GUIDING PRINCIPLES FOR PROVIDING EFFECTIVE ACCESS TO MEDICINES IN EMERGING MARKETS

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We will present three arguments

All else being equal, countries with better **Pricing and Patient Access (PPA)** systems achieve **better access** to innovative medicines.

Better access is achieved through determining **how much to invest** in a medicine based on **HT assessment**; this enables countries to **negotiate price and access** in an informed manner and deploy three powerful levers they have to obtain access – **reimbursement, time to reimbursement** and **creative financing** to support reimbursement.

Based on our analysis, we recommend to emerging markets a set of **guiding principles** for **PPA systems** that can improve **effective access** to innovative medicine for their populations.
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Emerging markets seeking to provide universal coverage face several barriers in increasing access to innovative medicines

Emerging markets are moving towards universal health coverage

- UHS covers >75% population; rest covered by insurance
- Investing in and expanding UHC
- Plans to achieve UHC by 2022
- Implementing UHC as per Social Security Providers (BPJS) Law
- Recently achieved UHC
- Implementing National Health Insurance for all
- Recently implemented UHC

However, several challenges remain for access to innovative medicine

- Insufficient funds and inadequate financing mechanisms
- Relatively poor health infrastructure
- Lack of awareness
- Structural challenges, e.g., perverse provider or distributor incentives
- Inability to evaluate and prioritise innovative medicines through a proper Pricing and Patient Access (PPA) system

This effort focuses on how countries, all else being equal, can improve access to medicines with a proper PPA system
PPA systems evaluate and prioritise new medicines to inform pricing and access decisions, given budget constraints.

1. **Receive Dossier**
   - Clinical
   - Cost-effectiveness
   - Real world evidence
   - Public health importance

2. **Assess value of medicine**
   - • Medical benefit over SoC
   - • Value for money over SoC
   - • Post-launch evaluation
   - • Broader social impact

3. **Set price and access**
   - Therapeutic referencing
   - International ref. pricing
   - Budget impact
   - Price caps
   - Price volume agreements
   - Mngd. entry agreements

4. **Launch**
   - • Price of therapeutically similar products
   - • Prices in comparable countries
   - • Managing to available budget
   - • Minimum discount, or maximum price cap
   - • Total budget cap
   - • Based on performance or utilisation

*Source: IMS Pharmaquery database*
Development of PPA systems varies significantly across countries

<table>
<thead>
<tr>
<th>Description</th>
<th>Example Countries</th>
</tr>
</thead>
</table>
| **Well developed PPA system** | • Structured and transparent  
• Sophisticated HTA that bases price and access on relative value of medicine across all TAs  
• Australia, Canada, France, Germany, Italy, Japan, Spain, South Korea, Taiwan, UK |
| **Moderately developed PPA system** | • Prioritises TAs and medicines based on public health need  
• Some use of HTA to inform price and access  
• Argentina, Brazil, Mexico, Poland, Turkey, USA |
| **Rudimentary but developing PPA system** | • Focus on public health priority  
• PPA system under development  
• New HTA systems, but limited impact on price and access  
• China, Thailand, Russia, Malaysia |
| **Weak or non-existent PPA system** | • No systematic assessment of medicine cost-benefit  
• No or blunt tools to manage price and access  
• South Africa, Egypt, Philippines, Indonesia, India, Vietnam |
To understand how PPA systems can facilitate effective access we analysed a representative sample of new products

Recently launched products across a range of therapeutic areas and clinical benefit

<table>
<thead>
<tr>
<th>Product</th>
<th>Patent Protected</th>
<th>Therapeutic area</th>
<th>ASMR rating</th>
<th>Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>MabThera</td>
<td>✓</td>
<td>Oncology</td>
<td>I</td>
<td>★</td>
</tr>
<tr>
<td>Herceptin</td>
<td>✓</td>
<td>Oncology</td>
<td>I</td>
<td>★</td>
</tr>
<tr>
<td>Prevnar 13</td>
<td>✓</td>
<td>Vaccine</td>
<td>I</td>
<td>★</td>
</tr>
<tr>
<td>Cerezyme</td>
<td>✓</td>
<td>Orphan</td>
<td>I</td>
<td>★</td>
</tr>
<tr>
<td>Humira</td>
<td>✓</td>
<td>RA</td>
<td>II</td>
<td>●</td>
</tr>
<tr>
<td>Ilaris</td>
<td>✓</td>
<td>Orphan</td>
<td>II</td>
<td>●</td>
</tr>
<tr>
<td>Plavix</td>
<td>✓</td>
<td>CVD</td>
<td>III</td>
<td>●</td>
</tr>
<tr>
<td>Glivec</td>
<td>✓</td>
<td>Oncology</td>
<td>III</td>
<td>★</td>
</tr>
<tr>
<td>Gardasil</td>
<td>✓</td>
<td>Vaccine</td>
<td>III</td>
<td>★</td>
</tr>
<tr>
<td>Avastin</td>
<td>✓</td>
<td>Oncology</td>
<td>III</td>
<td>★</td>
</tr>
<tr>
<td>Januvia</td>
<td>✓</td>
<td>Diabetes</td>
<td>IV</td>
<td>●</td>
</tr>
<tr>
<td>Alimta</td>
<td>✓</td>
<td>Oncology</td>
<td>IV</td>
<td>★</td>
</tr>
<tr>
<td>Enbrel</td>
<td>✓</td>
<td>RA</td>
<td>IV</td>
<td>●</td>
</tr>
<tr>
<td>Onglyza</td>
<td>✓</td>
<td>Diabetes</td>
<td>V</td>
<td>●</td>
</tr>
<tr>
<td>Cervarix</td>
<td>✓</td>
<td>Vaccine</td>
<td>V</td>
<td>●</td>
</tr>
</tbody>
</table>

The insights presented here is based on the analysis of these products across several developed and emerging markets

Sources: HAS http://www.has-sante.fr
Countries with better developed PPA systems provide speedier and broader access to innovative medicine

While richer countries do have better PPA systems; there are several instances of poorer countries achieving better access with an appropriate PPA system

Sources: IMS Health MIDAS Database; World bank Database 2011
...and achieve patient access at affordable prices

Countries with better developed PPA systems achieve more affordable prices, e.g., Korea and Turkey have lower prices than in countries with lower incomes such as Thailand & Egypt

Countries with rudimentary but developing PPA systems achieve more affordable prices than countries without any PPA system

PPA system: Well developed, Moderately developed, Developing, Weak or non-existent

Sources: IMS Health MIDAS Database; World bank Database 2011

Note: Cost index for India has been adjusted due to unavailability of prices for expensive innovative medicines on IMS MIDAS database; Brazil adjusted due to high list prices vs. net price
Even controlling for income, countries with more developed PPA system achieve better access to innovative medicines

- South Korea and Taiwan with better access than similar income Poland
- Brazil and Mexico with better access than Russia
- Thailand and China with better access than Egypt, Philippines, India, Vietnam

PPA system: Well developed, Moderately developed, Developing, Weak or non-existent

*Access to medicines score was calculated as the sum of standard deviations from the mean of comparative cost index, comparative affordability index, time to reimbursement, and level of coverage

Sources: IMS Health MIDAS Database; World bank Database 2011
We will present three arguments

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Better access is achieved through determining how much to invest in a medicine based on HT assessment; this enables countries to negotiate price and access in an informed manner and deploy three powerful levers they have to obtain access – reimbursement, time to reimbursement and creative financing to support reimbursement.

Based on our analysis, we recommend to emerging markets a set of guiding principles for PPA systems that can improve effective access to innovative medicine for their populations.
Although using different methods, countries with developed PPA systems evaluate and prioritise products similarly...

<table>
<thead>
<tr>
<th></th>
<th>Level of coverage within eligible patient population</th>
<th>Time to reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High (≥75%)</td>
<td>Slow (&gt;3 years post-launch)</td>
</tr>
<tr>
<td></td>
<td>Medium (≥ 25%, &lt;75%)</td>
<td>Delayed (1-3 years post-launch)</td>
</tr>
<tr>
<td></td>
<td>Low (&lt;25%)</td>
<td>Fast (within 1 year of launch)</td>
</tr>
<tr>
<td>High</td>
<td><img src="images" alt="" /></td>
<td><img src="images" alt="" /></td>
</tr>
<tr>
<td>Medium</td>
<td><img src="images" alt="" /></td>
<td><img src="images" alt="" /></td>
</tr>
<tr>
<td>Low</td>
<td><img src="images" alt="" /></td>
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</tbody>
</table>

**Mabthera**: Major effect on survival outcomes; favourable cost/QALY

**Herceptin**: Substantial impact on survival and survival relapses

**Ilaris**: Substantial actual benefit, and important improvement in patient management

**Humira**: Same improvement in actual benefit as other anti-TNFs

**Gardasil**: First vaccine against HPV, but no protection data > 5 years; significant public health benefit

**Gilenya**: Substantial actual benefit, but concerns over tolerance

**Januvia**: Substantial actual benefit, but minor improvement over existing therapy

<table>
<thead>
<tr>
<th>ASMR rating:</th>
<th>I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
</tr>
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</table>
...and change access levels based on new evidence or reduced prices

**Herceptin & Mabthera**
- Higher coverage of Herceptin and Mabthera at lower prices

**Gilenya**
- Gilenya was originally given a negative recommendation by NICE; but additional evidence of efficacy in sub-population and a discount improved cost-effectiveness and obtained access

**Humira**
- With evidence of effectiveness, Humira was granted access earlier in the treatment paradigm
After using HTA to establish acceptable price access combinations, countries have three levers to achieve access.

1. Leverage reimbursement to negotiate price down
   - Manufacturer desired price at launch
   - Manufacturer desired price post launch

2. Wait to grant reimbursement till price comes down due to competition, lower international reference price, etc.

3. Close remaining gap through creative financing such as co-payments, 3rd party contributions, manufacturer contribution for low income patients, etc.

Economically justifiable or affordable price-access combinations established by HTA

These three levers help countries to achieve access at the established economically justifiable or affordable price.
Brazil used the reimbursement and time to reimbursement as levers to gain an affordable price for Synflorix.

Manufacturer desired price for PCV at launch (~$40)

Synflorix price negotiated by GSK (~$16 to $7)

Brazil waits till new competitor enters and leverages full access for 10 years to negotiate acceptable price for access to Brazil (~$5-15)
UK used reimbursement as a lever to gain a cost-effective but confidential price through a patient access scheme.

Manufacturer desire price = $1,470/28caps = £19,196 per patient per year.

Gilenya price negotiated = confidential.

NICE gives Gilenya negative recommendation, and UK waits until manufacturer offers a cost-effective price.

Cost-effective price receives positive NICE recommendation.

UK leverages access and Novartis agrees to a substantial confidential discount based on a patient access scheme.

Economically Justifiable Price ($)
South Korea used all three levers to achieve a lower and more affordable price for Glivec.

1. **Manufacturer desire price = $19.50 per cap**

2. **South Korea waited as public pressure built on both the government and the manufacturer.**

3. **The remaining gap was closed with copay of which Novartis agreed to provide a one-third share.**

4. **Price acceptable for access to South Korea (~$15).**

**Economically Justifiable Price ($)**

- **Manufacturer desire price = $19.50 per cap**
- **Glivec price negotiated = ~$14-15 per cap**
- **Price acceptable for access to South Korea (~$15)**

**Access % of eligible patients**

- 100% of eligible patients
- 73% of eligible patients
- 83% of the average of 7 advanced markets...
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Based on our analysis, we propose the following guiding principles for effective access to innovative medicines

1. **Evaluate and prioritise medicines based on HTA**
   - Assess through national HTA body, or outsource analysis to another private or public organisation in country or in another country

2. **Based on this assessment, establish cost-effective/affordable price and access combinations**

3. **Leverage reimbursement to negotiate price for one of the price-access combinations**

4. **If no agreed price, and delayed access is acceptable, wait to provide access till price comes down to the established cost-effective/affordable level**
   - Assess depending on urgency or public health need for the product

5. **If necessary, close remaining gap with creative financing options**
   - Copayments, private insurance, tiered pricing for different patient groups, charitable contributions, etc.

*The PPA framework is key; it provides a rational basis for negotiations with manufacturers and makes it more likely that a mutually acceptable, sustainable solution is achieved*
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