African Civil Society Meeting

Intergovernmental Working Group
on Intellectual Property,
Innovation and Health

Topic: Considering Domestic Manufacturing Issues

Nairobi Kenya
28 -29 August 2007

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Doha Declaration

In November 2001, members of the WTO sought to restore a balance by adopting the Doha Declaration on TRIPS and Public Health. Paragraph 4 of the Doha Declaration states that the TRIPS Agreement, "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."

Policy Statement and commitment

Public Health Innovation, Essential health research and IPRs: towards a global strategy and plan of action

Statement of actions

to establish, in accordance with Rule 42 of the Rules of Procedure of the World Health Assembly, an Intergovernmental Working Group open to all interested Member States to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission;

such **strategy and plan of action** would aim, inter alia,

at securing an enhanced and sustainable basis for **needs-driven, essential health research and development relevant to diseases** that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area;

Resolution WHA59.24

Report on CIPIH to WHA 2006

The main outcome of the report was that

intellectual property rights do not stimulate research and development for medicines for diseases prevalent in developing countries. Simply, because the market in poor countries is considered to be too small or too uncertain.

- The key conclusion read:

"There is **no evidence that the implementation of the TRIPS agreement in developing countries will significantly boost R&D** in pharmaceuticals on Type II and particularly Type III diseases. Insufficient market incentives are the decisive factor."

World medicines production

- Trends from 1985 to 1999 indicate that the value of medicine production has grown four times more rapidly than the world's income.

- **Medicine production is highly concentrated in the industrialized countries, where just five countries – the USA, Japan, Germany, France and the UK – account for two-thirds of the value of all medicines produced.**
- Large volume markets of lower-price medicines exist in the highly competitive domestic markets of China and India.

- A small number of transnational companies dominate the global production, trade and sales of medicines. Ten of these companies now account for almost half of all sales. This concentration has increased considerably since 1987.

- **The 10 best-selling drugs account for 12% of the value of all medicine production.**

The World Medicine situation report 2004

Medicines Production in East Africa

- Over 30 registered local manufacturers in Kenya (local investments + 1 Multi)
- At least 2 others under construction (foreign investments)
- PPP Project - 7 (Kenya 6 & Tanzania 1)
- First inspection in August 2007 passed
- Others due for inspection by end of project

Quality issues

PPP Project between Germany NGOs and EA & Syria

Objective:

"***Improvement of quality and availability of Essential Drugs***" by strengthening GMP status of the pharmaceutical industries and competence of MoH GMP inspectorate in Kenya/Tanzania and Syria

The **project aim** is to

(i) qualify the partner manufacturers and government offices

(ii) to avail high quality drugs to the international community at affordable conditions directed to support humanitarian and development aid needs/demands.

Methodology

High level of training from university lecturers, consultants with hands-on experience and EU inspectors

- Training seminars theory & literature
- Practical exercises
- Inspections – mid term and Final

Outcome

- Confidence building

+ve change of attitude

- Infrastructure improvement to comply with modern standards (premises & equipment)
- Detailed documentation & evaluations
- International contacts and contracts
- Up scaling local standards – 1 out of 6 and Syria 3 out of 8 (more due)

Able to meet international GMP Standards

Lessons learnt

Regulatory authorities must take keen interest

- Qualification and GMP accreditations
- Upgrading and harmonization of RAs in Roles & responsibilities with focus on access issues, innovation & research
- Recognition of centers of excellence
- Technology transfer is an investment matter and within reach in EA

Cut throat competition:
"me too medicines"
lacks creativity
Discovery & innovation

R&D focus

- **Governments and pharmaceutical manufacturers are the main funders of the R&D of new medicines and other health products.**
- **Investment in health R&D is concentrated in the industrialized economies.**
- In the second half of the 20th century, rapid progress was made in developing powerful new medicines. More recently, new developments in molecular biology and genetics hold great promise for the discovery of new medicines. Yet the number of new molecular entities being brought to market has slowed in recent years.
- Manufacturers attribute the high prices of new medicines to R&D costs and the risks of new product development. However, critics query the actual cost of new medicines development and point to the neglect of disease problems affecting poor populations.
- **The pattern of new medicines R&D reflects market opportunities rather than global public health priorities. Only 10% of R&D spending is directed to the health problems that account for 90% of the global disease burden — the so-called 10/90 Gap.**
- Redeployment of a small portion of current public and private R&D funds and/or private medicines marketing funds could make a major contribution to the development of new medicines for neglected diseases. New incentives are needed for such a shift to occur.

The World Medicine situation report 2004

Estimated global health R&D funding US$, (1998)

source	Total $	%
Public funding: high-income and transition countries	34.5	47
Public funding: low- and middle-income countries	**2.5**	**3**
Private funding: pharmaceutical industry	30.5	42
Private not-for-profit funding	**6.0**	**8**
Total	73.5	100

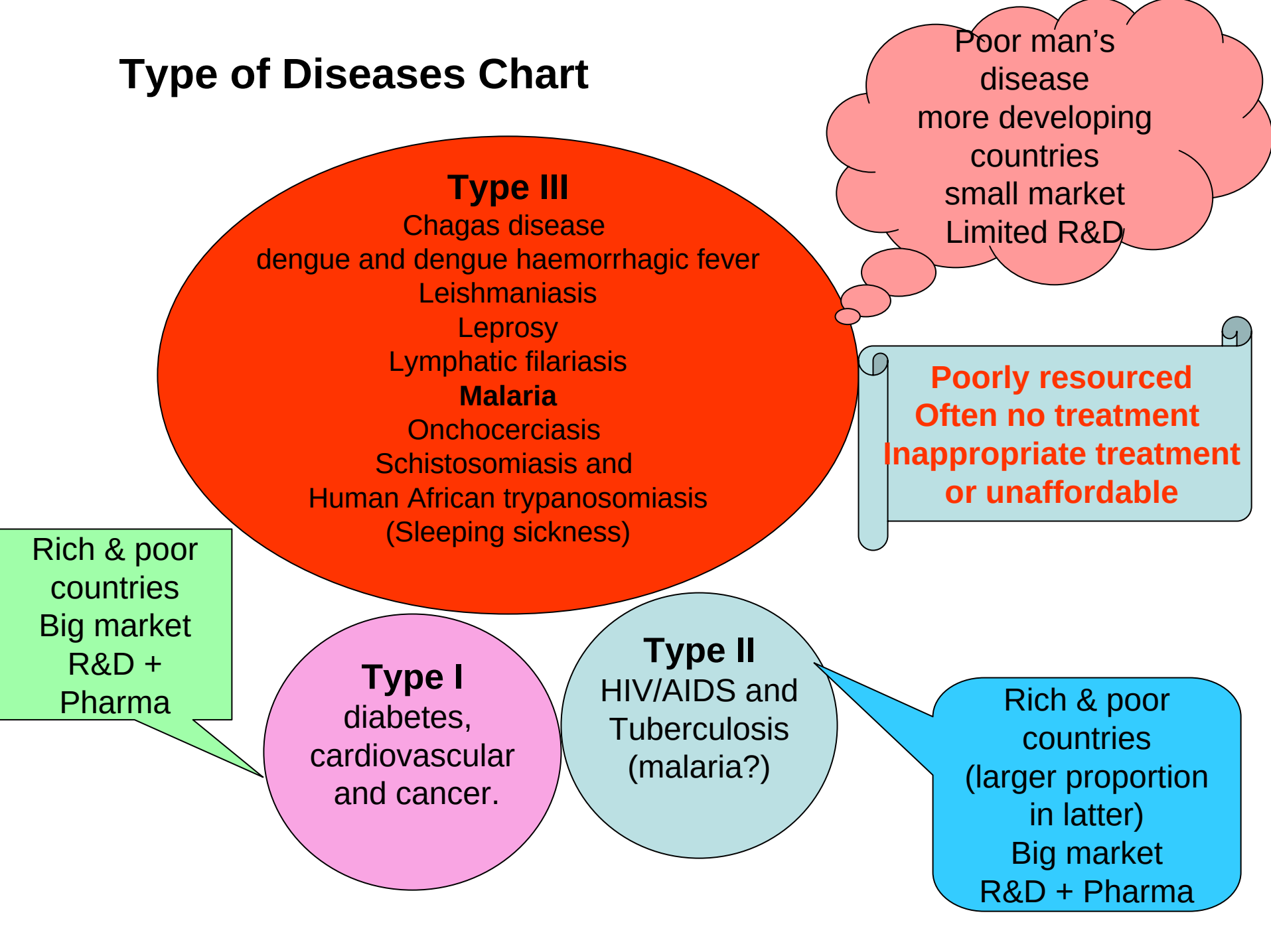
Funding of R&D mainly Private Industry

Common issues arising from DOHA & CIPIH

- ***promote access***
- **develop a strategy and plan of action**
- secure a sustainable **needs-driven, essential health research and development relevant to diseases**

POA to involve all stakeholders including domestic manufacturers, civil society and professionals

Type of Diseases Chart



No evidence

- The key conclusion read:

"There is no evidence that the implementation of the TRIPS agreement in developing countries will significantly boost R&D in pharmaceuticals on Type II and particularly Type III diseases. Insufficient market incentives are the decisive factor."

Innovations are not policy driven but market stimulated

Brussels 2 April 2007 Dr Christian Wagner, Health Action International

In 2006 the report of the WHO Commission on Intellectual property, Innovation and Public Health, was presented to the World Health Assembly.

Commercial viability vs Public Health

- Discontinuation of essential medicine because of commercial viability
- Eflornithine (DFMO) for treatment of human african trypanosomiasis (sleeping sickness)
- Developed in mid 70’s as anticancer by Merrel Dow
- Discovery for sleeping sickness 1985
- Developed by WHO & Merrel Dow
- Production ceased 1990s
- Technology patent and commercial rights to WHO after merger (Hoeschst Marion Rousel)
- No known manufacturer (any knowledge?)

Third World resurgence Aug/Sep 2000

Experiences on IP: Aluta continua

Concerted effort by the Kenyan civil societies, like-minded professionals in private and public sector plus media

- The IP Act 2001 incorporating most TRIPS flexibilities
- IP Amendments section 80 attempt
- Access to ARVs is real in Kenya
- Voluntary licensing (at least 2 companies in Kenya)
- Pfizer vs Madawa case on infringement (slow)

What is the problem? or Why the constrains?

- Industry is commercial oriented
- Little guidance from MOH on priorities
- Lack of PPP initiatives
- Student orientation towards type I and II and little on type III diseases in rural settings

Encourage philanthropic activities and patriotism

Health policies & strategic plans

Responsibility of governments:

right to protect public health and, in particular, to promote access to medicines for all.

- ***MOH identification of public health issues***
- ***Modalities and access to Treatment especially the minorities***
- ***Sustainable Local manufacturing and Imports***
- ***Strategic POA on R&D including resource mobilization***
- ***Creativity, Discovery and Innovation***

Encourage local country solutions

Stimulation of the markets to attract R & D

- Identify & Quantify needs in monetary terms
- Develop PPP concept paper with benefits
- Develop guidelines for PPP projects
  (especially Type III diseases)
- Policy on tax incentives to support funding of PPP Projects
- Exposure of Medical interns & post graduate students in rural settings
- Global Fund to support local solutions within the PPP framework

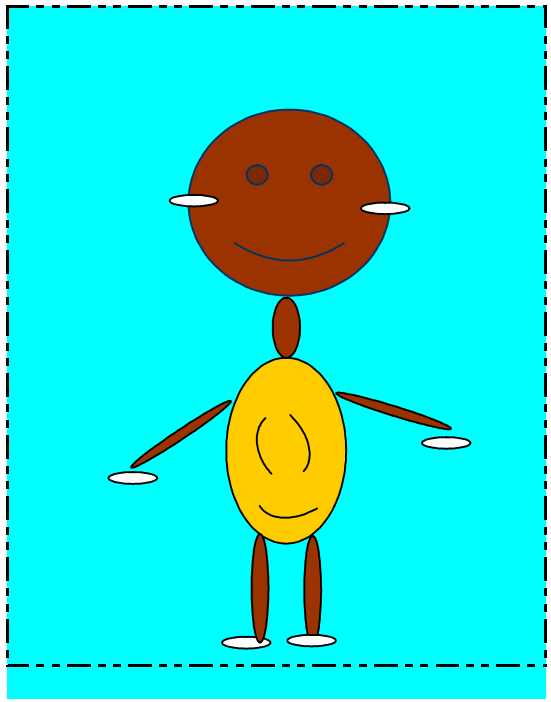
Issues to address in this forum

There is Mutual responsibility for Discovery & Innovation

- Establish national research priorities in health
- Propose R&D priorities and Budget and responsibilities
- Define role of training & Research Institutions mainly Medicine, pharmacy and Biomedical sciences institutions on R&D
- Make guidelines for Stimulation the local industry and role in R&D
- Develop Public Private Partnership concept
- Monitoring trends in terms of local and global burden of disease and how should they inform R&D and financing priorities
- Make guidelines on national patent systems need in implementing TRIPS and effect on R&D and
- Emphasize the Role of regulatory systems in developing countries to support innovation

Asante sana

Thank you very much
for listening!



Kwaheri
Bye- Bye