Creating Markets for technological Innovation

Ammar Shanneir
Introduction about Hikma:

- Hikma Pharmaceuticals PLC (Hikma) is a fast growing multinational pharmaceutical group founded in 1978 in Jordan.
- Hikma develops, manufactures and markets a broad range of branded, non-branded generic and in-licensed products.
- Hikma operates in the US, Europe and across the MENA region:
  - 6th largest generic company in the US by value
  - 3rd largest supplier of injectables in the US by volume
  - 5th largest pharmaceutical company in the MENA.
- Hikma is committed to the highest quality manufacturing with multiple FDA approved facilities.
- Hikma’s global team is currently over 8,000 employees.
Hikma’s Global Presence

29 manufacturing facilities in 11 countries – FDA approved facilities in 5 countries
Successful technology transfer elements:

**"Techno-ware":**
for the pharmaceutical industry this would include the transfer of physical objects such as equipment for use in research laboratories or production equipment for the manufacture of pharmaceuticals, or the formulation or packaging of final products.

**"Human-ware":**
skills and human aspects of technology management and learning, such as training for researchers or general practitioners. Technology transfer can also create positive spillover effects into associated industries and into the supporting public sector research infrastructure.

**"Info-ware":**
all techniques related to knowledge, information, and technology, in the form of a technology license.

**"Orga-ware":**
organizational and procedural knowledge needed to operate a given technology relating to a chemical or biological compound.

**"Gov-ware":**
Policies and procedures update to review and register high tech products.
Internal TT:

Research & Development (R&D)

Formulation

Analytical

Clinical

Technology transfer

Analytical methods technology transfer

Production

Quality control lab

Registration

Launch to market
Multi-manufacturing site internal TT:

<table>
<thead>
<tr>
<th>Site</th>
<th>Research &amp; Development (R&amp;D) 20% of Budget</th>
<th>Formulation</th>
<th>Analytical</th>
<th>Clinical</th>
<th>Registration</th>
<th>Manufacturing</th>
<th>Product price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site # 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site # 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site # 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site # 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site # 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Multi- manufacturing site internal TT:

Centralized Research & Development
Formulation  Analytical  Clinical

Technology transfer

Manufacturer

Registration

Product price

Site # 1

Site # 2

Site # 3

Site # 4

Site # 5
External TT:

Technologies transfer:
- Licensor (technology provider)
- Formulation
- Analytical
- Clinical

Analytical methods technology transfer:
- Production
- Quality control lab
- Registration
- Launch to market
External TT:

Manufacturer (high tech) → Analytical → Health authorities
Case study (high-tech pharmaceuticals products):

Herbal products
Ancient world

Extraction from animal
Last century (19th Century)
Chemical synthesis drugs
Modern drugs

(19th Century)

Recombinant DNA technology (mAbs)
High technology

(20th Century)

Gene therapy
High technology
Biotechnology (sometimes shortened to "biotech") is the use of living systems and organisms to develop or make useful products.

Biosimilars (Biologic generics) are term used to describe officially approved subsequent versions of innovator Biological products made by a different sponsor following patent and exclusivity expiry on the innovator product.

To bring a new drug to market (from discovery through clinical trials) costs an estimated $1 billion and can take 10 to 15 years or longer. Only one in 10 new drugs that makes it into human testing actually makes it to market.

Development of Biosimilar product is about 100 M $ while small molecules generics is about 1 M $.

Biosimilars reduce the cost by 20 – 40 % from the cost of the original innovator Biological product.

In March, 2010 Obama signed policies that allow registration of affordable Biosimilars (ObamaCare)
Top 10 selling products globally during 2016:

<table>
<thead>
<tr>
<th>Rank</th>
<th>Product</th>
<th>Company</th>
<th>Technology</th>
<th>Sales ($ billions)</th>
<th>Patent expiry (EU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Humira</td>
<td>Abbott &amp; Eisai</td>
<td>Monoclonal antibody</td>
<td>9.7</td>
<td>2016</td>
</tr>
<tr>
<td>2</td>
<td>Avastin</td>
<td>Roche</td>
<td>Monoclonal antibody</td>
<td>7.8</td>
<td>2022</td>
</tr>
<tr>
<td>3</td>
<td>Rituxan</td>
<td>Roche</td>
<td>Monoclonal antibody</td>
<td>7.7</td>
<td>2013</td>
</tr>
<tr>
<td>4</td>
<td>Crestor</td>
<td>AstraZeneca</td>
<td>Small molecule chemistry</td>
<td>7.5</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Enbrel</td>
<td>Wyeth, Amgen &amp; Takeda</td>
<td>Recombinant product</td>
<td>7.2</td>
<td>2015</td>
</tr>
<tr>
<td>6</td>
<td>Advair</td>
<td>GlaxoSmithKline</td>
<td>Small molecule chemistry</td>
<td>7.0</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Januvia</td>
<td>Merck</td>
<td>Small molecule chemistry</td>
<td>6.8</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Herceptin</td>
<td>Roche</td>
<td>Monoclonal antibody</td>
<td>6.5</td>
<td>2014</td>
</tr>
<tr>
<td>9</td>
<td>Remicade</td>
<td>SGP, J&amp;J &amp; Mitsubishi Tanabe</td>
<td>Monoclonal antibody</td>
<td>6.1</td>
<td>2014</td>
</tr>
<tr>
<td>10</td>
<td>Prevnar</td>
<td>Wyeth, Pfizer</td>
<td>Vaccine</td>
<td>5.8</td>
<td>2012</td>
</tr>
</tbody>
</table>

- 4 Biotech product of the top 5 selling products
- 7 Biotech products of the top 10 selling
- Biotech products represents 50% of the 100 top selling products
Worldwide Prescription Drug & OTC Pharmaceutical Sales: Biotech vs. Conventional Technology

Source: Evaluate, May 2017

Biotech Products Within Top 100
Rapid increase in share of Top 100 products:
- 2008: 30%
- 2016: 49%
- 2022: 52%

2022 Split:
Biotech: n=48 (avg. $3.5bn)
Conv.: n=52 (avg. $3.0bn)

Technology: % of Prescription & OTC Sales


Biotechnology
Conventional/Unclassified
Advantage of using Biotechnology products:

➢ Highly effective and potent action
➢ Fewer side effects
➢ The potential to actually cure diseases rather than merely treat the symptoms
Manufacturing process:

**Biologic manufacturing is complex**
Biosimilars will always be different from the original

Even if a biosimilar uses the same human gene as its innovator

It will differ in other parts of the process

Different process = different product

Analysis

Fermentation

Formulation
Manufacturing process (cont’d):
Hikma’s Biotechnology Initiative started in April / 2010 by signing agreement with a Korean company for marketing & distribution of high tech technology (Biosimilar products) in MENA region.

State of the art Biotechnology QC laboratory was established in 2012 to:

- Confirm quality of the product before distributing in the market
- Some MENA countries require the MAH to do analysis
- Reference lab: Facilitate registration & support authorities (TT with LNCPP, NORCB, Iraq, MOA with JFDA)
- Knowhow for Hikma, analysis is the first & easiest way to start with
ISO 17025 lab accreditation
New Product AMT (2 years)

- TT finalization
- Agreements (quality, TT)
- AMT preparation (documents exchange)
- Method qualification
- Training
- Trials (equipment equivalency)
- Materials shipping (samples, standards)
Thanks