Value is in the eye of the beholder: how can HTA help achieve better prices?

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So, what is the right price?

Or…why, in healthcare marketplaces, Value Based Pricing is not a tautology

When a payer decides about the price…

Ask family and friends for help

- Paying out of pocket the norm in most LMICs
- 150m people fall into poverty from healthcare (mostly product) costs

A philanthropist or development partner steps in

- Bill Gates' Willingness to Pay defined the price ceiling for the LTD deal
- For PCV AMC price ceiling decided after negotiation based on cost plus R&D costs (unclear what latter was based on)

Call a friend

- In the Philippines, government officials call contacts to ask about product retail price levels before establishing ceiling prices in government contracts

See what other countries (say they) are doing

- Colombia references own prices against a basket of public prices from countries from around the world

Run an auction

- In Russia, competitive bidding drives prices down for government contracts

Encourage competition and run market surveys

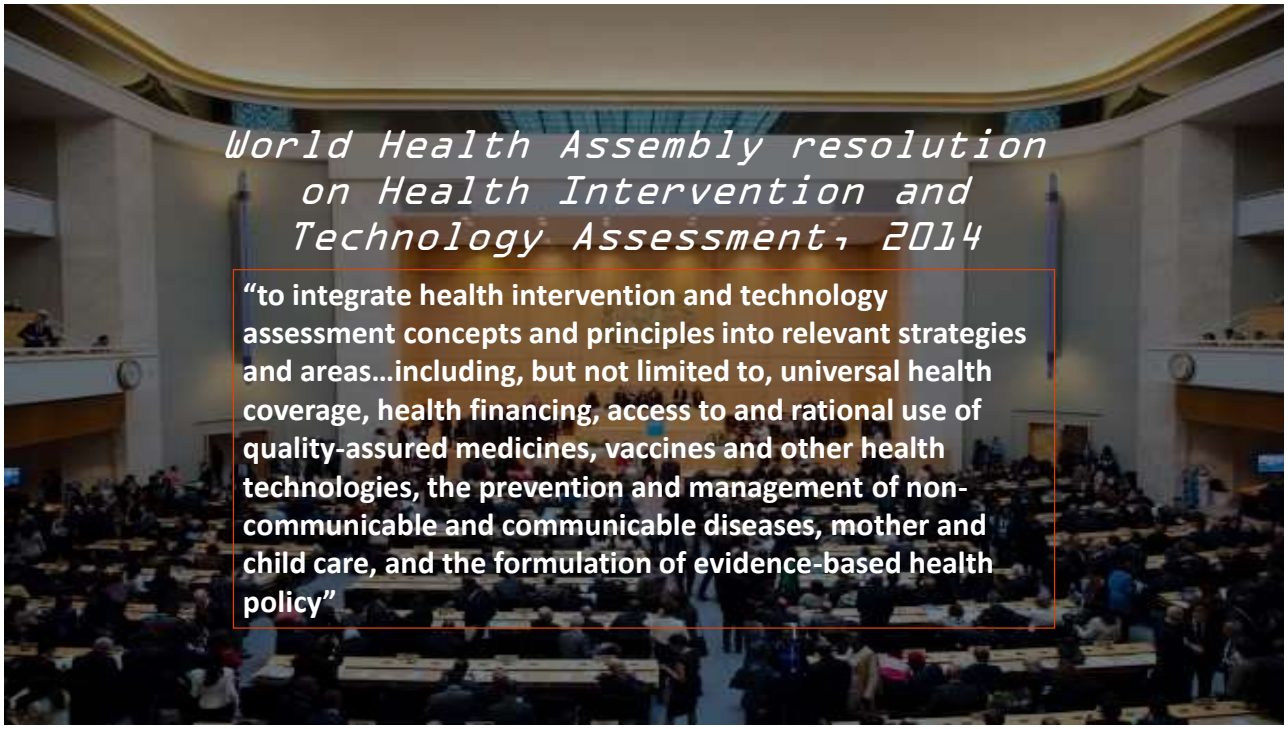
- In the English NHS, retail prices are averaged out after market surveys
- In Japan there is a two yearly price survey for driving prices to lowest quintile

For single source products, do a Health Technology Assessment

- In the English NHS, and Thai UC scheme NICE and HITAP, respectively, do HTAs of affordable price premium given incremental benefit + available budget
- In New Zealand, PHARMAC uses a combination of HTA and tenders to reduce public prices

Health Technology Assessment

Taking off as a means of assessing value from the payer's and the population's perspective



World Health Assembly resolution on Health Intervention and Technology Assessment, 2014

"to integrate health intervention and technology assessment concepts and principles into relevant strategies and areas…including, but not limited to, universal health coverage, health financing, access to and rational use of quality-assured medicines, vaccines and other health technologies, the prevention and management of non-communicable and communicable diseases, mother and child care, and the formulation of evidence-based health policy"

World Health Organization
Regional Office for South-East Asia

Center for Global Development

REGIONAL C

REGIONAL COMMITTEE — Provisional Agenda item 8.3

Seventieth Session
Maldives
6–10 September 2017

SEA/RC70/9

21 August 2017

Access to medicines

"Evidence helps when **negotiating price and rules on reimbursement**, which in turn affect access. Health technology assessment is a routine part of the decision-making process for adding medicines to the national benefit package in Thailand, and other countries such as Indonesia and India are introducing this approach."

HTA is becoming a major tool for priority setting and price negotiations for national governments in emerging markets...

National Health Insurance Act of 2013, Section 11- Excluded Personal Health Services
Philippines: "The Corporation shall not cover expenses for health services which the Corporation and the DOH consider cost-ineffective through health technology assessment…"

national treasury
Department:
National Treasury
REPUBLIC OF SOUTH AFRICA

Indonesia: Minister of Health's Decree No. 71 /2013 Article 34
(5)Health Technology Assessment Committee **provide policy recommendation to the Minister on the feasibility of the health service** as referred to in paragraph (4) **to be included as benefit package of National Health Insurance**

Service coverage (5.3):
South Africa "Detailed treatment guidelines, based on available evidence about cost-effective interventions, will be used to guide the delivery of comprehensive health entitlements. Treatment guidelines will be based on evidence regarding the most cost-effective interventions."
HTA unit budgeted @R368m in 2018 budget by country's Treasury

"the **India** Medical Technology Assessment Board for evaluation and appropriateness and cost effectiveness of the available and new Health Technologies in India…**standardized cost effective interventions that will reduce the cost and variations in care, expenditure on medical equipment…overall cost of treatment, reduction in out of pocket expenditure of patients…**'. Ref: MTAB, Ministry of Health & Family Welfare, Government of India

国家卫生计生委卫生发展研究中心
China National Health Development Research Center

October 2018: China legislates HTA and launches National Centre of Medicine and Health Technology Assessment

4. Knowledge translation and Decision Making

- Pricing Negotiation for 18 Generic Cancer Drug
- Updating National Essential Drug List
- Comprehensive Drug Assessment
- Reviewing Public Health Service Package
- Setting Up the List of Appropriate Technologies in County Level Hospitals

"We have fully utilized HTA...to balance financially sustainability and access to new cancer drugs...up to 30% price reductions compared to nearby countries"
Director of Chinese Medical Insurance Bureau, Beijing, October 2018

…in low and middle income markets…
(cont.)

5.14.3. Policy Statements
"The government will improve adequate knowledge in health technology assessment (HTA) for evidence based selection of quality and safe technology as well as realizing value for money."
National Health Policy 2017

- "Define an evidence-based benefit package for Kenyans under Universal Health Coverage: (A list of services that should be prioritized and made available taking into account the cost effectiveness, impact on financial protection, and equity in access across the population).
- Define a framework for institutionalization of Health Technology Assessment (HTA)."

Cabinet Secretary, Government Gazette, July 2018

TANZANIA HEALTH TECHNOLOGY ASSESSMENT COMMITTEE (THTAC)
The aim of the Tanzanian Health Technology Assessment Committee (THTAC) is to make evidence-informed recommendations to the MOHCDGEC based on the internationally recognized HTA framework. The committee will make recommendations about the public provision of health technologies that will contribute to maintaining and improving the health and well-being of Tanzanians, provide value for money and lead to the ultimate goal of Universal Health Care."
Committee Chaired by CMO and reports to Secretary, ToRs, 2018

- "MOH should develop a transition plan to ensure sustainable financing and operational management of the supply chain to transition to a government led supply chain system
- MOH should establish a National Pricing Committee for Medicines
- MOH should institutionalise Health Technology Assessment to provide technical advice to the NPC"

…and in high income economies in the EU…
(cont.)

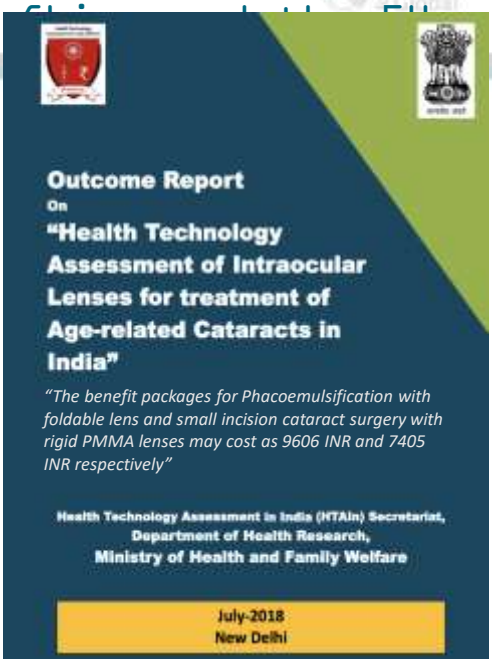
"The outcome of HTA is used to inform decisions concerning the allocation of budgetary resources in the field of health, for example, in relation to establishing the pricing or reimbursement levels of health technologies. HTA can therefore assist Member States in creating and maintaining sustainable healthcare systems and to stimulate innovation that delivers better outcomes for patients"
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on health technology assessment and amending Directive 2011/24/EU

…who use HTA to decide listing and pricing of new technologies as in India, [illegible]

Table 1. Summary of European Collaborations in Procurement of Health Innovations

Alliance	Member Countries	Initiation Date	Areas of cooperation
Valletta Declaration*	Malta, Cyprus, Greece, Italy, Spain, Portugal, Slovenia, Croatia, Ireland, Romania	May 2017	Information sharing on prices and markets, joint negotiation for purchasing to ensure affordability
Central Eastern European and South Eastern European Countries Initiative	Romania, Bulgaria, Croatia, Latvia, Poland, Serbia, Slovakia, Slovenia, Republic of Moldova, FYR Macedonia	November 2016	Price negotiation
Southerna European Initiative	Greece, Bulgaria, Spain, Cyprus, Malta, Italy, Portugal	June 2016	Information sharing on prices and markets, and collaboration on R&D
Declaration of Sofia	Bulgaria, Croatia, Estonia, Hungary, Latvia, FYR Macedonia, Romania, Serbia, Slovakia, Slovenia	June 2016	Information sharing on prices and markets, with potential for joint purchasing in the future
Nordic Pharmaceuticals Forum	Denmark, Iceland, Norway, Sweden	June 2015	Horizon scanning, information sharing on prices and markets
Romanian and Bulgarian Initiative	Romania, Bulgaria	June 2015	Joint negotiations in purchasing to get lower prices for pharmaceuticals and cross-border exchange of medicines in short supply to ensure continuity of access
Benelux Initiative on Pharmaceutical Policy	Belgium, Netherlands, Luxembourg, Austria, Ireland**	April 2016	HTA, horizon scanning, information sharing on prices and markets, joint negotiation for purchasing to ensure affordability
Baltic Partnership Agreement	Latvia, Lithuania, Estonia	May 2012	Centralized joint purchasing (tenders, negotiation, payment and distribution) to reduce expenditure and ensure continuity of access

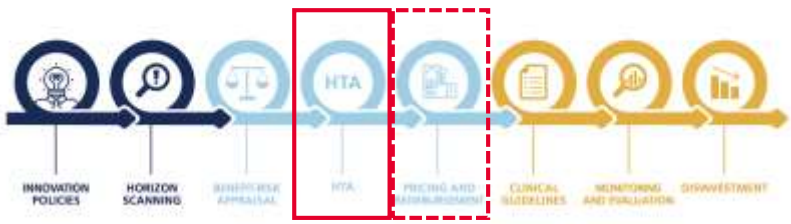
* Malta approved, 2017, 2018); ** Ireland recently joined (An Roinn Sláinte, 2018; Benelux, 2018a)



Published outcomes

Branded Name	Company[2]	Therapeutic Area	Year	HTA Type
Lojuxta	Aegerion	Hyper-cholesterolemia	2015	Belgium re-used Ducth HTA work
Orkambi	Vertex	Cystic fibrosis	2016	First submission – Joint HTA (Belgium and Netherlands); external referee (Dutch Zorginstituut); Luxembourg used final report
Praluent	Sanofi	Dyslipidemias	2016	External referee (Dutch Zorginstituut for Belgium)
Orkambi	Vertex	Cystic fibrosis	2017	Second submission - Joint HTA (Belgium Netherlands); external referee (Dutch Zorginstituut); final report sent to Luxembourg and Austria
Vyndaqel	Pfizer	Amyloidosis	2017	External referee (Dutch Zorginstituut for Belgium); Luxembourg used final report
Ocaliva	Intercept	Primary biliary cholangitis	2018	Joint HTA (Belgium and Netherlands)
Spinraza	Biogen	Spinal Muscular Atrophy	2018	Joint HTA (Belgium and Netherlands)[3]

United Kingdom). Of the 45 countries surveyed, 34 have at least one HTA agency in place, primarily in the public sector."



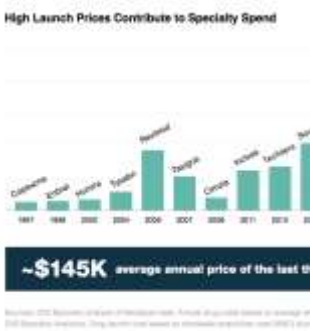
http://www.euro.who.int/__data/assets/pdf_file/0011/376625/pharmaceutical-reimbursement-eng.pdf?ua=1

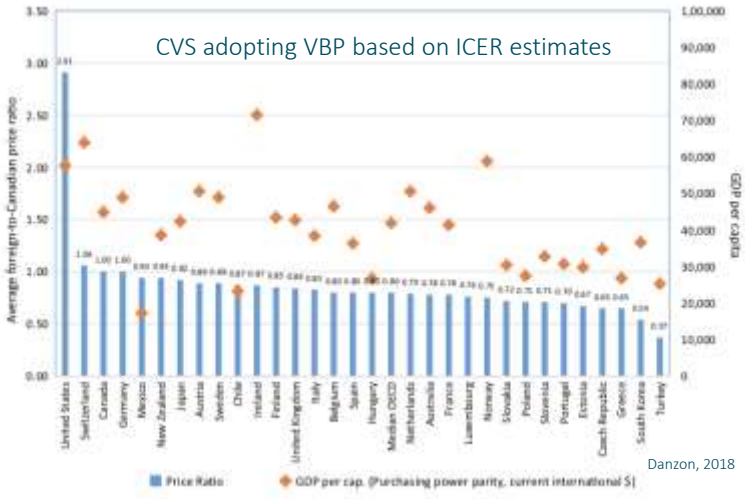
can make **private** markets work better

"Standards of care, evidence-based treatment protocols and processes for conducting [HTA] to assess the impact, efficacy and costs of medical technology, medicines and devices relative to clinical outcomes must be developed. Findings... should be published to **stimulate competition** in the market, to **mitigate information asymmetry**, and to **inform decisions about strategic purchasing by the public and private sectors**."

"The current government system of JKN does not link the **clinical and economic assessment of drugs for price negotiation and tariff setting**, which can lead to cost-effective drugs not being available to providers at an affordable rate (or conversely, the reimbursement rate not accounting for the market price of this drug)... The price-quantity negotiation process should... reflect the HTAs/Economic Assessment results more broadly beyond certain high-price but low-volume top-up drugs, reflecting the affordability and cost-effectiveness thresholds that Indonesia wants to set..."

And even in the USA private insurers adopt HTA…





Danzon, 2018

https://cvshealth.com/sites/default/files/cvs-health-current-and-new-approaches-to-making-drugs-more-affordable.pdf

Potential (BIG) problems with VBP

Getting the threshold wrong

Using the wrong (bad value) comparators

Not dealing with non marginal effects (ie high budget impact)

Introducing exceptions.,..and more exceptions…and more exceptions…

(cancer, children, rarity, domestic industry…)

Not weighing non-CEA considerations (equity, age…) for displaced techs

Including wide productivity benefits when paying out of health budget

But what is the alternative…? Cost-plus pricing?

How can the cost of development of each "innovative" product be meaningfully established? *and then…*

Who decides what is a 'fair' margin? Or how the "surplus" is shared between seller and buyer during patent protection? *And even if "fair" is agreed by some…*

How can this be enforced in a non-unified purchaser world?*…unless patents are challenged and the current (broken) system of R&D is replaced by a state run system…but…*

Can/will national governments step in as financiers of R&D? *and finally…*

What problem are we solving for? LIMCs >90% of market by value is (or should/could be) generics

And even greater problems with "fair" pricing

Paying for inputs hence failing to drive relevant R&D	Missed chance for emerging markets successfully to signal their own priorities and drive global R&D investment to meet needs of own populations. E.g. no significant treatment option for TB and very little in pipeline
Fighting for access to things that offer clinically insignificant benefit over alternatives	Vast majority of latest cancer drugs offer minimal health benefit but lack of value assessment in the USA leads to inflated prices for US and global markets.
Confounding access in LICs and LMICs with access in HICs and MICs	Vast majority (>90%) of pharma market in LICs and LMICs is generics incl. branded generics with over 50% mark ups. The policy prescription ought to be different.
Imposing far greater informational info data and social value requirements than necessary	There is no precedent for reliably and verifiably allocating costs of production for innovative products. There is no empirical evidence of how society would like to see the surplus divided.

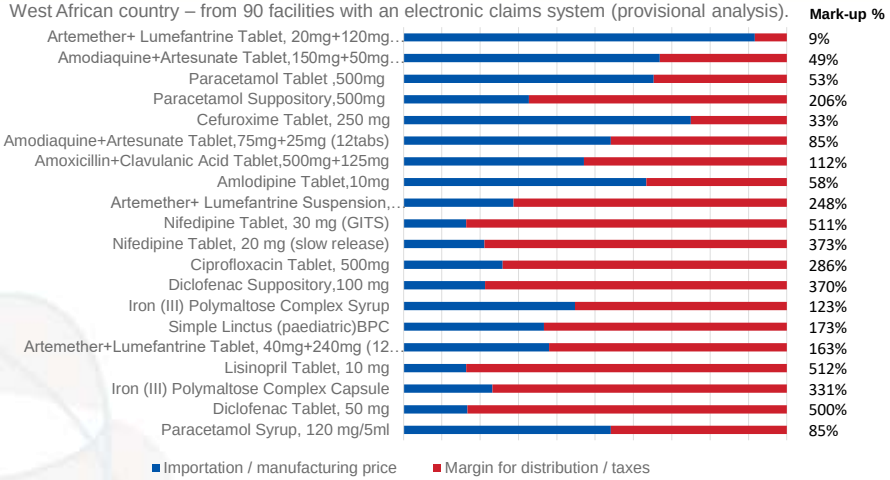
Adding a margin onto which price?

- The list price?
  - On average, HIC payers (public and private) get 50-60% off the published list price through confidential discounts in secret price negotiations.
  - Some of these get passed on to consumers and some not (e.g. PBM/private insurance controversy in the USA).

- The procurement price?
  - In LMICs, the price to patient can be up to 60-80% higher than the (public or private) procurement price (SmartChain, IMS, 2018)
  - Private monies mostly OOP makes up for 60-70% of the LMICs commodities market (CGD global health procurement WG, 2018)

Commercial margins for medicines suffer from great disparity: on paper, the price list allows an average mark-up of 111% from import or manufacture - to cover taxes and distribution to patient.

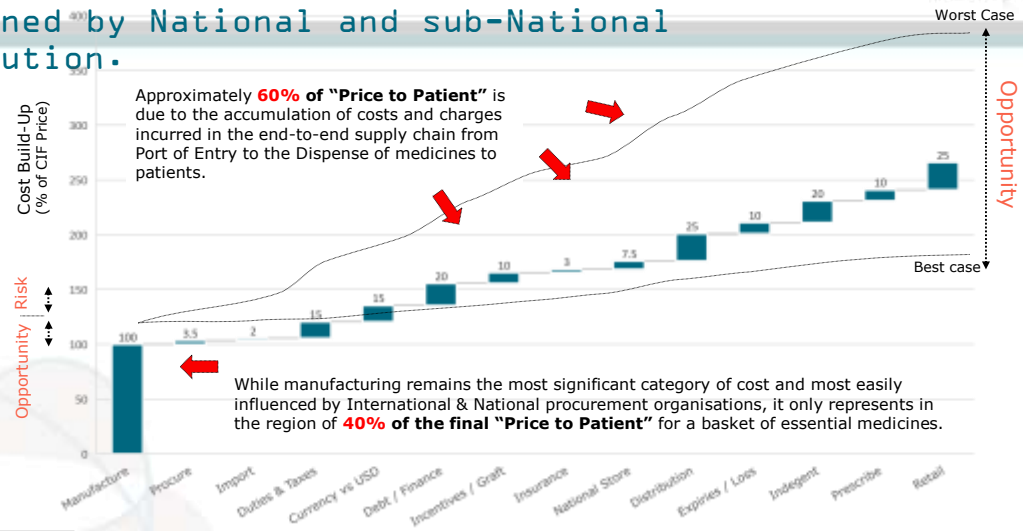
As an example: the average mark-ups for the top 20 most commonly claimed for medicines in one West African country – from 90 facilities with an electronic claims system (provisional analysis).



These price and margin disparities are echoed across many countries in Sub-Saharan Africa.

SmartChain

While procurement remains the largest cost category, 60% of the final Price to Patient is determined by National and sub-National distribution.



Categories of Cost along the End-to-End Supply Chain

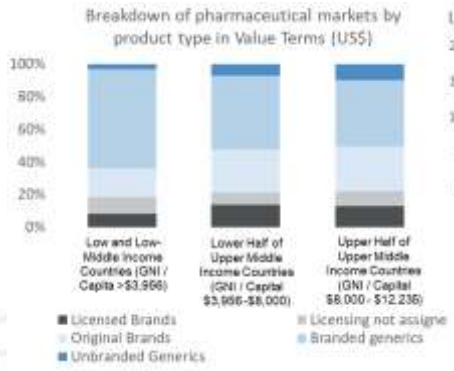
Build-up of Price to Patient for a basket of essential medicines (indicative) (CIF Price = 100%)

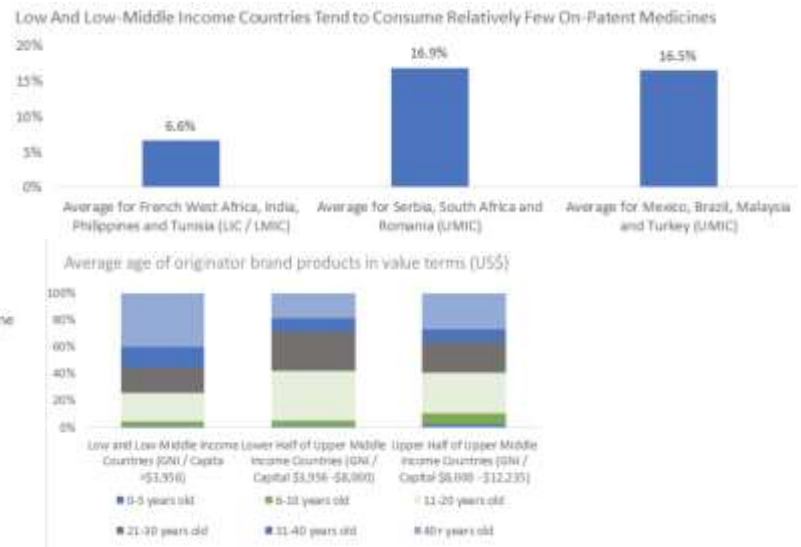
SmartChain

- development partners shaping LMIC markets. Then what?

- Dynamic efficiency
  - *Supply side*: What WTP do market shaping deals signal to multinationals in terms of price elasticity and preferred type of technology and priority disease areas?
  - *Demand side*: How affordable will innovation be as countries become payers and inherit funding decisions made by development partners and investors?
- Static efficiency
  - *Supply side*: Companies prioritise portfolio based on non-domestically articulated demand. Depending on priorities and KPIs of donor (disease, tech, subpopulation), issues of OOP, uptake and appropriate use (quality) in the system are left unaddressed
  - *Demand side*: Risk of crowding out effects if DALY impact is not netted out in estimates (e.g. see Malawi HBP work) with implications on spending, outcomes and distribution
- Institutional/capabilities gap: in context of aid transition, countries are left with major institutional weaknesses in price negotiation as market shaping happens outside government and NHI functions.
  - Gilead's Sofosbuvir in Africa: Lower price alone does not ensure access or health impact.

will cost plus pricing (ie doing away with patents) help the poor in poor countries access medicines?





Probably not…

Regulation

Domestic industrial policies

Cost of capital

corruption

Not just about IP - voluntary licensing of HepC drug results in limited access in SSA

Forex fluctuations

Transport costs

Regressive taxes (eg VAT on essential medicines)

WHO owes us all guidance on how to implement WHA 67.23 (HITA 2014) - VBP is only "dangerous: if done badly.

Guidance on country specific thresholds (great that the 1-3 GDP pc is gone, but now what?)

More context-sensitive economics in all WHO EML, STGs, and MDG targets

A Reference Case for economic analysis with a methods research agenda

A capacity building programme and dedicated WHO CCs

"The industry has been moving toward this notion of value-based pricing. This is very dangerous," Marie-Paule Kieny, WHO assistant director-general for health systems and innovation, said in an interview with *IP Watch*. "Getting out of the area of medicine, you can say if an airbag can save my life, why isn't the cost of an airbag what I would be willing to pay for my life? And that would be a lot." May 2017

Nobody said it was going to be easy…

"An appropriately implemented value based pricing scheme could offer significant benefits to the NHS in the short and longer term. There are, however, some dangers. A poorly specified pricing scheme could damage rather than improve the NHS and could undermine the evidence base for future NHS practice. The current pharmaceutical price regulation scheme is dead. The debate about what principles should guide its renegotiation, the meaning of value, and the relation between guidance, price, value, and evidence is, however, very much alive."

Claxton et al, Value based pricing for NHS drugs: an opportunity not to be missed? BMJ, 2008