Innovation and Access and the WHO

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WHO and Medicines Policy

- 1975 WHA resolution calling on WHO to assist countries in selection and provision of medicines
- 1977 1st Essential Drugs List published – contained 207 items
- Selection and provision of medicines core function of government
- Generic medicines at the core of the policies
- “a peaceful revolution in international health” (E. Lauridsen)
- Nevertheless at the time a controversial concept
- Pharma concerned that gov intervention would limit their freedom to operate
- IP – Andean countries excluded essential drugs from patentability
Essential medicines

• 1977 WHO definition of “essential medicines” was that they were ‘of utmost importance, basic, indispensable, and necessary for the healthcare needs of the population’

• Current: ‘Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility.’
May 1986 World Health Assembly adopted the RDS which contained a series of strategies to:

- Increase availability of essential medicines
- Improve the use of medicines ("Rational use of Drugs")
- Established the concept of "essential medicines"
- Rooted in the promotion of generics

*Patents /IP issues not on the table!*
Meanwhile at the General Agreement on Tariffs and Trade (GATT) ...

- Powerful lobby to ensure intellectual property issues would be part of the GATT framework -> TRIPS
- Contentious:
  - 49 of the 98 members of the Paris Convention excluded medicines from patentability
  - Developing countries opposed substantive IP provisions. Concerns for the effect on access to medicines was central.
- TRIPS signed in 1994 (GATT became the WTO in 1995)
- **Public Health community largely absent - WHO did not work on IP and medicines issues until after 1996 (RDS expanded)**
1995 WTO – what changed?

- TRIPS sets out minimum requirements for the protection of intellectual property (IP) for all WTO member countries
- Most relevant for access to medicines:
  - minimum 20 year patents
    - Right to exclude others from making, using, offering for sale, selling, and importing the patented product granted by a national or regional authority for a certain period of time (minimum 20 years)
  - protection of data (article 39.3)
At the same time ...

- HIV/AIDS pandemic
- Highly effective ARV treatments became available in 1996
- No access in developing countries
- ARVs priced out of reach at 10/15000 US$ pppy
- Controversy over medicines pricing and patents e.g. Big Pharma vs Mandela ‘99
People in LMICs on treatment

Lowest generic price first line ARV regimen

Originator price of first-line ARVs
Global ARV Market Share of Indian Generics

2001 WTO Doha Declaration

• Attempt at rebalancing
• Highlighted various flexibilities under patent law at the disposal of governments e.g.:
  – Compulsory licensing
  – Government use
  – Parallel import
• Created new rights: Non enforcement/granting of pharmaceutical product patents and data protection by LDCs until 2016
Patent landscape pre- and post-1995

Total number of product patents pending or granted, by jurisdiction, for older HIV compounds (pre-1995) and newer HIV compounds (post-1995)*
Changing ARV Patent Landscape

TRIPS Transition for Developing Countries

TRIPS Transition for Least Developed Countries

Zidovudine
Didanosine
Stavudine
Saquinavir
Nevirapine
Abacavir
Emtricitabine
Lamivudine
Indinavir
Efavirenz

Darunavir
Ritonavir
Lopinavir
Atazanavir
Tenofovir DF
Fosamprenavir
Maraviroc
Etravirine
Rilpivirine
Raltegravir
Elvitegravir
Dolutegravir
Cobicistat
SPI-452
The Treatment
Timebomb
Problems with Fixed Dose Combinations

- Patents on one component can block access to the whole FDC
- There are also patents on the combinations themselves

Drug #1, Co. A
Generic access

Drug #2, Co. B
Generic access

Drug #3, Co. C
Patented

Fixed Dose Combination (FDC)
The Medicines Patent Pool

Established in 2010 with the support of UNITAID

Generics version of existing compounds
FDCs
Adapted formulations (e.g. paediatrics)
“We have no model which would met the need for new drugs in a sustainable way .. You can’t expect for-profit organisations to do this in a large scale. If you want to establish a system where companies systematically invest in this kind of area you need a different system” – Daniel Vasella, CEO Novartis in The FT 2006
Public health
innovation and
intellectual property rights

REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH

WHO and IP

Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination


World Health Organization
I+A - A key role for WHO

• New models for innovation and financing that put access at the center
  – De-linkage
  – Licensing – patent pooling for research and access
  – Priority setting driven by health needs
  – Greater coordination

• Recommends negotiations start for a medical R&D treaty
Thank You!