

South Centre/UNDP Workshop on Mechanisms to promote and increase financing for R&D for TB, Malaria and other Neglected Tropical Diseases (NTDs)

Framing Access to Medicines: The current international debate

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Germán Velásquez
Special Adviser for Health and Development
South Centre, Geneva



Plan of the presentation

1. **Background of the A2M international negotiations**
2. **Some indicators of the failure of the current R&D system/model**
3. **Major threats to the A2M global debate**
4. **Conclusions: Good news to share on IP and A2M**



Background of the A2M international negotiations 1996 - 2014

- 1996 WHA 49.14 « Revised drug strategy Resolution »
- 1997 « the WHO red book » Globalization and A2M: implications of the WTO/TRIPS Agreement
- **2001** (April) court case by 39 pharmaceutical companies against the South African Medicines Act
- **2001** (June) The African group at WTO request a debate on A2M
- **2001** (November) the DOHA Declaration on the TRIPS agreement and public health
- 2002 UK Commission on IP and development

Background of the A2M international negotiations... (2)

- 2006 The WHO Commission on IP and Public Health -CIPIH-
- 2008 WHO Global Strategy GSPOA
- 2010 the failure of the WHO EWG report
- 2012 the WHO – CEWG recommendation to start negotiations for a binding global instrument on R&D
- 2013 (May) WHA decision recommending “demonstration projects and a WHO R&D observatory”
- 2013 (December 4-5) : “failure to achieve the fundamental and principal recommendation of CEWG” MSF statement

A binding convention for R&D for pharmaceutical products

- A central point of the Global strategy:
- Study the possibility of a international treaty as an alternative to the R&D of pharmaceuticals model. (as was recommended by the report of the commission on intellectual property in 2006).
- On April 5, 2012 an expert group of the WHO announced that it will recommend the start of intergovernmental negotiations on **“a mandatory instrument for R & D and innovation in health”**.
- **Why a binding convention for R&D?**

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Some indicators of the failure of the current R&D system/model

1. Pharmaceutical **innovation** has significantly **decreased** in recent years.
2. Lack of transparency on the real **cost of R&D**
3. **High drug prices** are blocking access
4. **IP is more a barrier** to access, than an incentive to innovation.

Some indicators of the failure of the current R&D system/model

INNOVATION IS DECREASING Example of France.*

Important therapeutic progress 2006- 2012

- 2006: 22 products
- 2007: 15 products
- 2008: 10 products
- 2009: 7 products
- 2010: 4 products
- 2011: 1 product
- 2012: 0

*Cfr. Rev. Prescrire 2012.

Some indicators of the failure of the current R&D system/model (2)

INNOVATION IS DECREASING*

- From the 336 new chemical entities introduced in the world pharmaceutical market from 2000 to 2011, only 4 (1.1%) were for neglected diseases.
- From the 150.000 clinical trials in the same period only 2.000 (1.3%) were for neglected diseases.

*Cfr. Lancet October 24, 2013.

Some indicators of the failure of the current R&D system/model (3)

From the 4.408 products patented in the 5 countries of the study, there is a little patenting in relation to diseases that disproportionately affect developing countries (C. Correa SC RP 41 Sep. 2011) :

Nervous system	823		
Antineoplastic and immunomodulating agents.....	785		
Anti-infectives for systemic use	707		
Alimentary tract and metabolism.....	589		
Cardiovascular system	381		
Muscle-skeletal system.....	233		
		TOTAL	3.518 = 79.8%

Some indicators of the failure of the current R&D system/model (4)

COST OF R&D

- IFPMA: 1.300 million US\$
- LSE study (2011): 43.4 million US\$ (average)
- DNDi (Drugs for neglected diseases initiative):
from **10 to 40** million Euros to improve a drug
from **100 a 150** million Euros for a new chemical entity



Some indicators of the failure of the current R&D system/model (5)

DRUG PRICES

- 10 out of the 12 treatments for cancer approved by the FDA in 2012 cost more than 100.000 US\$. per person per year.
- Drug prices in France (in average) are 3 times higher than in Italy
- Some UN agencies are advocating for “differential pricing”. In fact medicines are often more expensive in the South compared with the North controlled prices.

Some indicators of the failure of the current R&D system/model (4)

IP MORE A BARRIER THAN INCENTIVE

- 20 to 30 new molecules per year... **thousands of patent applications**... In 2012 Mexico 2.500, Argentina: 54 patents granted in 2012.

- The investigation (2000 – 2007) found that a single medicine may be protected by up to 1,300 patents or pending patent applications.

<http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>

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Major threats to the A2M debate...

GLOBAL SPENDING ON MEDICINES*

- Annual global spending growth will increase from \$30Bn in 2012, to \$70Bn in 2016, driven by volume growth in the emerging markets.
- In the developed markets, including the USA, Europe and Japan, spending will decline.

*Source: IMS Market Prognosis, May 2012; Economist Intelligence Unit, Jan 2012

Major threats to the A2M debate...

PER CAPITA SPENDING IN MEDICINES in US.\$ (2012)*

- USA, 892, Japan 644, Canada, 420, EU 375, Brazil 180, China 121, India 33.
- **Is the spending model of industrialized countries an example to be followed by the emerging countries?**
- The answer is clearly NO. The pharmaceutical consumption model should be changed.

*Source: IMS Market Prognosis, May 2012; Economist Intelligence Unit, Jan 2012

R&D Philosophy...

« Over the past two decades the pharmaceutical industry has moved very far from its original high purpose of discovering and producing useful new drugs. Now primarily a marketing machine to sell drugs of dubious benefit, this industry uses its wealth and power to co-opt every institution that might stand in its way, including the US Congress, the FDA, academic medical centers, and the medical profession itself..” (Marcia Angell, **The Truth About the Drug Companies** editora del New England Journal of Medicine)

USA and EU strategy to delay the debate on the treaty...

- The Lancet in an editorial dated 26 January 2013 stated:

"In April 2012, the CEWG recommended a framework for sustainable financing and coordination implemented through a legally binding convention. However, this week WHO's Executive Board has been asked to endorse a less ambitious plan by member states for a more vaguely defined WHO Observatory on Global Health R&D, which is weak on concrete action despite international consensus that the current R&D model needs revision.

Major threats to the A2M debate

- The demonstration projects exercise may delay the implementation of the central recommendations of the CEWG.
- The ongoing privatization of WHO.
- The tripartite report by the WTO, WIPO and the WHO on 5 February 2013, and the “marriage” of WHO with WTO and WIPO.

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The binding convention for R&D

- In CIPIH 2006
- In GSPOA 2008
- In CEWG 2012
- Beginning of negotiations 2015
...2016 ?

Ability of WHO to adopt conventions

- Article 19 of the WHO Constitution:
- “The Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. A two-thirds vote of the Health Assembly shall be required for the adoption of such conventions or agreements, which shall come into force for each Member when accepted by it in accordance with its constitutional processes.”

Main components of a treaty on R+D for medicines

- Compulsory public **financing** mechanism for the countries that ratify the treaty.
- **Coordination** of public R&D for pharmaceuticals products.
- Definition of R&D **priorities** based on real health needs.

Conclusions: good news to share...

- Important national and regional debates... France, China, UNASUR...
- There are new initiatives like the Colombian new incentive x R&D.
- Increasing numbers of universities research on A2M and the possible treaty in particular.
- Generic pharmaceutical industry “discovering” the idea of a treaty.



Goods news to share on IP and A2M (2)

- ISAGS (UNASUR), ISGlobal/Harvard conferences (Barcelona), Geneva Graduate Institute...
- Good progress of the only binding health convention (The tobacco convention) negotiated in WHO
- Indian Supreme Court victory against Novartis. Section (3 c) can be replicated in other countries.
- UNDP/SC research on mechanisms...



Thank you

For more information: gvelasquez.gva@gmail.com

South Centre website : <http://www.southcentre.org>



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