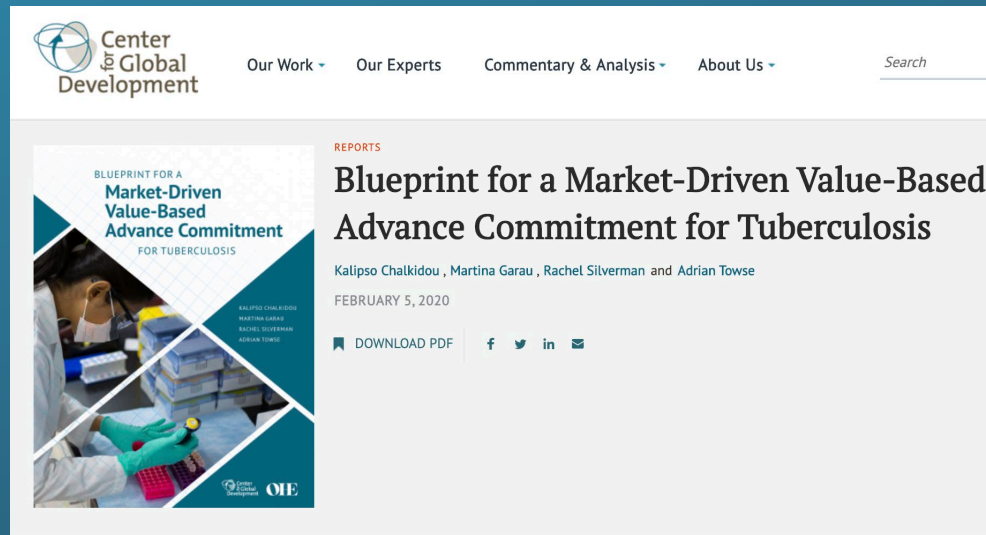


Additional slides

Based on [MVAC](#)



The screenshot shows the Center for Global Development website. The header includes the logo and navigation links: 'Our Work', 'Our Experts', 'Commentary & Analysis', and 'About Us'. A search bar is also present. The main content area features a report titled 'Blueprint for a Market-Driven Value-Based Advance Commitment for Tuberculosis' by Kalipso Chalkidou, Martina Garau, Rachel Silverman, and Adrian Towse, dated February 5, 2020. The report cover image shows a person in a lab coat and gloves working with medical supplies. The report is categorized as 'REPORTS' and includes a 'DOWNLOAD PDF' button and social media sharing icons for Facebook, Twitter, LinkedIn, and Email.

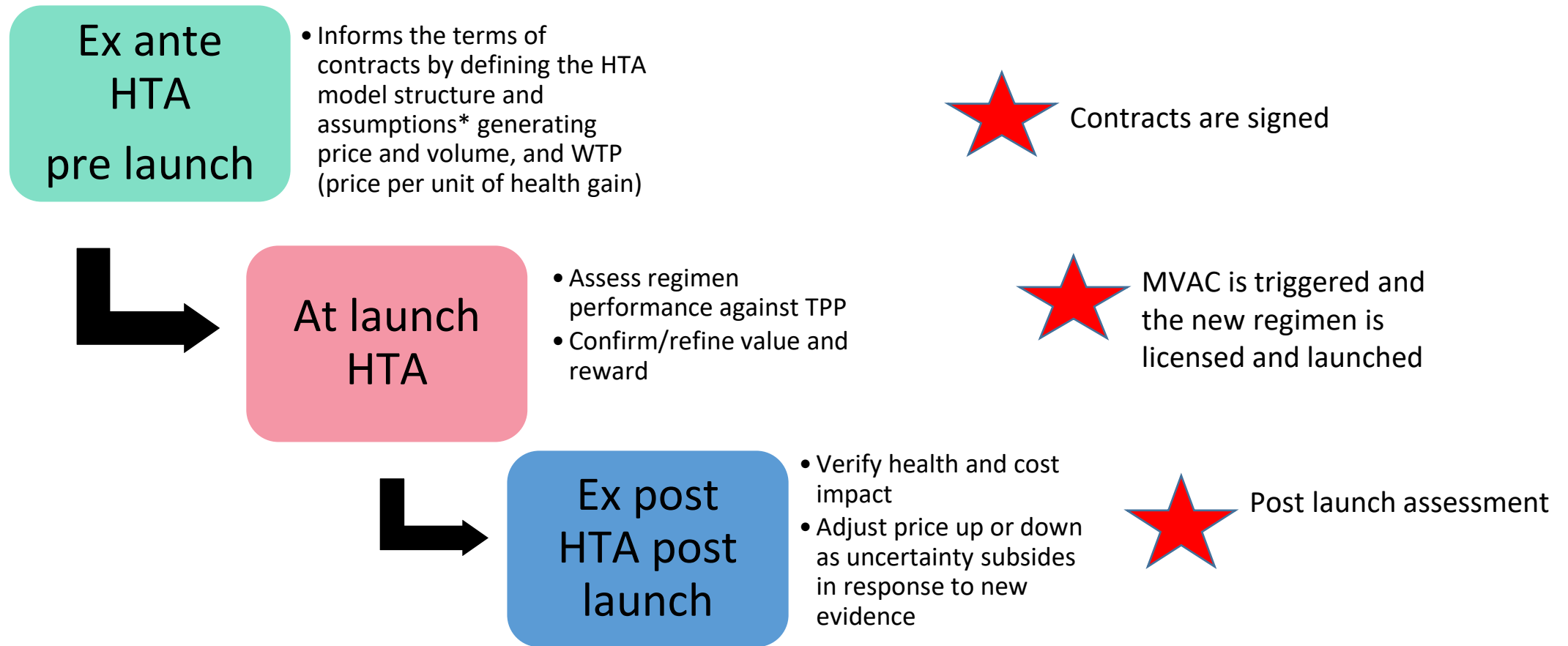
<https://www.cgdev.org/publication/blueprint-market-driven-value-based-advance-commitment-tuberculosis>



The screenshot shows a BMJ Global Health article. The header includes the 'Commentary' label. The article title is 'Market-driven, value-based, advance commitment (MVAC): accelerating the development of a pathbreaking universal drug regimen to end TB'. The authors listed are Kalipso Chalkidou, Adrian Towse, Rachel Silverman, Martina Garau, and Ganesh Ramakrishnan.

<https://gh.bmj.com/content/bmjgh/5/4/e002061.full.pdf>

Benefit-Based Commitment through HTA



Ability to Pay

From arbitrary price-setting to a realistic value-based price grounded in country budgets

Cost benefit analysis

Extrapolated VSL within a cost benefit framework.

Healthcare budget

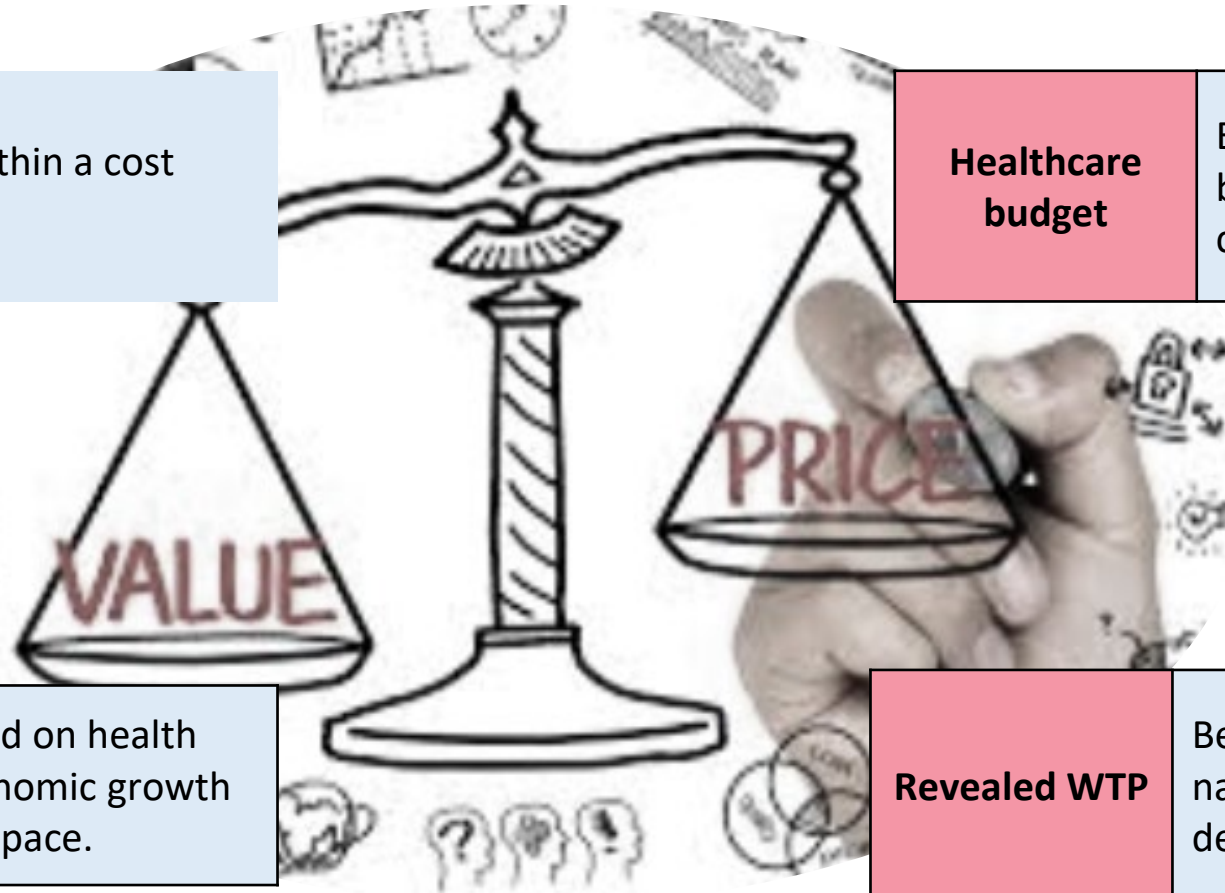
Empirically derived based on budgetary allocation to health current and projected.

Fiscal space analysis

Budget neutral based on health system savings, economic growth and resulting fiscal space.

Revealed WTP

Benchmarked against past national technology adoption decisions.

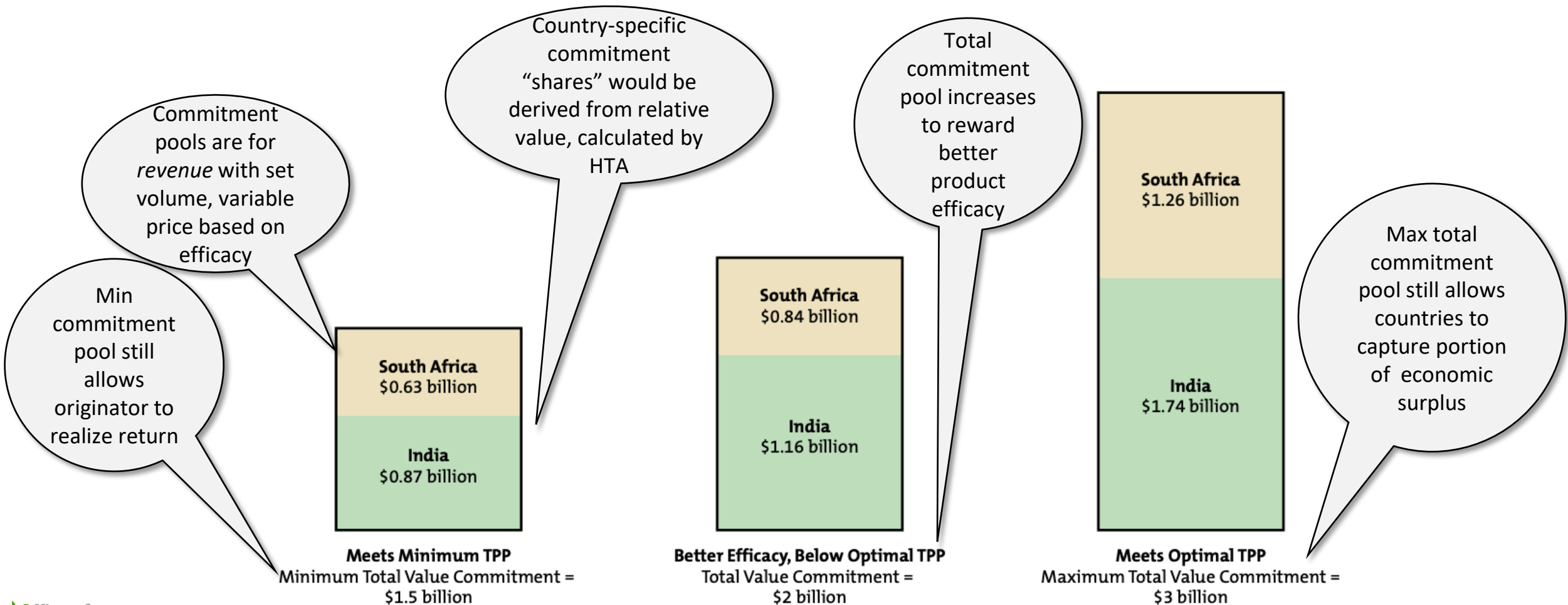


How a Value Commitment Can Be Set and Adapted Over Time: A “Commitment Pool” Tied to Product Efficacy

Step 1: First movers assess value: One or more high-burden countries would need to take a leadership role as “first movers” —for example, UK, Norway, Thailand, India and South Africa. Ex-ante HTA for those countries would give several important pieces of information:

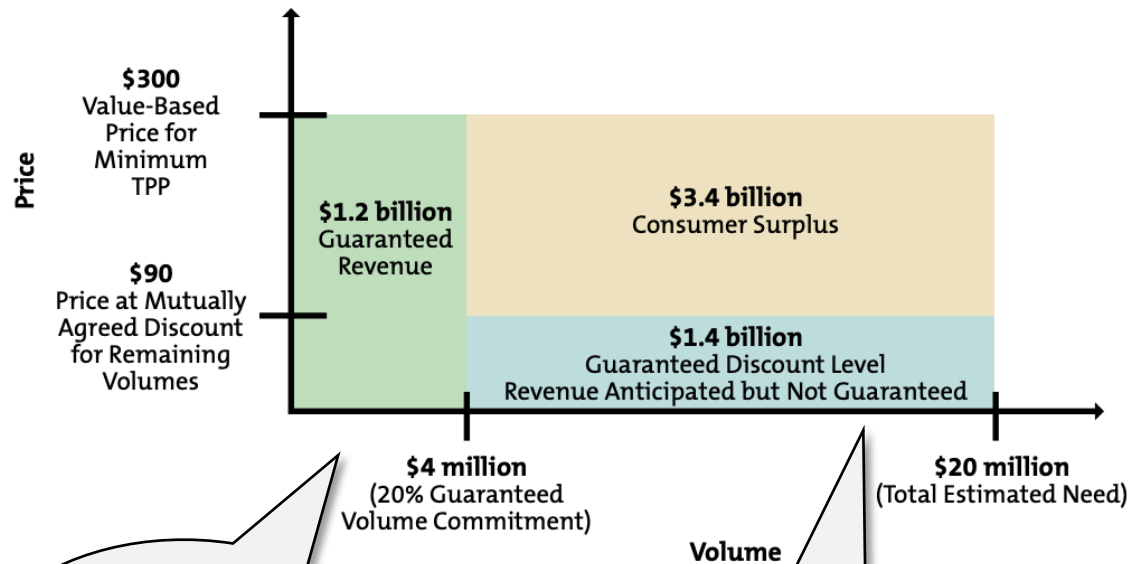
- The total value-based market: HTA would provide an upper bound for value-based commitments.
- Relative value by country: HTA would show how the total value proposition of a vaccine varies across countries.
- Relative value by product profile: HTA would show how the total value proposition of a vaccine varies vis-à-vis specific product characteristics.

Step 2: First movers define and divide a value-based commitment pool; *example based on two countries*



Structure and Size of Commitment Pool: One Model

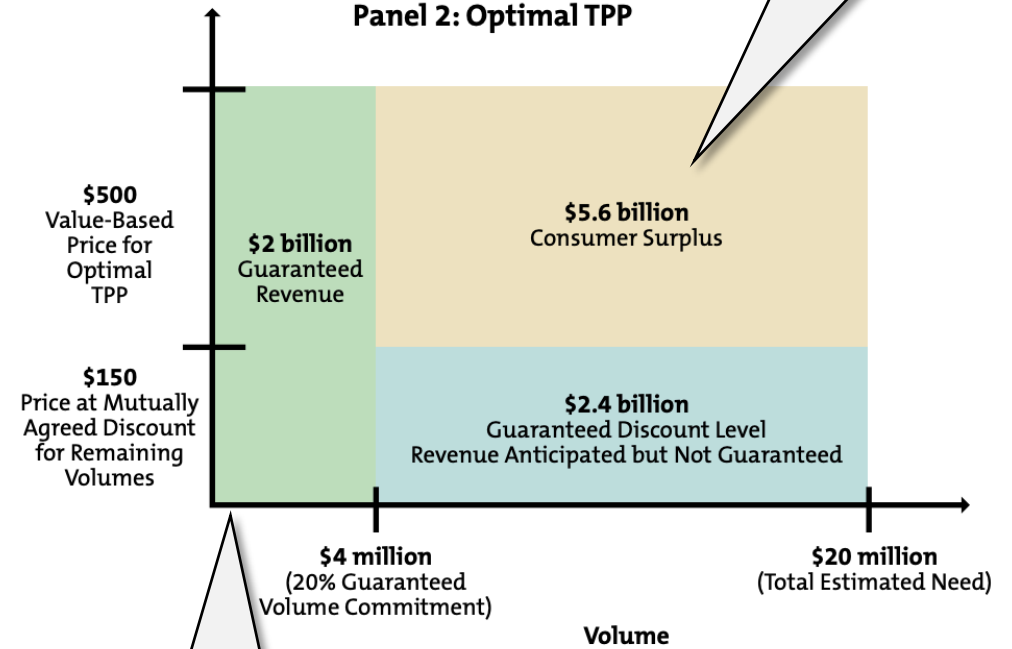
Panel 1: Minimum TPP



Portion of total estimated demand guaranteed at max value-based price

Countries entitled (but not obligated) to purchase remainder of demand at pre-agreed discount from value-based price

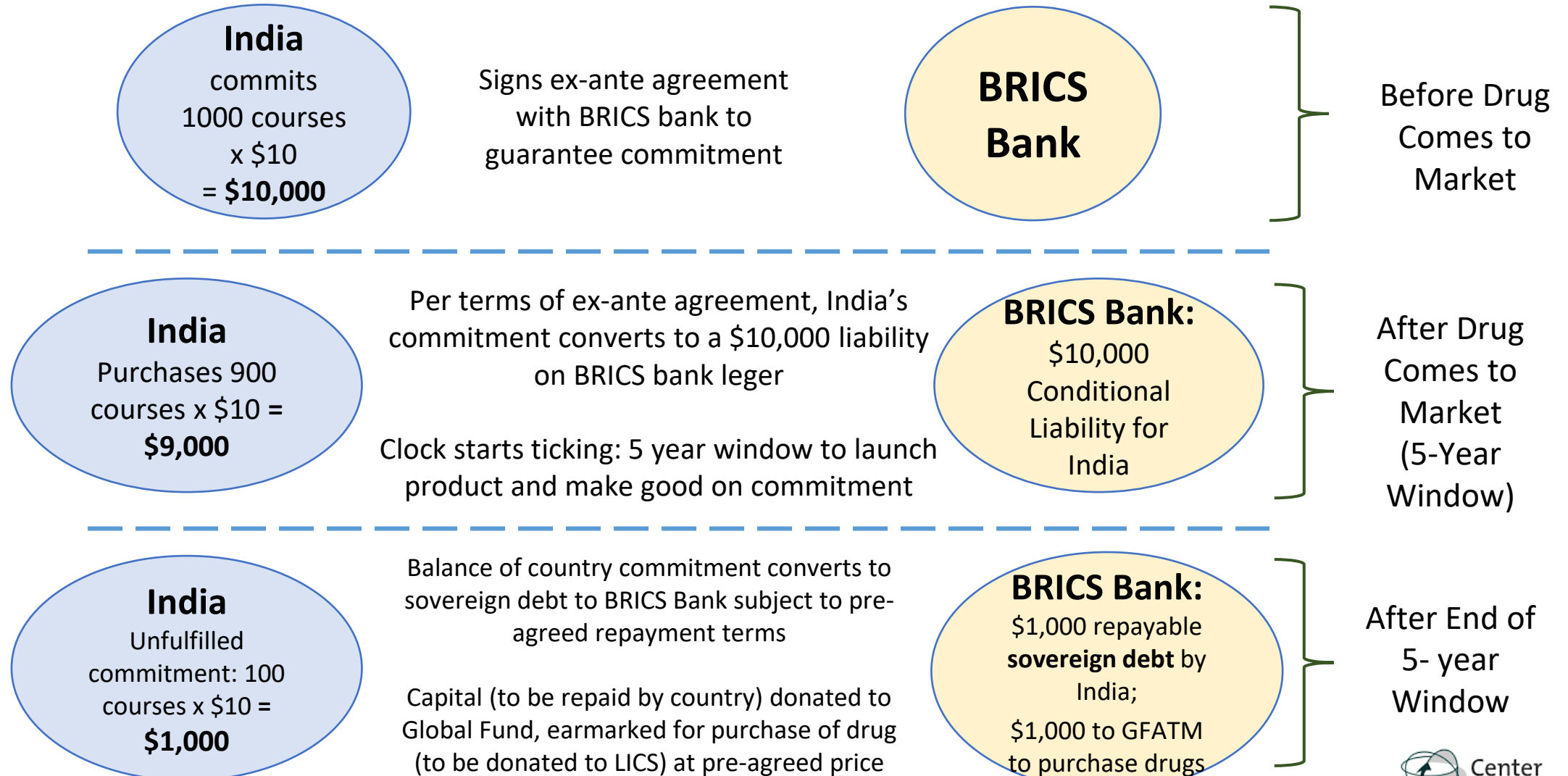
Panel 2: Optimal TPP



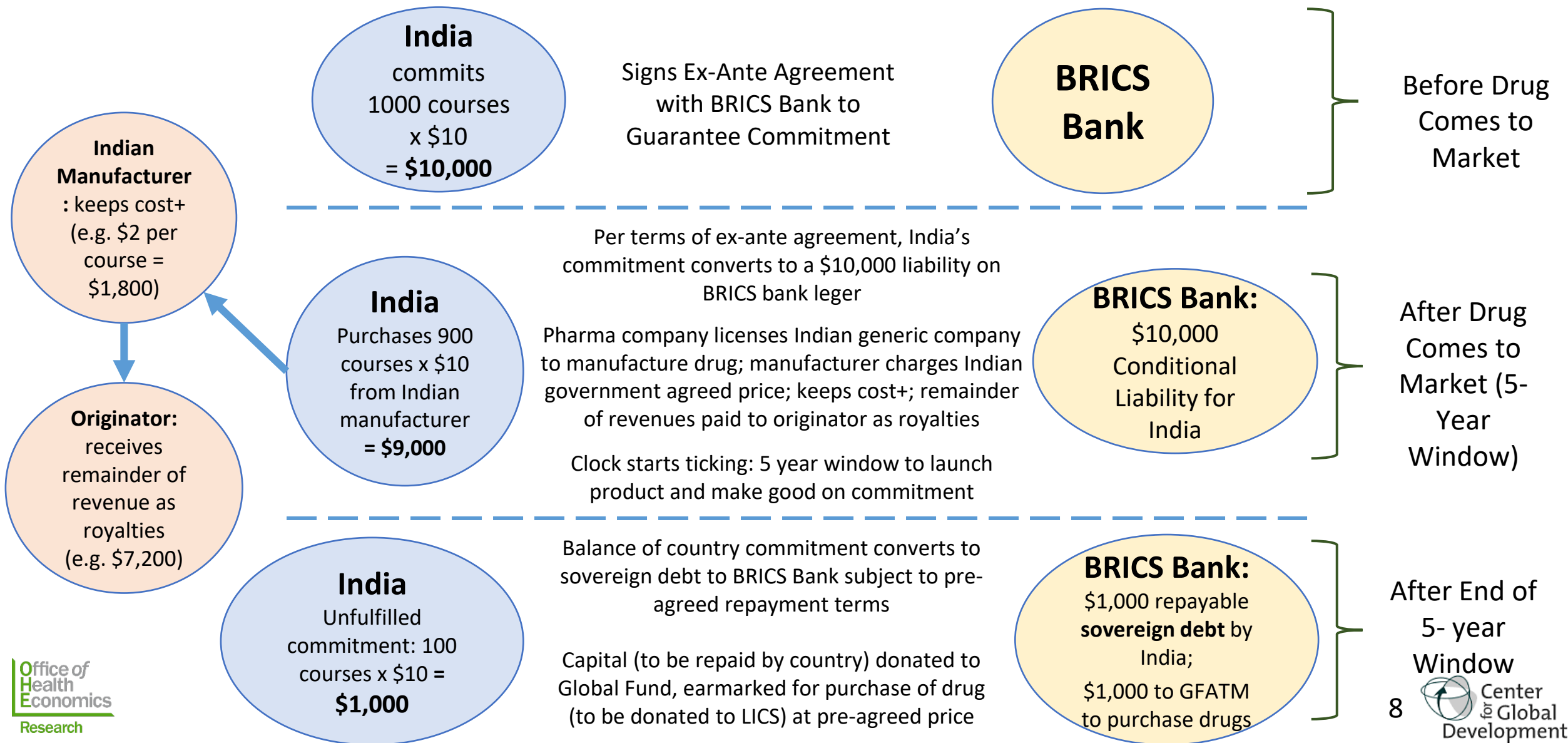
Discounts on additional volumes allow countries to capture more consumer surplus

More effective products get higher max price, and higher price for remainder of volume at discounted price

SOVEREIGN CREDIT TO SECURE ADVANCED COMMITMENTS: A SIMPLE MODEL



UNDERWRITING: WITH LOCAL LICENSING



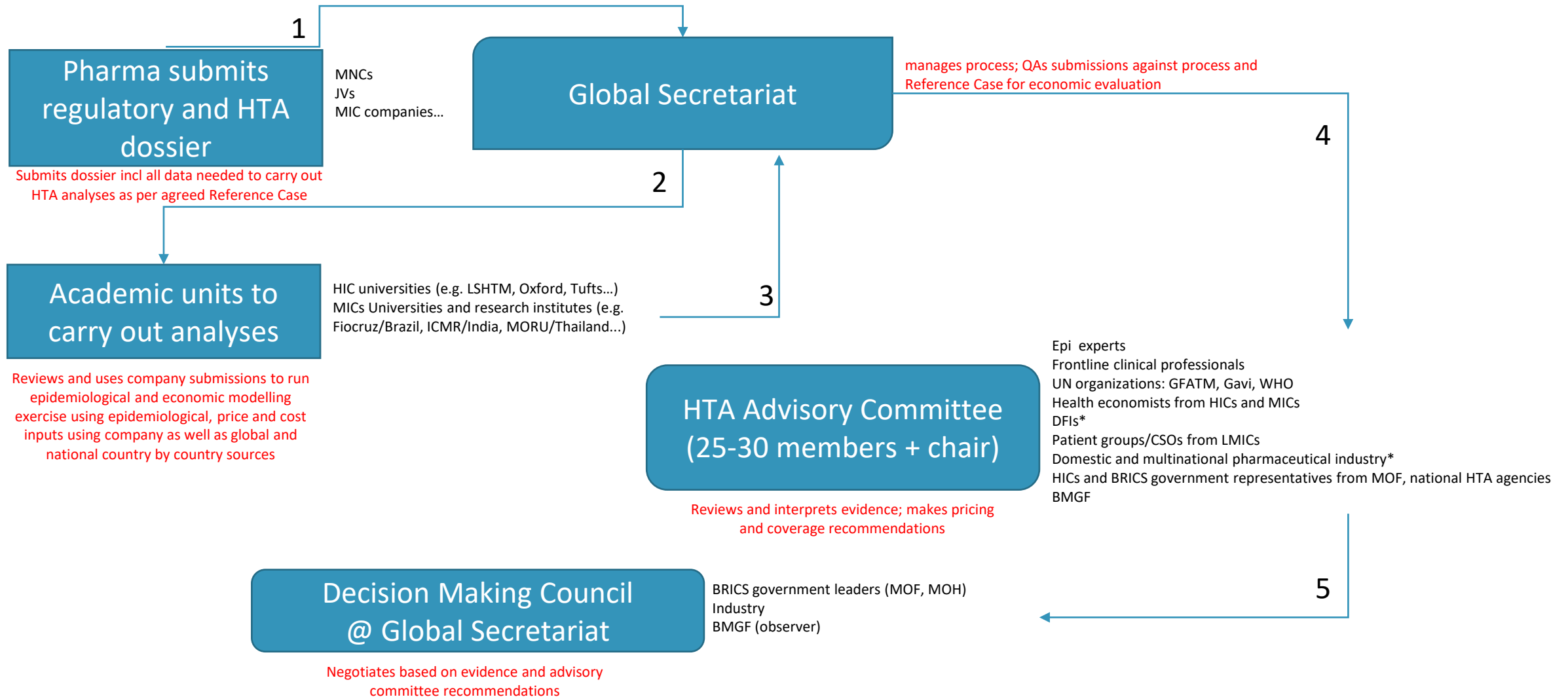
India
 commits
 1000 courses
 x \$10
 = **\$10,000**

FULFILLING THE COMMITMENT: THREE SCENARIOS WITH ONE SUPPLIER

**BRICS Bank
 Guarantee:**
 \$10,000
 Conditional
 Liability for India

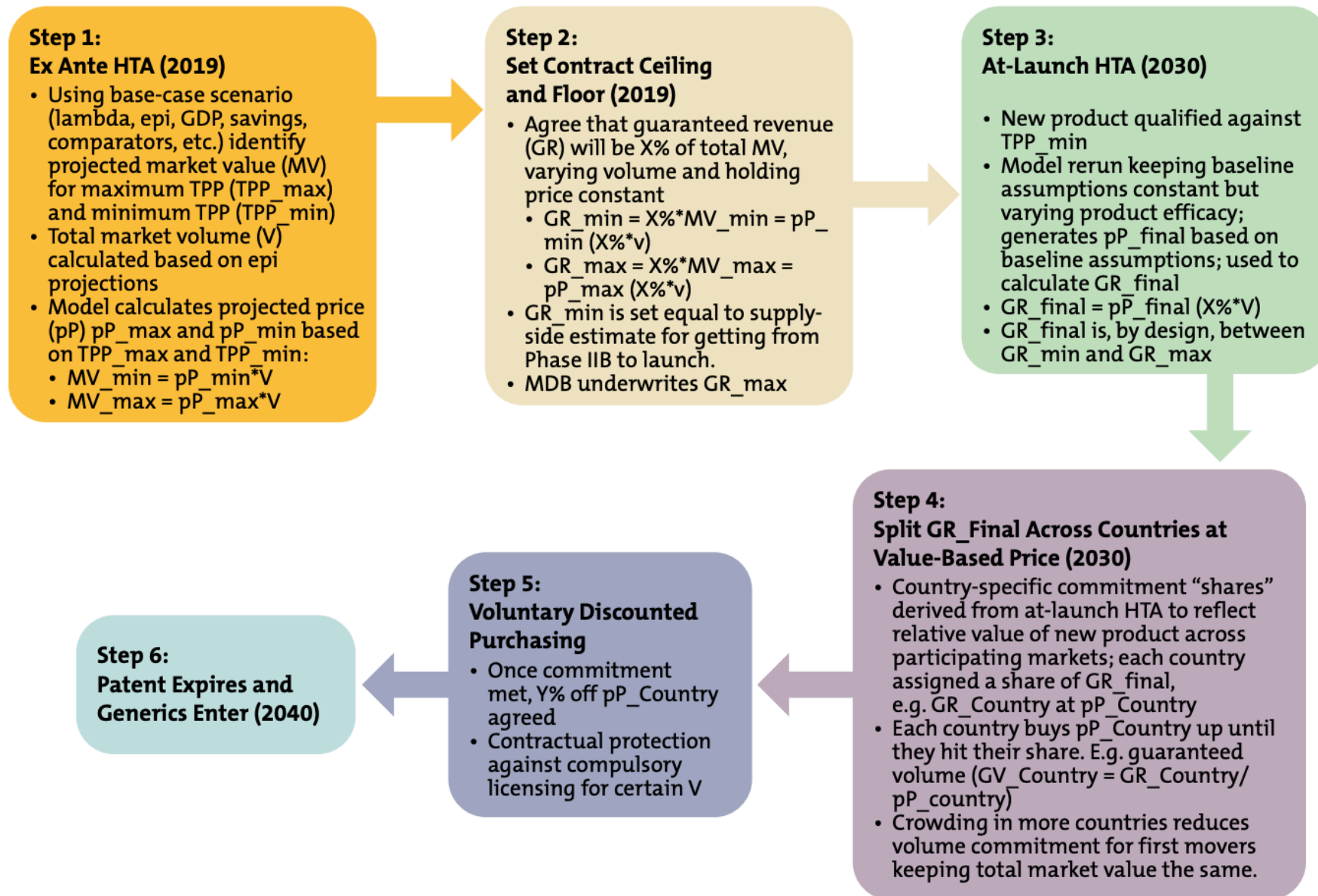
Scenario	Description	What Happens After 5-Year Window
Scenario 1: Country Fulfills Commitment	As agreed, India purchases 1,000 courses at \$10 per course = \$10,000	Nothing; BRICS Bank erases conditional liability
Scenario 2: Country Fulfills Price Commitment, but not Volume Commitment	India purchases drug at agreed price (\$10) – but only purchases 900 courses = \$9,000	BRICS Bank donates balance of commitment (\$1,000) to Global Fund; Global Fund <u>must</u> use money to purchase drug at India’s agreed price (\$10) for use in LICs. India must repay \$1,000 to BRICS bank as loan.
Scenario 3: Country Fulfills Volume Commitment, but not Price Commitment	India rescinds price commitment and tells company it will only pay \$5 – but purchases agreed quantity (1,000 courses) = \$5,000	BRICS Bank guarantees original commitment price. BRICS Bank gives balance (\$5,000) directly to company. India must repay \$5,000 loan to BRICS Bank.

What would a locally legitimate global hta structure look like?



*subject to COI rules employees whose product is being assessed will excuse themselves; DFIs will participate if final model involves a DFI

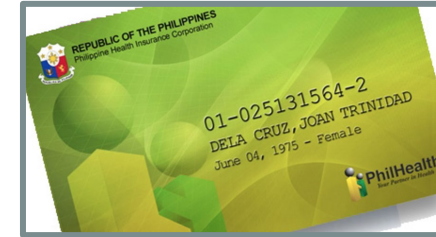
Process for Calculating and Fulfilling Advance Purchase Commitments



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



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

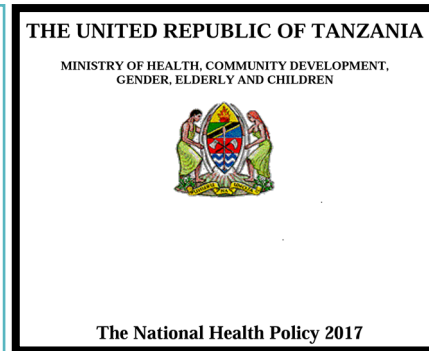


...in low and middle income markets... (cont.)

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”

National Health Summit 2018 - plan

Ministry of Health
Ghana



2018 Aide Memoire

Message from the Hon. Minister of State (MoHFW)



I/315-3469/2018
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



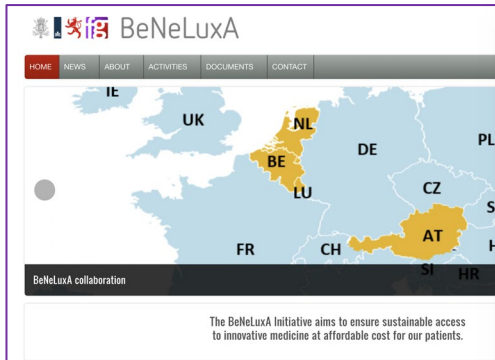
Systematic assessment of value makes markets work better: Evidence from South Africa



“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.**”

...and in high income economies in the EU...

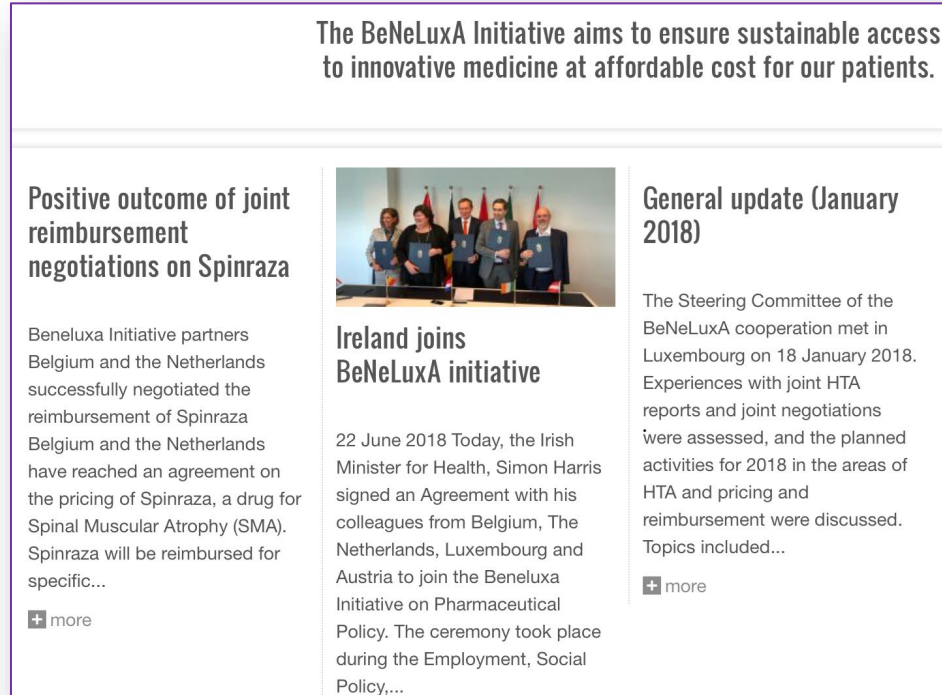
(cont.)



The BeNeLuxA website header includes a navigation menu with links for HOME, NEWS, ABOUT, ACTIVITIES, DOCUMENTS, and CONTACT. Below the menu is a map of Europe with several countries highlighted in yellow, representing the BeNeLuxA collaboration area. The highlighted countries include Ireland (IE), United Kingdom (UK), Belgium (BE), Netherlands (NL), Luxembourg (LU), France (FR), Germany (DE), Austria (AT), Czech Republic (CZ), Slovakia (SK), Poland (PL), Hungary (HU), and Slovenia (SI). A text box below the map states: "The BeNeLuxA Initiative aims to ensure sustainable access to innovative medicine at affordable cost for our patients."



The document cover features the European Commission logo and the following text: "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 page is titled "PUBLIC HEALTH" and is part of the European Commission website. The breadcrumb trail is: "European Commission > DG Health and Food Safety > Public health > Health technology assessment > EU cooperation". The main heading is "HEALTH TECHNOLOGY ASSESSMENT". The navigation menu includes: "All topics", "Overview", "HTA Network", "EUNetHTA Joint Actions", and "EU cooperation". A link is provided: "Go back to Health technology assessment > EU cooperation". The main article is titled "Strengthening EU cooperation beyond 2020". The text states: "In 2016, the European Commission started work on strengthening EU cooperation on Health Technology Assessment in response to calls from EU countries, the European Parliament, and interested parties to ensure its sustainability beyond 2020. In its 2017 Work Programme, the European Commission announced that this would extend to improving the functioning of the single market for health technologies." A section titled "Legislative proposal" states: "A legislative proposal was adopted by the European Commission on 31 January 2018. It is the result of an extensive reflection process following the results of the impact assessment outlined below. It has been sent to the European Parliament and the Council with the aim of adoption by 2019. The proposal and related information can be found here:"

“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

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

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
Southern 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 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)



Outcome Report On “Health Technology Assessment of Intraocular Lenses for treatment of Age-related Cataracts in India”

“The benefit packages for Phacoemulsification with foldable lens and small incision cataract surgery with rigid PMMA lenses may cost as 9606 INR and 7405 INR respectively”

**Health Technology Assessment in India (HTAI) Secretariat,
Department of Health Research,
Ministry of Health and Family Welfare**

**July-2018
New Delhi**

Benefit Based Price and volume: Axes of Exogenous Long-Term uncertainty

Economic



Low GDP per Capita Growth--recession:
Lower Price, Lower Volumes

High GDP per Capita Growth:
Higher Price, Higher Volumes

Epidemiologic
al



Investment in Health/GHS Stagnates or Declines:
Lower Price, Lower Volumes

Investment in Health/GHS Increases:
Higher Price, Higher Volumes

Commercial



Contracting Disease Burden, herd immunity, low
seasonality:
Lower Price, Lower Volumes

Expanding Disease Burden, no herd immunity;
second peak:
Higher Price, Higher Volumes



No Change:
No Change in Price, Volume

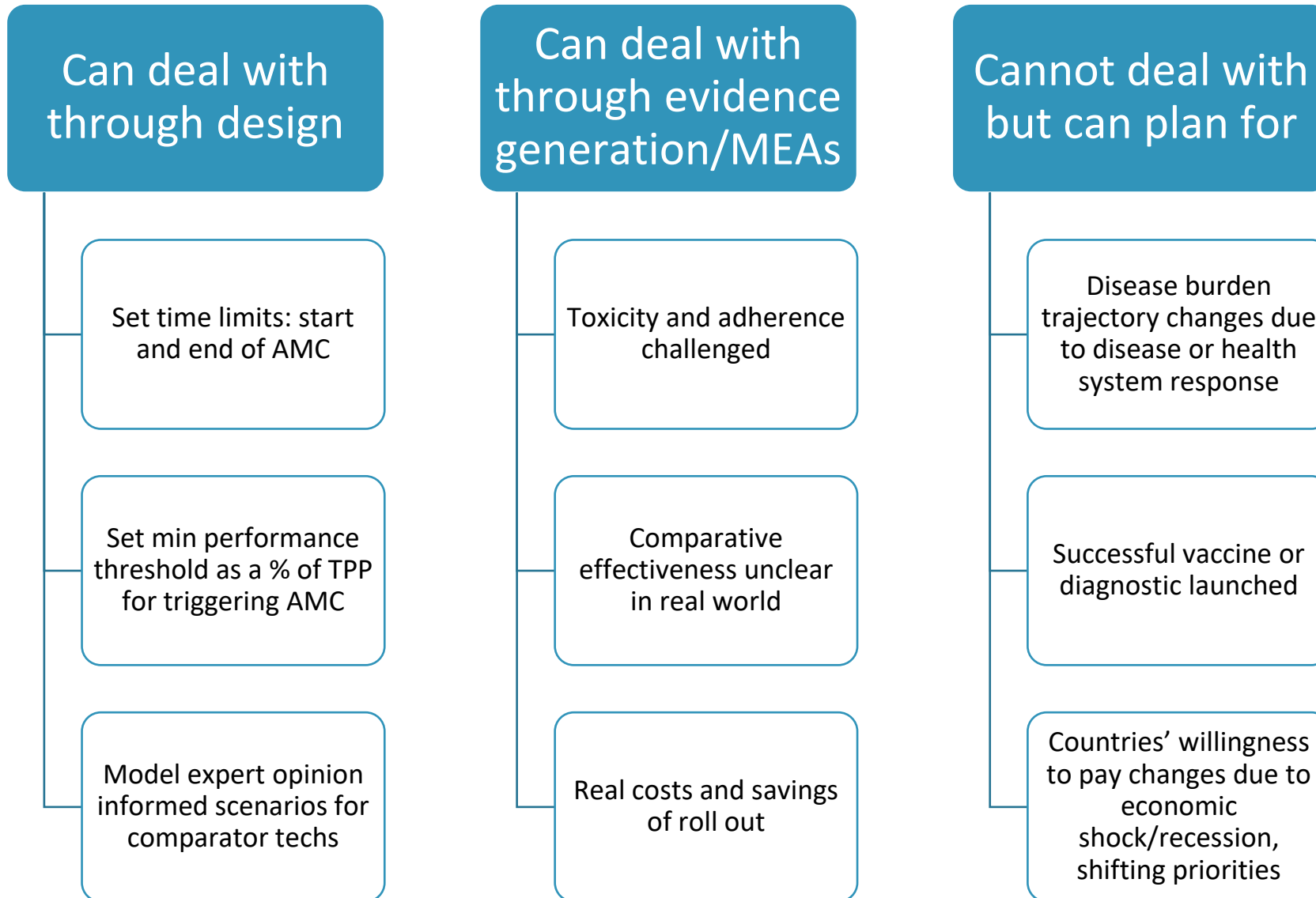
Entry of Comparator (eg treatment, TTI tech) Products/Price Reductions or Scale-Up
for Existing Products:
Lower Price, Indeterminant Volume Effect



No Change:
No Change in Price, Volume

More Effective/Cost-Effective Diagnostics allow TTI:
Higher Volume, Indeterminate Price Effect

Uncertainty to be dealt with through Design



BB AMC proposes a moderate level of collaborative purchasing

Minimal Collaboration

- Countries make political commitment to use pre-defined HTA process at launch to determine price and volume
- Commitments are unsecured; reputational commitment only
- HTA process implemented by country governments
- No secretariat, or skeleton secretariat to track commitments only

BB AMC

- Countries make coordinated, secured purchase commitments via a financial intermediary
- Central Secretariat (coordination unit) sets TPP (and minimum TPP); sets and enforces common HTA approach; tracks commitment fulfillment; and negotiates directly with R&D actors
- HTA process to define price and volume commitments implemented by Secretariat in partnership with country governments
- Each country pays country-specific value-based price for regimen
- Each country manages own purchasing to draw down against commitment

Joint Purchasing

- Countries make coordinated, secured purchase commitments via a financial intermediary
- HTA processes and price/volume setting implemented by MVAC secretariat; all countries pay the same price
- All purchasing is done directly through a joint (centralized) purchasing unit; countries must make financial contributions to the central unit to cover their purchases

← **Less Collaborative**

More Collaborative →