

Influenza Virus & Benefit Sharing

**Sangeeta Shashikant
Third World Network**

Background

- Early 2007 Indonesia Health Minister announced.. no longer provide bird flu viruses to the WHO “Global Influenza Surveillance Network” – (GISN).
- GISN is made up of the WHO National Influenza Centres (NICs), 4 WHO Collaborating Centres (WHO CCs) based in Australia, Japan, UK and US; WHO H5 Reference Laboratories. Essential Regulatory Labs is another set of labs.
- GISN recommends the content of influenza vaccine and for this purpose it relies on NICs, which submits viruses to the labs in GISN.
- Basically system obtains viruses from affected countries. Designated labs turn these viruses into candidate vaccine viruses which are then passed to private sector entities for vaccine development using Material Transfer Agreement (MTA).
- Indonesia claimed that this was not in accordance with WHO guidelines in force then i.e. that WHO was not suppose to share the candidate vaccine viruses with entities outside the WHO Network. Also Indonesia claimed that although MTAs were used to transfer candidate vaccine virus to entities outside the GISN, it was not allowed to transfer biological materials to designated labs using MTAs.

- In addition:
 - the vaccines that are produced are often too costly and unavailable to affected developing countries that need them.
 - There is only a limited amount of vaccines that can be produced in the event of a pandemic. Developed countries have already made advance purchases of the vaccines.
 - Patent claims have been made on the viruses and parts of thereof by WHO network labs as well as by the private sector that received the viruses (See Edward Hammond: “Some Intellectual Property Issues Related to H5N1 Influenza Viruses, Research and Vaccines”)

- All of these issues came to ahead at the 2007 World Health Assembly.
- A resolution 60.28 was passed that linked virus sharing to benefit sharing.
- The legal basis that led to the resolution 60.28 is the internationally recognized principle of law that States have sovereign right over their biological resources, and the linked principles of prior informed consent and the right to fair and equitable sharing of benefits arising from the use of the resources.
- A major part of the resolution also outlines processes that would work on setting terms and conditions and mechanisms for virus and benefit sharing.
- Several meetings have taken place since the 2007 WHA. Presently a pandemic influenza preparedness framework is being negotiated.

- Some of the key elements of the framework being discussed:
 - Standard Material Transfer Agreement (SMTA) that would contain terms and conditions governing virus sharing and benefit sharing;
 - Entities that should be governed by the SMTA,
 - Benefit sharing and IPRs.
- Generally developing country position:
 - virus sharing is linked to benefit sharing and both must be elaborated on in the SMTA which will be the legal contract when virus sharing takes place.
 - the SMTA would contain T&C on what can and cannot be done with the viruses received including terms on IPRs and it would also contain benefit sharing provisions.
 - SMTA would apply to all entities including the industry that receive biological materials from WHO.
- Generally developed countries:
 - don't like the idea of a SMTA and that if there is a SMTA it must not involve the industry
 - like to see voluntary benefit sharing e.g. donations from industry.....see this as a sustainable way forward.

- In the virus and benefit sharing debate, one major outstanding issue is the issue of IPRs.
- This issue has come up in the debate in 2 ways.
 - First during discussion on the T&C in the SMTA as well as in the PIP Framework.
 - Second as an issue in relation to technology transfer.

The first part pertains to the extent to which entities receiving biological materials from the WHO Network can make IPR claims over the biological materials and parts thereof received and products developed using such materials.

This can be further broken down to 4 issues:

- (a) Whether WHO Network labs should be allowed to claim IPRs over biological materials and parts thereof?
- (b) Whether WHO Network Labs should be allowed to claim IPRs over the products/processes developed using biological materials and parts thereof?
- (c) Whether entities outside WHO Network labs that receive biological materials should be allowed to claim IPRs over the biological materials and parts thereof.
- (d) Whether entities outside WHO Network labs that receive biological materials should be allowed to claim IPRs over products/processes developed using the biological materials and parts thereof

- Argued that in situations (a), (b) and (c), IPRs should not be allowed to be claimed.
- In situations (a) and (b), the recipients are WHO network labs (e.g. WHO CC/H5RL/ERL) tasked to conduct research for non-commercial public health purposes on biological materials countries have contributed for global public health without financial gain.
- Allowing patenting sets a very bad precedent for other treatment areas in WHO and undermines trust in the WHO network labs.
- In situation (c) as well there is simply no reason for allowing IPRs to be claimed over these materials since entities outside WHO network labs receive biological materials because they are shared for global public health.
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- On (d) developing countries have shown some flexibility in allowing IPRs to be claimed provided entities of developing countries are granted royalty free licenses.

- In this regard it is interesting to note the following proposal made by WHO Secretariat to member states:

“If intellectual property rights are obtained on inventions derived from the use of PIP Biological Materials, the holder of such rights should grant to WHO a non-exclusive, royalty-free, sub-licensable licence with respect to such rights. Licences to WHO shall be subject to the following terms:

(a) WHO shall, upon request, have the right to grant sub-licences of said licence (hereinafter “WHO sub-licences”) for public health purposes;

(b) WHO may subject WHO sub-licences to appropriate conditions based on sound public health principles. (fn1)

(fn1): For example, the commitment, ability and readiness of a potential recipient to use the sub-licence; and agreement on the territorial application of the sub-licence.

- According to WHO document it is based on Data and Materials Sharing Agreement used by the Bill and Melinda Gates Foundation.
- One weakness is that it only proposes this paragraph to deal with all issues raised in (a) – (d) which means that it does not making a distinction between WHO network labs and entities outside WHO network labs and between biological materials and the products developed using the biological materials.
- Important distinctions has been left out.
- Another weakness is that the proposal is heavily conditioned.
- But it is a proposal that could be part of the solution on IPRs.

In relation to technology transfer: in 2007, the Africa Group made the following proposal:

- (i) The Third Party will grant on request, a non-exclusive, royalty-free license to any domestic influenza vaccine manufacturer from developing and least developed countries in particular to the First Party to use its intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of influenza vaccine development and production in particular pre-pandemic and pandemic vaccines.
- (ii) The Third Party will on request allow access to and transfer of its technology, know-how, all information and knowledge used in the process of influenza vaccine development and production as well as provide the necessary capacity building, to domestic influenza vaccine manufacturers from developing and least developed countries in particular to the First Party in order to encourage domestic manufacturing of influenza vaccines in developing and least developed countries particularly pre-pandemic and pandemic vaccines, to fulfil domestic and regional needs.
- (iii) In relation to (ii) the Third Party will provide the access and transfer at no cost [or on terms which are reasonable and favourable to developing countries in particular to the First Party]

- **In December 2008: the following was tentatively agreed on technology transfer in the section on benefit sharing in the Pandemic Influenza Preparedness Framework.**
- 6.13.1 The Director-General will continue to work closely with Member States and influenza vaccine manufacturers to implement the WHO Global Pandemic Influenza Action Plan to Increase Vaccine Supply, including its strategies to build new production facilities in developing and/or industrialized countries and through transfer of technology, skills and know-how.
- 6.13.2 Member States should urge influenza vaccine, diagnostic and pharmaceutical manufacturers to make specific efforts to transfer these technologies to other countries, particularly developing countries, as appropriate.

- 6.13.3 Technology transfer should be conducted in a manner consistent with applicable national laws and international laws and obligations, facilitated progressively over time, on mutually agreed terms, and be suitable to the capacity of recipient Member States, to empower developing countries to study and manufacture influenza vaccines, diagnostics and pharmaceuticals.
- 6.13.4 Influenza vaccine manufacturers who receive PIP biological materials may grant, subject to any existing licensing restrictions, on mutually agreed terms, a non-exclusive, royalty-free licence to any influenza vaccine manufacturer from a developing country, to use its intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of influenza vaccine development and production, in particular for pre-pandemic and pandemic vaccines for use in agreed developing countries.

- ---weak language as not binding. But the framework is based on such language.
- TT may once again be an issue during discussions on benefit sharing in the context of the SMTA.
- certainly a huge push for this from developing countries. The H1N1 pandemic has highlighted the importance of benefit sharing.
- Much depends on the type of benefit sharing options that will be agreed to.
- e.g. proposal of a fund.....use part of the fund for TT
- e.g. idea of a patent pool.... Wherein it could be a requirement that to access the biological materials the recipients have to place certain technologies they own into a patent pool and agree to share know-how and build capacity.
- The technologies in the pool would then be accessible on certain T&C that would have to be negotiated, with preferential terms being given to developing country entities.