Intellectual Property, Access to Medicines and Innovation: Perspective from Médecins Sans Frontières

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MSF and Access to Medicines

Médecins Sans Frontières (MSF), founded in 1971, is an international, independent, medical humanitarian organization that delivers emergency aid to people affected by armed conflict, epidemics, natural disasters and exclusion from healthcare in nearly 70 countries.

Nobel Peace Prize Lecture 1999

Dr. James Orbinski

Médecins Sans Frontières International President

"*Today, a growing injustice confronts us. More than 90% of all death and suffering from infectious diseases occurs in the developing world. Some of the reasons that people die from diseases like HIV/AIDS, tuberculosis, sleeping sickness and other tropical diseases is that---*

- **Life saving essential medicines are either**
  - **too expensive,**
  - **are not available because they are not seen as financially viable,**
  - **or because there is virtually no new research and development for priority tropical diseases.**
- This market failure is our next challenge.

The challenge however, is not ours alone. It is also for governments, international government institutions, the pharmaceutical industry and other NGOs to confront this injustice.

What we as a civil society movement demand is change, not charity. *"*

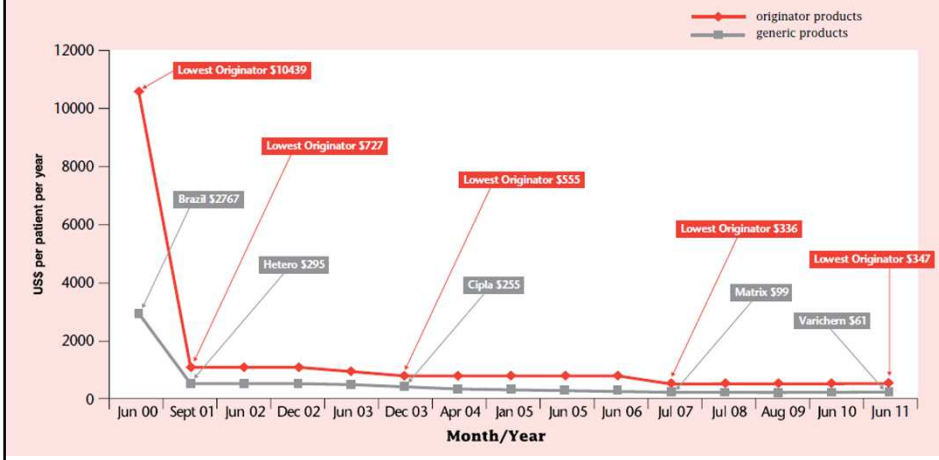
Access Campaign

- Launched in 1999, in the wake of MSF doctors & nurses' frustration and witness while working in developing countries
- Focus on:
  - legal and regulatory barriers to access, incl. intellectual property
  - insufficiency with medical innovation system

Key learning on access:
Competition = The Price of AIDS Drugs Fell by 99%

GRAPH 3: GENERIC COMPETITION AS A CATALYST FOR PRICE REDUCTIONS.

The fall in the price of first-line combination of stavudine (d4T), lamivudine (3TC), and nevirapine (NVP), since 2000.



Source: MSF Untangling the Web of Antiretroviral Price Reductions, 15th Edition, July 2012

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Challenges Ahead with Access

GRAPH 6: PRICE COMPARISON OF TREATMENT REGIMENS

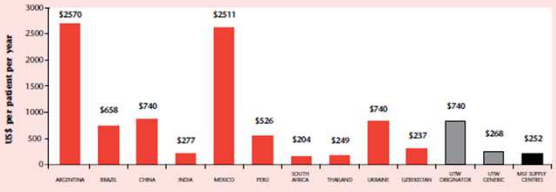
*Note: The price of the third-line ARV regimen of US$2,006 was calculated by adding the three individual prices of the originator product.

HIV

-The price of a third-line regimen is **more than 14 times higher** than the recommended first-line
- Middle income country dilemma

Source: MSF Untangling the Web of antiretroviral Price Reductions, 17th Edition, July 2014

GRAPH 4: 2013 PRICE PER PATIENT PER YEAR LPV/R AS COMPONENT OF SECOND-LINE ARV REGIMEN



Sources: Argentina, Peru and Mexico: Antiretroviral Treatment in the Spotlight[25]; Thailand, Ukraine, Uzbekistan: The Global Fund Price and Quality Reporting[17]; Brazil, China, India, South Africa: responses to questionnaires sent from MSF to countries.

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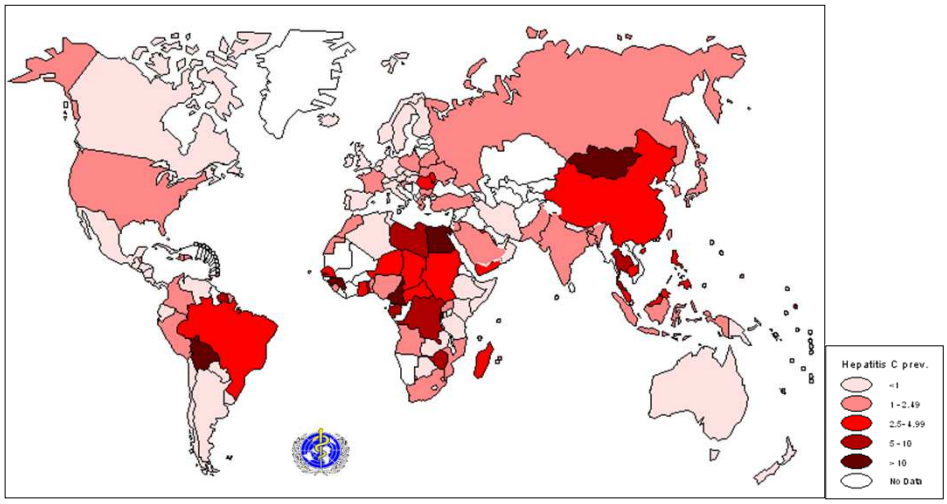
Challenges Ahead with Access

Hepatitis C: global prevalence

About 180m people are infected with hepatitis C and 350,000 people die each year from related liver diseases



New Medicines: But not reachable by millions

- Price: $84,000 in US, and differential in different countries
- Voluntary license:

Means of improving access

- **TRIPS flexibilities** safeguarding health – to be used by all countries
  - Patentability criteria and examination: scrutinizing misuse, India patent law Sec 3(d)
  - Compulsory license: temporary cease of privilege to balance misuse or serve public
  - Pre/post-grant oppositions, invalidations procedures
  - Exceptions to accelerate generic competition and research
  - Parallel import to manage price difference
- **Other voluntary means:**
  - Voluntary license
  - Medicines Patent Pool (voluntary license based)
  - Differential pricing

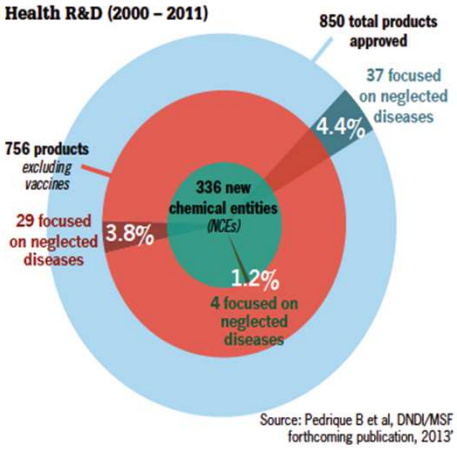
Limitations with voluntary means

- Voluntary license
  - Non-transparent (bilateral licenses) to interest parties – patients, care providers, public health agencies
  - Insufficient legal mechanism to regulate
  - 'Voluntary' exclusion; middle-income dilemma
  - Contractual conditions in conflict with TRIPS flexibilities
- Differential pricing
  - Middle income country dilemma
  - Unsustainable and unjustifiable

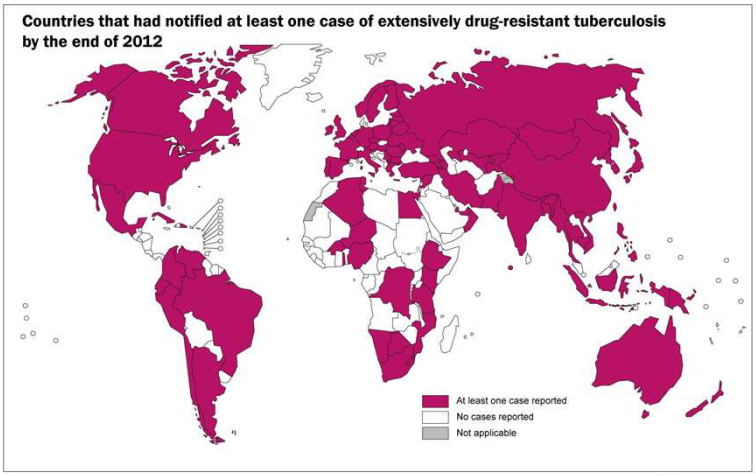
Challenges Ahead with R&D

- Deficiency with Patent centric model on medical R&D
  - 1975-1999: 1,393 new chemical entities markets; only 1% of new drugs developed are for neglected diseases
  - 1999-2004: + 163 NCEs, + 3 new drugs for neglected diseases

Trouiller et al., Lancet 2002, 359:2188-94; updated figures: Torreele, Chirac 2005



Drug Resistant TB



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: *Global Tuberculosis Report 2013*. WHO, 2013.

World Health Organization

The issues – Multi Drug Resistant-TB treatment

- **Medicines:**
  - Old – 'newest' drug in current regimens was introduced 50 years ago; Two new drugs...no new regimens.
  - Expensive – Can cost up to $5000 in drug costs alone

- **Treatment:**
  - Long – Treatment takes two years and
  - Toxic – extreme side effects include deafness, psychosis, constant nausea and vomiting, weight loss and more; and
  - Complex – different treatment regimens for individual resistance patterns; about 5 different drugs (14,000 pills), including 8 months of painful injections
  - Inadequate – high default rates and low cure rates (~50%) contribute to further resistance; no paediatric formulations

•**Funding:** Private funding decrease; lacking interests of accelerating clinical trial

•Patent centric model does not work for TB R&D
•Time to think differently and test Open Collaboration Model

Remarks

Access

•Access to medicines face continuous challenges at global level

•Using TRIPS flexibilities remain backbone

•Ensure national IP law and policy change with fully recognizing public health needs

•Voluntary measure bears limitations in achieving universal access

Innovation

•Patent centric model fails to meet pressing health need at global level

•Alternative approach needed with true willingness of collaboration

- Thank you!

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