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

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

http://apps.who.int/medicinedocs/en/d/Jh2931e/#Jh2931e
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

2005 2006 2007 2008 2009

FPP  API  CRO  QCL  total
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

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

<table>
<thead>
<tr>
<th>ORGANISATION(S)</th>
<th>TITLE</th>
<th>WEBSITE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinton Foundation</td>
<td>Antiretroviral (ARV) price list</td>
<td><a href="http://www.clintonfoundation.org/what-we-do/clinton-hiv-aids-initiative/information-center-resources">http://www.clintonfoundation.org/what-we-do/clinton-hiv-aids-initiative/information-center-resources</a></td>
</tr>
<tr>
<td>Health Action International</td>
<td>WHO/HAI database of medicine prices, availability, affordability and price components</td>
<td><a href="http://www.haiweb.org/GlobalDatabase/">http://www.haiweb.org/GlobalDatabase/</a></td>
</tr>
<tr>
<td>International Trade Centre / World Health Organization</td>
<td>The market news service for pharmaceutical starting materials</td>
<td><a href="http://www.intracen.org/mns/Pharmaceuticals.htm">http://www.intracen.org/mns/Pharmaceuticals.htm</a></td>
</tr>
<tr>
<td>Médecins Sans</td>
<td>Untangling the web of</td>
<td><a href="http://itw.msfaccess.org/">http://itw.msfaccess.org/</a></td>
</tr>
</tbody>
</table>
### NATIONAL MEDICINE PRICE SOURCES

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#### NATIONAL PRICE SOURCES


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<tr>
<th>COUNTRY</th>
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<th>WEBSITE</th>
</tr>
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<tbody>
<tr>
<td>Austria</td>
<td>The Common European Drug Database (CEDD)</td>
<td><a href="http://cedd.oep.hu/">http://cedd.oep.hu/</a></td>
</tr>
<tr>
<td>Brazil</td>
<td>Banco de Precos Em Saude</td>
<td><a href="http://bpreco.saude.gov.br/bprefd/owa/consulta.inicio">http://bpreco.saude.gov.br/bprefd/owa/consulta.inicio</a></td>
</tr>
</tbody>
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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

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

In May 2003 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

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*

High:Low Price Ratio

- Generic Version
- Brand Version

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

Regression found only 6 of 19 solid dosage forms showed relationship between volume and price. Found no relationship in highest volume products.

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<tr>
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<tbody>
<tr>
<td>zidovudine 100mg</td>
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<td>ref</td>
<td></td>
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<tr>
<td>sta40+lam +nvp</td>
<td>13.3%</td>
<td>13.7%</td>
<td>ref</td>
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<tr>
<td>sta30+lam +nvp</td>
<td>10%</td>
<td>13.3%</td>
<td>ref</td>
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<td>stavudine 30mg</td>
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<td>ref</td>
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<tr>
<td>stavudine 40mg</td>
<td>16.7%</td>
<td>15.2%</td>
<td>ref</td>
</tr>
<tr>
<td>efavirenz 600mg</td>
<td>14.3%</td>
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<td></td>
</tr>
</tbody>
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Figure 1: Unit cost by order size for Nevirapine 200mg and generic non-generic versions

- 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*

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

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

Source
Average price per IMS Standard Unit index

Global and WHO regions

(Evolution on Q1 08)

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

Source
Comparing Prices and Total Pharmaceutical Expenditure

Switzerland has highest prices

Spain and France have lower prices than OECD average

Source
OECD 2008 Pharmaceutical Pricing Policies in a Global Market
Comparing Prices and Total Pharmaceutical Expenditure

Spain and France have the highest per capita pharmaceutical expenditures in OECD.

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.
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

  http://www.globalizationandhealth.com/content/6/1/9


  http://www.who.int/bulletin/volumes/87/7/08-058925.pdf