Influences on product pricing outside of CoGs

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Presentation outline

1. UNITAID's market-based approach & product pricing

2. Influences on prices outside of CoGs
- Market size/economies of scale
- Generic competition
- Market capture
- Supply stability & security / API issues
- Donor pricing policies and practices
- National pricing policies
- Other influencers

3. Conclusions

1. UNITAID's market-based approach & product pricing

UNITAID Goal: why UNITAID works through markets

UNITAID aims to promote “healthy”, dynamic market conditions whereby manufacturers have **incentives to invest and innovate**, while at the same time supply **quality** public health products at **affordable prices** and in **acceptable formulations** that enable the maximum number of people to access them.

How UNITAID intervenes

UNITAID's role depends upon the particular circumstances in a given market:

- **Market creator:** provide incentives for manufacturers to produce otherwise unattractive products with low demand that yield little profit but substantial public health benefit to those in need; and

- **Market catalyst:** identify and facilitate adoption and uptake of new and/or superior public health products; and

- **Market "fixer":** address severe market inefficiencies (e.g. grossly inaccurate demand forecasts and excessive transaction costs) that contribute to low access to quality-assured public health products.

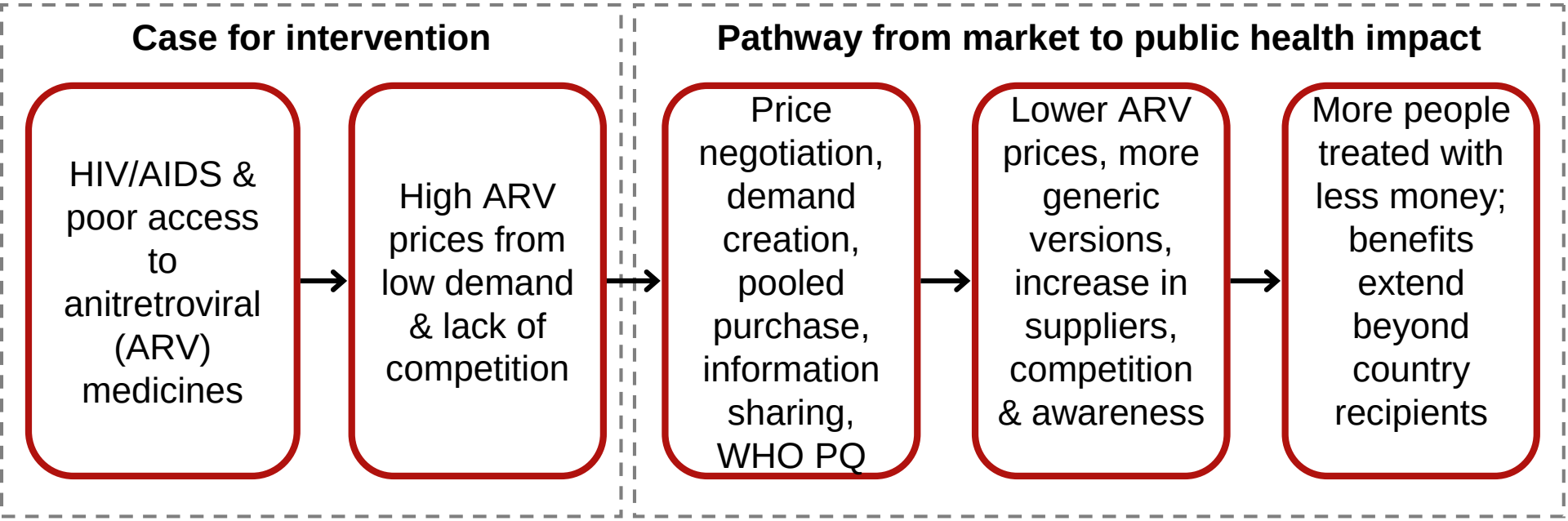
UNITAID Market Effects Framework

Market Shortcomings: Price; Availability; Quality; Acceptability; Delivery

Reasons for Market Shortcomings:

- Absence of market / lack of commercial incentives for product development
- Insufficient regulation/quality control
- IP barriers
- Unbalanced market structure (e.g.,monopsony / oligopsony)
- Structural & capacity issues along the supply chain

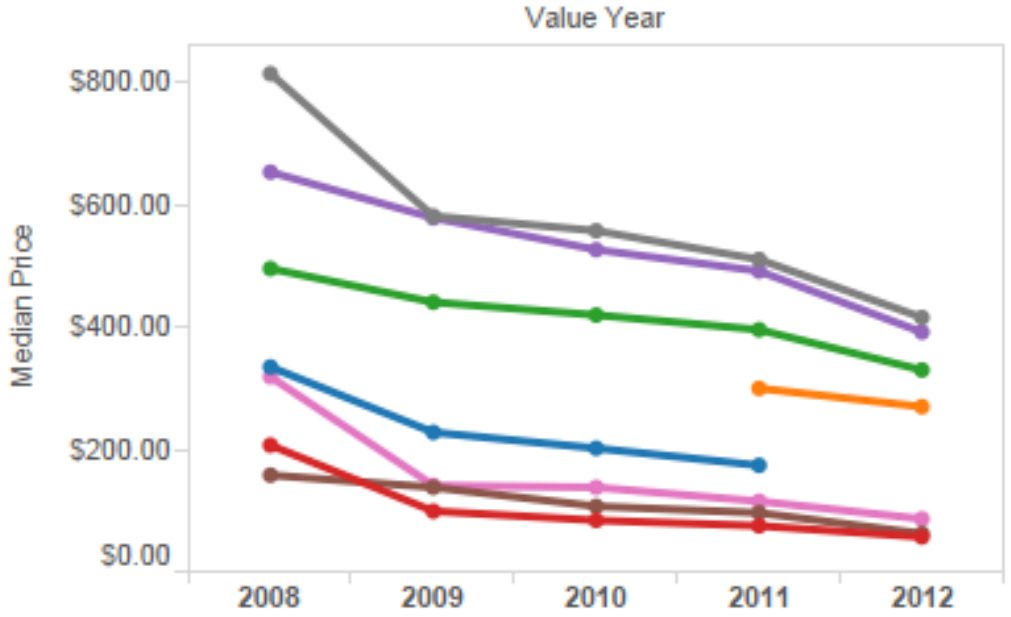
UNITAID Market Effects Framework Example: Second-line ARV market



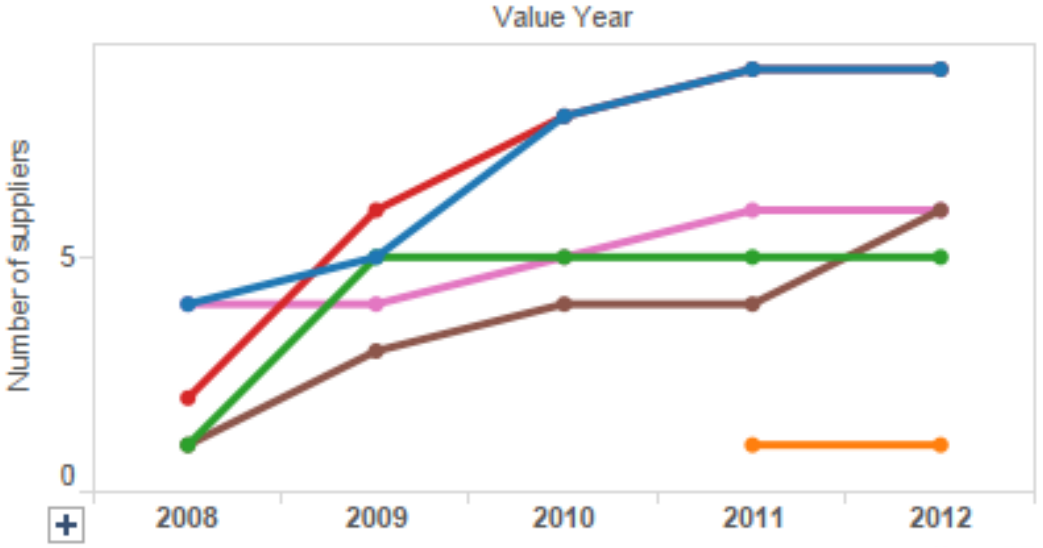
Second-line ARV market: trends

Product
- ABC 300 mg
- ATV/r (300 / 100 mg)
- LPV/r (200/50 mg) Tab (HS)
- TDF 300 mg
- TDF/3TC (300/300 mg) Tab
- TDF/FTC (300/200 mg)
- TDF/FTC (300/200 mg) & LPV/r (200/50 mg)
- TDF/3TC (300/300 mg) & LPV/r (200/50 mg)

Prices

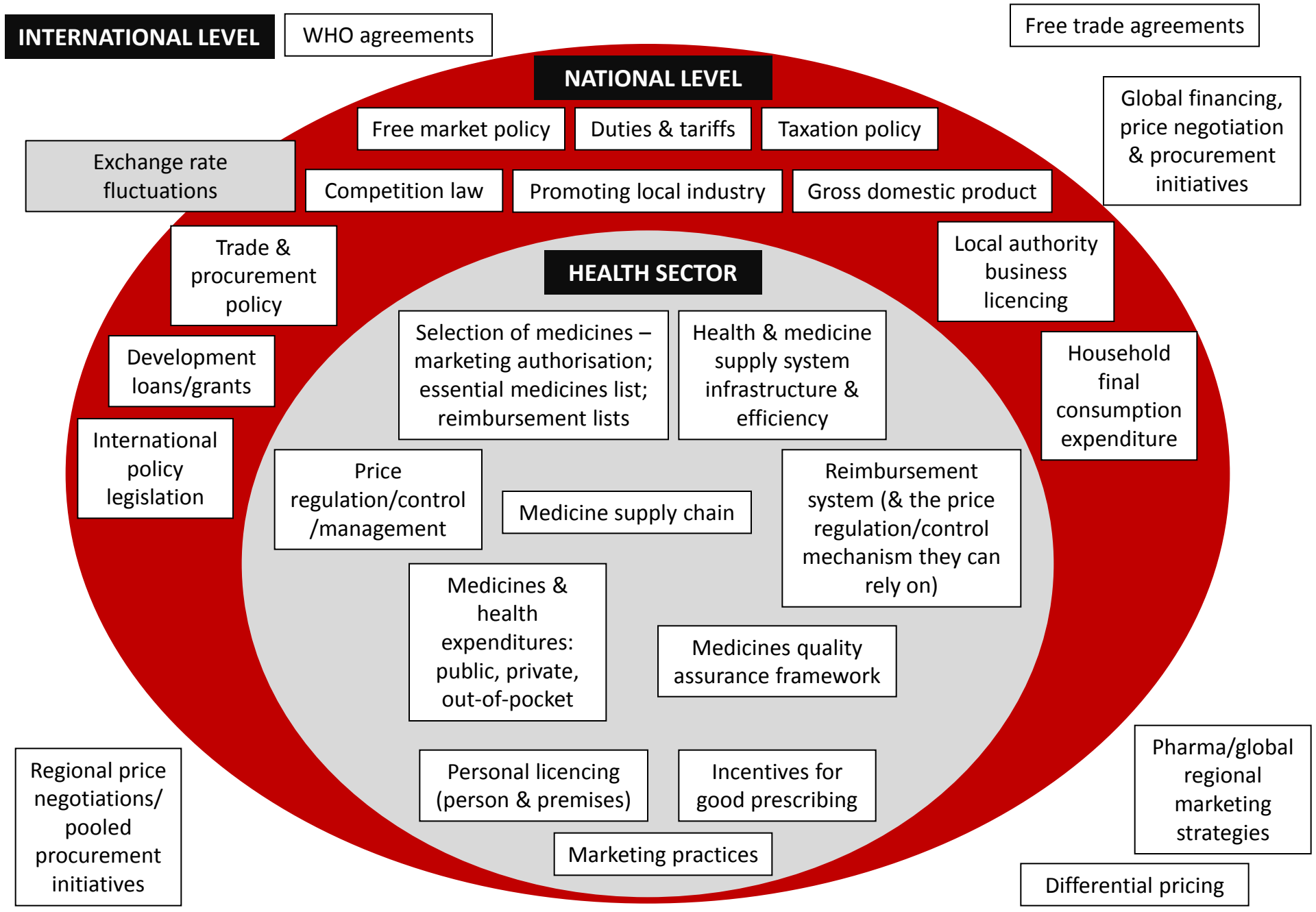


Suppliers



2. Influences on prices outside of CoGs

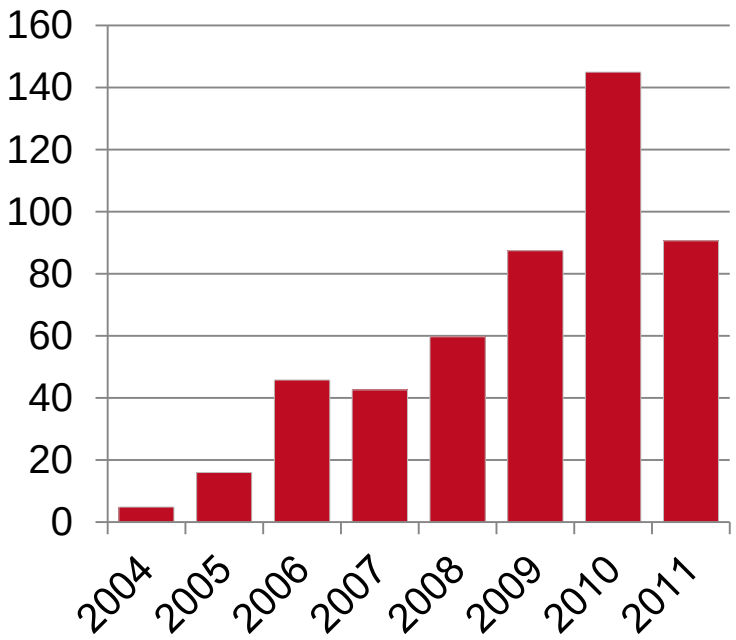
Influences on price are diverse and occur at different levels



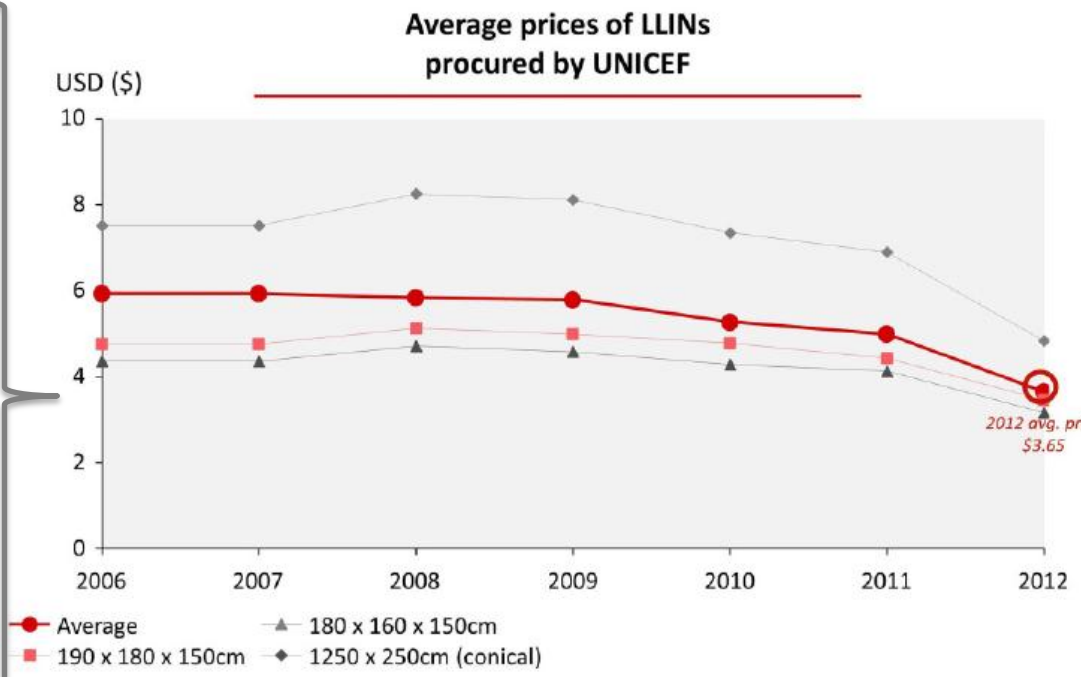
Market size/economies of scale

Ex 1: LLIN market evolution

LLIN deliveries (M), SS Africa



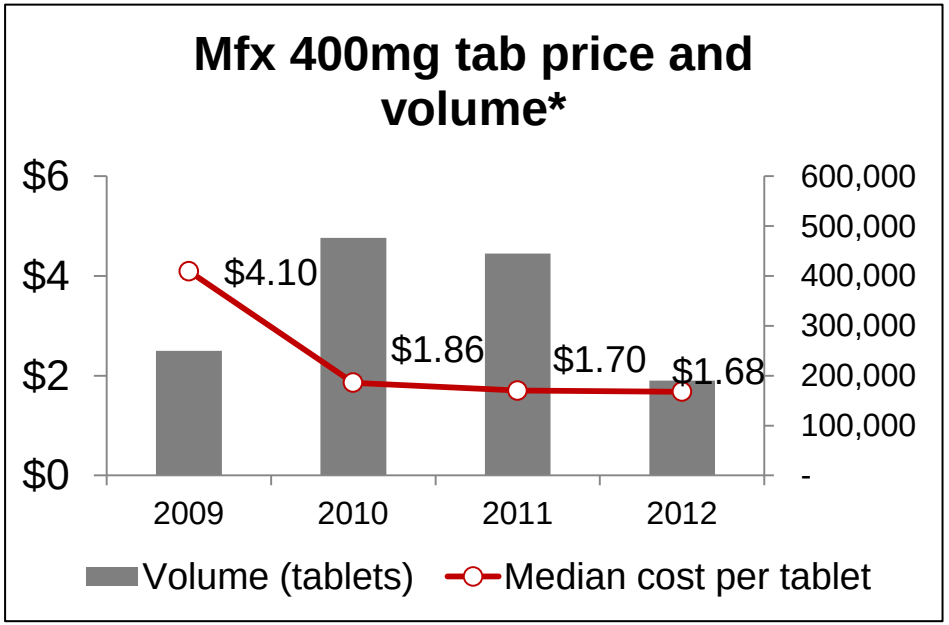
WHOPES approved suppliers, from 1 in 2002 to 10 in 2012

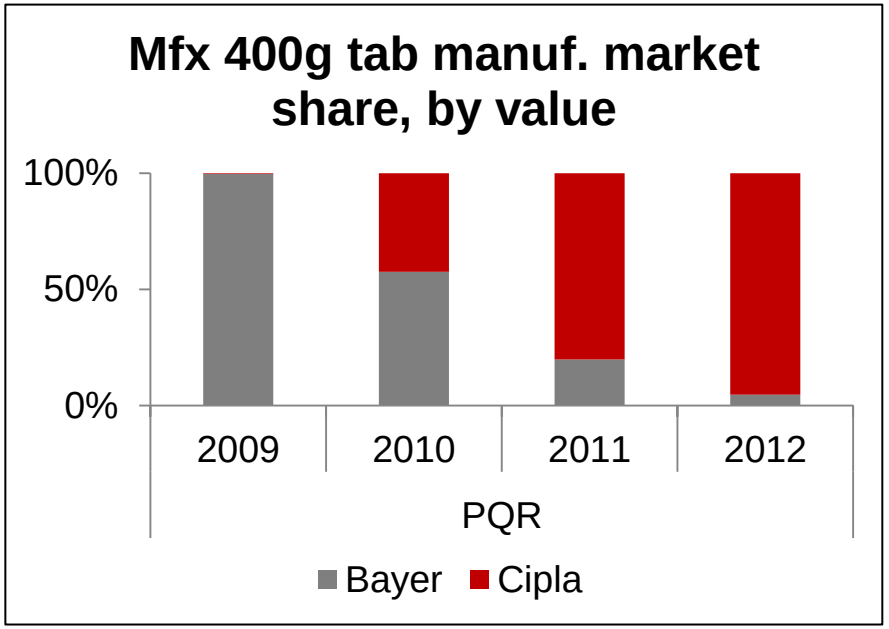


Source: UNITAID Vector Control Commodities Landscape. Geneva, 2013.

Generic competition

Ex 1 - Moxifloxacin: directional price trends following expiry of Bayer's basis patent





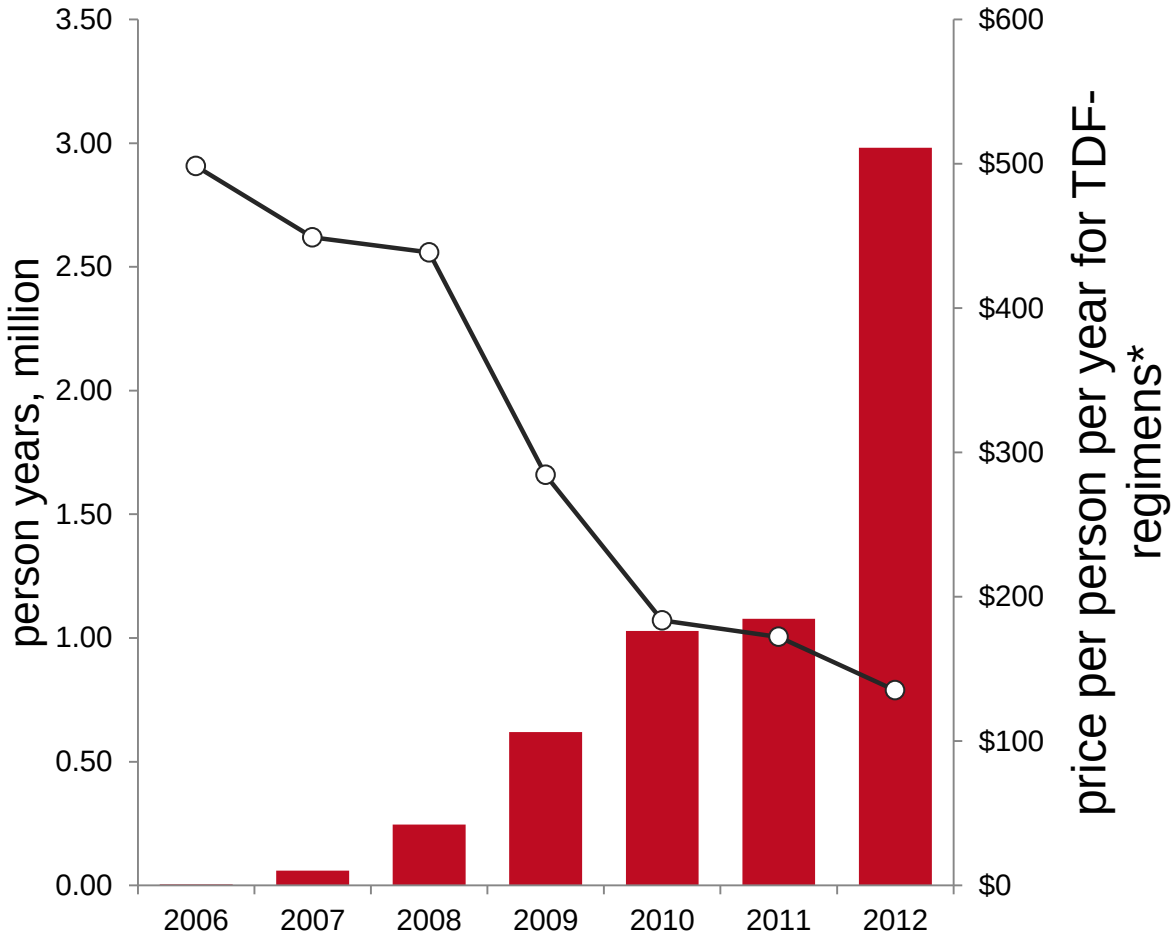
* Global Fund procurement, median cost and volume procured

Source: UNITAID TB Medicines Technology and Market Landscape, 1st ed. Sept 2013. Reflects UNITAID analysis of Global Fund PQR database, 2009-2012 transactions, excluding those pending verification. Dataset downloaded 3 March 2013; partial data only for 2012.

Generic competition

Ex 2 – Tenofovir-based ARV regimens

TDF regimen volumes and prices trends for TDF+3TC+EFV



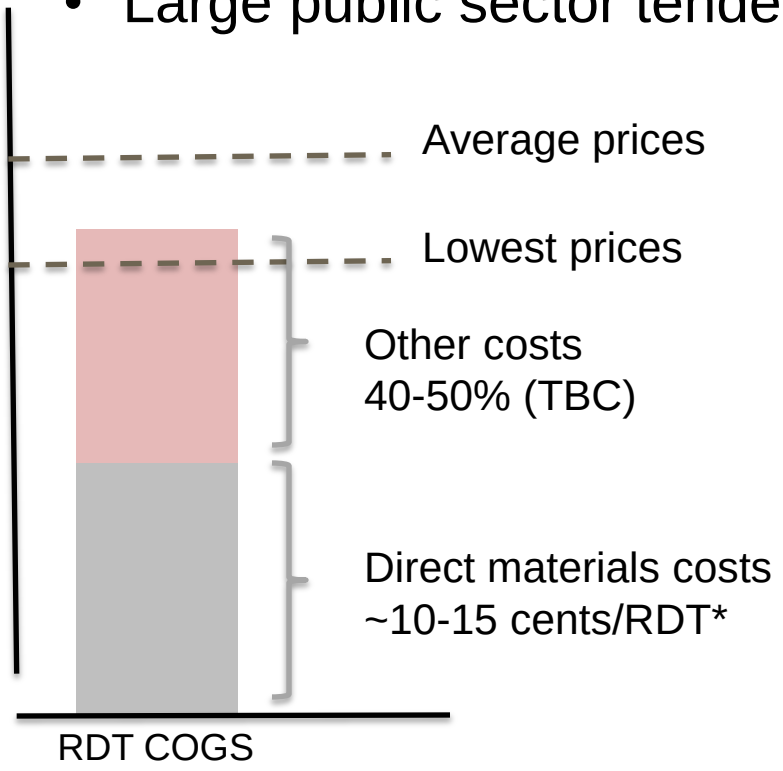
PQ'ed manufacturers: 1 → 9

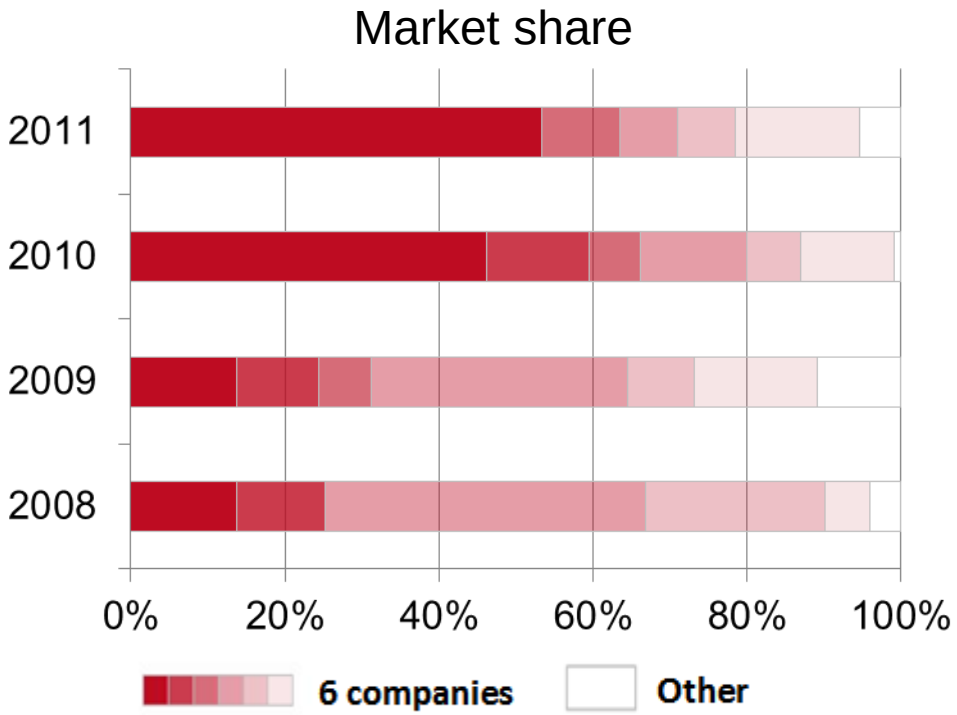
Source: UNITAID HIV Medicines Technology and Market Landscape. Geneva, March 2014.

Market capture

Ex - Malaria RDTs: efforts to capture market have led to very low prices and supplier concentration

- 30-45% price decrease since 2006
- PQR (low price) $.27 for pf, $.33 for combination
- Large public sector tenders mid-$.20's



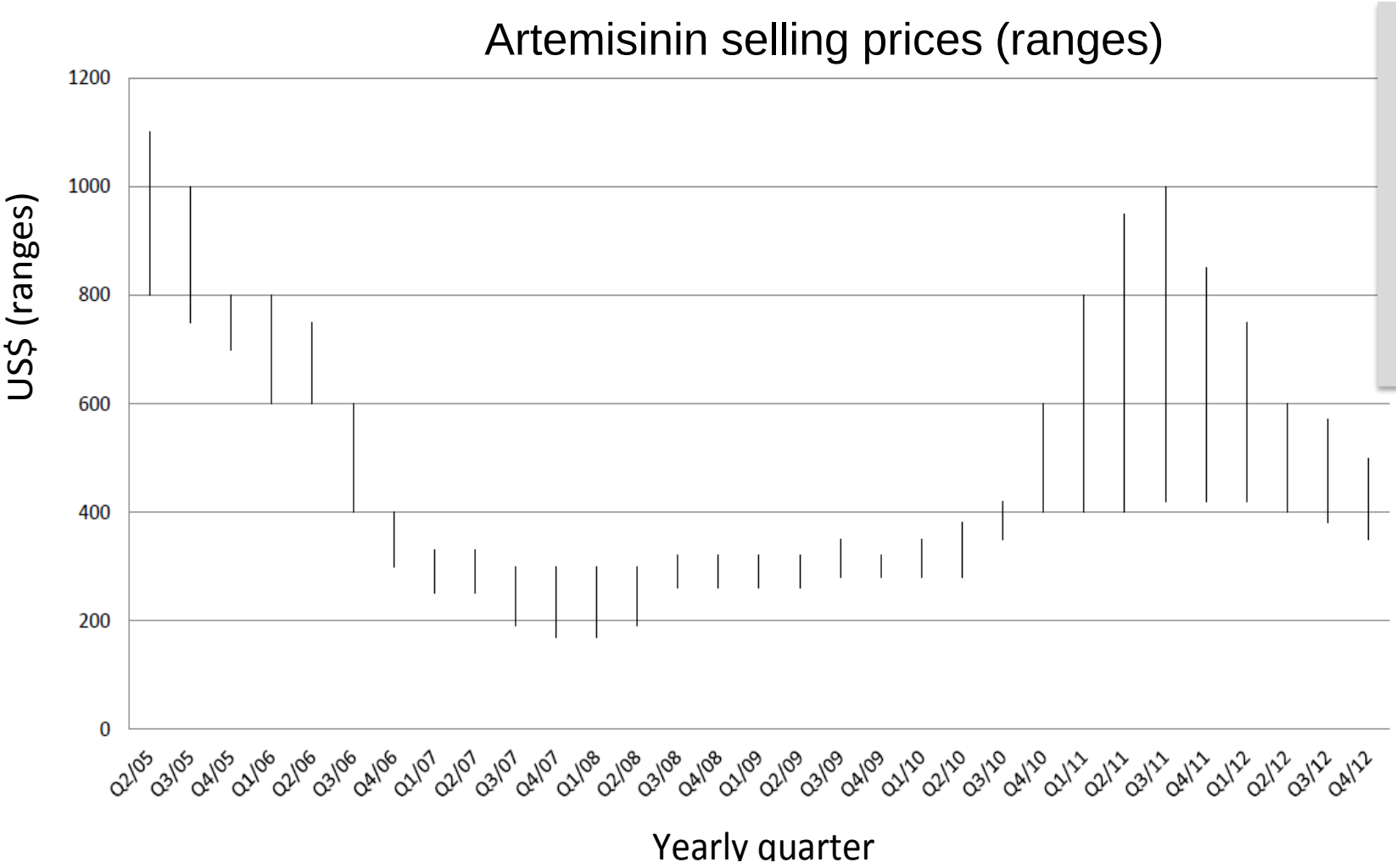


** Based on RDT supplier interviews for 2012 UNITAID Landscape*

Source: UNITAID Malaria Diagnostics Technology and Market Landscape. Geneva, 2013.

Supply stability & security / API issues

Ex - Artemisinin supply & price volatility



Future demand? SSA, AMFm transition, GFATM NFM

Source: Artemisinin market. Jacques Pilloy Oteci/AEDES. Presentation at the Artemisinin Conference, Nairobi, Kenya, 15-16 Jan. 2013.

Donor pricing policies and practices

Examples:

- **Price negotiation** – price ceilings often based on cost-plus analysis
- **Differential pricing** – different prices offered to countries based on income level and disease burden
- **Demand consolidation/ pooled procurement** – grouping of multiple purchasers into a single purchasing unit, effort to lower prices through economies of scale
- **Advanced market commitments** – guaranteed future market volumes for a product under development

Ex 1: Impact of global strategies on donor funded ARV prices

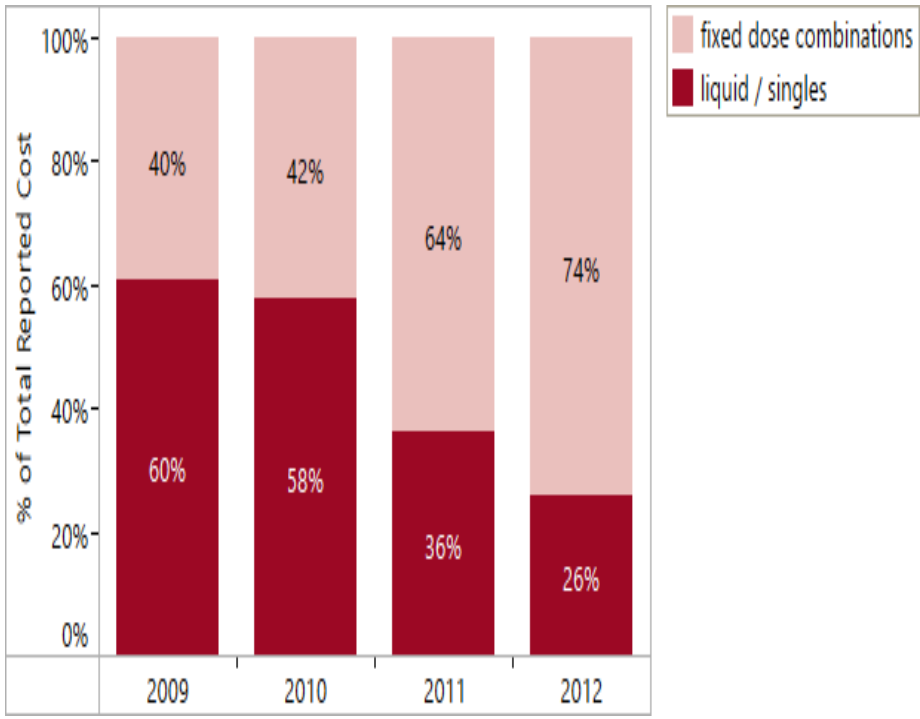
- **No association between purchase volume and price** at country level for 79% of dosage forms
  - 5 dosage forms – high volume purchases 4-21% less expensive
- **Negotiated prices were 6-36% less than non-negotiated price**, with biggest differences 1-2 years after negotiation with suppliers
- **Purchases under differential pricing schemes significantly more expensive** than non-negotiated generic prices (price differences of 23-398%)
  - Where generic competition was lacking, differentially priced brand was 73% less expensive than generic

Source: Waning B et al. Global Strategies to reduce the price of antiretroviral medicines: evidence from transactional databases. Bull World Health Organ 2009;87:520-528.

Ex 2: Demand consolidation in the paediatric ARV market

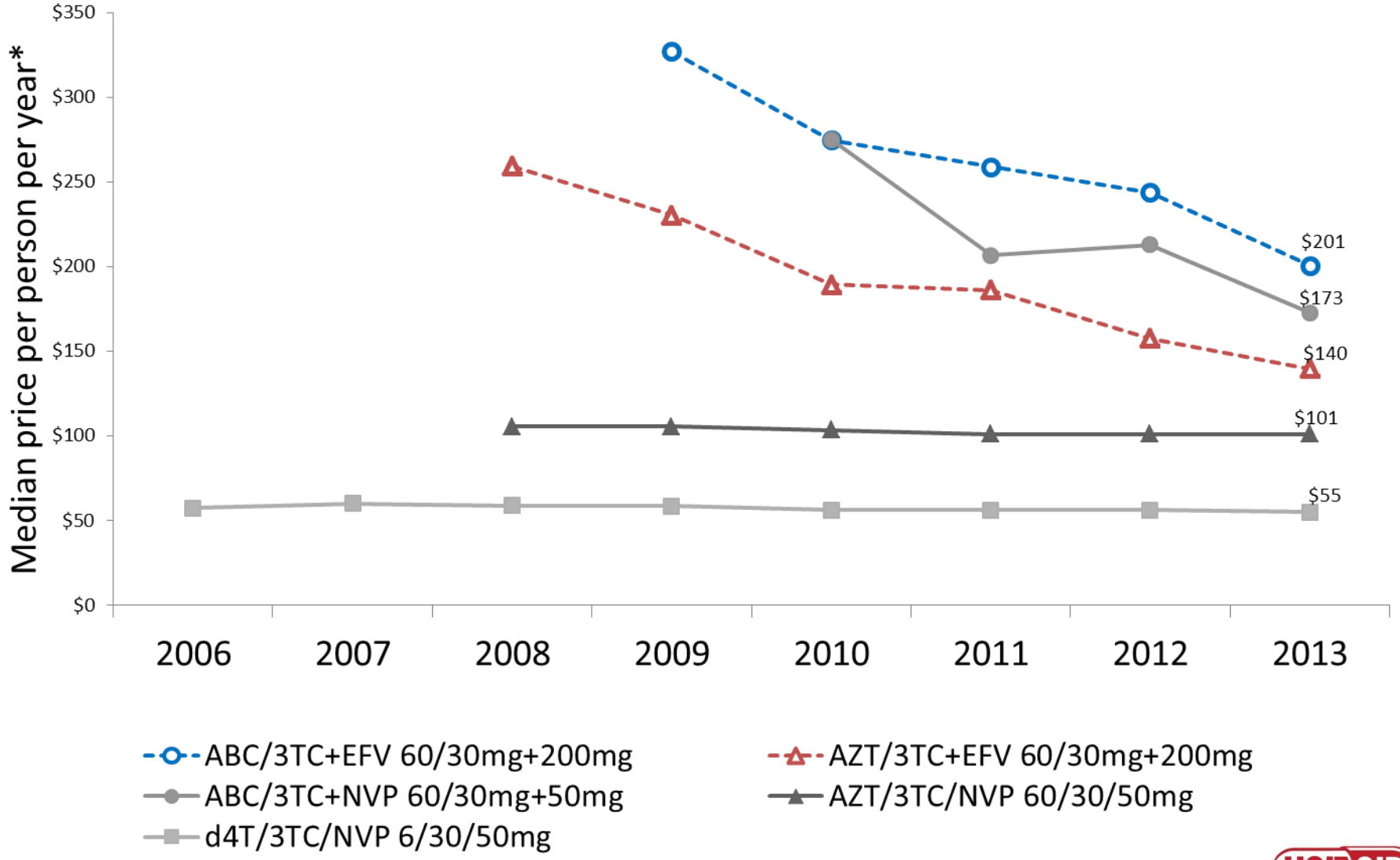
- Small, fragmented market
- Limited incentives for manufacturers to enter
- Consolidation of demand across a small number of organizations to assure minimum volumes from reliable purchasers
- Donor market increased from USD 5M in 2004 to USD 34M in 2008
- UNITAID
- UNITAID-funded procurement - nearly 2/3 of market between 2005 and 2012
- Demand aggregation around FDCs

Donor-funded pediatric market share, by value, of FDCs and single or liquid products



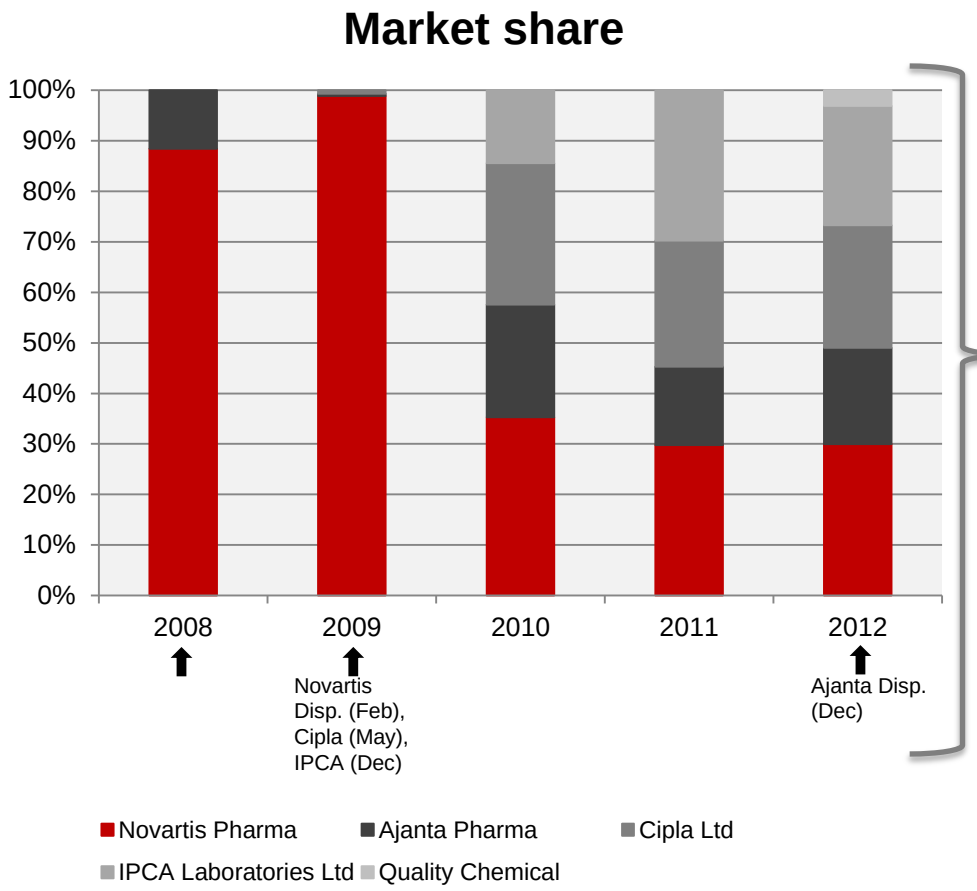
Source: UNITAID HIV Medicines Technology and Market Landscape. Geneva, March 2014.

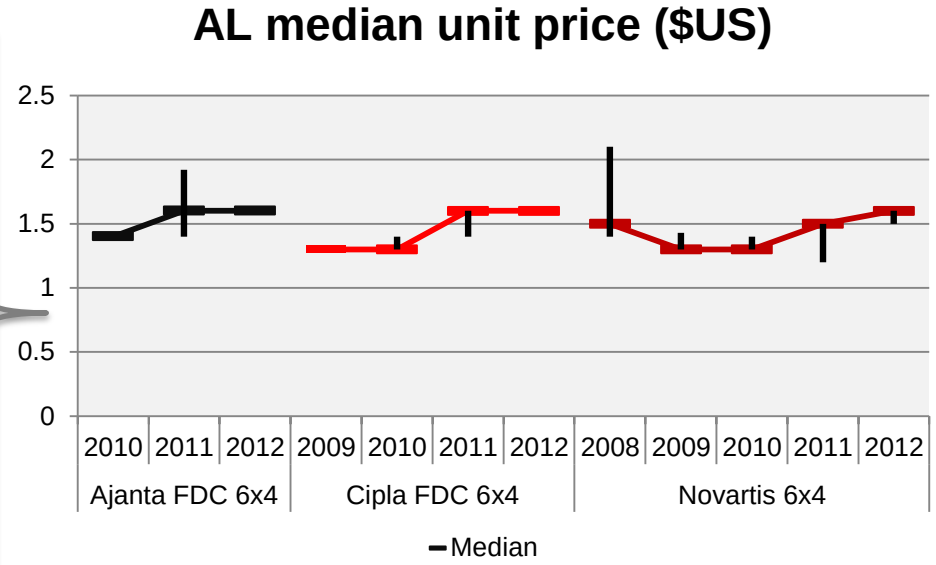
Price trends of main pediatric ART regimens



Source: UNITAID HIV Medicines Technology and Market Landscape. Geneva, March 2014.

Ex 3: Artemether-lumefantrine - increasing competition but limited impact on price





However, recent GFATM data suggest price decreases, e.g.:

Ajanta AL 6x4: Mar 2013 - $1.27/pack

Ajanta AL 6x4: Nov 2012 - $1.25/pack

Source: UNITAID Malaria Medicines Landscape. Geneva, December 2013.

National pricing policies and practices

Selected examples:

- Cost-plus pricing
- External reference pricing
- Value-based pricing
- Regulation of wholesale/retail margins

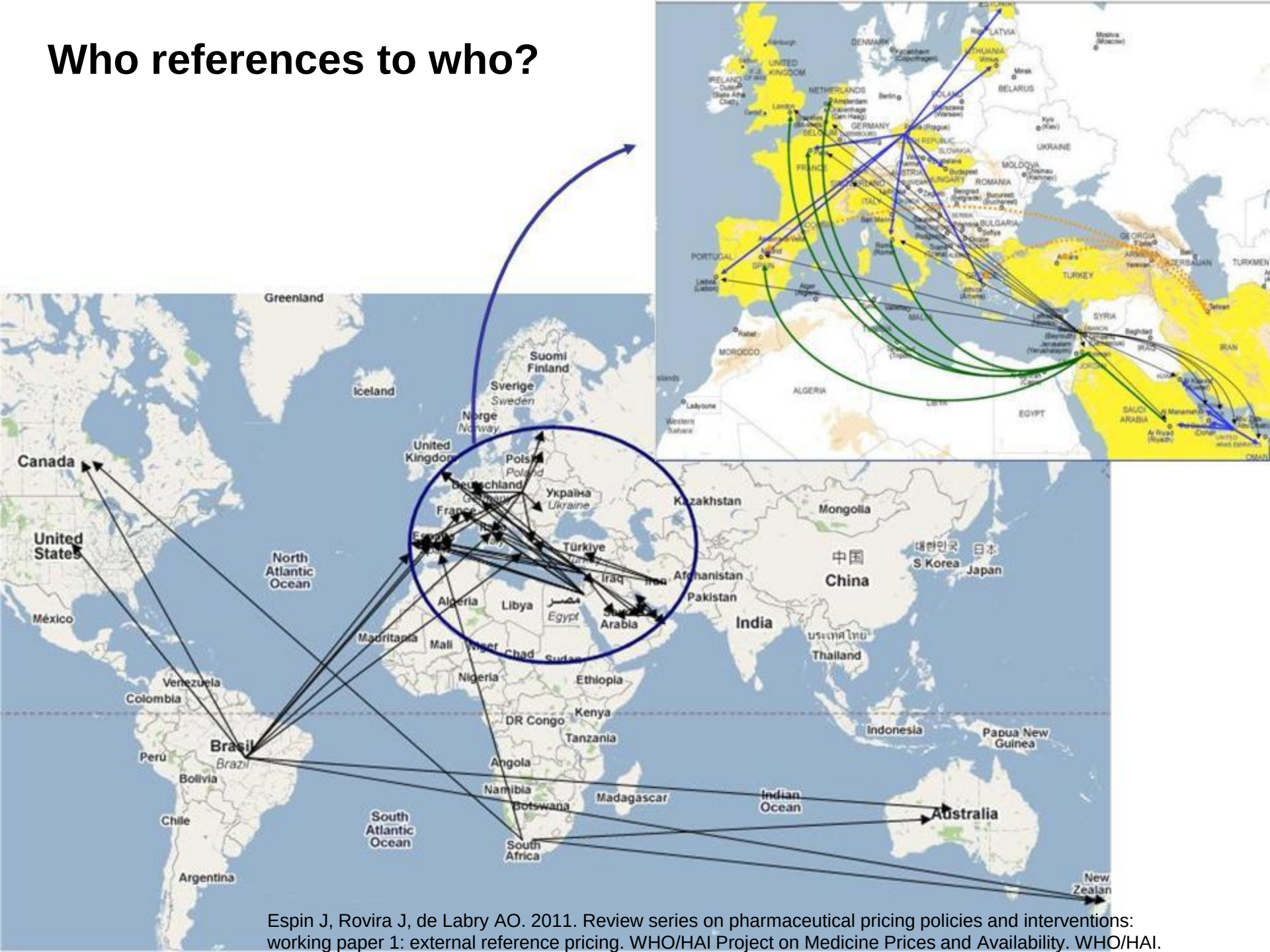
Cost-plus price setting

- Price based on cost of production plus a margin to cover distribution costs
- At national level, used primarily for domestic pharmaceutical industry; not easy to get information for imported medicines
- Challenges:
  - Information: revelation of true information on cost?
  - Various method of costing (e.g., indirect cost allocation)
  - In case of fixed percentage margin, manufacturers/distributors prefer high cost medicines
  - Limits incentives to improve production efficiency
  - Requires regular review to account for changes

External reference pricing

- Also called international reference pricing, external price benchmarking
- Uses the prices of medicines in other countries to set or negotiate the price of medicines in a country
- Highly dependant on choice of reference countries
- Average (simple or weighted) of prices or lowest price in the countries of comparison
- Weak theoretical foundation: simply assuming that price in other countries are optimal or we do not want to pay more than other countries do

Who references to who?



Espin J, Rovira J, de Labry AO. 2011. Review series on pharmaceutical pricing policies and interventions: working paper 1: external reference pricing. WHO/HAI Project on Medicine Prices and Availability. WHO/HAI.

Value-based pricing

- Benefit package and/or price decisions based on cost-effectiveness of new drugs over those currently available
- Increasing interest in HTA worldwide e.g. Latin America collaborating on a HTA regional network
- Different models with different resource implications
- **Challenges**
  - Requires more technical expertise than other methods
  - Generalizability of (clinical) study results from other countries
  - Equity consideration: application of the same ICER threshold to different population groups? e.g.: Small benefits to a large number of patients with minor illnesses or big benefits to a small number of patients with severe illnesses?

National pricing policies – general considerations

- Most HICs use a mix of approaches, limited evidence of impact
- All policies have pros and cons, must watch for unintended effects
- Implementation and enforcement a significant challenge
- Generally preferable to regulate whole market vs. subset, to avoid unnecessary and potentially inappropriate drug switching
- Choice of strategy depends on resource availability, enforcement capacity, pharmaceutical market structure, health and industrial policies, sector, type of medicine, etc.
- Monitoring medicine prices & sales is essential to evaluate effects of pricing regulations, both intended and unintended

Other influencers

- risk / reliability of payment
- lead time between when an order is placed and when it is needed (linked to clarity/opacity of forecasts)
- quality requirements
- IP regulation
- purchase incentives such as bundling, rebates and discounts

Conclusions

- Wide range of complex factors influencing price, difficult to disentangle impact
- Choice of pricing strategy is very context- and product-specific, no general rules about which approach works best
- Must consider impact of pricing strategies on other market characteristics, in the short and longer term
- Market monitoring is needed to be able to adapt to changes

Thank you