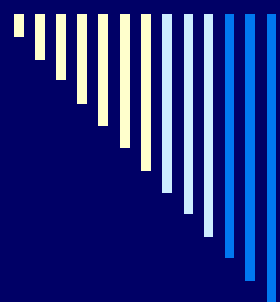


Setting the Stage: The WHO and the IGWG (Intergovernmental Working Group on Public Health, Innovation & Intellectual Property)

February 19, 2008

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What is the IGWG?

- Established in 2006 by the World Health Assembly by resolution WHA 59.24
- Reports back to the 61st WHA in May 2008 with a global strategy and plan of action on IP rights, Innovation and Public Health "giving particular attention to needs-driven research and other potential areas for early implementation."



Context

- The world is facing a growing burden of diseases and conditions disproportionately affecting developing countries
 - More needs to be done in funding initiatives to develop new vaccines, screens and drugs for diseases such as AIDS, malaria, and multi-drug resistant tuberculosis
-



Definition of Diseases

- *Type I diseases* - “incident in both rich and poor countries” (diabetes, cancer and cardiovascular disease)
 - *Type II diseases* - “incident in both rich and poor countries but with substantial proportion of the cases in poor countries” (HIV/AIDS and tuberculosis)
 - *Type III diseases* – “overwhelmingly or exclusively in developing countries (dengue, leishmaniasis, leprosy, malaria, onchocerciasis)
-



IGWG First Session December 2006, Geneva

- "It's about saving lives," acting WHO Director-General Anders Nordström said of the group's task at its opening session. "It's about making sure people don't die because they don't have access to health-care products."
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IGWG First Session

December 2006, Geneva *cont'd*

- “...an opportunity to explore alternatives to drug patents as a means of encouraging the development of new and affordable drugs. One proposal under consideration calls for a global treaty for funding pharmaceutical innovation, which would have governments fund research and development (R&D) and make the findings public. Drugs thus developed could then be produced and sold cheaply, since manufacturers would not have to recoup heavy expenditures on research.”
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IGWG First Session

December 2006, Geneva *cont'd*

- WHO Commission on Intellectual Property Rights, Innovation, and Public Health (CIPRH) report prepared by the WHO Secretariat:
 - identify research and development priorities
 - promote research and development
 - build innovative capacity
 - improve delivery and access
 - ensure sustainable financing mechanisms
 - establish monitoring and reporting systems
-



IGWG First Session

December 2006, Geneva *cont'd*

- CIPIH expanded the IGWG plan of action to include elements on “technology transfer and the management of intellectual property”.
 - This included recommendations such as to “encourage innovations adapted to realities of health-care delivery in developing countries.”
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IGWG First Session

December 2006, Geneva *cont'd*

- A ten-member regional group of countries from South and Southeast Asia, and a 22-member group of North African and Middle Eastern countries both expressed support for the notion of a global treaty on research and development
 - (yet, only 5% of pharmaceutical R&D in India is on type II & III diseases)
-



Draft global strategy and plan of action – July 2007

- ❑ Prioritizing Research and Development needs;
 - ❑ Promoting Research and Development;
 - ❑ Building and Improving Innovative Capacity;
 - ❑ Transfer of Technology;
 - ❑ Management of Intellectual Property;
 - ❑ Improving Delivery and Access;
 - ❑ Ensuring Sustainable Financing Mechanisms;
 - ❑ Establishing Monitoring and Reporting Systems
-



Draft Recommendations

- Promote legislation to apply flexibilities consistent with the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)
 - non-discrimination
 - National treatment
 - Most-favoured nation treatment (partners in the WTO)
 - intellectual property protection should contribute to technical innovation, the transfer of technology, and economic and social welfare
 - Doha Declaration exempts public health and access to medicines from TRIPS
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Draft Recommendations *cont'd*

- Promote upstream R&D in developing countries by considering legislation compliant with TRIPS research exemptions
 - Extended IP protection for developing countries
 - Open access to compound libraries

 - Promote transfer of technology and the production of health products in developing countries
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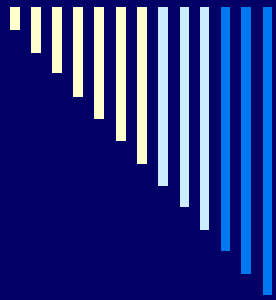
Draft Recommendations *cont'd*

- ❑ Promote bilateral trade deals that do not contain “TRIPS-plus” requirements and that such bilateral deals should be “regularly monitored” as to their impact on health
 - ❑ The pharmaceutical industry should reduce prices for developing countries
 - ❑ Promote competition and ensure that pricing of medicines is consistent with public health policies
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Draft Recommendations *cont'd*

- A medical R&D treaty should be supported; complementary incentive schemes separating innovation from prices should be explored and implemented
 - The progress indicator for this element will be the number of countries with manufacturing capacity that have enacted legislation for compulsory licensing of medicines for export to developing countries declaring a public health emergency
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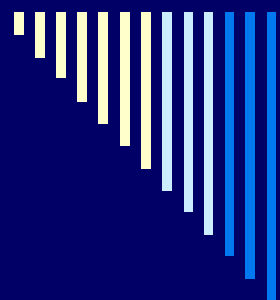
Subsequent steps

- Second public hearing (web-based), August 2007
 - 70 submissions!
 - Regional Consultations, October 2007
 - IGWG met November 5-10, 2007
 - Publishes ideas from submissions that *supported* IGWG but *not* those that didn't
 - NGO's request status
 - WHO Executive met January 21-28, 2008
 - Approves relations with.....
-



Subsequent steps *cont'd*

- World Plumbing Council
 - International Society for Quality in Health Care
 - World Association for Sexual Health
 - International Federation of Anti-Leprosy Associations
 - International Association of Medical Regulatory Authorities
 - European Association for Injury Prevention and Safety Promotion
 - International Alliance of Patients' Organizations!
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Next Step?

- IGWG second session scheduled for April
 - Possibility of NGO participation
- World Health Assembly, May 19-24, 2008

