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# The Impact of Patent Protection and Data Exclusivity on Access to Medicines in LMICs – what's the evidence? & The Sustainability of the Global Access Regime

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# A Heated Debate and a Lack of Evidence

Empirical research on impact of IP on access:

- Scarce
- Methodologically complex
- Focus on high-income countries

(demand structure in LMICs differs considerably, especially because demand has to be met largely through out-of-pocket payments)



## The Impact of Patents on Access (I)

In the US and Western Europe, patent expiry normally results in rapid entry by generics (US Congressional Budget Office 1998; Grabowski and Vernon 1992).

Evidence, particularly from the US, that post-patent expiry generics prices decrease considerably compared to the originator prices (OTA 1993).

Generics entry led to a considerable price decrease in HIV drugs for developing countries (Waning et al 2010)

## The Impact of Patents on Access (II)



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Drug bundles containing at least one originator drug in a patent-regime were on average priced 70 percent higher than drug bundles containing only generics drugs marketed in a non-patent regime (Borrell, 2007).

## The Impact of Patents on Access (III)



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Patent rights have a negative effect on unsubsidized access to HIV/AIDS drugs. Between 1995 and 1999, switching all HIV/AIDS drugs from a patent regime to a no patent regime would have actually increased access to therapy at least by 30 percent (Borrell and Watal, 2002).

Patents hurt access most in LMICs with higher per capita income (Borrell and Watal, 2002).

## The Impact of Patents on Access (IV)



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### Fluoroquinolones in India :

Patent enforcement would result in a large welfare loss for The Indian economy estimated to range from \$144 million to \$450 million annually, depending on the way policies are implemented, the extent of price regulation, and the degree to which foreign multinationals respond to patent protection by expanding their distribution networks or using licensing (Chaudhuri, Goldberg and Jia 2006) .



# The Impact of Data Exclusivity on Access



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Thailand: for five years of data exclusivity, the annual cost increase was predicted to be between USD 146.3 million to a USD 696.4 million (Akaleephan et al 2009).

Guatemala: patent and data exclusivity reduced the availability of some generic drugs that had already been on the market (Shaffer and Brenner 2009).

# Can Compulsory Licenses Facilitate Access?



Prices in India could decrease by up to 90 per cent for some drugs (Watal 2000).

Assumption: compulsory licenses would result in a highly competitive supply of generics

There is a possibility that compulsory licenses for export may not make much economic sense for potential generic producers (Gehl-Sampath 2005).



# To Conclude...



Empirical evidence remains scarce. Hence, conclusions have to be drawn with considerable caution.

The limited empirical evidence that we do have seems to suggest that patent protection and data exclusivity may be linked to higher drug prices in LMICs.

Given how hotly the issue is being discussed, we urgently need more empirical research.

# References (I)



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# The Sustainability of the Global Access Regime

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# The Global Access Regime



Focus of analysis:

- The Global Fund to Fight AIDS, TB and Malaria
- GAVI
- PEPFAR
- The Global TB Drug Facility
- UNITAID



# Sustainability at Risk?



## Concerns:

- The impact of financial crisis on donor budgets;
- The rising demand for donor support of healthcare in LMICs;
- And the effects that international programmes have on health systems at the national level.

# Sustainability in the Literature



Approx. 40 papers raise issue of sustainability as a concern;

Only two papers make it their focus of analysis – both of which examine GAVI.

In these papers, problems identified include:

- Vaccines currently promoted are affordable only at GAVI subsidized prices; when commitment ends and vaccines reach market prices several recipient gvts may no longer be able to afford them;
- GAVI funds distort national priorities and actual need.

# Hypotheses



- (1) There is a growing gap between the supply of and the demand for funding.
- (2) There are significant inefficiencies in resource spending.
- (3) Recipient governments are unable to continue treatment programmes once donor financial and technical support ends.
- (4) Donor-led health programmes can damage LMIC's health systems.



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Comments and suggestions very welcome!

Thank you.

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