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

ISPOR, November 2018

Kalipso Chalkidou, ***MD, PhD***
Professor of Global Health Practice, Imperial College London
Director, international Decision Support Initiative
Director of Global Health Policy and Senior Fellow, Center for Global Development

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

REGIONAL COMMITTEE

Seventieth Session
Maldives
6–10 September 2017

Provisional Agenda item 8.3

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."

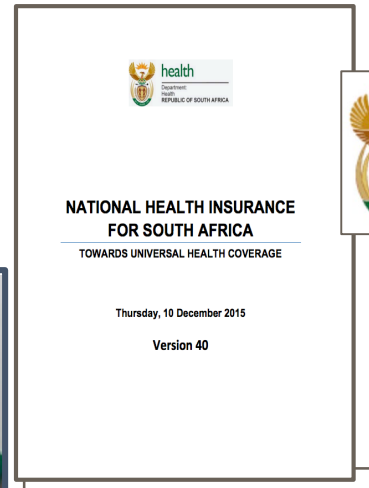
HTA is becoming a major tool for priority setting and price negotiations for national governments in emerging markets…

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…"

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**



national treasury
Department:
National Treasury
REPUBLIC OF SOUTH AFRICA

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

सत्यमेव जयते
MINISTRY OF HEALTH & FAMILY WELFARE

JANUARY, 2018
Health Technology Assessment in India - HTAIn

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

FU Wei

Director-General, Research Fellow, China National Health Development Research Center, National Health Commission

FU Wei once served as Consultant, Director and Deputy Director of the former Division of Primary Health and Maternal and Child Care, the Department of Rural Health Management, the Department of Maternal and Child Health and Community Health, and the Medical Reform Office of the Ministry of Health, as well as Deputy Director of the Department of Healthcare Reform of former National Health and Family Planning Commission of the PRC (Medical Reform Office of the State Council). Other social posts includes: Vice President of the China Health Economics Association, Chairman of the Health Expenditure and Policy Committee, Chairman of the Application Evaluation and Protection Committee of Chinese Health Information and Big Data Association, Chairman of China Health Policy and Technology Assessment Research Network Committee, and Director of the Collaborative Center for Term Classifications and Standards of the World Health Organization.

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

中华人民共和国中央人民政府
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关于发布2018年抗癌药医保准入专项谈判药品范围的通告

2018-08-17 09:25 来源：国家医疗保障局

按照国务院要求，国家医保局加快推进抗癌药医保准入专项谈判工作，组织了来自全国20个省份的70余名专家通过评审、遴选投票等环节，并经书面征求企业谈判意愿，确认12家企业的18个品种纳入本次抗癌药医保准入专项谈判范围，具体名单见附件。

附件：2018年抗癌药医保准入专项谈判药品范围

中华人民共和国国家卫生健康委员会
National Health Commission of the People's Republic of China

首页 | 机构职能 | 新闻中心 | 政务公开 | 政务服务 | 交流互动 | 专题专栏

新闻发布

国务院办公厅关于完善国家基本药物制度的意见

发布时间：2018-09-19

国办发〔2018〕88号

各省、自治区、直辖市人民政府，国务院各部委、各直属机构：

国家基本药物制度是药品供应保障体系的基础，是医疗卫生领域基本公共服务的重要内容。新一轮医改以来，国家基本药物制度的建立和实施，对健全药品供应保障体系、保障群众基本用药、减轻患者用药负担发挥了重要作用。同时，也还存在不完全适应临床基本用药需求、缺乏使用激励机制、仿制品种与原研品种质量疗效存在差距、保障供应机制不健全等问题。为贯彻落实全国卫生与健康大会、《“健康中国2030”规划纲要》和深化医药卫生体制改革的部署要求，进一步完善国家基本药物

（二）完善目录调整管理机制。优化基本药物目录遴选调整程序，综合药品临床应用实践、药品标准变化、药品新上市情况等因素，对基本药物目录定期评估、动态调整，调整周期原则上不超过3年。对新审批上市、疗效较已上市药品有显著改善且价格合理的药品，可适时启动调入程序。坚持调入和调出并重，优先调入有效性和安全性证据明确、成本效益比显著的药品品种；重点调出已退市的，发生严重不良反应较多、经评估不宜再作为基本药物的，以及有风险效益比或成本效益比更优的品种替代的药品。原则上各地不增补药品，少数民族地区可增补少量民族药。

2018年全国药政工作会在京召开 明确加快短缺药品供应保障体系建设等7项重点

发布时间：2018-10-15

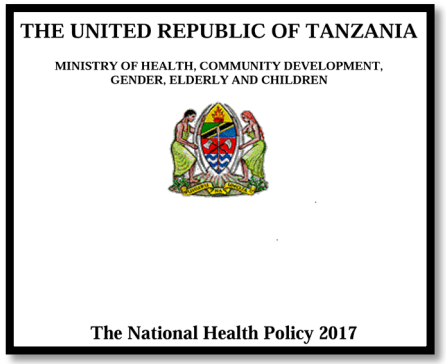
10月15日，2018年全国药政工作会议在京召开。明确近期我国药政工作将着力围绕加快短缺药品供应保障体系建设、全面实施国家基本药物制度新政策、全面落实药品采购“两票制”、提高药品供应保障能力、开展药品临床综合评价、推进国家药物政策体系和协调机制建设等7个方面重点展开。

...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

REPUBLIC OF KENYA
Ministry of Health

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"

National Health Summit 2018 - plan

Ministry of Health
Ghana

2018 Aide Memoire

Message from the Hon. Minister of State (MoHFW)

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

अनुप्रिया पटेल
Anupriya Patel

सत्यमेव जयते

I/315-3/69/2018
स्वास्थ्य एवं परिवार कल्याण राज्य मंत्री
भारत सरकार
MINISTER OF STATE FOR
HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA

MESSAGE

Health Technology Assessment (HTA) is a form of policy research that examines short- and long-term consequences of the application of a health-care technology. Prime objective of HTA is to ensure value for money to the patients, efficient utilization of the resources and ensure that the actual benefit of innovations reaches to the patients. HTA can solve numerous medical queries and problems for example cardiovascular problems can be resolved by various techniques like reduction of stress at workplace, cessation of smoking or heart by-pass surgeries.

Recognizing the importance of HTA in health services design, management, and delivery of health system, the Government of India has established the Health Technology Assessment in India (HTAIN) with a view to providing the maximum utilization of health care benefits to people.

Our achievements in various fields like **life expectancy, infant & maternal mortality rate, accessibility of healthcare services in rural areas, intensive health campaigns, sanitation devices and increase in number of Government & private hospitals etc** are significant. Improvement in immunization coverage and literacy rate, have improved the overall health of the country. But, the factors like, less health insurance coverage, large number of population lying in the low income group and High bills of medical care for long term disease are of great concern. The majority of healthcare spending in India, is out of pocket (OOP) (82.2%), 74.7% of which is spent on medicines. Many patients in India have been forced below the poverty line due to healthcare expenditure. Set against this backdrop, only 3 – 5% of Indians are covered under any form of health insurance.

I am confident that HTAIN will be a transparent, effective and systematic and unbiased system, which will be able to accelerate the process of providing access to new research and development to the patients and lead to 100% utilization of existing resources.

(Anupriya Patel)

Stakeholders

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


EUROPEAN COMMISSION

Brussels, 31.1.2018
COM(2018) 51 final

2018/0018 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on health technology assessment and amending Directive 2011/24/EU

(Text with EEA relevance)

{SWD(2018) 41 final} - {SWD(2018) 42 final}


The BeNeLuxA Initiative aims to ensure sustainable access to innovative medicine at affordable cost for our patients.

Positive outcome of joint reimbursement negotiations on Spinraza

Beneluxa Initiative partners Belgium and the Netherlands successfully negotiated the reimbursement of Spinraza Belgium and the Netherlands have reached an agreement on the pricing of Spinraza, a drug for Spinal Muscular Atrophy (SMA). Spinraza will be reimbursed for specific...

more

Ireland joins BeNeLuxA initiative

22 June 2018 Today, the Irish Minister for Health, Simon Harris signed an Agreement with his colleagues from Belgium, The Netherlands, Luxembourg and Austria to join the Beneluxa Initiative on Pharmaceutical Policy. The ceremony took place during the Employment, Social Policy,...

General update (January 2018)

The Steering Committee of the BeNeLuxA cooperation met in Luxembourg on 18 January 2018. Experiences with joint HTA reports and joint negotiations were assessed, and the planned activities for 2018 in the areas of HTA and pricing and reimbursement were discussed. Topics included...

more

"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"

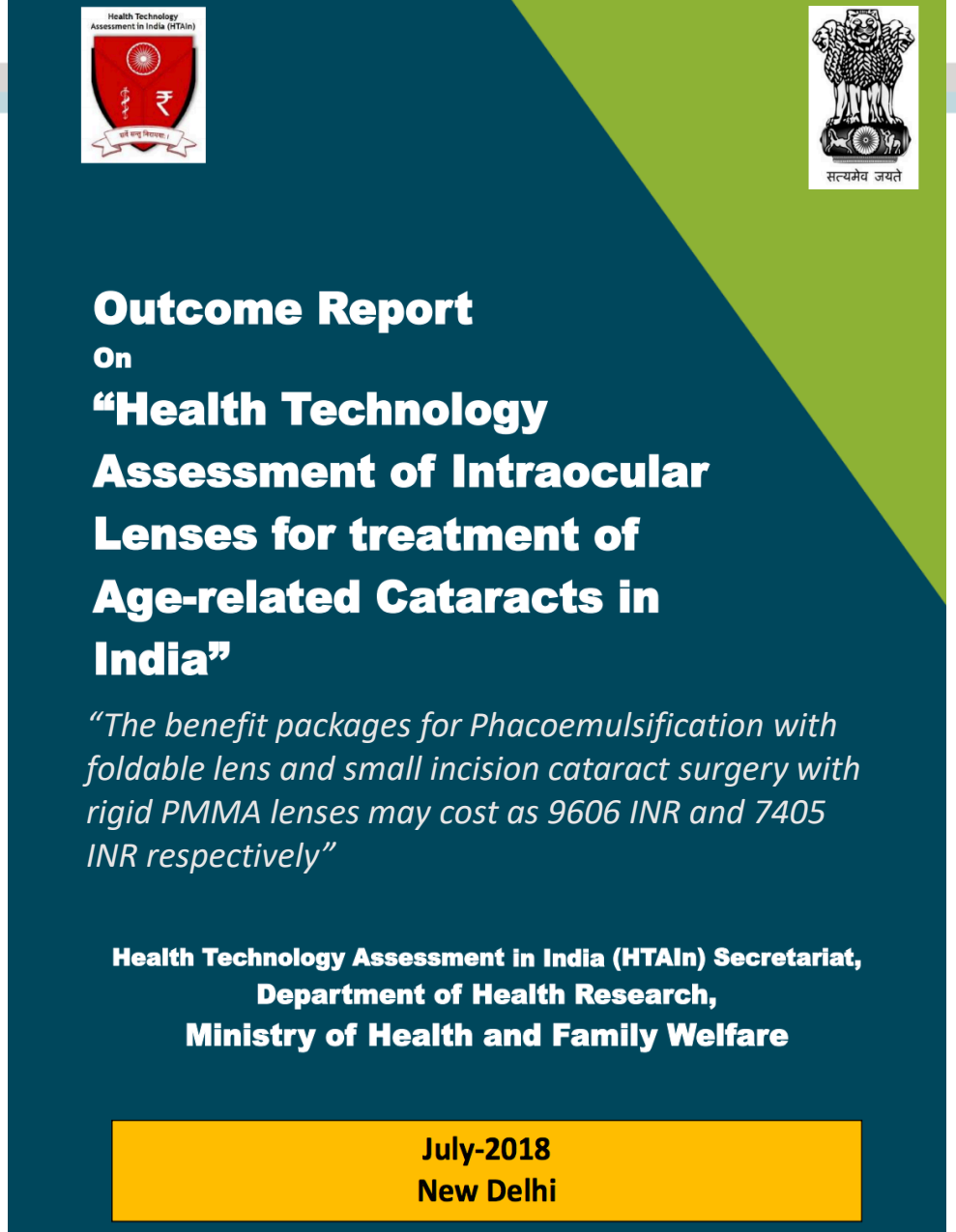
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on health technology assessment and amending Directive 2011/24/EU

…who use HTA to decide listing and pricing of new technologies as in India, China and the EU

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, Sebia, 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	Horison 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
Beneluxa Initiative on Pharmaceutical Policy	Belgium, Netherlands, Luxembourg, Austria, Ireland**	April 2015	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

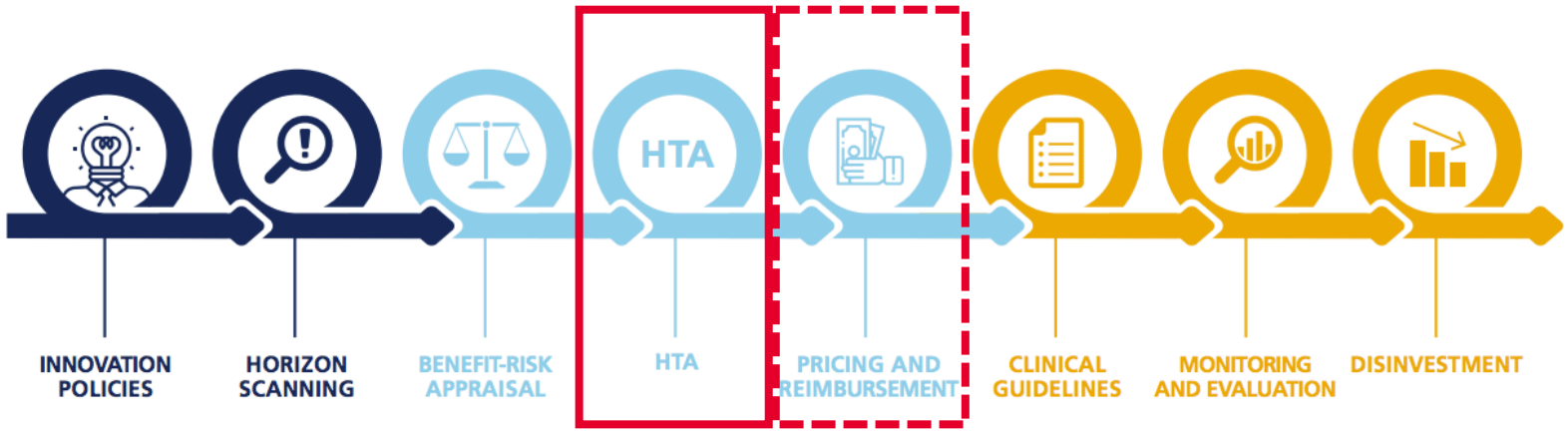
* Michalopoulos, 2017, 2018; ** Ireland recently joined (An Roinn Slainte, 2018; Beneluxa, 2018a)



Published outcomes

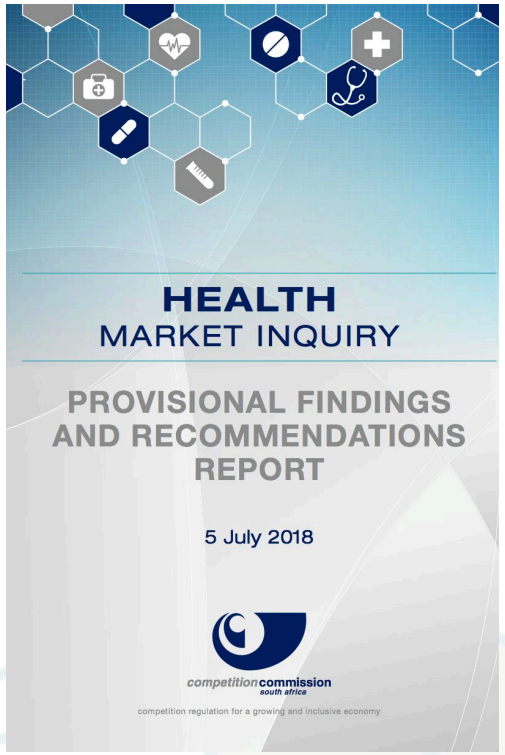
Branded Name	Company[2]	Therapeutic Area	Year	HTA Type
Lojuxta	Aegerion	Hyper-cholesterolemia	2015	Belgium re-used Ducth HTA work
Orkambi	Vertex	Cystic fibrosis	2016	First submission – Joint HTA (Belgium and Netherlands); external referee (Dutch Zorginstituut); Luxembourg used final report
Praluent	Sanofi	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]

(such as 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

Systematic assessment of value can make private markets work better

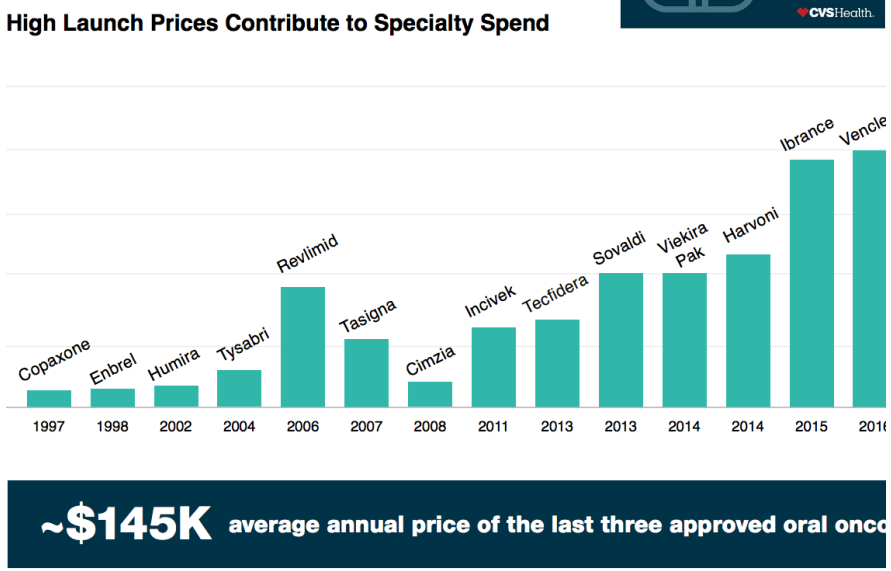


"Standards of care, evidence-based treatment protocols and processes for conducting [HTA] to assess the impact, efficacy and costs of medical technology, medicines and devices relative to clinical outcomes must be developed. Findings... should be published to **stimulate competition** in the market,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

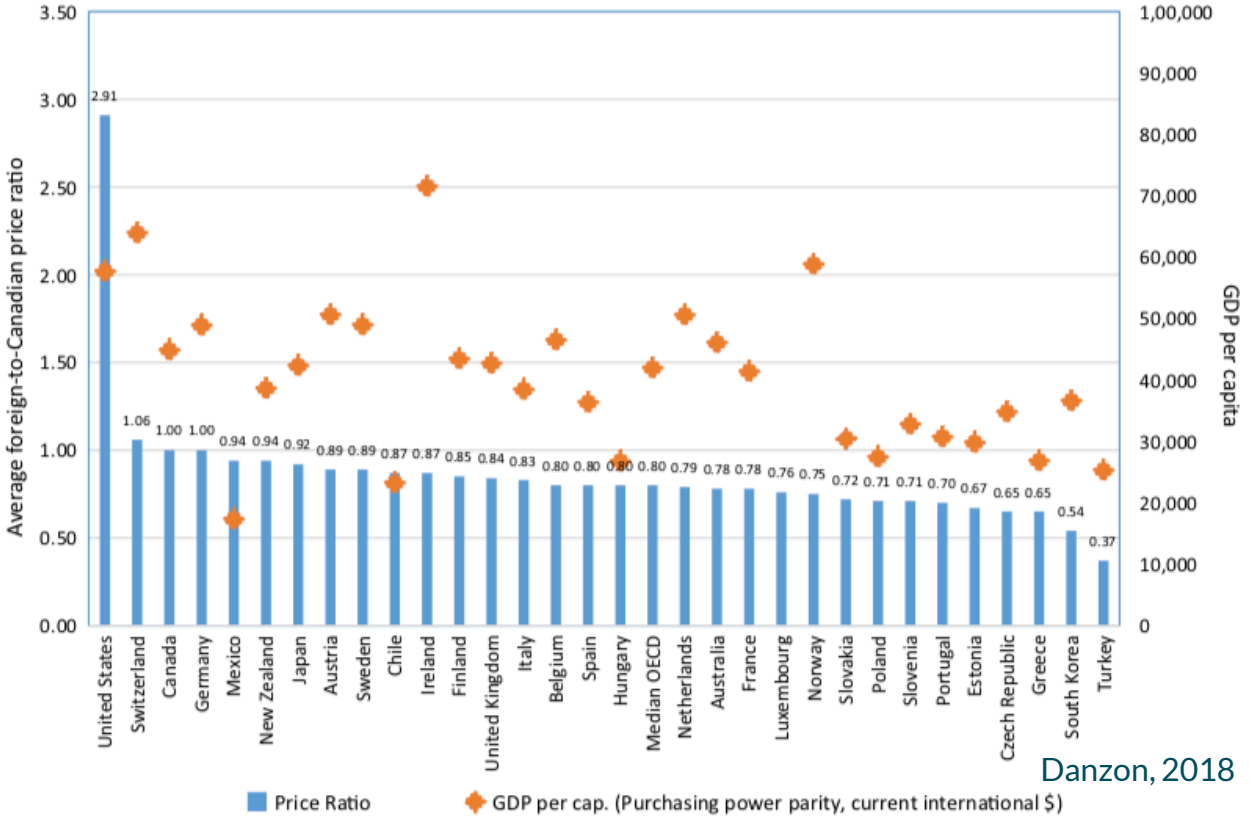
"The current government system of JKN does not link the **clinical and economic assessment of drugs for price negotiation and tariff setting**, which can lead to cost-effective drugs not being available to providers at an affordable rate (or conversely, the reimbursement rate not accounting for the market 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…

CVS adopting VBP based on ICER estimates



"CVS Caremark is initiating a program that



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

Center for Global Development

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… (orphans, children, domestic manufacturers…)

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?

Center for Global Development

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

Generics markets are very competitive and price pressures can lead to both stock outs as manufacturers exit for more profitable ventures and quality lapses as manufacturers cut corners with lower quality and/or quantity of APIs (e.g. Indonesia, GFATM procurement…)

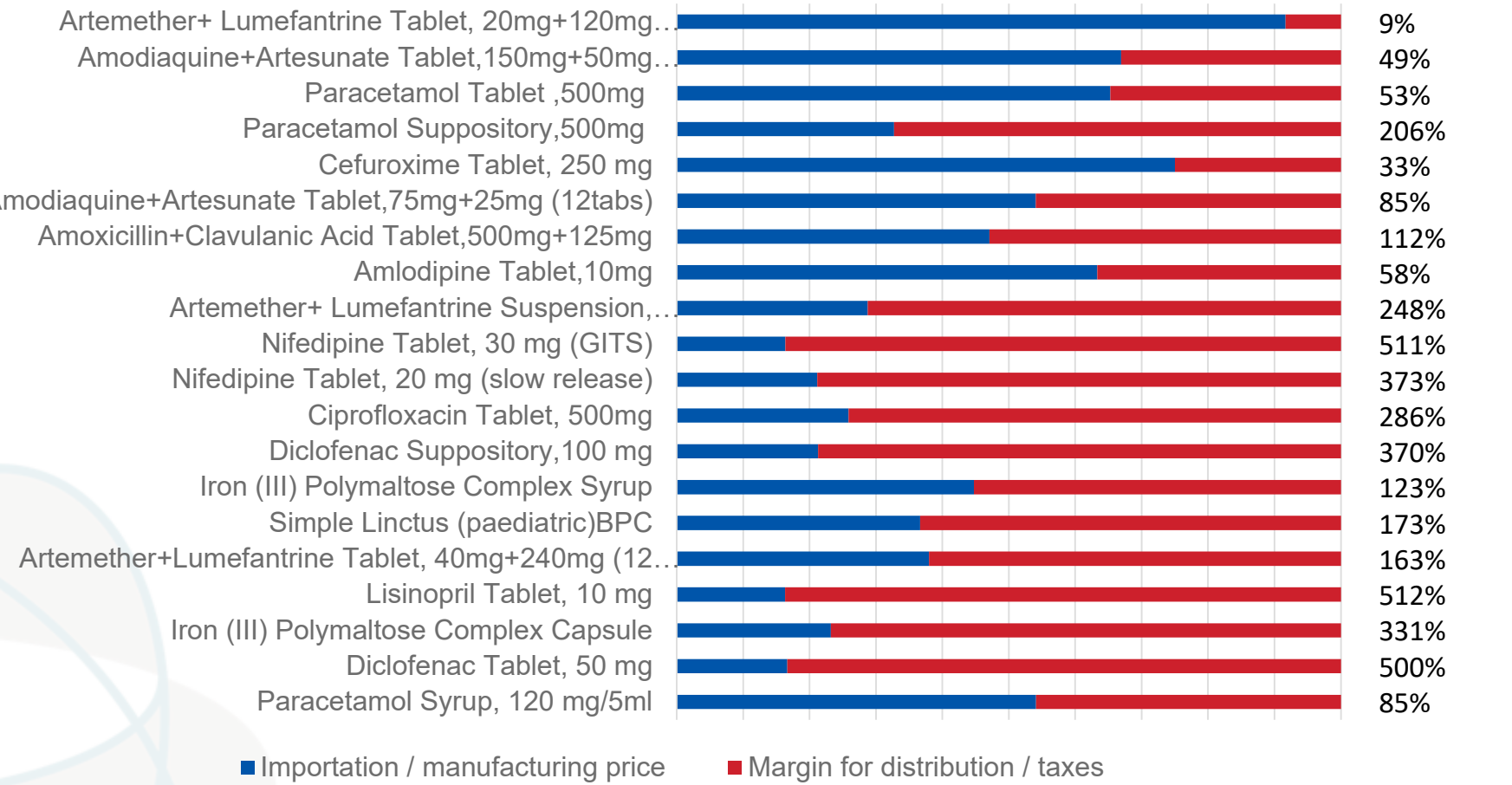
Adding a margin onto which price?

- 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)

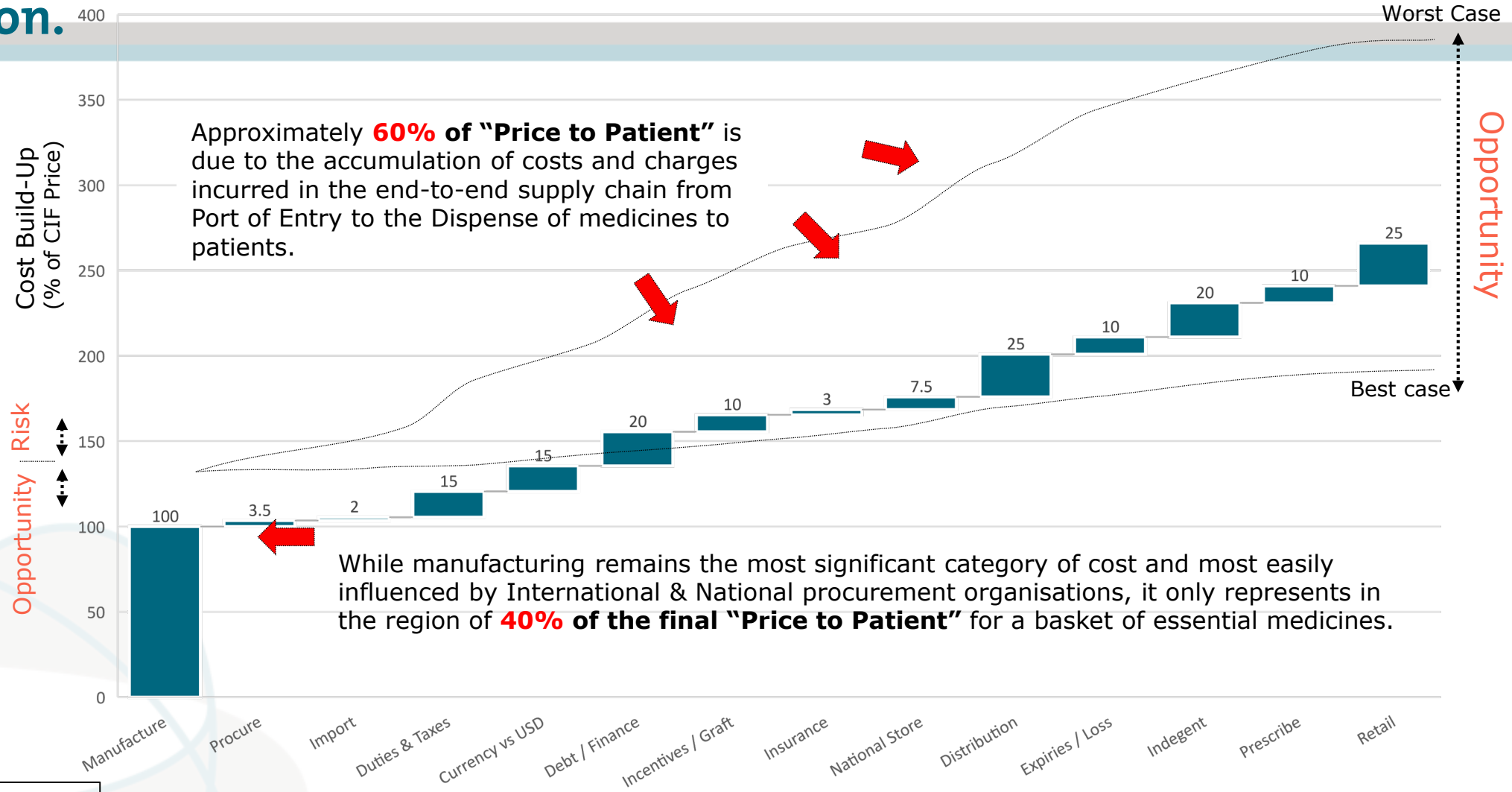
Commercial margins for medicines suffer from great disparity: on paper, the price list allows an average mark-up of 111% from import or manufacture – to cover taxes and distribution to patient.

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.

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



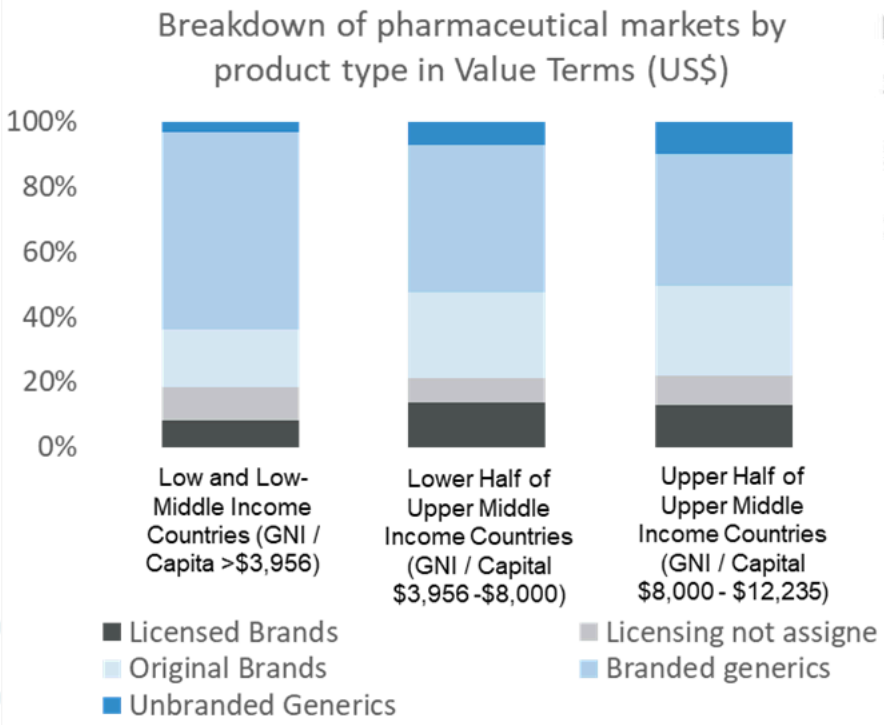
Build-up of Price to Patient for a basket of essential medicines (indicative) (CIF Price = 100%)

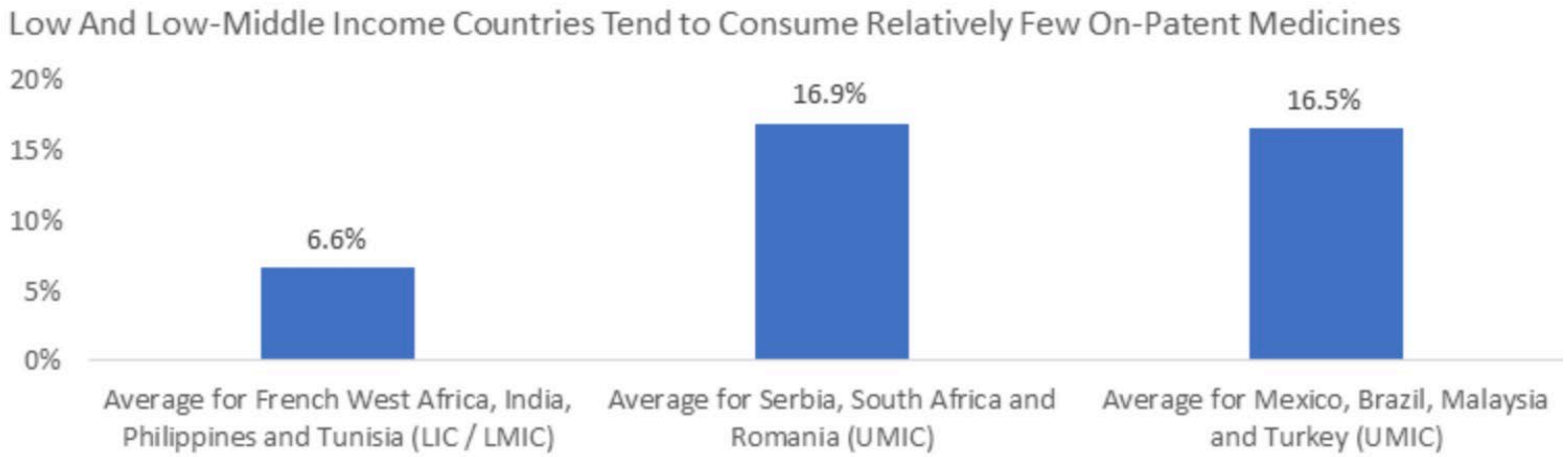
Development partners shaping LMIC markets. Then what?

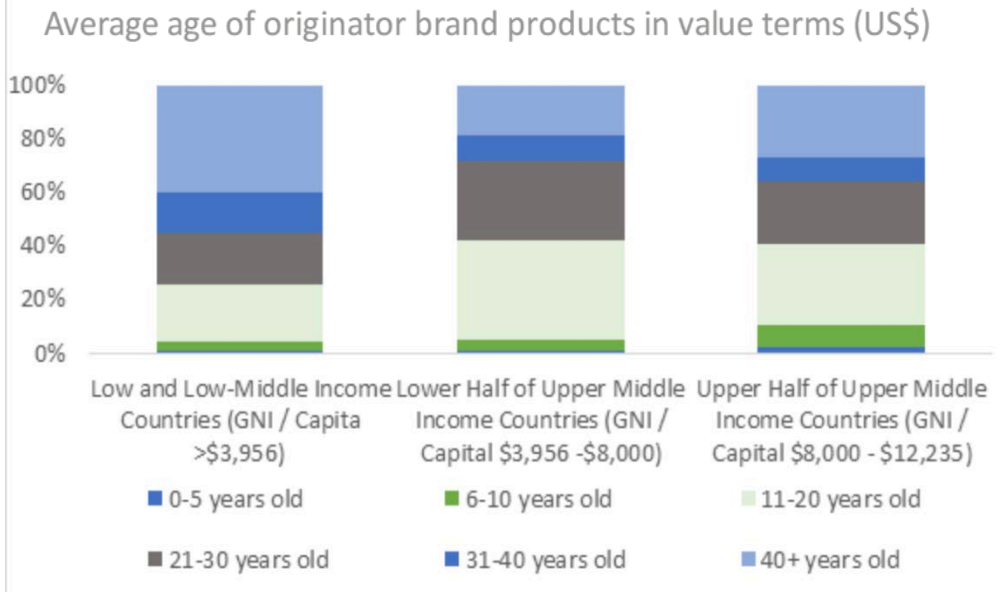
- **Dynamic efficiency**
  - *Supply side*: What WTP do market shaping deals signal to multinationals in terms of price elasticity and preferred type of technology and priority disease areas?
  - *Demand side*: How affordable will innovation be as countries become payers and inherit funding decisions 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?

Center for Global Development







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)

Snapshot

Gilead has agreements with 11 Indian companies to manufacture generic hepatitis C medicines for **101 developing countries**

There are **103 million** people living with hepatitis C in these developing countries

Gilead also offers its branded hepatitis C medicines at a **significantly reduced flat price** in these countries

Indian exports of branded generic Sofosbuvir to destination countries in number of packs - up until November 2016

Asia (Central and South)		Sub-Saharan Africa	
Myanmar	92626	Burundi	1299
Vietnam	42538	Cameroon	998
Mongolia	10412	Kenya	315
Nepal	7395	South Africa	180
Turkmenistan	2425	Ghana	46
Kyrgystan	2378		
Uzbekistan	1452		

rce: Indian export database 2014 – November 2016 – Zauba

AFRX CONSULTING

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