Different View on Emerging Markets - The Big Biologic Opportunity

Tom Baker, Principal, IMS P&MA

March 3rd, 2011
IMS projects significant overall pharmaceutical market growth from emerging markets throughout the decade

Source: IMS Health Market Prognosis, Sep 2010

Most manufacturers have increased their exposure to emerging markets
In addition, the industry is increasingly focusing on biologics and other high cost therapeutics to drive growth.

**Biologics Global Sales Growth**

- **Growth by 250%**
- **$39 B** in 2001
- **$136 B** in MAT 9-2010

**Leading Biologics and High-Costs Therapies by Global Sales**

<table>
<thead>
<tr>
<th>Rank</th>
<th>Product</th>
<th>Annual Sales 10’ (in billions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Enbrel</td>
<td>$6.1</td>
</tr>
<tr>
<td>2</td>
<td>Remicade</td>
<td>$5.9</td>
</tr>
<tr>
<td>3</td>
<td>Humira</td>
<td>$5.7</td>
</tr>
<tr>
<td>4</td>
<td>Avastin</td>
<td>$5.5</td>
</tr>
<tr>
<td>5</td>
<td>Mabthera</td>
<td>$5.0</td>
</tr>
<tr>
<td>6</td>
<td>Herceptin</td>
<td>$4.1</td>
</tr>
<tr>
<td>7</td>
<td>Neulasta</td>
<td>$3.8</td>
</tr>
<tr>
<td>8</td>
<td>Epogen</td>
<td>$3.3</td>
</tr>
<tr>
<td>9</td>
<td>Copaxone</td>
<td>$2.8</td>
</tr>
<tr>
<td>10</td>
<td>Lucentis</td>
<td>$2.7</td>
</tr>
</tbody>
</table>

**Note:** sales are based on Q4_2009 to Q3_2010

Source: IMS Health, MIDAS MAT 2010
However, the realization of the biologic opportunity has been very limited in emerging markets.

<table>
<thead>
<tr>
<th></th>
<th>Biologics</th>
<th>Retail Products</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Price</strong></td>
<td>$$$</td>
<td>$</td>
</tr>
<tr>
<td><strong>Reimbursement</strong></td>
<td>• Fewer products are covered</td>
<td>• More products are covered</td>
</tr>
<tr>
<td></td>
<td>• Even covered, patient co-pay is higher due to co-insurance or coverage caps</td>
<td>• Patient co-pay portion is lower</td>
</tr>
<tr>
<td><strong>Accessibility</strong></td>
<td>• Only in fewer specialized/advanced hospitals in rich, urban areas</td>
<td>• Accessible in more primary care clinics</td>
</tr>
<tr>
<td><strong>Patient Affordability</strong></td>
<td>• Low</td>
<td>• High</td>
</tr>
</tbody>
</table>
Using China as an example, the price of most biologics is well in excess of the average income – despite an “emerging middle class”

### Monthly prices in China ($) – select biologic agents

<table>
<thead>
<tr>
<th>Biologic Agent</th>
<th>Price per month (Ex-M, $)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avastin</td>
<td>$5,389</td>
</tr>
<tr>
<td>Humira</td>
<td>$2,717</td>
</tr>
<tr>
<td>Herceptin</td>
<td>$2,381</td>
</tr>
<tr>
<td>Remicade</td>
<td>$1,864</td>
</tr>
<tr>
<td>Remicade</td>
<td>$961</td>
</tr>
<tr>
<td>PegIntron</td>
<td>$566</td>
</tr>
<tr>
<td>Monthly GDP per capita</td>
<td>$627</td>
</tr>
</tbody>
</table>

Source: MIDAS data; Economist Intelligence Unit, IMS analysis
As OOP rises as a share of expenditure, total per capita expenditure falls, reinforcing the importance of reimbursement.

**Source:** World Health Organization WHOSIS database; IMS analysis
In some markets, however, reimbursement and OOP costs may also vary by disease or therapeutic area.

*Insurance will only subsidize up to 100 RMB/month for Rx drug.

Source: provincial government BMI website.

*Inspection will only subsidize up to 100 RMB/month for Rx drug.

Source: provincial government BMI website.
In addition, limited clinic and hospital accessibility in emerging markets further constrains biologics access.

Source: World Health Organization, WHOSIS database
Therefore, it is critical to identify the real opportunities for biologics in Emerging Markets.

Although retail products have been the growth engine in Emerging Markets...

Due to limitations on sales data for many biologics in emerging markets, generating an accurate estimate of the size of the biologics market in many EMs remains problematic.

Note: country list defined by IMS, based on data availability
To address this, we developed an econometric model to predict biologics market size in emerging markets.

**Predictive Econometric Model**

- Total expenditure on health as % of GDP
- Per capita expenditure on health
- OOP expenditure as % of private expenditure on health
- Per capita health expenditure as % of per capita GDP
- Private expenditure on health as % of total on health
- GDP growth rate
- Gini coefficient
- % population living on < $2
- Share of income captured by top 10% population
- Biologic Sales

**Biologic market value in emerging markets**
Our analysis identified three key drivers that are closely correlated to the sales of biologics in EMs:

**Top 3 Drivers**

- **% population living on < $2 per day**
  - Low poverty level, often associated with a more urbanized setting, reflects better infrastructure for biologic dispensing.

- **Per capita government expenditure on health**
  - Government spending highlights the importance of reimbursement for biologics.

- **Per capita total expenditure on health**
  - Level of spending highlights the ability to pay for high cost products.

**Implication on Biologics**
The model also reveals a different pattern of biologic opportunities of emerging markets from retail products.

**Pharma Market Value**
- largely driven by retail products

<table>
<thead>
<tr>
<th>Country</th>
<th>Value (mil)</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>20,000</td>
</tr>
<tr>
<td>India</td>
<td>10,000</td>
</tr>
<tr>
<td>Brazil</td>
<td>8,000</td>
</tr>
<tr>
<td>Russia</td>
<td>4,000</td>
</tr>
<tr>
<td>S. Korea</td>
<td>3,000</td>
</tr>
<tr>
<td>Turkey</td>
<td>2,000</td>
</tr>
<tr>
<td>Mexico</td>
<td>1,500</td>
</tr>
<tr>
<td>Venezuela</td>
<td>1,000</td>
</tr>
<tr>
<td>Indonesia</td>
<td>700</td>
</tr>
<tr>
<td>S. Africa</td>
<td>500</td>
</tr>
<tr>
<td>Argentina</td>
<td>400</td>
</tr>
<tr>
<td>Taiwan</td>
<td>300</td>
</tr>
<tr>
<td>Thailand</td>
<td>200</td>
</tr>
<tr>
<td>Czech</td>
<td>100</td>
</tr>
<tr>
<td>Philippines</td>
<td>50</td>
</tr>
</tbody>
</table>

**Biologic Market Value**

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<tr>
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</tr>
<tr>
<td>Russia</td>
<td>1,000</td>
</tr>
<tr>
<td>China</td>
<td>800</td>
</tr>
<tr>
<td>Turkey</td>
<td>600</td>
</tr>
<tr>
<td>Mexico</td>
<td>500</td>
</tr>
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<td>400</td>
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<tr>
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<td>300</td>
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<td>Taiwan</td>
<td>200</td>
</tr>
<tr>
<td>Thailand</td>
<td>100</td>
</tr>
<tr>
<td>Chile</td>
<td>50</td>
</tr>
<tr>
<td>Colombia</td>
<td>40</td>
</tr>
<tr>
<td>Hong Kong</td>
<td>30</td>
</tr>
<tr>
<td>Venezuela</td>
<td>20</td>
</tr>
<tr>
<td>Slovakia</td>
<td>10</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>5</td>
</tr>
</tbody>
</table>

Note: country list defined by IMS, based on data availability.

Not in top 15

Not in top 15
This shift in ranking highlighted the different level of attractiveness of biologic markets today.

- **Highly Attractive**: Brazil, Russia, Mexico, Argentina, Chile, Colombia.

- **Moderately Attractive**: China.

- **Less Attractive**: India, Indonesia, Vietnam.

Ranking of biologic sales:
- Increases (e.g., Latin America, Russia).
- Decreases but vol is large (e.g., China).
- Significantly decreases (e.g., India, Indonesia, Vietnam).
Highly attractive biologic markets present near-term opportunities for meaningful sales – and may represent more fertile ground than many mature markets, such as the UK.

### Market Characteristics

<table>
<thead>
<tr>
<th>Urbanization Level</th>
<th>Gov Spending on HC</th>
<th>Patient Spending on HC</th>
<th>Reimbursement for Biologics</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>High</td>
<td>Med - High</td>
<td>Positive</td>
</tr>
</tbody>
</table>

### Manufacturer Strategies

- These markets reflect a decade or more of market development by Western manufacturers.
- Formal reimbursement is generally the most desirable – and feasible – strategy.
- However, price concessions and other supplementary programs may be necessary to support access.

### Success Stories

- In Brazil, biologic sales have been increasing ~20% annually with western brands penetrating ~80% of the market.
- High-cost products achieved access, including Glivec, Erbitux, Humira, Enbrel, Remicade, etc.
The moderately attractive biologic markets represent the battlegrounds that require different strategies.

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<tbody>
<tr>
<td>Med-High</td>
<td>Low</td>
<td>Low – Med</td>
<td>Inconsistent</td>
</tr>
</tbody>
</table>

### Manufacturer Strategies

- Targeted reimbursement strategies to negotiate sub-national deals with economically-advanced cities or provinces
- Develop a strong brand identity to support private and public strategies
- Province-by-province reimbursement strategy

### Success Stories

- In China, Glivec increased market penetration and achieved regional reimbursement via Patient Assistance Program (GIPAP)
- China became the second-largest market after the US for Xeloda after lengthy yet successful negotiation for access in select regions
The less attractive biologic markets present limited opportunities today and may require significant investment to grow the market in the long run.

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<th>Patient Spending on HC</th>
<th>Reimbursement for Biologics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Negative</td>
</tr>
</tbody>
</table>

### Manufacturer Strategies

- Despite often large populations, near-term opportunities have been limited due to poor reimbursement and low affordability relative to per capita incomes.
- Skimming represents the most common strategy.
- Markets require significant investment to achieve long-term returns.

### Success Stories

- Limited opportunities exist for high cost western brands yet biosimilars or local brands often achieved significant sales.

Images of flags and icons indicate less attractive market characteristics and near-term strategies.
Winning in Emerging Markets

IMS 2011 Market Access Conference
New York
March 3, 2011

Tarun Khanna
HBS
Matching Aspirations

Recruiting companies were wasting time and money looking for 'employable' candidates among the millions of graduates. So these savvy brothers came up with a match-making test.
Transaction Facilitator

Credibility Enhancer

Information Analyzer

Aggregator

Adjudicator
Is that really Decaf?
For current 16 global biologic performers, most launched in Brazil after 2003; all have secured reimbursement over time

*CEAF is the high cost medicines list managed by the national health insurance plan; APAC (Authorization for High Complexity Treatments) operates similarly as DRG in the US
Health care in Brazil

Core Actors

1. Ministry of Health
2. CENEPI – coordination of national epidemiological surveillance system and collection of data on incidence of various diseases

Peripheral Actors

1. Fiocruz – production of vaccines, research, education, field services
2. Anvisa - sanitary surveillance
3. Hemobras – production of blood components
4. INTO – treatment of patients with orthopedic trauma
5. ANS – health insurance regulation
6. INCA – treatment of cancer patients
Genzyme in Brazil

PERIPHERY OF INFLUENCE

- Genzyme
- INTO
- Fiocruz
- ANS
- INCA
- Hemobras
- Anvisa

Exchange resources (transfer of employees)

Exchange information on disease incidence

VETO-POINTS CORE

Ministry of Health

CENEPI
Health care in China

Core Actors

1. **State food and drug administration (SFDA)** - registration of drugs and medical devices
2. **Ministry of health** - pricing of medical services
3. **Development and reform commission** – Tendering drugs and medical devices
4. **Human resource and social/labor security agency (HRSLA)** – preparing catalogue of drugs eligible for government reimbursement.

Peripheral Actors

1. **Chinese Charity federation (CCF)** - government endorsed ‘NGO’ affiliated to ministry of civil affairs
2. **State run hospitals**
Genzyme in China

PERIPHERY OF INFLUENCE

Chinese Charity Foundation

Hospitals

Food & Drug Authority, Ministry of Health, HR & Social/ Labor security agency, Dev. & Reform Commission

VETO-POINTS CORE
Genzyme in Costa Rica

PERIPHERY OF INFLUENCE

Genzyme

National Ombudsman

Constitutional Court

Committee of doctors in Children’s hospital

Ministry of Health

VETO-POINTS CORE
Chinese Market Share

- Nokia
- Samsung
- LG Electronics
- Others
- Motorola
- Sony Ericsson
- Research In Motion

Courtesy: Juan Alcacer, HBS
Germany, Mobile Phones, % Retail Volume

Source: Euromonitor Global Market Information Database

France, Mobile Phones, % Retail Volume

Source: Euromonitor Global Market Information Database

Courtesy: Juan Alcacer, HBS
South Korea, Mobile Phones, % Retail Volume

Source: Euromonitor Global Market Information Database

Japan, Mobile Phones, % Retail Volume

Source: Euromonitor Global Market Information Database
Winning in Emerging Markets

• Mapping the institutional voids provides a template for understanding the role that an organization has played, and the evolving roles it will play going forward.

• Entrepreneurs have an opportunity to shape the institutional context, preferably in conjunction with the state.