

Procurement, selection, prequalification, pricing and monitoring of medicines



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Medicines Information and Evidence for Policy,
Essential Medicines and Pharmaceutical Policies
World Health Organization



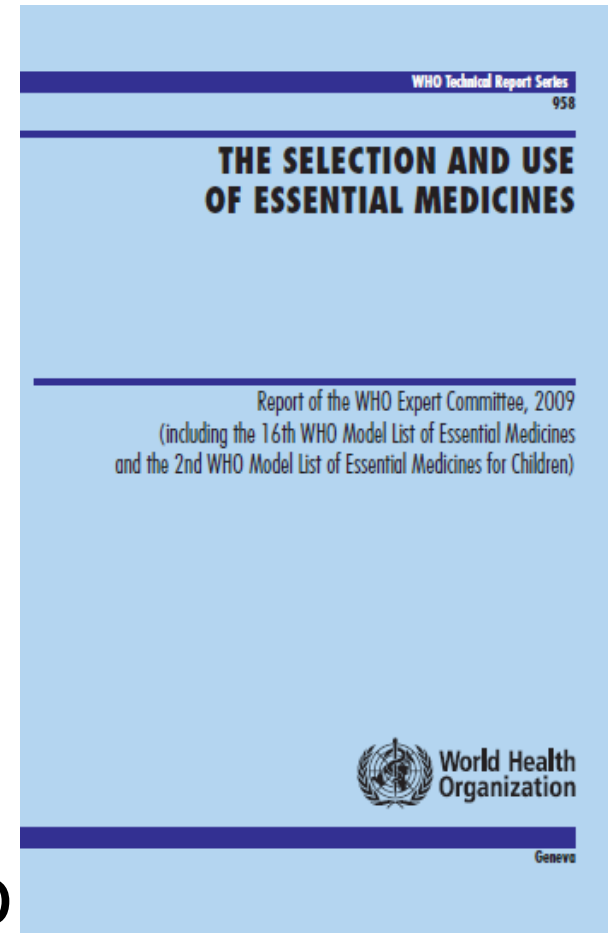
Procurement, prequalification, pricing, availability of drugs

- Selection
- Quantification
- Quality Assurance
- Pricing
- Monitoring



Selection

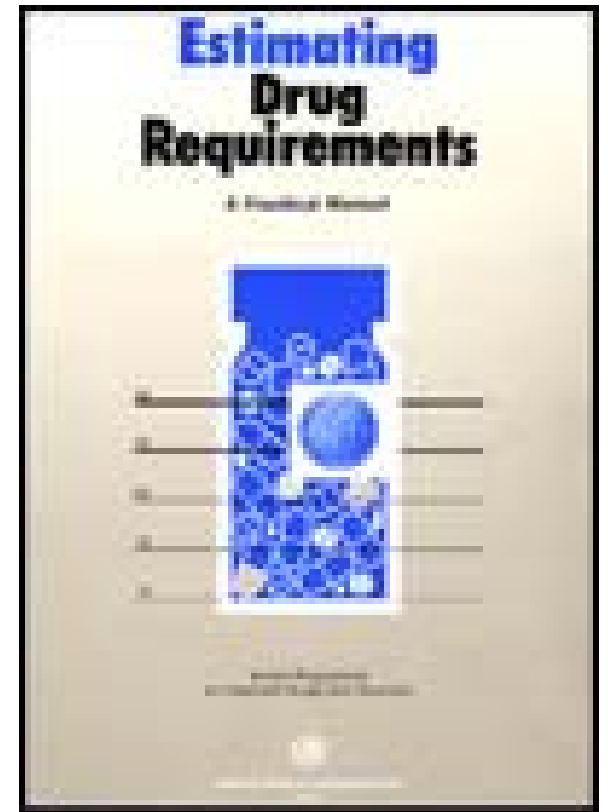
- First edition 1977
- Revised every two years
- Now contains 423 medicines including children's medicines
- Patent status NOT considered in selection
- Over time has contained 5% to 10% patent protected medicines



See http://www.who.int/selection_medicines/en/index.html

Quantification

- Estimating requirements is a challenge when expanding programmes or when data collection is weak
- Two methods used
 - Morbidity based
 - Consumption based
- Combination of approaches usually used



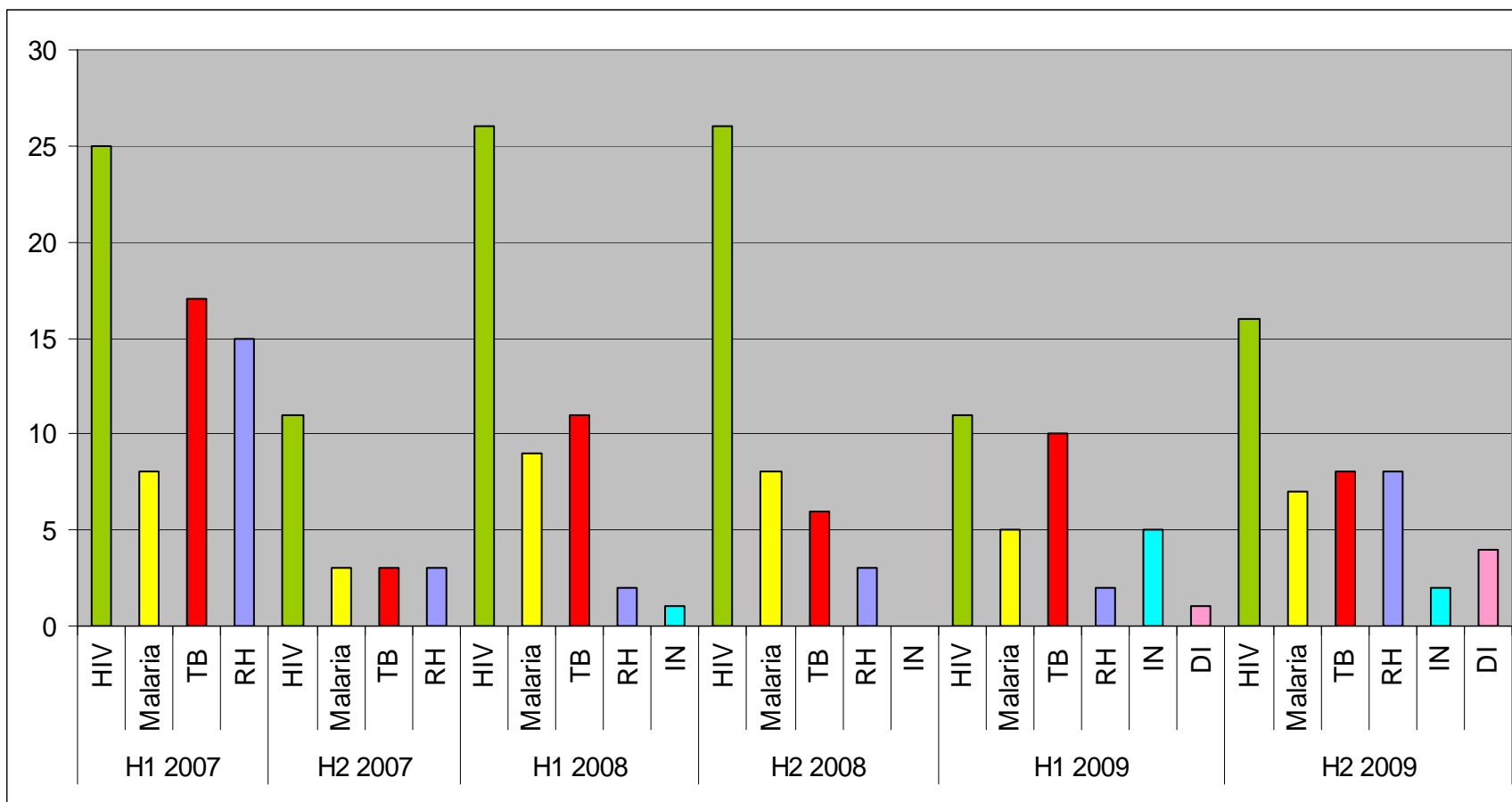
Quality Assurance

- Prequalification
 - Dossier Review
 - GMP Inspection
 - Laboratories
 - Training and Capacity development
- Regulatory Support
 - Norms and Standards
 - Country Support

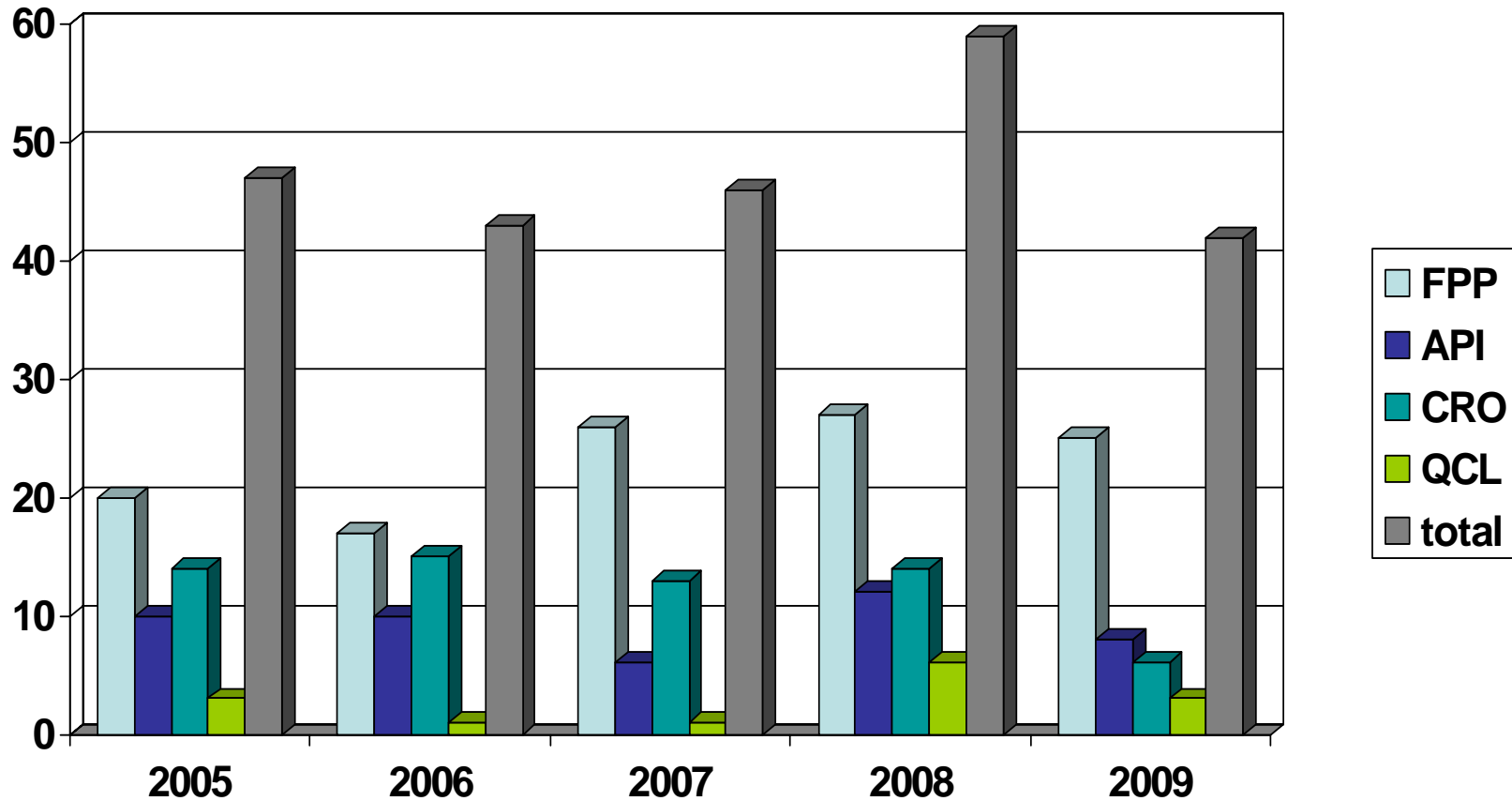


See <http://apps.who.int/prequal/>

Dossiers submitted 2007-2009



Number of inspections

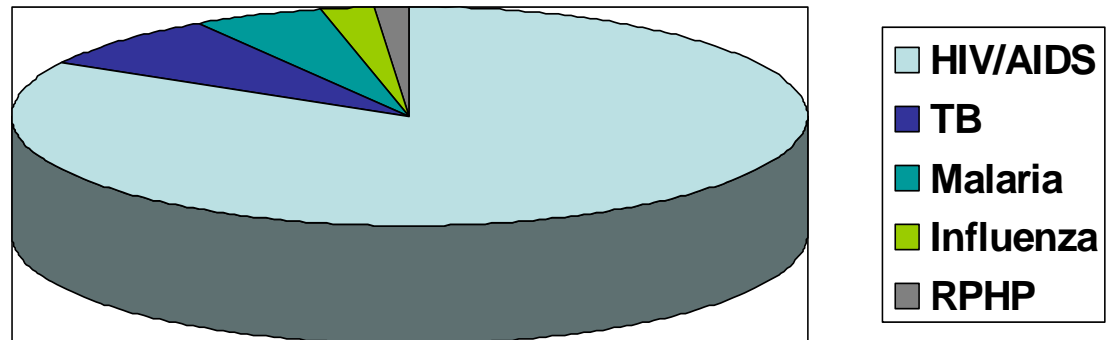


List of WHO Prequalified Medicinal Products

9 July 2010

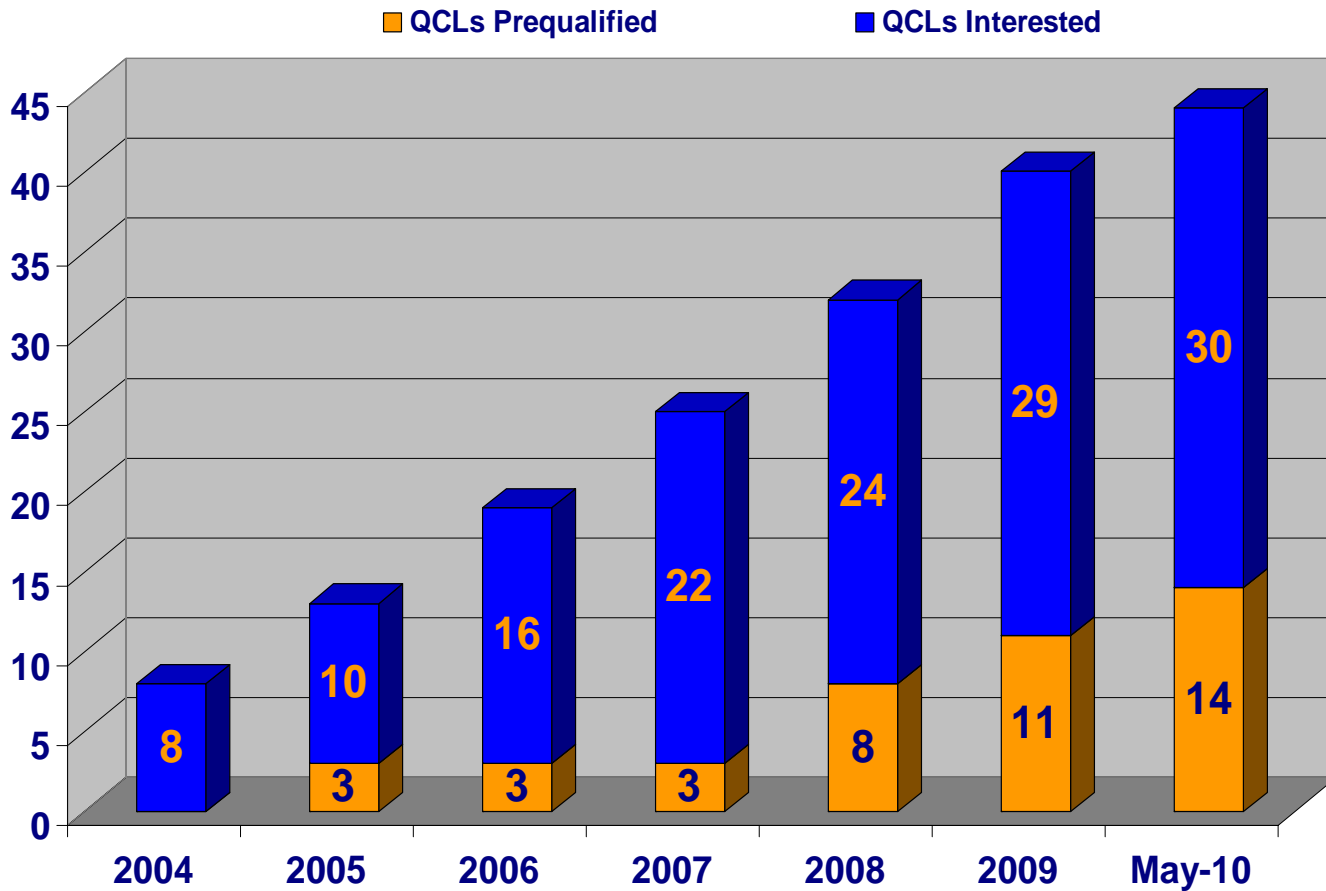
275	HIV/AIDS
27	Tuberculosis
17	Malaria
7	Influenza
5	Reproductive health

Total 331



Prequalified / interested laboratories

May 2010



Prequalified QCLs:

- South Africa, RIIP+CENQAM (2005)
- Algeria, LNCPP (2005)
- South Africa, Adcock Ingram (2007)
- Morocco, LNCM (2008)
- Kenya, NQCL (2008)
- India, Vimta Labs (2008)
- France, CHMP (2008)
- Vietnam, NIDQC (2008)
- Kenya, MEDS (2009)
- Singapore, HSA (2009)
- Singapore, TÜV (2009)
- Canada, K.A.B.S. Laboratories (2010)
- Ukraine, CLQCM (2010)
- Ukraine, LPA (2010)



PQ Outcomes . . .

- Recognition: Donors (Gates, UNITAID) also supported by the Global Fund (QA policy), World Bank etc
- Transparent: Positive and negative outcomes published, Suspension and withdrawals when needed
- Sampling and testing programmes monitor and prove good quality medicines
- Ongoing inspections and investigations, maintenance of products
- Harmonization, cooperation (e.g. agreements including with FDA)
- By rotating national inspectors through PQ unit and involvement in dossier review and GMP inspections national regulatory capacity built

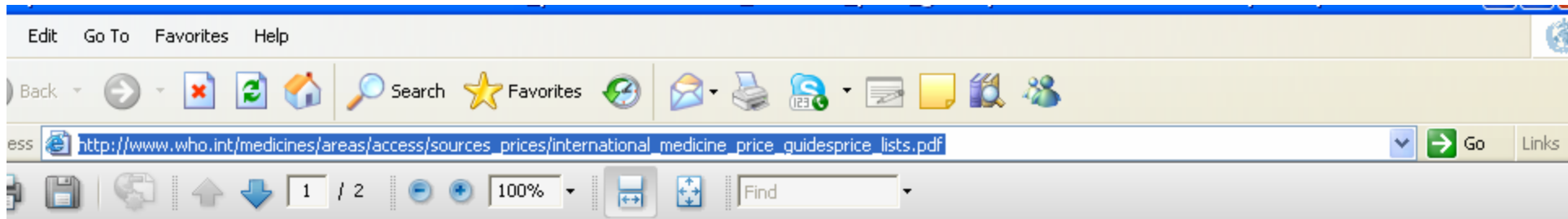


Medicines Pricing

- Sources of Information about prices
 - WHO website
 - International and national sites
 - Procurement Information Exchange ([PIE](#))
from Western Pacific Region
- WHO/HAI Pricing Project
- Pricing Analysis of ARVs



<http://www.who.int/medicines/areas/access/ecofin/en/index.html>



http://www.who.int/medicines/areas/access/sources_prices/international_medicine_price_guidesprice_lists.pdf

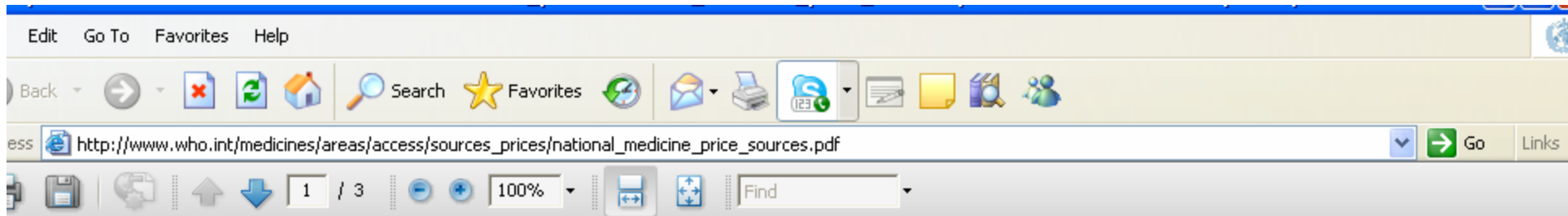
INTERNATIONAL MEDICINE PRICE GUIDES

Detailed information on type of price information for some of the websites below can be found on the HAI medicine prices website!

MULTI-COUNTRY PRICE SOURCES

<http://www.haiweb.org/medicineprices/international-medicine-prices-sources.php>

<u>ORGANISATION(S)</u>	<u>TITLE</u>	<u>WEBSITE</u>
Clinton Foundation	Antiretroviral (ARV) price list	http://www.clintonfoundation.org/what-we-do/clinton-hiv-aids-initiative/information-center-resources
Global Fund for AIDS, TB & Malaria	Price & Quality Reporting (PQR)	http://www.theglobalfund.org/en/procurement/pqr/
Health Action International	WHO/HAI database of medicine prices, availability, affordability and price components	http://www.haiweb.org/GlobalDatabase/
International Trade Centre / World Health Organization	The market news service for pharmaceutical starting materials	http://www.intracen.org/mns/Pharmaceuticals.htm
Management Sciences for Health	International drug price indicator guide	http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=English
Médecins Sans	Untangling the web of	http://utw.msfaccess.org/



http://www.who.int/medicines/areas/access/sources_prices/national_medicine_price_sources.pdf

NATIONAL MEDICINE PRICE SOURCES

Detailed information on type of price information for some of the websites below can be found on the HAI medicine prices website!

NATIONAL PRICE SOURCES

<http://www.haiweb.org/medicineprices/national-medicine-prices-sources.php>

<u>COUNTRY</u>	<u>TITLE</u>	<u>WEBSITE</u>
Australia	Schedule Pharmaceutical Benefits	http://www.pbs.gov.au/html/home
Austria	The Common European Drug Database (CEDD)	http://cedd.oep.hu/
Bahrain	Ministry of Health	http://www.moh.gov.bh/EN/E-ervices/DrugPrices.aspx
Belgium	Institut national d'assurance maladie-invalidité / Rijksinstituut voor ziekte- en invaliditeitsverzekering	http://www.inami.fgov.be/
Brazil	Banco de Precos Em Saude	http://bpreco.saude.gov.br/bprefd/owa/consulta.inicio
Canada	Patented Medicine Prices Review Board (PMPRB)	http://www.pmprbcepmc.gc.ca/english/view.asp?x=572
Canada	Ontario Drug Benefit Formulary	http://www.health.gov.on.ca/english/odrugs/odrugs.html

Price Information Exchange for Selected Medicines in the Western Pacific Region

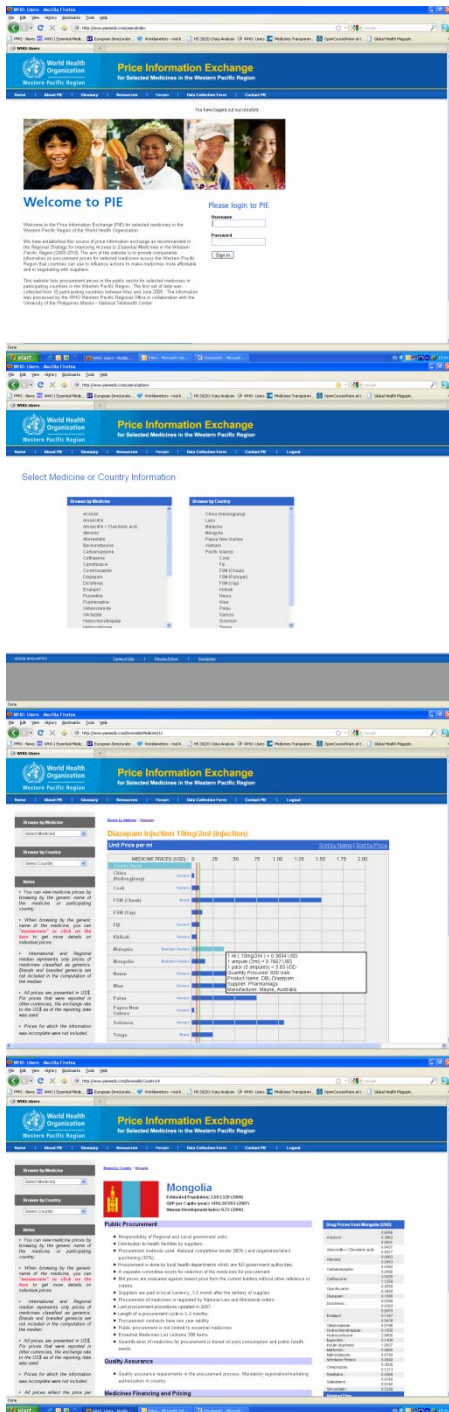
www.piemeds.com (also in .net, .org)

The website provides comparative information on **procurement prices** that countries can use in influencing actions to make medicines more affordable and in negotiating with suppliers.

round 1 (2009) 31 medicines, 18 countries
round 2 (2010) 40 medicines, - - countries (in process)

Presentation:

- Browsing by medicine – the unit price of medicines (brand, branded generic, generic) in comparative charts
- Each bar unfolds details on pack size, price per pack, product name, manufacturer, supplier and quantity
- International and Regional median in vertical lines (generics only)
- Browsing by country – brief description of countries' medicines procurement. Link to countries' health information profiles
- Other features – description of PIE, glossary, external resources, forum & data collection form



WHO/HAI Pricing Project

++ Health Action International Europe ++ [Focus] - Microsoft Internet Explorer provided by WHO

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Refresh Print Mail RSS Feeds

Address <http://www.haiweb.org/medicineprices/> Go Links

HEALTH ACTION INTERNATIONAL

hai EUROPE

home undertaking a survey survey reports database related surveys publications and advocacy other sources of prices help haiweb.org

Medicine Prices, Availability, Affordability & Price Components

In May 2008 Health Action International (HAI) and the World Health Organization (Department of Medicine Policy and Standards) published the 2nd edition of a manual to collect and analyse medicine prices (patient prices and government procurement prices) across sectors and regions in a country, as well as medicine availability, treatment affordability and all price components in the supply chain from manufacturer to patient (taxes, mark-ups etc.).

Governments, civil society groups and others concerned about the prices of medicines are encouraged to undertake a survey using the methodology outlined in the manual. Reliable data is the first step to exploring policy options and taking action to reduce prices and improve the availability and affordability of essential medicines. The results of over 50 surveys are currently available on the database, along with survey reports and other information.

Latest Surveys, Reports and Advocacy

A one day snapshot of the price of a medicine

Select a medicine Soluble human insulin 100 IU/ml 11 May 2010 Compare Originator Brand Lowest Price Generic

Map Satellite Terrain

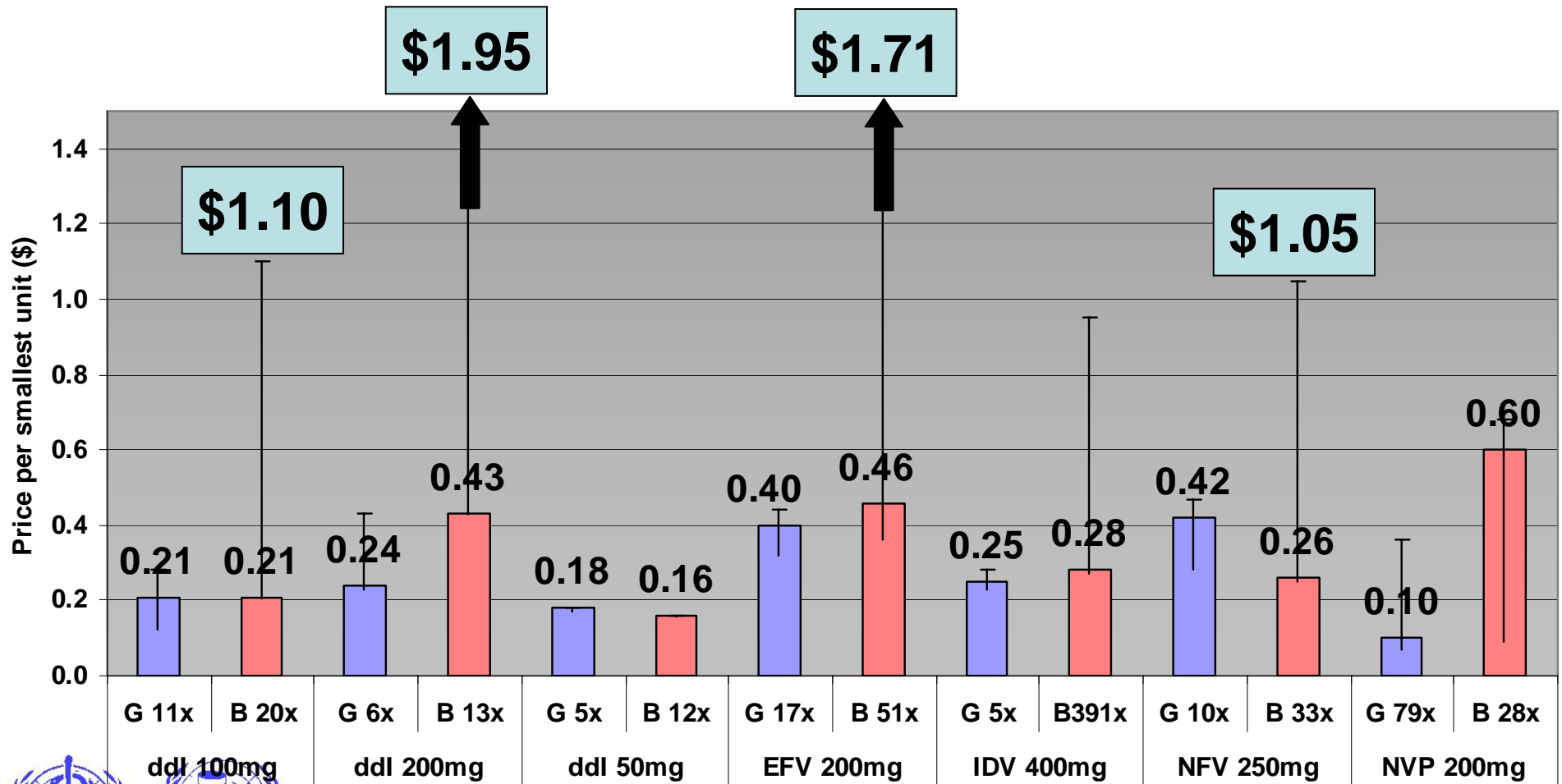
Done Done Internet Internet

start 6 Micros... 3 Micros... 7 Micros... J:\DivDat... 7 Intern... TR5958.p... EN My Computer 13:09



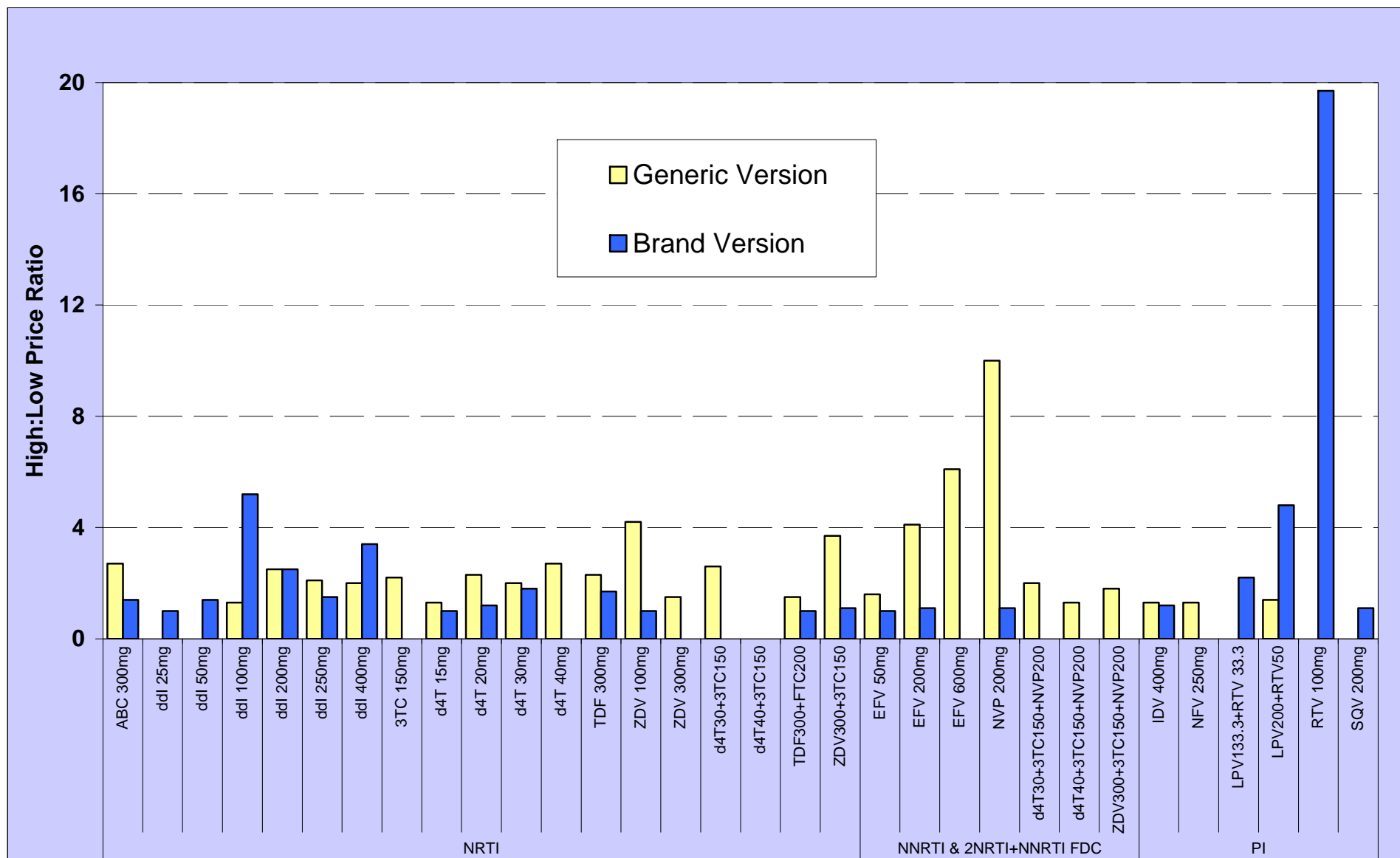
<http://www.haiweb.org/medicineprices/>

Generic and Brand ARV Prices: some findings refute conventional wisdom



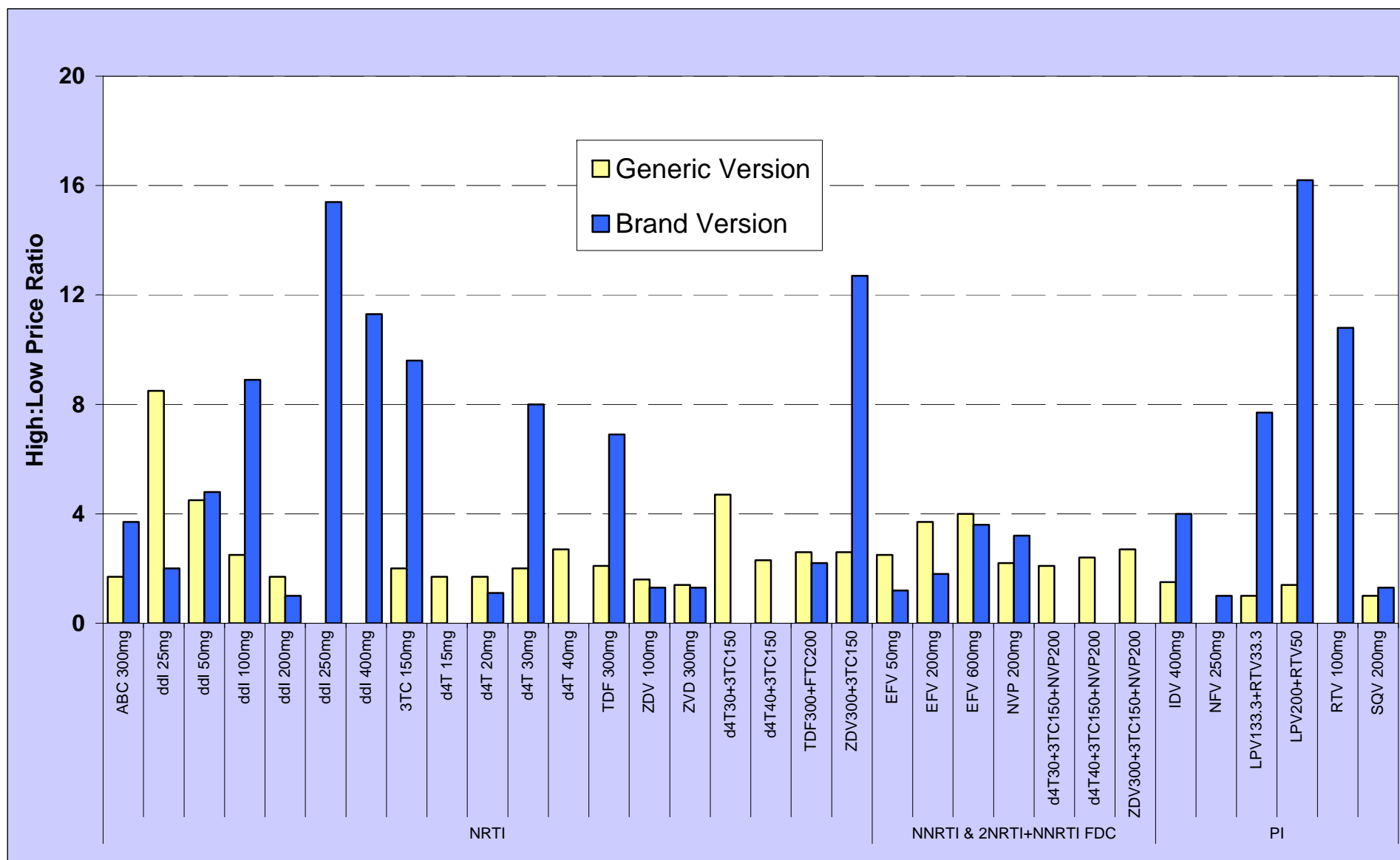
Prices shown are per tablet 7/05-6/06

Ratio of highest price paid to lowest price paid, antiretroviral medicines in low-income countries 2008*



*Waning et al. *Temporal Trends in Brand and Generic Prices of Antiretroviral Medicines Procured with Donor Funds in Developing Countries*. Journal of Generic Medicines 2010;7:159-175.

Ratio of highest price paid to lowest price paid, antiretroviral medicines in middle-income countries 2008*

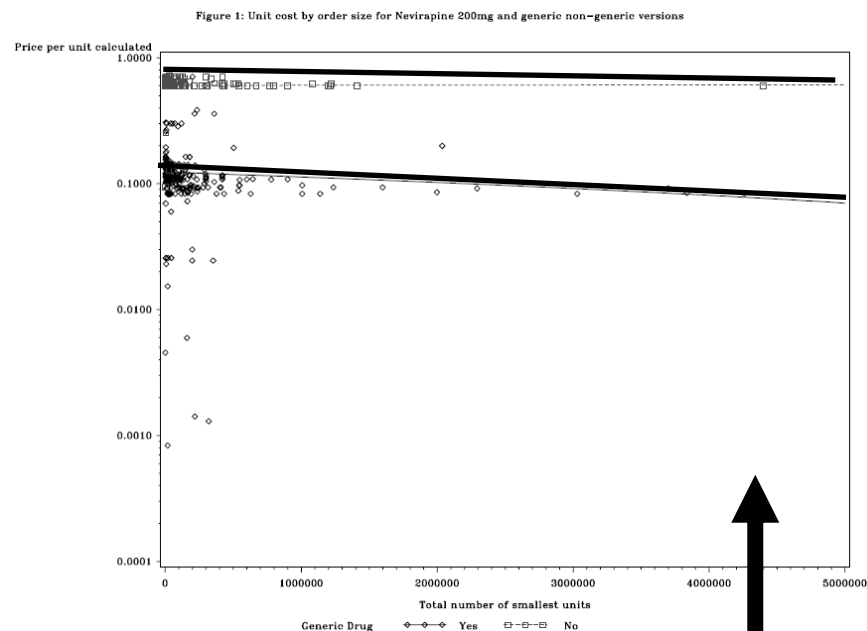


*Waning et al. *Temporal Trends in Brand and Generic Prices of Antiretroviral Medicines Procured with Donor Funds in Developing Countries*. Journal of Generic Medicines 2010;7:159-175.

Regression found only 6 of 19 solid dosage forms showed relationship between volume and price

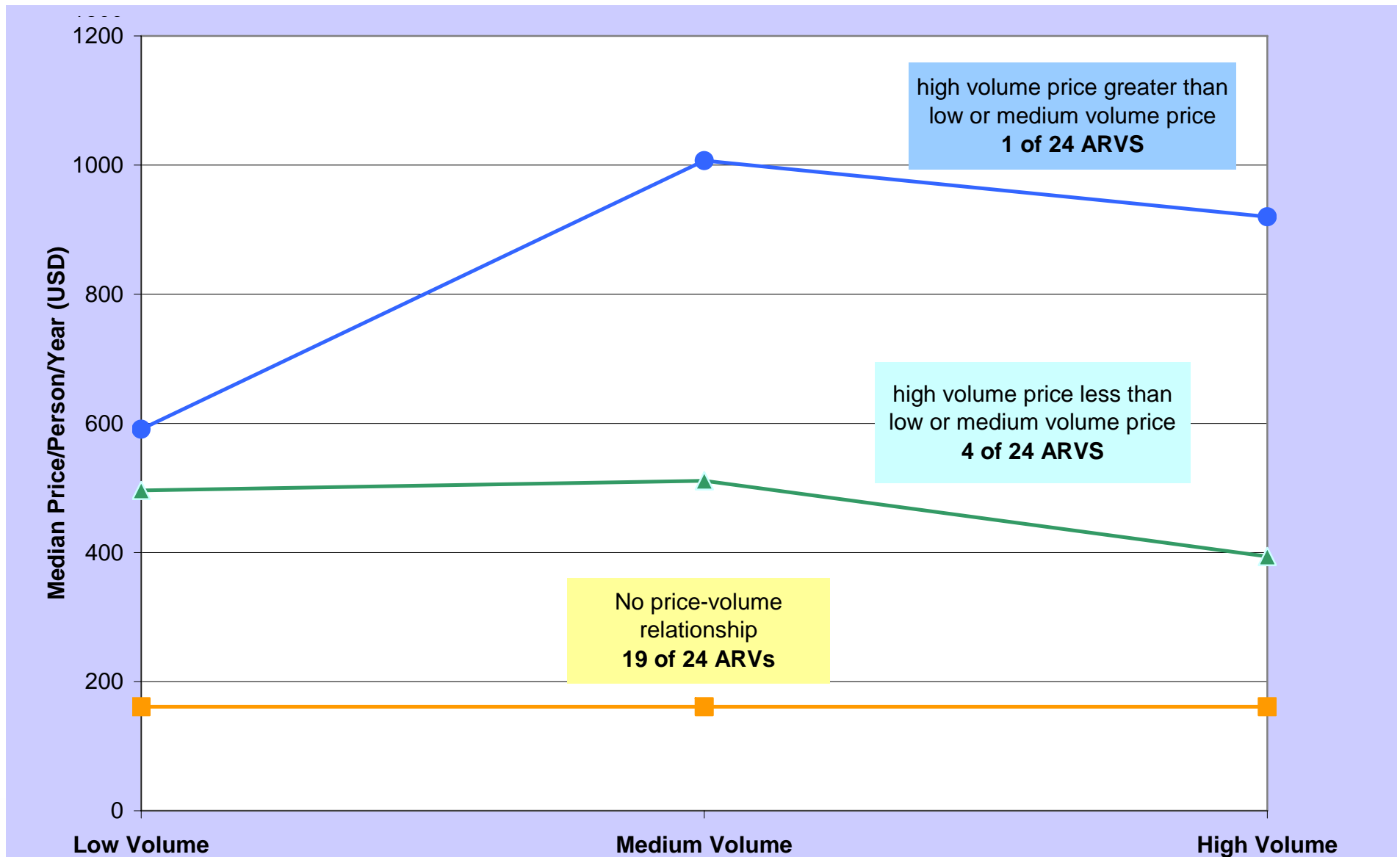
-found no relationship in highest volume products

Dosage Form	Low Vol.	Middle Vol.	High Vol.
zidovudine 100mg	7.2%		ref
sta40+lam +nvp	13.3%	13.7%	ref
sta30+lam +nvp	10%	13.3%	ref
stavudine 30mg	13.3%		ref
stavudine 40mg	16.7%	15.2%	ref
efavirenz 600mg	14.3%		



linear regression
 nevirapine 200mg
 generic $p=0.35$
 brand $p=0.47$

Regression analyses: no relationship between purchase volume & price for 19 of 24 antiretroviral medicines*



*Waning et al. *Analysis of Global Strategies to Reduce Prices of Antiretroviral Medicines: Evidence from a Transactional Database.* Bull World Health Organ 2009;87(7):520-528.

Monitoring Consumption & Prices

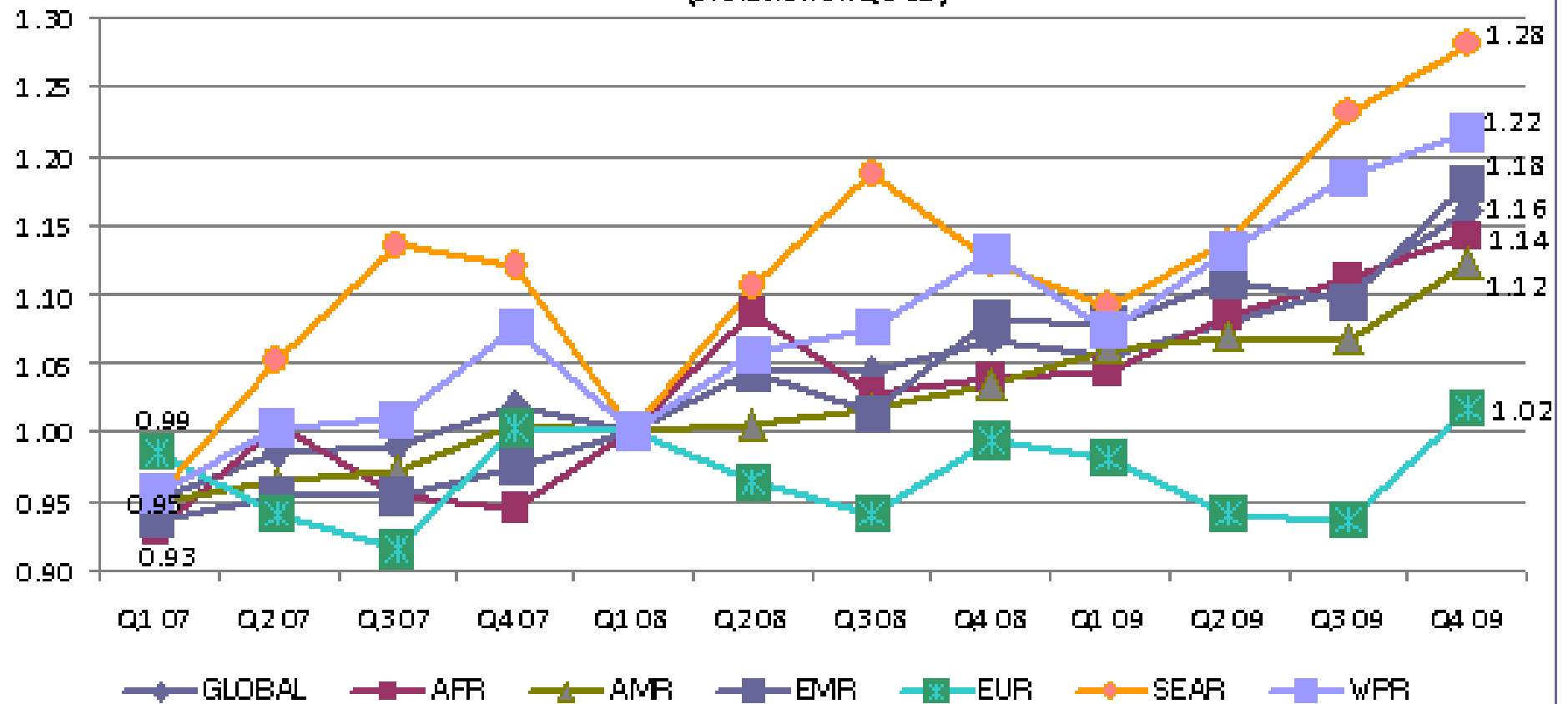
- In collaboration with IMS Health WHO has been tracking the impact of the global recession on pharmaceutical consumption, expenditure and prices in 83 countries
- Data shows that only Baltic and eastern European countries have been substantially impacted
- Methods could be used to monitor the impact of policy changes e.g. Data exclusivity



See

<http://www.who.int/medicines/areas/policy/imsreport/en/index.html>

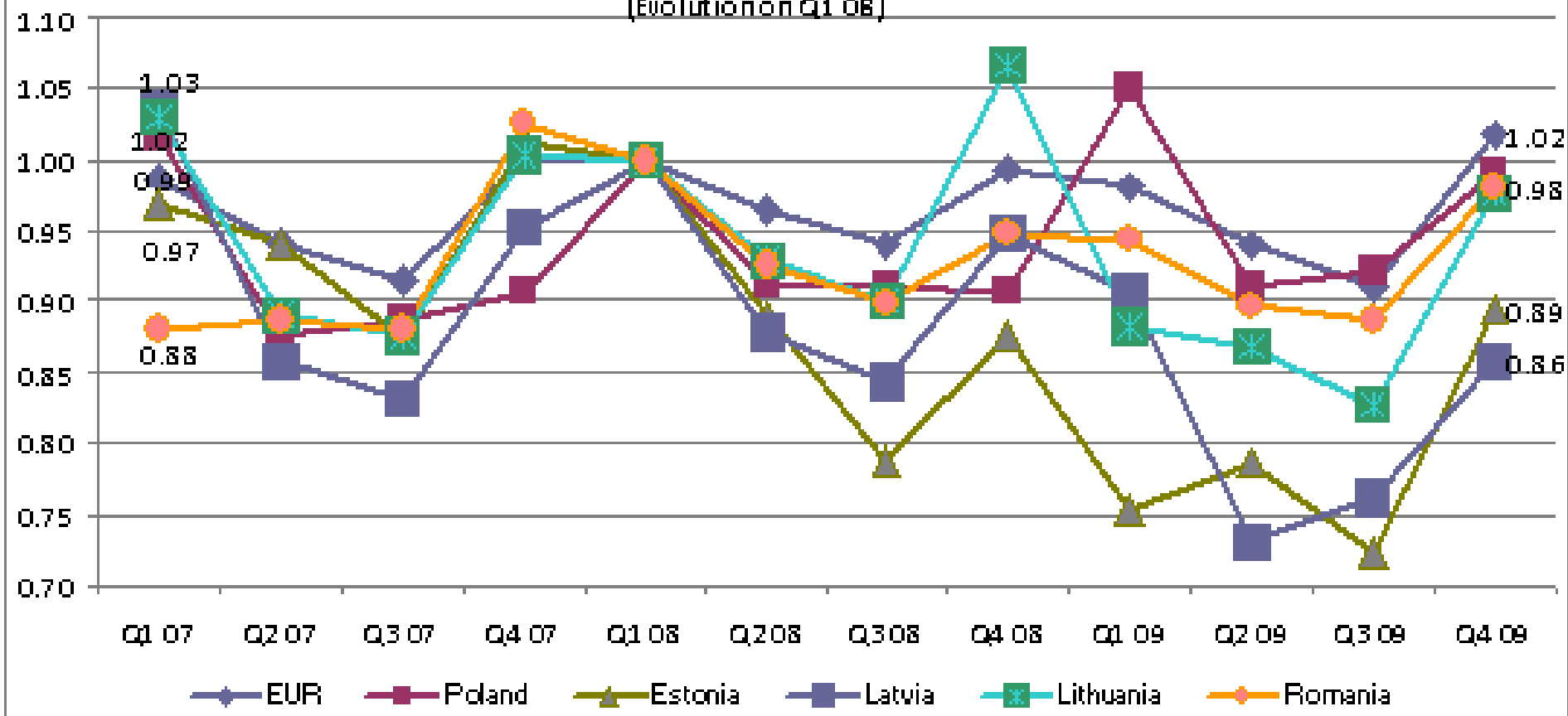
Average pharmaceutical consumption index Global and WHO regions (Evolution on Q1 08)



Source

<http://www.who.int/medicines/areas/policy/imsreport/en/index.html>

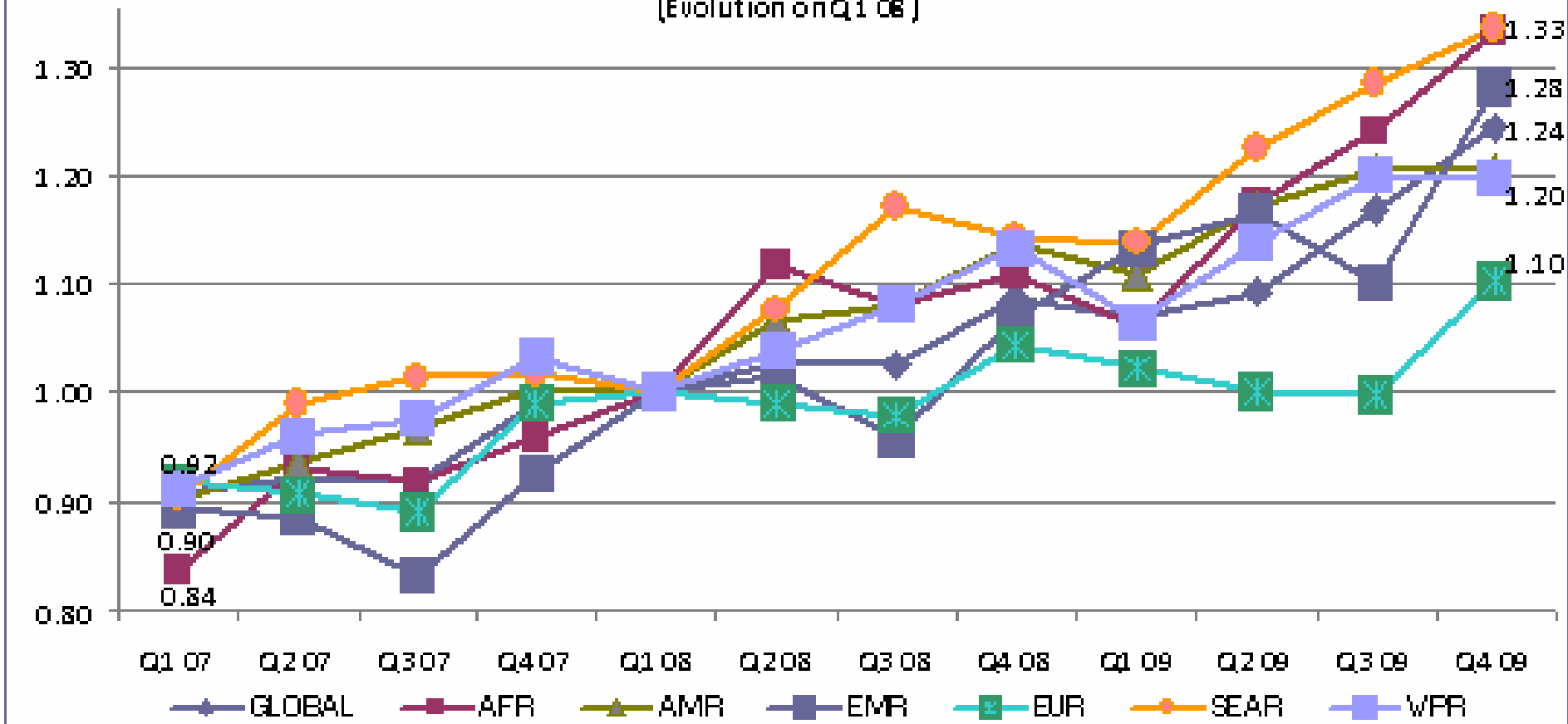
Pharmaceutical consumption EUR, Poland, Romania and Baltics (Evolution on Q1 08)



Source

<http://www.who.int/medicines/areas/policy/imsreport/en/index.html>

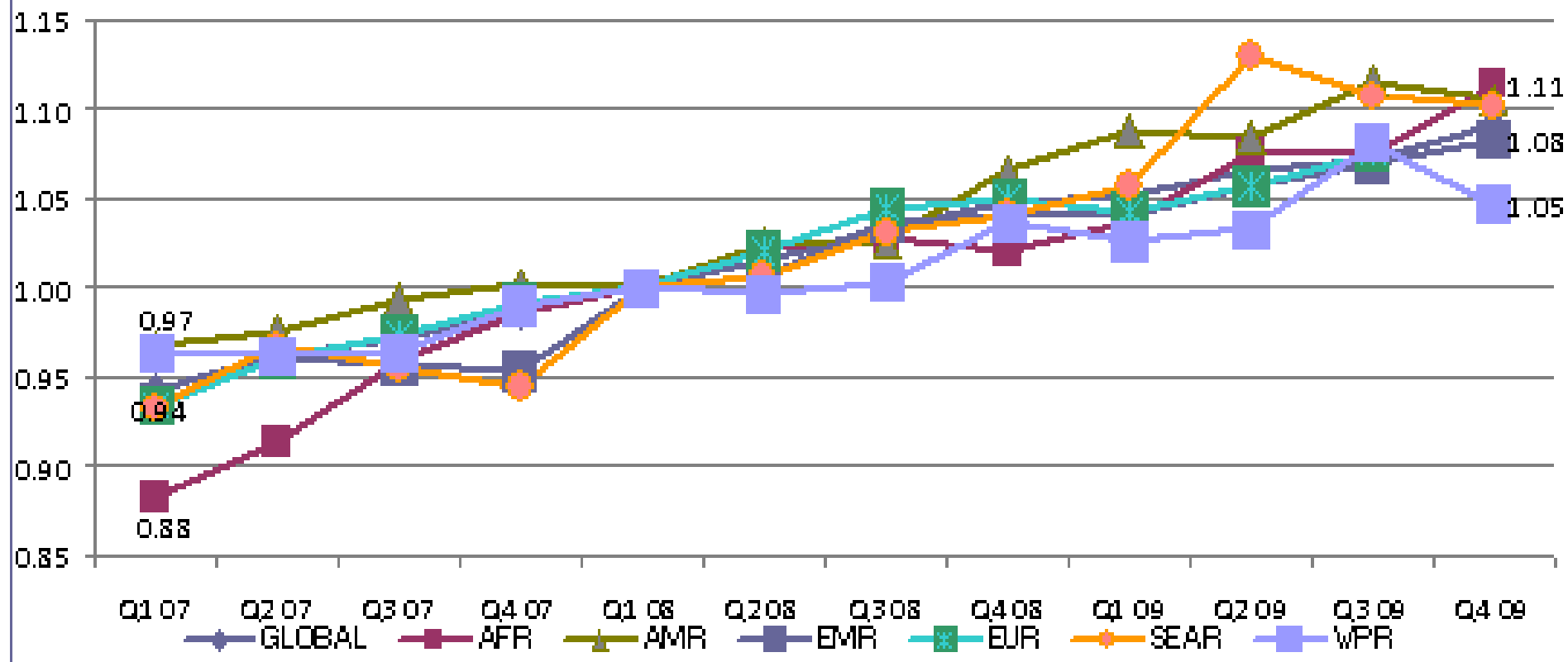
Average pharmaceutical expenditure index Global and WHO regions (Evolution on Q1 08)



Source

<http://www.who.int/medicines/areas/policy/imsreport/en/index.html>

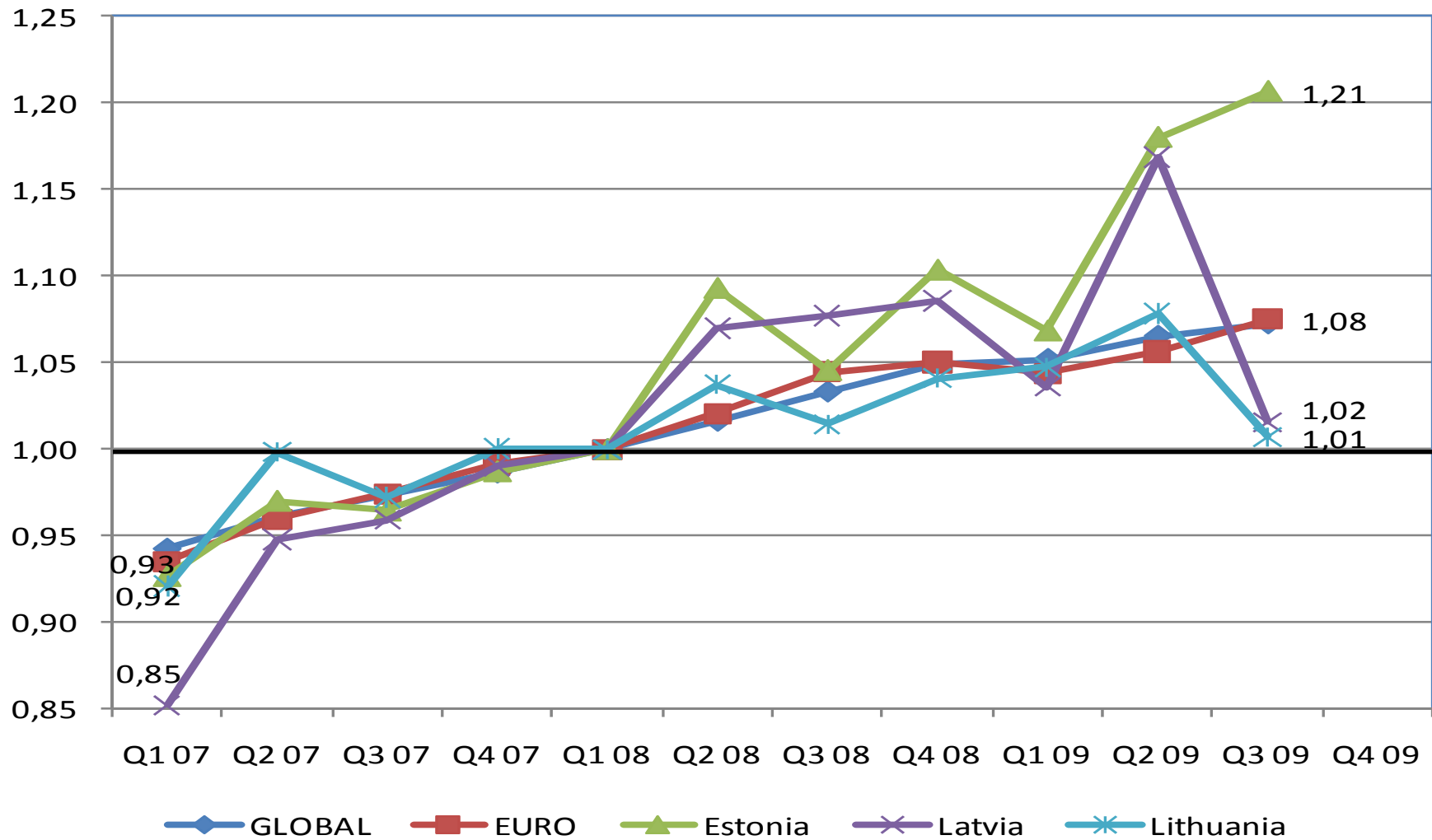
Average price per IMS Standard Unit index Global and WHO regions (Evolution on Q1 08)



Source

<http://www.who.int/medicines/areas/policy/imsreport/en/index.html>

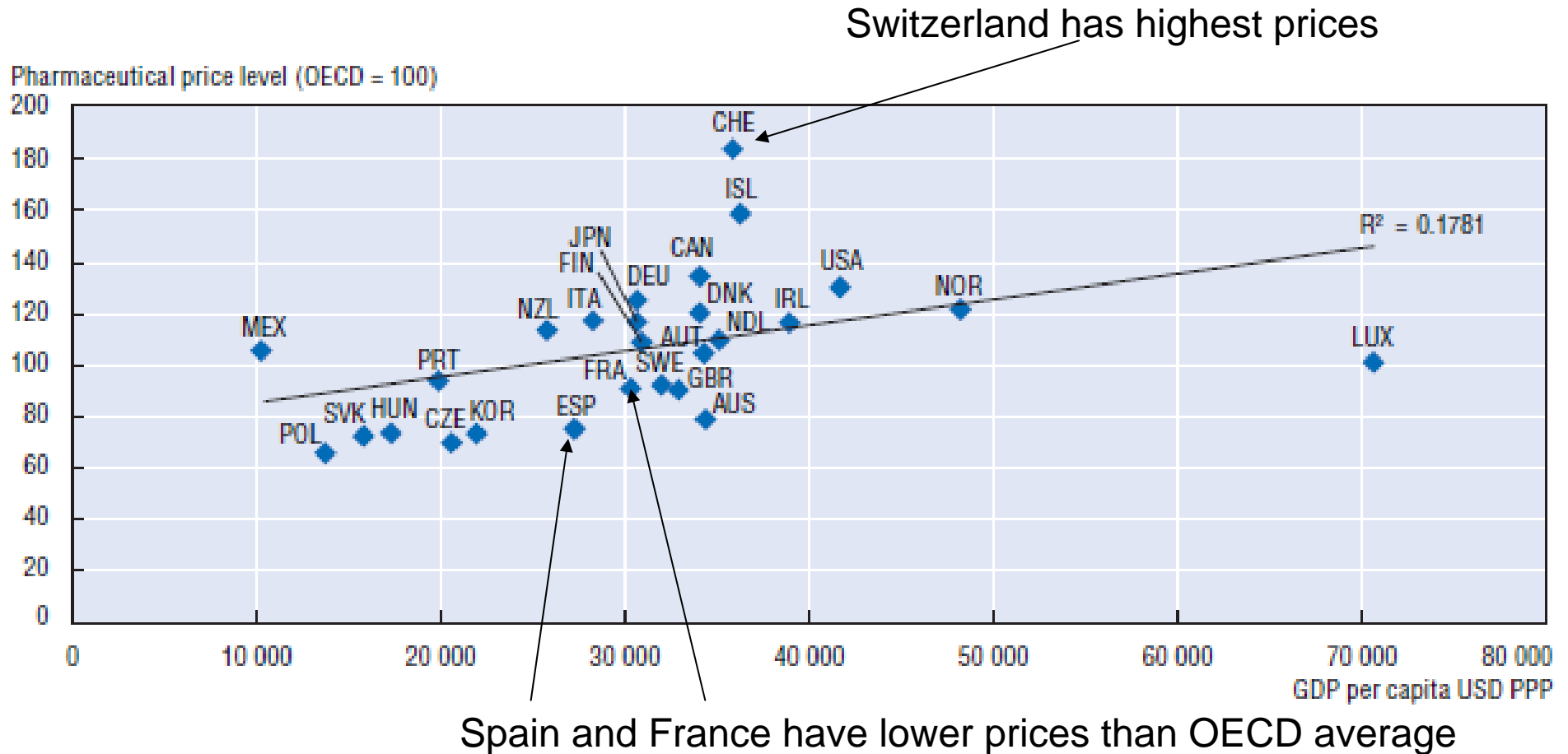
Price per IMS Standard Unit Global, EURO, Baltics (Evolution on Q1 08)



Source

<http://www.who.int/medicines/areas/policy/imsreport/en/index.html>

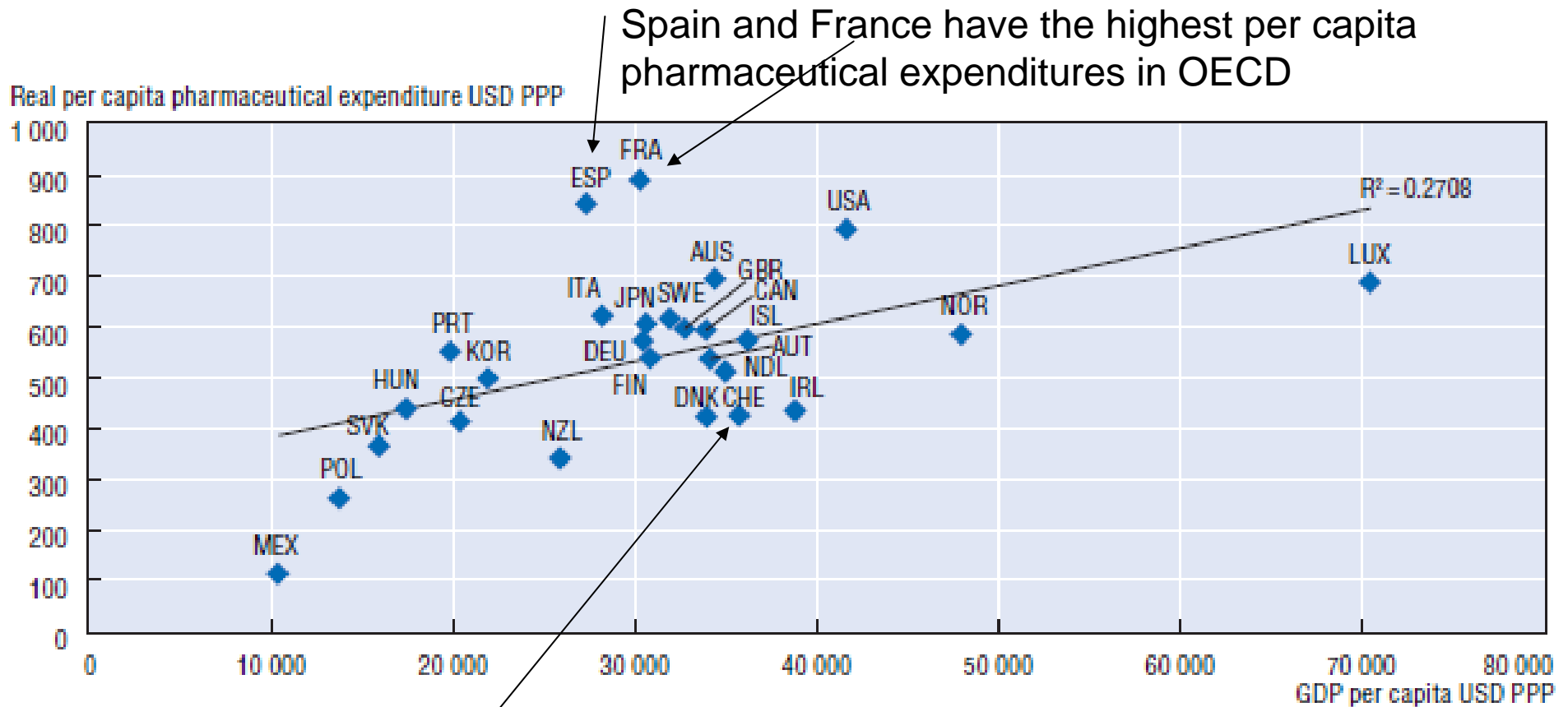
Comparing Prices and Total Pharmaceutical Expenditure



Source

[OECD 2008 Pharmaceutical Pricing Policies in a Global Market](#) ²⁷

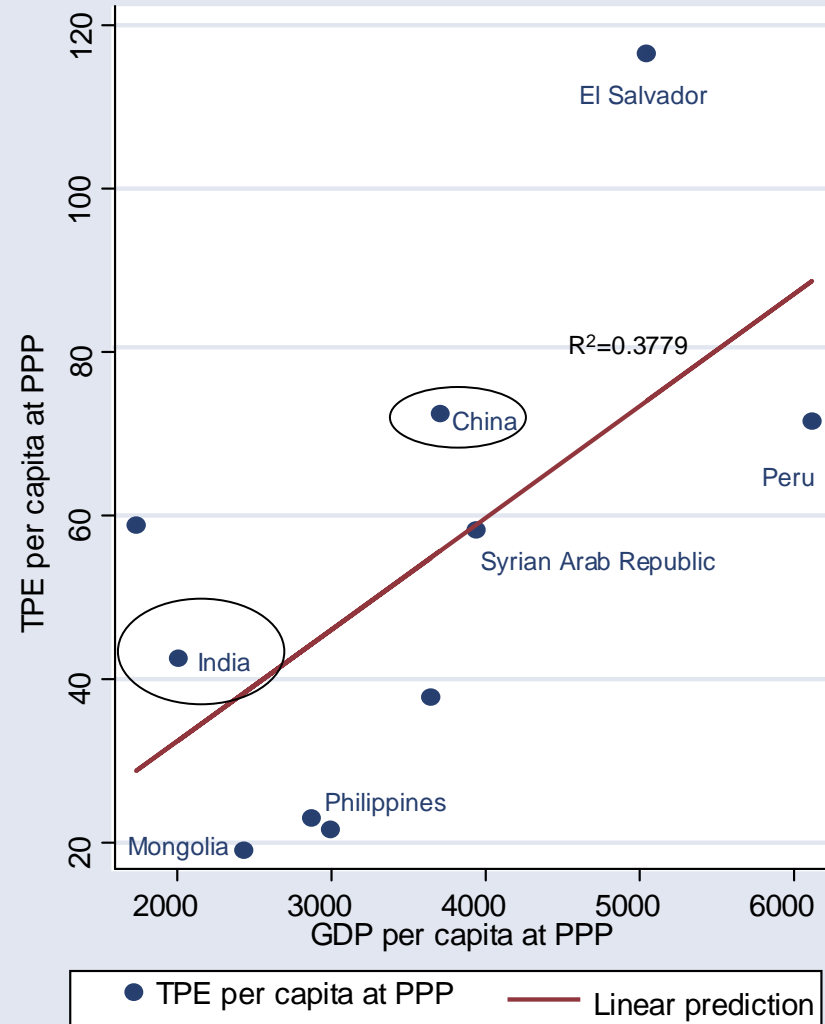
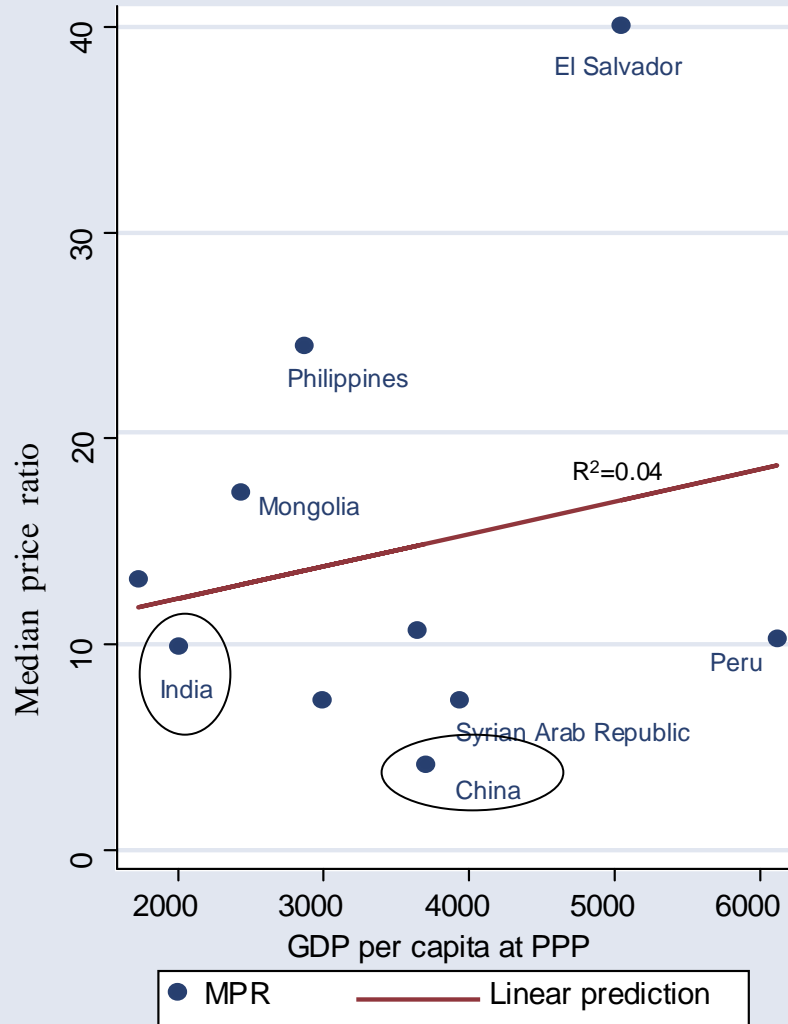
Comparing Prices and Total Pharmaceutical Expenditure



Switzerland has lower per capita pharmaceutical expenditures than OECD average

Despite low prices both China and India spend more than other low and middle income countries on pharmaceuticals

Medicine price, TPE per capita and GDP per capita, 2004
(at PPP, low and middle income countries)



Conclusion

- There is much to procurement beyond patents, copyright and data exclusivity
- Data resources and methods currently available allow evaluation of policy or programmatic actions at global, regional or national levels
- Many opportunities to cooperate at a technical and at a country support level



Citations

- Waning B, Kyle M, Diedrichsen E, Soucy L, Hochstadt J, Bärnighausen T, Moon S. *Intervening in global markets to improve access to HIV/AIDS treatment: an analysis of international policies and the dynamics of global antiretroviral medicines markets.* Globalization and Health 2010;6:9.
<http://www.globalizationandhealth.com/content/6/1/9>
- Waning B, Kaplan W, Fox MP, Boyd-Boffa M, King AC, Lawrence DA, Soucy L, Mahajan S, Leufkens HG, Gokhale M. *Temporal Trends in Brand and Generic Prices of Antiretroviral Medicines Procured with Donor Funds in Developing Countries.* Journal of Generic Medicines 2010;7:159-175.
<http://www.palgrave-journals.com/jgm/journal/v7/n2/full/jgm20106a.html>
- Waning B, Kaplan W, King AC, Lawrence DA, Leufkens HG, Fox MP. *Analysis of Global Strategies to Reduce Prices of Antiretroviral Medicines: Evidence from a Transactional Database.* Bull World Health Organ 2009;87(7):520-528.
<http://www.who.int/bulletin/volumes/87/7/08-058925.pdf>

