Framework contains two contractual instruments called Standard Material Transfer Agreements (SMTAs) to regulate the sharing of influenza viruses.<sup>80</sup> These deal with parties within the WHO network of Collaborating Centres and Reference Laboratories (SMTA 1) and entities receiving PIP biological materials from the WHO Global Influenza Surveillance and Response System (GISRS) such as pharmaceutical manufacturers, research and academic institutions and biological firms (SMTA 2).<sup>81</sup>

#### **Mutually agreed terms: Article 4 of the SMTA 2**

The SMTA 2 permits the sharing of virus samples conditioned upon donations or reserves of vaccine/ antiviral medicine or grants of royalty-free or non-exclusive licences to WHO or manufacturers in developing countries on mutually agreed terms.<sup>82</sup> Article 4 of the SMTA offers developing countries an innovative opportunity to improve their prospects in accessing pandemic influenza vaccine by requiring PIP recipients to commit to at least two options including:<sup>83</sup>

- A1. Donate at least 10%<sup>84</sup> of real time pandemic vaccine production to WHO;
- A2. Reserve at least 10% of real time pandemic vaccine production at affordable prices to WHO;
- A3. Donate at least X treatment courses of needed antiviral medicine for the pandemic to WHO;
- A4. Reserve at least X treatment courses of needed antiviral medicine for the pandemic at affordable prices;

<sup>73</sup> World Health Organisation, n 9 at cl 6, Pandemic influenza preparedness benefit sharing system.

<sup>74</sup> World Health Organisation, n 9 at cl 6, Pandemic influenza preparedness benefit sharing system.

<sup>75</sup> World Health Organisation, n 9 at cl 6.10, Access to vaccines in the inter-pandemic period for developing countries.

<sup>76</sup> World Health Organisation n 9 at cl 6.8, Antiviral stockpiles, and cl 6.10, Access to vaccines in the inter-pandemic period for developing countries.

<sup>77</sup> World Health Organisation, n 9 at cl 6.10, Access to vaccines in the inter-pandemic period for developing countries.

<sup>78</sup> World Health Organisation, n 9 at cl 6.12, Tiered pricing.

<sup>79</sup> World Health Organisation n 9 at cl 6.13, Technology transfer.

<sup>80</sup> World Health Organisation, n 9 at cl 5.4, Standard material transfer agreements.

<sup>81</sup> World Health Organisation, n 9 at Annex 2.

<sup>82</sup> World Health Organisation, n 9 at Annex 2, Art 4, Obligations of the recipient.

<sup>83</sup> World Health Organisation, n 9 at Annex 2, Art 4, Obligations of the recipient.

<sup>84</sup> In recognising a need to be flexible in negotiating with manufacturers, the contract allows for a range of 5-20% for donations or reserved contributions.

- A5. Grant to manufacturers in developing countries licences on mutually agreed terms that should be fair and reasonable including in respect of affordable royalties, taking into account development levels in the country of end use of the products, on technology, know-how, products and processes for which it holds IPR for the production of (i) influenza vaccines, (ii) adjuvants, (iii) antivirals and/or (iv) diagnostics;
- A6. Grant royalty-free licences to manufacturers in developing countries or grant to WHO royalty-free, non-exclusive licences on IPR, which can be sublicensed, for the production of pandemic influenza vaccines, adjuvants, antivirals products and diagnostics needed in a pandemic. WHO may sublicense these licences to manufacturers in developing countries on appropriate terms and conditions and in accordance with sound public health principles.

The emergence and rapid spread of new diseases are exacerbated by factors of modern society such as increased human mobility, densely populated cities and environmental changes.<sup>85</sup> Therefore, when a novel influenza virus spreads quickly and easily around the world, it is evident that vaccines and antiviral drugs are the only practical medical intervention for reducing infection and mortality.<sup>86</sup> Thus, through Art 4, developing nations can pursue either donations or affordable pricing on vaccine and antiviral medicine, in addition to access to the technology and know-how to manufacture their own vaccine.

Aside from the already identified technical problems of mass-producing pandemic influenza vaccines, there are also global and political issues.<sup>87</sup> Attempts by the WHO to establish local vaccine production in developing countries was hindered by a failure to secure manufacturing partners willing to transfer technology.<sup>88</sup> When 90% of the world's influenza vaccine production is carried out in just nine countries, predominately in Europe and the United States,<sup>89</sup> the potential for nationalisation of vaccine-manufacturing facilities by host countries is a real threat to any equitable distribution to those in the greatest need as opposed to those with pre-purchase contracts.<sup>90</sup>

Fidler, writing in early 2010, posited that negotiating equitable access to pandemic influenza vaccine is an arduous diplomatic endeavour because national interests favour the “existing imbalanced, reactive and ad hoc approach to vaccine access” over legally binding options.<sup>91</sup> Historically, measures taken by the WHO to negotiate donations from vaccine producers and larger nations of the North have proved fruitless in that they typically lacked delivery dates or were pledged only after the national needs of the North were addressed.<sup>92</sup>

In developing the Framework, countries in the industrialised North were not in favour of the binding terms and conditions nor the option of arbitration to settle disputes.<sup>93</sup> The intrinsic value of the mutually agreeable terms contained within Art 4 can only be determined by examining the South's ability to legally enforce them. Article 5 of the Framework provides for methods of resolution in the event of dispute between contracting parties.

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<sup>85</sup> Chuengsatiansup K, “Ethnography on Epidemiologic Transition: Avian Flu, Global Health Politics and Agro-industrial Capitalism in Thailand” (2008) 15 *Anthropology and Medicine* 53 at 55.

<sup>86</sup> Fidler, n 58; Wyman, n 12, p 3; World Health Organisation, *WHO Strategic Action Plan for Pandemic Influenza* (WHO/CDS/EPR/GIP/2006.2a, 2007) p 15, [http://www.who.int/csr/resources/publications/influenza/StregPlanEPR\\_GIP\\_2006\\_2.pdf](http://www.who.int/csr/resources/publications/influenza/StregPlanEPR_GIP_2006_2.pdf) viewed 12 September 2011.

<sup>87</sup> Chuengsatiansup, n 85 at 57.

<sup>88</sup> World Health Organisation, n 24, p 39.

<sup>89</sup> World Health Organisation, n 24, p 39.

<sup>90</sup> Tadataka Y, “Poverty, Wealth, and Access to Pandemic Influenza Vaccines” (2009) 361 *NEJM* 1129.

<sup>91</sup> Fidler, n 58.

<sup>92</sup> Hayden, n 5; Fidler, n 58.

<sup>93</sup> Shashikant S, “Milestone Virus/Benefit-sharing Agreement with Shortcomings” *Third World Network Info Services on Intellectual Property Issues* (21 April 2011), <http://www.twinside.org.sg/title2/health.info/2011/health20110404.htm> viewed 28 June 2011.

## Dispute resolution: Article 5 of the SMTA 2

The importance of virus samples and sequence data to vaccine research and development by the global health community is underscored by the obligations upon member states to submit samples in a rapid, systematic and timely manner to the GISRS.<sup>94</sup> Further obligations are espoused by the *International Health Regulations 2005*, which are “global rules to enhance national, regional and global public health security”.<sup>95</sup> Member states have freely contributed to the virus-sharing network under a perceived obligation to international public health and as part of a global cooperation to address both domestic and global health security.<sup>96</sup>

Principles of the Framework include recognition of WHO leadership and the organisation’s oversight functions, as well as a reaffirmation of the obligations of states parties under international health regulations.<sup>97</sup> Contained within Art 5 of SMTA 2 are the prescribed avenues for dispute resolution between contracting parties. It states:

If a dispute cannot be resolved through negotiations or other non-binding means of the parties’ choice, disputes shall be subject to binding arbitration on conditions that are mutually agreed by the parties.<sup>98</sup>

Therefore the means by which parties resolve their differences are through negotiation or alternative non-binding means before pursuing arbitration.

While the Framework provides for its implementation and functioning, there is no designated body set forth by the WHO to deal with enforcement or violation of the SMTAs. This is in contrast to the WTO’s dispute resolution mechanism, which has successfully governed the interaction between members by implementing trade sanctions on non-complying parties. The WTO is an international body established to deal with trade relations between members and a central pillar of its multilateral trading system is the dispute resolution mechanism.<sup>99</sup> The WTO dispute mechanism utilises trade sanctions to induce compliance by its members, with special procedures for least-developed countries.<sup>100</sup>

The Dispute Settlement Body (DSB), which administers the rules and procedures of the WTO Agreement, has the authority to grant a member state the ability to suspend the application of concessions or other obligations once all other dispute settlement procedures have been exhausted.<sup>101</sup> Similarly to the SMTA 2, arbitration within the WTO is recognised as an alternative to dispute settlement where parties mutually agree on the procedures to be followed.<sup>102</sup>

The WHO lacks the legal authority or mechanisms for enforcing agreements entered into for the sharing of pandemic influenza material and vaccines and other benefits.<sup>103</sup> Without a body of authority to enforce the terms of the SMTA 2, there is the potential for a world health crisis to negate the efficacy of SMTAs in favour of national health policies or, as previously identified, the nationalisation of vaccine manufacturers. The effect of these actions would be to curtail access by the South at the very time that the agreement is needed.

<sup>94</sup> World Health Organisation, n 9 at cl 5.1.1.

<sup>95</sup> World Health Organisation, *International Health Regulations (IHR)*, <http://www.who.int/ihr/en> viewed 27 September 2011.

<sup>96</sup> Elbe, n 6 at 477.

<sup>97</sup> World Health Organisation, n 9 at PP6 and PP10.

<sup>98</sup> World Health Organisation, n 9 at Annex 2, Art 5, Dispute resolution.

<sup>99</sup> World Trade Organisation, *Understanding the WTO*, [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/disp1\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm) viewed 22 September 2011.

<sup>100</sup> WTO Agreement, Art 24; World Trade Organisation, *Understanding on Rules and Procedures Governing the Settlement of Disputes: Annex 2 of the WTO Agreement*, [http://www.wto.org/english/tratop\\_e/dispu\\_e/dsu\\_e.htm#24](http://www.wto.org/english/tratop_e/dispu_e/dsu_e.htm#24) viewed 22 September 2011; Charnovitz S, “Rethinking WTO Trade Sanctions”, paper prepared for the Festschrift in honour of Robert E Hudec (2001), <http://www.ssrn.com/abstract=256952> or doi:10.2139/ssrn.256952 viewed 22 September 2011.

<sup>101</sup> WTO Agreement, Art 22.

<sup>102</sup> WTO Agreement, Art 25.

<sup>103</sup> Gostin L, “A Shot in the Arm for the WHO and CDC”, *Washington Post* (1 May 2009), <http://www.washingtonpost.com/wp-dyn/content/article/2009/04/30/AR2009043003517.html> viewed 27 September 2011.

## CASE STUDY: 2009 INFLUENZA A (H1N1) SWINE FLU VACCINE ACCESS

### The state of the PIP Framework in 2009

In May 2009, WHO member states came together to continue negotiating equitable access to influenza vaccines and other benefits, through the IGM-PIP only days prior to the 62nd World Health Assembly. While the North and South agreed to most elements of the benefit-sharing provisions of the Pandemic Influenza Preparedness Framework, differences continued on the issue of the Standard Material Transfer Agreements.<sup>104</sup>

The discrepancy between North-South positions on binding legal agreements, which linked virus sharing and access and benefits, remained at the heart of the SMTA debate.<sup>105</sup> The South called for reform of the system as well as highlighting bias within the WHO practice of focusing on virus-sharing and not benefits-sharing.<sup>106</sup> Reluctance by the North to commit to obligatory benefit-sharing, especially upon third parties such as the industry, also stalled meaningful resolutions.<sup>107</sup>

Due to the emergence of a possible pandemic, the 62nd session of the World Health Assembly was shortened by three days.<sup>108</sup> It was agreed that, rather than the IGM continuing to try to resolve the outstanding elements of the Pandemic Influenza Preparedness Framework, including the STMA, the Director-General was to carry on this function in a transparent process and report to the Executive Board in January 2010.<sup>109</sup>

The 2009 swine flu outbreak reinforced for the global health community long-recognised deficiencies in the influenza virus-sharing system.<sup>110</sup> These include a need to increase global production capacity, especially during pandemics when demand overwhelms supply.<sup>111</sup> The delay created by using the current egg-based technology for vaccine formulation needs to be addressed in order to produce and distribute vaccines more quickly during fast-spreading influenza pandemics.<sup>112</sup> In addition, distribution uncertainties caused by batch failure and lags in production lead-time between virus seed to vaccine, continue to be of concern when influenza vaccine is in greatest demand.<sup>113</sup>

### Swine flu in the Americas

The outbreak of swine flu in North and South America was unexpected in that it was assumed that Southeast Asia would be the point of origin, given the past two pandemics.<sup>114</sup> Following on from the H5N1 (avian influenza) and severe acute respiratory syndrome (SARS) that swept through Asia in 2003, many in the North had, or were at the very least in the planning stages of, global pandemic

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<sup>104</sup> South Center and the Center for International Environmental Law (CIEL), "WHO Pandemic Influenza Preparedness Intergovernmental Meeting (IGM)" (2009) *Intellectual Property Quarterly Update* 16, [http://www.ciel.org/Publications/IP\\_Update\\_2Q09.pdf](http://www.ciel.org/Publications/IP_Update_2Q09.pdf) viewed 15 September 2011.

<sup>105</sup> The PIP-OEWG meeting in December 2010 failed to achieve any meaningful progress due to the positions taken by the North, particularly the European Union and the United States: Third World Network, n 65.

<sup>106</sup> Third World Network, n 65.

<sup>107</sup> Third World Network, n 65.

<sup>108</sup> "World Health Assembly Closes with Resolutions on Public Health", *News Release* (Geneva, 22 May 2009), [http://www.who.int/mediacentre/news/releases/2009/world\\_health\\_assembly\\_20090522/en/index.html](http://www.who.int/mediacentre/news/releases/2009/world_health_assembly_20090522/en/index.html) viewed 28 June 2011.

<sup>109</sup> "World Health Assembly Closes with Resolutions on Public Health", n 108.

<sup>110</sup> Fidler, n 58.

<sup>111</sup> Fidler, n 58.

<sup>112</sup> World Health Organisation, n 86, p 18.

<sup>113</sup> World Health Organisation, n 25, Executive Summary.

<sup>114</sup> Roos R, "H1N1 Lessons Learned: Pandemic Underscored Influenza's Unpredictability", *Center for Infectious Disease Research and Policy News* (23 April 2010), <http://www.cidrap.umn.edu/cidrap/content/influenza/panflu/news/apr2310pandemic-jw.html> viewed 25 August 2011.

preparedness plans.<sup>115</sup> Those member states had stockpiles of Oseltamivir (Tamiflu) and Zanamivir (Relenza)<sup>116</sup> and/or pre-emptive purchase contracts in place with pharmaceutical companies to supply them with the necessary vaccines should a novel influenza arise.<sup>117</sup>

At an extraordinary meeting on the influenza A (H1N1) 2009 pandemic, SAGE noted with concern that only a small number of developed countries had access to the majority of global vaccine output, primarily through purchase agreements, which consequently limited vaccine for developing countries.<sup>118</sup> Indonesia's Health Minister's speech at the 2009 62nd World Health Assembly reiterated Indonesia's call for transparency, stating that advance contracts by the North for vast quantities of vaccine ultimately leaves the South asking, "What is left for us?".<sup>119</sup>

On 11 June 2009 the WHO Director-General, Dr Margaret Chan, officially declared that the influenza A (H1N1) swine flu virus had reached "Phase 6".<sup>120</sup> The first identified case of H1N1 was traced to an outbreak of respiratory illness in Mexico.<sup>121</sup> Thus, Mexico found itself at the epicentre of a global pandemic as it experienced the first wave of swine flu and the majority of fatalities.<sup>122</sup> During a keynote speech in July 2009 Dr Chan commended Mexico for its early warning, transparent reporting and "generous sharing of data and samples".<sup>123</sup> Even though Mexico freely contributed its virus specimens to the global surveillance network,<sup>124</sup> it found itself alongside other developing nations in the global scramble for the WHO-recommended vaccine based upon those samples.<sup>125</sup> Mexican Health Secretary, Jose Angel Cordova, stated that Mexico "had to wait in the second line to buy the vaccine, because obviously the first shipments were for the countries that make the vaccine".<sup>126</sup>

The lion's share of available vaccine went to the largest of the developed countries. For example, by June 2009 the United States had awarded multi-million dollar contracts to MedImmune, Sanofi,

<sup>115</sup> Hayden, n 5.

<sup>116</sup> Previously these antiviral drugs have proven effective against seasonal and some strains of H1N1 and H5N1.

<sup>117</sup> Australia's Howard Government stockpiled Tamiflu following the avian influenza in 2004; however, the Rudd Government needed to replace 1.9 million doses which expired by the time of the 2009 swine flu. See "Australian Stockpiles of Anti-viral Drug Tamiflu are Out of Date", *Sunday Telegraph* (3 May 2009), <http://www.news.com.au/national/australian-anti-flu-drugs-are-out-of-date/story-e6frfkvr-1225707143051> viewed 25 August 2011.

<sup>118</sup> Strategic Advisory Group of Experts on Immunization, "Report of the Extraordinary Meeting on the Influenza A (H1N1) 2009 Pandemic" (2009) 30 *Weekly Epidemiological Record* 301.

<sup>119</sup> Supari, n 4.

<sup>120</sup> The WHO elevation to Phase 6 was not a reflection of the severity of the virus but rather the virus's sustained spread across multiple WHO regions: World Health Organisation, *Global Alert and Response (GAR): Current WHO Phase of Pandemic Alert for Avian Influenza H5N1* (2009), <http://www.who.int/influenza/preparedness/pandemic/h5n1phase/en> viewed 26 August 2011; Statement to the Press by Director-General of the World Health Organisation, "World Now at the Start of 2009 Influenza Pandemic", *News Release* (Geneva, 11 June 2009), [http://www.who.int/mediacentre/news/statements/2009/h1n1\\_pandemic\\_phase6\\_20090611/en/index.html](http://www.who.int/mediacentre/news/statements/2009/h1n1_pandemic_phase6_20090611/en/index.html) viewed 26 August 2011.

<sup>121</sup> World Health Organisation, *Characteristics of the Emergent Influenza A (H1N1) Viruses and Recommendations for Vaccine Developments* (2009), <http://www.who.int/csr/resources/publications/swineflu/H1N1Vaccinevirusrecommendation26May2009.pdf> viewed 23 August 2011.

<sup>122</sup> "Health Assembly to Discuss A/H1N1 Influenza, Other Health Issues", *China View* (18 June 2009), [http://www.news.xinhuanet.com/english/2009-05/18/content\\_11395932.htm](http://www.news.xinhuanet.com/english/2009-05/18/content_11395932.htm) viewed 14 September 2011.

<sup>123</sup> Chan M, "Influenza A (H1N1): Lessons Learned and Preparedness", keynote speech at a high-level meeting on influenza A (H1N1), *Lessons Learned and Preparedness* (Cancun, Mexico, 2009), [http://www.who.int/dg/speeches/2009/influenza\\_h1n1\\_lessons\\_20090702/en/index.html](http://www.who.int/dg/speeches/2009/influenza_h1n1_lessons_20090702/en/index.html) viewed 25 August 2011.

<sup>124</sup> Fidler, n 58.

<sup>125</sup> Hayden, n 5; Butler, n 5.

<sup>126</sup> Koon Chan C, "Equitable Access to Pandemic Flu Vaccines", paper presented at the Conference on Strengthening Health and Non-health Response Systems in Asia: A Sustained Approach for Responding to Global Infectious Disease Crises (co-organised by Nanyang Technological University and the World Health Organisation, 18-19 March 2010, Singapore), [http://www.twinside.org.sg/title2/intellectual\\_property/info.service/2010/ipr.info.100311.htm](http://www.twinside.org.sg/title2/intellectual_property/info.service/2010/ipr.info.100311.htm) viewed 10 August 2012.

Novartis, CSL Biotherapies and GlaxoSmithKline (GSK) to supply H1N1 vaccine antigen.<sup>127</sup> These orders were in addition to millions worth of adjuvant.<sup>128</sup> At that time, numerous pharmaceutical companies had received the influenza A (H1N1) seed virus via the WHO virus-sharing system with the aim of having a vaccine ready in the northern hemisphere prior to the flu season.<sup>129</sup>

Developing countries such as Mexico turned to the World Bank for emergency loans to fund medicine and medical equipment and also to assist in setting up operations to deal with the outbreak.<sup>130</sup> At the start of the pandemic, Mexico requested 100,000 packs of Relenza from GSK.<sup>131</sup> As Mexico had no domestic influenza vaccine manufacturing and was completely reliant on foreign vaccine manufacturers, by January 2010 Canada decided to lend five million doses of H1N1 vaccine to Mexico to help meet its pandemic needs.<sup>132</sup> Canada expected the vaccine to be replenished a few months later when Mexico took possession of their vaccine orders.<sup>133</sup> Mexico's delivery was much later than the United States or Canada, even though all three countries were the first affected by the swine flu virus.

Swine flu in the northern hemisphere proved to be less deadly than first predicted and mortality rates fell well below modelling.<sup>134</sup> What the swine flu did reveal was that where surge demand overwhelms normal supply, the inequity of the virus-sharing network is exposed. Mexico's failure to receive first production delivery of the H1N1 vaccine while the North had pre-orders satisfied, reinforced the Indonesian argument that developing countries miss out on the benefits of participating in the virus-sharing network.

## CONCLUSION

This article demonstrates that the (H5N1) 2007 pandemic and the (H1N1) 2009 pandemic exposed a disproportionate sharing of vaccines and other benefits between the North and South to the detriment of the world's poorest people. National interests of the largest of the developed nations has, through a monopoly of global vaccine output, restricted access for all others, especially the countries of the South which are confronted with cost-prohibitive medications and limited access to vaccine and technologies.

The WHO's focus upon virus-sharing and not benefit-sharing caused nations of the South to query their ongoing voluntary virus submissions with the global health community when few to no benefits were flowing back to their own people. A perceived obligation under the *International Health Regulations* and global cooperation to share viruses on an equal footing has not been reciprocated in ensuring equitable access to influenza vaccine, technology and other benefits arising out of the virus-sharing process.

A significant and widely recognised flaw within the global pandemic preparedness scheme is the insufficient supply of influenza vaccine to meet the surge in demand created by a pandemic. A

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<sup>127</sup> Butler, n 5.

<sup>128</sup> Adjuvants are stretchers (such as a water-oil mixture) that reduce the amount of vaccine needed. The United States has a conservative approach to the use of adjuvants and there were no licensed adjuvants for use during the 2009 pandemic. See Centre for Disease Control and Prevention, *CDC Briefing on Investigation of Human Cases of H1N1 Flu* (transcript, 17 July 2009), <http://www.cdc.gov/media/transcripts/2009/t090717.htm> viewed 2 August 2011; Butler, n 5.

<sup>129</sup> Hayden, n 5; Butler, n 5.

<sup>130</sup> Bosley S, "Mexico Granted \$205m Swine Flu Loan from World Bank", *The Guardian* (27 April 2009), <http://www.guardian.co.uk/world/2009/apr/27/mexico-loan-imf-swine-flu> viewed 25 August 2011.

<sup>131</sup> GlaxoSmithKline, "Emergence of a New H1N1 Influenza A Strain (Swine Influenza)", *Press Release* (London, 27 April 2009), [http://www.gsk.com/media/pressreleases/2009/2009\\_pressrelease\\_10046.htm](http://www.gsk.com/media/pressreleases/2009/2009_pressrelease_10046.htm) viewed 28 August 2011.

<sup>132</sup> "Canada Sends 5mln Doses of H1N1 Vaccine to Mexico" (Reuters, 6 January 2010), <http://www.reuters.com/article/2010/01/06/idUSN06148239> viewed 26 August 2011.

<sup>133</sup> "Canada Sends 5mln Doses of H1N1 Vaccine to Mexico", n 132.

<sup>134</sup> Detailed Report from the *H1N1 Countermeasures Strategy and Decision Making Forum*, hosted by the Pandemic Influenza Working Group of the National Biodefense Science Board, Maryland, US, 2009, p 11, <http://www.phe.gov/Preparedness/legal/boards/nbsb/meetings/Documents/060718-h1n1-forum.pdf> viewed 28 July 2011.

substantial increase in vaccine production capacity is critical in the fight against pandemic influenza, yet the global health community has continued with ad hoc practices to assist the countries of the South with little success. The introduction of a new Framework that includes SMTAs is not simply shifting access from the North to the South. Rather, by granting developing countries access to technologies, thus enabling them to establish local production of vaccine, it will ensure sustainable increases in pandemic vaccine production, which means access for both North and South.

In order to address the problem of increased influenza vaccine production and equitable distribution during a pandemic, the Framework needed to link the contributions of virus specimens and the benefits arising out of that collaboration. The SMTAs are legally binding contracts between parties that govern the transfer of influenza virus samples in exchange for access to vaccine, antiviral medicines and/or technology. The negotiable content of Art 4 within SMTA 2 assists the developing South to leverage their high-value virus seeds in the negotiating process in return for benefits that were previously unattainable or unavailable to them.

Article 5 of SMTA 2 prescribes the means by which disputes may be resolved, but unlike similar agreements within the WTO, the Framework is silent on the forum under which negotiation or arbitration can take place or the repercussions for non-adherence. Without a mechanism in place to enforce the terms of the SMTAs, the efficacy of the new Framework is challenged. The nearly four years to develop a new fair, equitable and transparent system and the ongoing debate between North and South members is demonstration that the WHO is clearly powerless in ensuring such agreements will be adhered to. There remains a real threat that domestic health policies and nationalisation of vaccine manufacturers by host countries will undermine PIP material sharing agreements during a widespread and deadly pandemic.

Existing mechanisms for public health governance based upon international cooperation has functioned to the advantage of industrialised vaccine-producing nations. The introduction of the Framework is an opportunity for the South to level the playing field by sharing influenza viruses through transparent mechanisms and enabling fair and equitable access to vaccines and other benefits.