Additional slides

Based on MVAC


https://gh.bmj.com/content/bmjgh/5/4/e002061.full.pdf
Benefit-Based Commitment through HTA

**Ex ante HTA (pre launch)**
- Informs the terms of contracts by defining the HTA model structure and assumptions* generating price and volume, and WTP (price per unit of health gain)

**At launch HTA**
- Assess regimen performance against TPP
- Confirm/refine value and reward

**Ex post HTA (post launch)**
- Verify health and cost impact
- Adjust price up or down as uncertainty subsides in response to new evidence

Contracts are signed
- MVAC is triggered and the new regimen is licensed and launched

Post launch assessment
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

Commitment pools are for revenue with set volume, variable price based on efficacy.

Min commitment pool still allows originator to realize return

<table>
<thead>
<tr>
<th>Country</th>
<th>Commitment</th>
<th>Total Commitment</th>
</tr>
</thead>
<tbody>
<tr>
<td>South Africa</td>
<td>$0.63 billion</td>
<td>$1.26 billion</td>
</tr>
<tr>
<td>India</td>
<td>$0.87 billion</td>
<td>$1.74 billion</td>
</tr>
</tbody>
</table>

Country-specific commitment “shares” would be derived from relative value, calculated by HTA.

Total commitment pool increases to reward better product efficacy.

Max total commitment pool still allows countries to capture portion of economic surplus.
Structure and Size of Commitment Pool: One Model

Panel 1: Minimum TPP

- $300 Value-Based Price for Minimum TPP
- $1.2 billion Guaranteed Revenue
- $3.4 billion Consumer Surplus
- $1.4 billion Guaranteed Discount Level Revenue Anticipated but Not Guaranteed
- $4 million (20% Guaranteed Volume Commitment)

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

Panel 2: Optimal TPP

- $500 Value-Based Price for Optimal TPP
- $2 billion Guaranteed Revenue
- $5.6 billion Consumer Surplus
- $150 Price at Mutually Agreed Discount for Remaining Volumes
- $4 million (20% Guaranteed Volume Commitment)

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

Discounts on additional volumes allow countries to capture more consumer surplus
SOVEREIGN CREDIT TO SECURE ADVANCED COMMITMENTS: A SIMPLE MODEL

India
Commits 1000 courses x $10 = $10,000

BRICS Bank
Signs ex-ante agreement with BRICS bank to guarantee commitment

India
Purchases 900 courses x $10 = $9,000

Per terms of ex-ante agreement, India’s commitment converts to a $10,000 liability on BRICS bank ledger

Clock starts ticking: 5 year window to launch product and make good on commitment

India
Unfulfilled commitment: 100 courses x $10 = $1,000

Balance of country commitment converts to sovereign debt to BRICS Bank subject to pre-agreed repayment terms

Capital (to be repaid by country) donated to Global Fund, earmarked for purchase of drug (to be donated to LICS) at pre-agreed price

BRICS Bank:
$10,000 Conditional Liability for India

BRICS Bank:
$1,000 repayable sovereign debt by India;
$1,000 to GFATM to purchase drugs

Before Drug Comes to Market

After Drug Comes to Market (5-Year Window)

After End of 5-year Window
UNDERWRITING: WITH LOCAL LICENSING

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

BRICS Bank

Per terms of ex-ante agreement, India’s commitment converts to a $10,000 liability on BRICS bank lever.

Pharma company licenses Indian generic company to manufacture drug; manufacturer charges Indian government agreed price; keeps cost+; remainder of revenues paid to originator as royalties.

Clock starts ticking: 5 year window to launch product and make good on commitment.

Balance of country commitment converts to sovereign debt to BRICS Bank subject to pre-agreed repayment terms.

Capital (to be repaid by country) donated to Global Fund, earmarked for purchase of drug (to be donated to LICs) at pre-agreed price.

BRICS Bank: $1,000 repayable sovereign debt by India;
$1,000 to GFATM to purchase drugs.

Originator: receives remainder of revenue as royalties (e.g. $7,200)

Indian Manufacturer: keeps cost+ (e.g. $2 per course = $1,800)

India

Purchases 900 courses x $10 from Indian manufacturer = $9,000

BRICS Bank: $10,000 Conditional Liability for India

After Drug Comes to Market (5-Year Window)

After End of 5-year Window

Before Drug Comes to Market

India

Unfulfilled commitment: 100 courses x $10 = $1,000

BRICS Bank:

$1,000 to GFATM to purchase drugs

After Drug Comes to Market

India

Unfulfilled commitment: 100 courses x $10 = $1,000
### FULFILLING THE COMMITMENT: THREE SCENARIOS WITH ONE SUPPLIER

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

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

- **BRICS Bank Guarantee:**
  - **$10,000**
  - Conditional Liability for India
What would a locally legitimate global hta structure look like?

Pharma submits regulatory and HTA dossier

Academic units to carry out analyses

HTA Advisory Committee (25-30 members + chair)

Decision Making Council @ Global Secretariat

Global Secretariat

- MNCs
- JVs
- MIC companies...

- HIC universities (e.g. LSHTM, Oxford, Tufts...)
- MICs Universities and research institutes (e.g. Fiocruz/Brazil, ICIR/India, MORU/Thailand...)

- Epi experts
- UN organizations: GFATM, Gavi, WHO
- Health economists from HICs and MICs
- DFIs*
- Patient groups/CSOs from LMICs
- Domestic and multinational pharmaceutical industry*
- HICs and BRICS government representatives from MOF, national HTA agencies
- BMGF

*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

Step 1: Ex Ante HTA (2019)
- Using base-case scenario (lambda, epi, GDP, savings, comparators, etc.) identify projected market value (MV) for maximum TPP (TPP_max) and minimum TPP (TPP_min)
- Total market volume (V) calculated based on epi projections
- Model calculates projected price (pP) pP_max and pP_min based on TPP_max and TPP_min:
  - MV_min = pP_min*V
  - MV_max = pP_max*V

Step 2: Set Contract Ceiling and Floor (2019)
- Agree that guaranteed revenue (GR) will be X% of total MV, varying volume and holding price constant
  - GR_min = X%*MV_min = pP_min*V
  - GR_max = X%*MV_max = pP_max*V
- GR_min is set equal to supply-side estimate for getting from Phase IIb to launch.
- MDB underwrites GR_max

Step 3: At-Launch HTA (2030)
- New product qualified against TPP_min
- Model rerun keeping baseline assumptions constant but varying product efficacy; generates pP_final based on baseline assumptions; used to calculate GR_final
- GR_final = pP_final (X%*V)
- GR_final is, by design, between GR_min and GR_max

Step 4: Split GR_Final Across Countries at Value-Based Price (2030)
- Country-specific commitment “shares” derived from at-launch HTA to reflect relative value of new product across participating markets; each country assigned a share of GR_final, e.g., GR_Country at pP_Country
- Each country buys pP_Country up until they hit their share. E.g., guaranteed volume (GV_Country = GR_Country/pP_country)
- Crowding in more countries reduces volume commitment for first movers keeping total market value the same.

Step 5: Voluntary Discounted Purchasing
- Once commitment met, Y% off pP_Country agreed
- Contractual protection against compulsory licensing for certain V

Step 6: Patent Expires and Generics Enter (2040)
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

“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

**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
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”
Message from the Hon. Minister of State (MoHFW)

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.”
“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”

...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

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

* Michalopoulos, 2017, 2018; ** Ireland recently joined (An Roinn Slainte, 2018; Beneluxa, 2015a)
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

**Ability to Pay**
- Investment in Health/GHS Stagnates or Declines: Lower Price, Lower Volumes
- Investment in Health/GHS Increases: Higher Price, Higher Volumes

**Disease Burden Trajectory**
- Contracting Disease Burden, herd immunity, low seasonality: Lower Price, Lower Volumes
- Expanding Disease Burden, no herd immunity; second peak: Higher Price, Higher Volumes

**Comparator Landscape**
- 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

**Diagnostic Landscape**
- 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

**Can deal with through design**
- Set time limits: start and end of AMC
- Set min performance threshold as a % of TPP for triggering AMC
- Model expert opinion informed scenarios for comparator techs

**Can deal with through evidence generation/MEAs**
- Toxicity and adherence challenged
- Comparative effectiveness unclear in real world
- Real costs and savings of roll out

**Cannot deal with but can plan for**
- Disease burden trajectory changes due to disease or health system response
- Successful vaccine or diagnostic launched
- Countries’ willingness to pay changes due to economic shock/recession, shifting priorities
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  
BB AMC  
Joint Purchasing  
More Collaborative