



Biosecurity Symposium

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Access to H5N1 and Other
Potential Pandemic Virus
Samples
Governance Issues



Background

- Access to influenza virus samples generally freely available through WHO Collaborating Centres
- Dec 2006 Indonesia unilaterally blocked transfer of H5N1 Virus samples
- Indonesian Minister of Health complained of commercial use of its intellectual property without prior consent or benefit sharing agreement



Example Used

- Australia specifically identified by Indonesia
- CSL announced development of new vaccine
 - Aust Govt provided \$7.17 million towards development costs. (source CSL Press Release Jan 2007)
- CSL stated it had received virus sample from WHO



International Context

- WTO debate on Intellectual Property - TRIPS Agreement
- Convention on Biological Diversity - States have sovereign rights over their own biological resources
- FAO - World Seed Banks - International Treaty on Plant Genetic Resources



WHO Response to Indonesia

- Established institution arrangements to attempt to resolve the issue
- Several Expert and Intergovernmental Meetings held - Jakarta, Singapore, Geneva and formal sessions of the WHA and EC
- Objective - to ensure on-going access to virus samples



WHO Negotiating Framework

- World Health Assembly - Res: **WHA60.28**
- Intergovernmental : Pandemic Influenza Preparedness: sharing of influenza viruses and access to vaccines and other benefits
- Includes developing: Terms of Reference for sharing influenza viruses and sequence data, stockpiling H5N1 vaccines and establishing a financing mechanism



Negotiations: politically and technically complex

- Key issues revolve around the use of virus samples, including defining ownership - prior informed consent, benefit sharing. Access to vaccines, technology, capacity building.
- How to effectively maintain tracking of samples provided to Third Parties
- Use of Material Transfer Agreements - role of intellectual property



Agreement - Traceability Mechanism Established

- WHO will establish a technical and feasible system as soon as possible **to track all shared H5N1 and other potential pandemic human viruses and parts thereof.**
- **An interim system providing full disclosure of information on transfer and movement of viruses shall be made operationally immediately.**



Agreement: Create a new Advisory Group

- To monitor, provide guidance to strengthen functioning of system and undertake necessary assessment of the trust-based system needed to protect public health.
- Established and managed by an institutional oversight body including ‘representative’ Member States



Demonstration of goodwill

- Viruses and samples are to be shared within the WHO system **consistent with national laws and regulations**
- Australia already has legislation governing use of genetic resources
- The detailed framework for virus sharing and benefit sharing continues to be developed.....



Consequences for Global Collaboration

- Imposes levels of conditionality
- Focus on IP rights expected to expand
- Intellectual Property - contentious issue
- Scientific Research - integrating governance and ethical obligations