





Impact of EU Trade Agreements on Access to Medicines:

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Health Action International

- **A not-for-profit global network**
- **Established in 1981**
- **Made up by consumers, public interest NGOs, health care providers, academics, media and individuals**
- **HAI Europe: European office, based in Amsterdam**
- **Working on access to essential medicines and rational use of medicines policy.**

Health Action International (HAI) is an independent, global network, working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy.

Medicines and IP

- *TRIPS Agreement: Agreement on Trade Related Aspects of Intellectual Property. 1995 WTO*
- *Decreased access to cheap generic medicines for developing countries: 'trips flexibilities'*
- *TRIPS –Plus rules: exceed minimum WTO obligations and create new barriers that impede access to medicines in developing countries.*
- *having failed to introduce stricter IP rules at the WTO, the pharmaceutical industry now relies heavily on litigation, lobbying, FTAs and other agreements to impose Trips plus rules in dev countries*



EU IP Policy

- Intellectual Property protection seen as core to knowledge economy
- Lisbon agenda > EU most competitive knowledge based economy by 2010
- Global Europe Strategy Paper> IP indicated as one of priorities.
- New Enforcement regulations
- Pharmaceutical industry is an important industry for the EU



EU IP policy and third countries

Strategy:

Three main measures

- *Free Trade Agreements (EPAs, Association Agreements, /.)*
- *Bilateral pressure*
- *Enforcement agenda (ACTA, Internal EU regulation having effect on transit, IMPACT, WIPO SECURE, etc)*

Trade Agreements EU

New role for EU ; Engaged in trade agreements in a different way

- *Adherence to other treaties*
- *Data exclusivity*
- *Patent extensions*
- *Enforcement chapter with border measures.*
- *Moves to limit use of flexibilities.*



- **Data exclusivity:** Significantly enhancing protection for clinical trial data by providing up to 11 years of exclusive use of such data to obtain marketing approval. Effectively prolonging monopoly protection of medicines.
- **Patent extensions:** Extending patent protection through supplementary protection certificates. The extension will be equal to the time elapsed between the filing of the application for a patent and the date of the first market authorization (keeping protection at minimally 15 years)

Enforcement chapter

- Potentially obstruct the import, transit or export of legitimate generic medicines.
- Public resources employed to protect the rights of western multinational right holders
- Costs of implementation significant

The implementation of these measures will force developing countries to channel government resources into protection of trademarks and patents of multinational pharmaceutical companies. As such, enforcing private rights will place a significant burden on developing countries and impede countries to address more pressing public policy priorities.

Enforcement chapter 2

- *Under such a framework the position of the IP rights-holder would be strengthened, to the detriment for generic competitors , effectively leading to extended monopolies in developing countries.*
- *Generic companies would be less able to challenge frivolous patents and would fear seizures of their medicines.*
- Example of measure: in order to speed up dispute proceedings, the alleged infringer is not given the opportunity to be heard. This means that sentences could be passed based merely on presumptions.
- Example 2: Border measures > seizures of generic medicines in Netherlands, Germany and Paris.

An environment that fails to encourage competition leads to high prices



Flexibilities: Safeguards to protect public health

- Patentability criteria
- compulsory licensing (data exclusivity)
- No commitments on technology transfer.
- DOHA DECLARATION
- PAR 6 amendment

Important Trade agreements with regards to IP and Access

- EU – India
 - Pharmacy of the developing world' 67% of its generic medicines (80% of ARVs) exported to developing countries
 - FTA would have significant consequences on millions in India and around the world
- EU – Peru / Colombia
- EU – Central America
- EU - ASEAN



CAN-EU Alliance

- Established in May 2008
- At the request of civil society in the Andean region, HAI Europe joins Latin American NGOs to form a coalition to protect public health.
- **Publication:** *Health Protection in the European and Andean Community Association Agreement* by Xavier Seuba (Jan 2009)
- **Research:** Impact studies on the IP chapter envisioned by EU for Colombia and Peru.



Impact studies - Methodology

Guide to estimating the impact of IPR changes on access to medicines

Published Barcelona (2007)

- Consortium to improve and apply the methodology. WHO, PAHO, WBI (World Bank Institute), UNDP, ICTSD.
- From 2005 to 2009 - Used on 12 occasions: 10 in Latin American countries
- Impact studies conducted in Colombia and Peru

Impact studies - Methodology

- Intellectual Property Rights Impact Assessment
= **IPRIA** model
- Comparative scenarios methodology
- Impact = difference between:
 - **Basic scenario**: Existing situation (no changes on IPRs)
 - **Alternative scenarios**: With IPR changes due to trade agreements/national regulations

IP Measures & TRIPS +

- Basic scenario = US Trade Promotion Agreement
- Alternative scenarios:

Based on the round in February 2009

1. Supplementary Protection Certificate (Patent extension): 4 years
2. Data exclusivity: 10 years
3. Combined: Combination of the two measures

IP Measures & TRIPS +

The study forecasts, at different moments in time, the impact of the trade agreement on:

Level of exclusivity of medicines in the market



Impact on the average price in the market



Impact on pharmaceutical expenditures



Impact on consumption of medicines

Research Findings: Peru

Effect of combined scenario in 2025:

Increase in total pharmaceutical expenditure:
459 million USD (to maintain current consumption levels)

or

20% decrease in consumption

due to

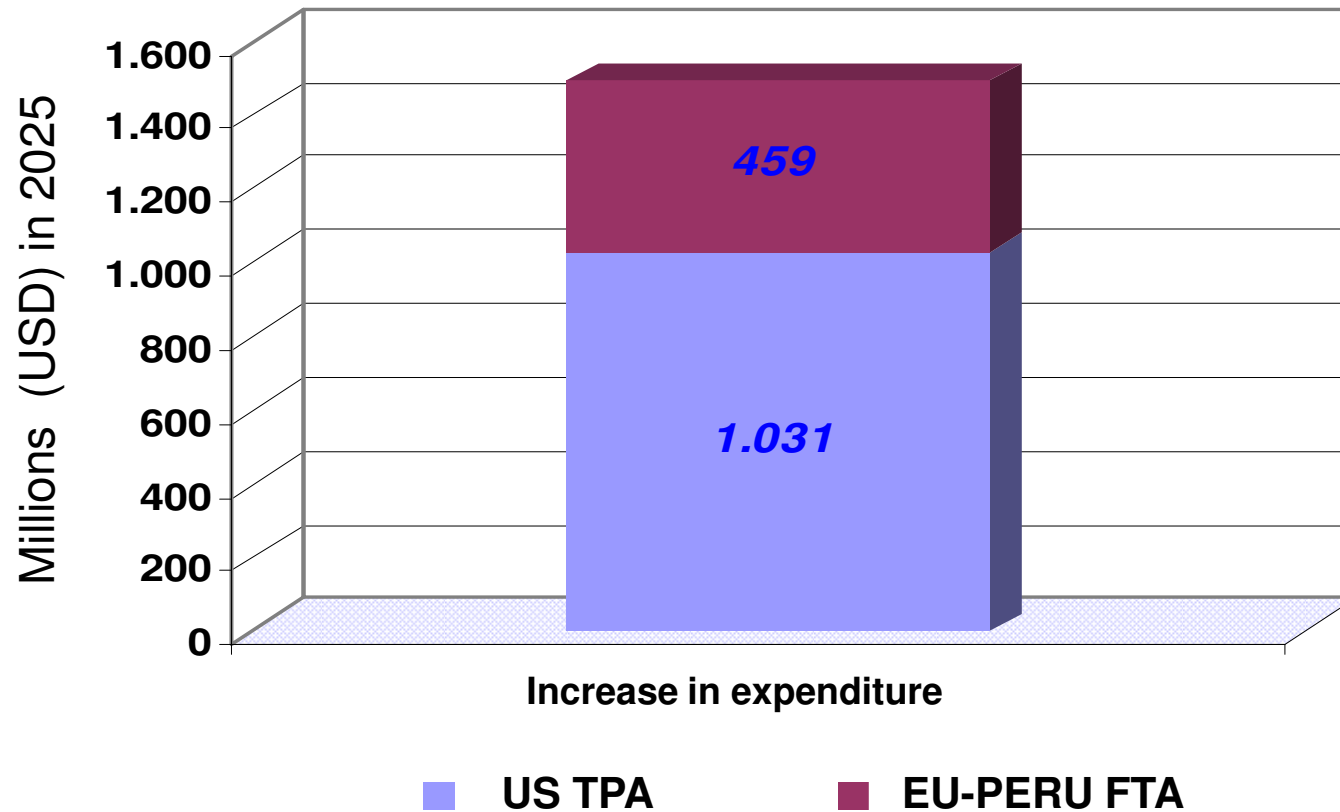
26% increase in medicines' prices

because of

11% increase in the number of IPR protected
medicines



US-Peru Trade Promotion Agreement and EU-Peru Free Trade Agreement



Conclusions

- Current EU policy or ambitions on IP towards third countries hurts access and are not fair.
- The EU has done much to advance health care in developing countries in recent years and yet...
- EUs trade policy is now testament of a severe lack of policy coherence, not in line with
 - health & development objectives
 - the position of the EP and some Member States
- When civil society is engaged & well organized, raising awareness and providing strong public pressure, problematic measures can be prevented.



Thank you

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This arises from the Developing Rational Use of Medicines in Europe project, which has received funding from the European Union, in the framework of the Health programme

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