Think forward, think pharma

Pharma Industry

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BARCELONA - MARCH 2019
Topics to be covered today..

- History
- Drug$ Economics
- R&D. The core of the Industry
- RISK Factors
- Current trends
History
Some Important Events

- American Civil War
- Legislation – UK Cruelty to Animals Act (1876); US Federal Food and Drug Act (1906)
- World War 1 - Development of UK regulatory rules
- World War 2 – antibiotics
- Vaccines – Smallpox: Jenner (1796) – eradicated in 1977
- Thalidomide (1960) – report adverse drug reactions
- AIDS (1980s) – fast track approval, “buyer power”
- Viagra (1998)
- NICE (1999) – the affordability factor
- Vioxx – anti-inflammatory – 1999-2004 due to litigation
History of the Drugs

- The early days - Egyptians, Greeks, Arabs, China, India
- Plant-derived medicines
  - morphine (1805), quinine (1819), colchicine (1820), pilocarpine (1875)
- Hormones
  - insulin (1921), estradiol (1929), testosterone (1931), “the pill” (1960)
- Antibiotics, Psychoactive drugs (post-1945 to 1960’s)
  - penicillin (1944), streptomycin (1944), valium (1963)
- Treatment of metabolic disorders (1960’s to current day)
  - Search for gene therapies (1990), stem cell-based therapies
  - Stem-cell replacement of a trachea (2008)
DRUG$
Health expenditure as % of govt budget

- Low (36): 10.8%
- Lower-middle (53): 9.8%
- Upper-middle (56): 11.7%
- High (52): 14.0%
- Global (197): 11.5%

Abuja Target: 16%
## Table 4.1.5: Total Pharmaceutical Expenditures (2010)

<table>
<thead>
<tr>
<th>Country group (number of countries)</th>
<th>Population</th>
<th>Total Pharmaceutical Expenditure</th>
<th></th>
<th></th>
<th></th>
<th>Per capita (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Millions</td>
<td>%</td>
<td>Million US$</td>
<td>%</td>
<td>%THE</td>
<td>%GDP</td>
</tr>
<tr>
<td>WHO region</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Africa (43)</td>
<td>819</td>
<td>12.1%</td>
<td>$19,464</td>
<td>1.7%</td>
<td>23.0%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Americas (35)</td>
<td>923</td>
<td>13.6%</td>
<td>$436,004</td>
<td>38.7%</td>
<td>19.8%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Eastern Mediterranean (19)</td>
<td>573</td>
<td>8.4%</td>
<td>$20,763</td>
<td>1.8%</td>
<td>20.1%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Europe (52)</td>
<td>896</td>
<td>13.2%</td>
<td>$331,683</td>
<td>29.5%</td>
<td>21.5%</td>
<td>1.6%</td>
</tr>
<tr>
<td>South-East Asia (10)</td>
<td>1,783</td>
<td>26.2%</td>
<td>$41,157</td>
<td>3.5%</td>
<td>33.2%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Western Pacific (27)</td>
<td>1,800</td>
<td>26.5%</td>
<td>$276,362</td>
<td>24.6%</td>
<td>18.7%</td>
<td>1.2%</td>
</tr>
<tr>
<td>World Bank income group</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High-income (49)</td>
<td>1,092</td>
<td>16.1%</td>
<td>$775,305</td>
<td>68.9%</td>
<td>18.5%</td>
<td>1.4%</td>
</tr>
<tr>
<td>Upper-middle-income (55)</td>
<td>2,474</td>
<td>36.4%</td>
<td>$283,864</td>
<td>25.2%</td>
<td>21.2%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Lower-middle-income (50)</td>
<td>2,480</td>
<td>36.5%</td>
<td>$59,580</td>
<td>5.3%</td>
<td>23.6%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Low-income (32)</td>
<td>749</td>
<td>11.0%</td>
<td>$6,683</td>
<td>0.6%</td>
<td>27.7%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Global</td>
<td>6,795</td>
<td></td>
<td>$1,125,433</td>
<td>20.8%</td>
<td>1.4%</td>
<td></td>
</tr>
</tbody>
</table>

National Health Accounts, 2013
What criteria MUST new drugs meet?

- Drugs must address a **new need** or provide a significant "**added benefit**" over an existing medicine.
- Drugs must also meet five criteria:
  - Must be safe, effective, of high quality
  - ...cost effective (1980s)
  - ...........affordable (1990s)
  - ...............**REALLY** affordable (2000+)
Economics
Economics of the Pharmaceutical Industry

- Worldwide revenues > $1,143.3 billion/year
- Sales for the 10 largest drug companies: $437 billion in 2017
- Greater than 5000 companies worldwide
- Top 5 companies have market shares about 4 - 5 %
- US = Largest markets (40 % of worldwide sales)
The companies in 2017

<table>
<thead>
<tr>
<th>Company</th>
<th>$Billions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer</td>
<td>53</td>
</tr>
<tr>
<td>Roche</td>
<td>44</td>
</tr>
<tr>
<td>Sanofi</td>
<td>37</td>
</tr>
<tr>
<td>Johnson &amp; Johnson</td>
<td>36</td>
</tr>
<tr>
<td>MSD</td>
<td>35</td>
</tr>
<tr>
<td>Novartis</td>
<td>33</td>
</tr>
<tr>
<td>AbbVie</td>
<td>28</td>
</tr>
<tr>
<td>Gilead</td>
<td>26</td>
</tr>
<tr>
<td>GSK</td>
<td>24</td>
</tr>
<tr>
<td>Amgem</td>
<td>23</td>
</tr>
</tbody>
</table>
Economics

- 18.6% profit margin in 2013
- 16.4% in 2000 ($24 billion)

Largest of any industry

4 times greater than average return of all fortune 500 companies

8 out of 25 most profitable U.S. companies are pharmaceutical companies
Mergers and Acquisitions

- Drug company mergers
  - Pfizer-Warner-Lambert, Upjohn-Pharmacia, Glaxo-Wellcome-SmithKline Beecham, etc.

Pfizer acquired Pharmacia in 7/02 for $60 billion to become the world’s most powerful drug conglomerate. In 2015, Pfizer acquires Hospira
Who pays the party?

- 55% out-of-pocket
- 25% private insurance
- 17% medicaid
- 3% Other (VA, Workman’s Comp, IHS, etc..)
Where Prescription Money Go

- Research and development - 12%
  preclinical testing - 6%
  clinical testing - 6%
- Manufacturing and distribution - 24%
- Sales and marketing - 26%
- Administrative / miscellaneous expenses - 12%
- Taxes - 9%
- Net profit - 17%
R&D. The core of the Industry
The “Pay Off”......to the companies

- R&D = 15 to 25 % of sales turnover
- Patent protection – 20 years from filing
- On average, 11yrs. of productive market life
  - Losec – $2.7Bn in 1998; Nexium (single enantiomer) $7.7Bn in 2008
  - Lipitor - $1Bn in 1998; $13.8Bn in 2008
Cost of launching an NCE continues to rise

<table>
<thead>
<tr>
<th></th>
<th>25th percentile</th>
<th>75th percentile</th>
<th>Average</th>
<th>Standard deviation</th>
<th>Standard error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry (n=20) $M</td>
<td>782</td>
<td>1235</td>
<td>1064</td>
<td>311</td>
<td>70</td>
</tr>
</tbody>
</table>

Source: CMR International © THOMSON REUTERS
Pharmaceutical Industry Facts

- Revenues from approved drugs (1 of 5 to 10,000) must cover the “dry holes” of non approved compounds.
- Average cost of bringing a drug to market is 1000 million dollars.
- Average approval time is 12 to 15 years.
- Time to recoup investment is shrinking- generic drugs and limited patent life
Pharma Industry: Innovators vs. Generics

Generic

Innovator
Pharmaceutical Industry Facts Generics

- High competition
- Price Pressure
- Short product lifecycle
- Same regulatory requirements
Pharmaceutical Industry Facts Generics

Cetirizine Generic Price Decline

Source: Wavedata

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**R&D for Pharmaceuticals and Other Industries (% of Sales)**

**Industrial Sector Comparison:**

- Research-based Pharmaceutical Companies*: 20.8%
  - Drugs and Medicine*: 12.0%
  - Office Equipment and Services: 7.6%
  - Electrical and Electronics: 6.0%
  - Telecommunications: 5.1%
  - Leisure Time Products: 4.9%
  - Automotive: 4.1%
  - Aerospace and Defense: 3.7%
  - Metals and Mining: 0.9%
  - Paper and Forest Products: 0.9%

*“Research-based Pharmaceutical Companies” Based on Ethical Pharmaceutical Sales and Ethical Pharmaceuticals R&D Only as Tabulated by PhRMA; “Drugs and Medicine” Sector as Tabulated by Standard & Poor’s Compustat, a Division of McGraw-Hill

Source: PhRMA, 1999, Based on Data From PhRMA Annual Survey and Standard & Poor’s Compustat, a Division of McGraw-Hill
Compound Success Rates: 1 in 10,000 Reach FDA Approval

**Discovery**
(2–10 Years)

**Preclinical Testing**
Laboratory and Animal Testing

**Phase I**
20–80 Healthy Volunteers Used to Determine Safety and Dosage

**Phase II**
100–300 Patient Volunteers Used to Look for Efficacy and Side Effects

**Phase III**
1,000–5,000 Patient Volunteers Used to Monitor Adverse Reactions to Long-term Use

**FDA Review/Approval**

**Additional Postmarketing Testing**

Source: PhRMA, Based on Data From the Tufts Center for the Study of Drug Development, 1995
## Top 10 Therapies - sales in 2008 (US$Bn)

<table>
<thead>
<tr>
<th>Therapy</th>
<th>2008 sales</th>
<th>% share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oncology agents</td>
<td>45.8</td>
<td>6.4</td>
</tr>
<tr>
<td>Lipid regulators</td>
<td>34.2</td>
<td>4.8</td>
</tr>
<tr>
<td>Respiratory agents</td>
<td>30.7</td>
<td>4.3</td>
</tr>
<tr>
<td>Acid pump inhibitors</td>
<td>26.7</td>
<td>3.8</td>
</tr>
<tr>
<td>Antidiabetics</td>
<td>26.0</td>
<td>3.7</td>
</tr>
<tr>
<td>Antipsychotics</td>
<td>22.4</td>
<td>3.1</td>
</tr>
<tr>
<td>Angiotensin antagonists</td>
<td>21.6</td>
<td>3.0</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>20.4</td>
<td>2.9</td>
</tr>
</tbody>
</table>

**Total: US$227.8Bn, 32.1%**
Drug Reimbursement Systems

- Copayments
  - income variation
  - exempted groups
- Cost-sharing
- Expenditure limits
- Positive and negative prescribing lists
- Therapeutic efficacy categories
COST Perspective

What is the cost if pharmaceutical manufacturers did not create revolutionary drugs........
COST of Uncured Disease States

Figure 5
Prevalence, Cost, and Medicines in Development for Selected Major Diseases in the United States

<table>
<thead>
<tr>
<th>Uncured Disease</th>
<th>Approximate Annual Economic Cost ($Billions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alzheimer's Disease</td>
<td>$100.0</td>
</tr>
<tr>
<td>Arthritis</td>
<td>$54.6</td>
</tr>
<tr>
<td>Asthma</td>
<td>$6.2</td>
</tr>
<tr>
<td>Cancer</td>
<td>$107.0</td>
</tr>
<tr>
<td>Congestive Heart Failure</td>
<td>$20.2</td>
</tr>
<tr>
<td>Coronary Heart Disease</td>
<td>$95.6</td>
</tr>
<tr>
<td>Depression</td>
<td>$53.0</td>
</tr>
<tr>
<td>Diabetes</td>
<td>$98.2</td>
</tr>
<tr>
<td>Hypertensive Disease</td>
<td>$31.7</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>$13.8</td>
</tr>
<tr>
<td>Schizophrenia</td>
<td>$23.0</td>
</tr>
<tr>
<td>Stroke</td>
<td>$43.3</td>
</tr>
</tbody>
</table>

Source: Compiled by PhRMA, 2000.
The “Pay Off”......to us

- Massive contributions to health, quality of life, reduced child mortality, life expectancy
- Vaccines have eradicated major disease – smallpox; vaccines for malaria and pneumonia soon.......?
- But costs and accessibility to healthcare are becoming major social and geopolitical issues
- And, is there something seedy about making money out of illness?
- What will happen into the future?
RISK Factors
Vioxx ®

- $2.5 Billion annual sales in 2003
  - #1 arthritis and acute pain medicine outside the US
  - #2 in the US
- Use >18 months will cause heart attack and stroke
- Voluntarily withdraw worldwide (Sep 30, 2004)
- Share price dropped from $45.07 to $33.00 (one day)
- $27 billion in market cap was erased
Vioxx®

- 9,650 Vioxx liability lawsuits have been filed (Dec 31, 2005)
- 19,100 plaintiffs involved (Dec 31, 2005)
- The company spent $285 Million in legal defense during 2005
- Increase the reserve amount to $685 Million for legal fees through 2006 and 2007 (Dec 2005)
- Unpredictable outcomes in lawsuits, substantial damages, fines, criminal penalties
Other Risk Factors

• Failure in developing and acquiring commercially successful products

• Failure in regulatory approval

• Competition from other products
  1) More efficiency
  2) Price pressure

• Unexpected future changes in government laws and regulations
Too many companies, too few products

Molecules Losing Exclusivity in Germany and USA
2008-2015

Source: Newport Horizon Premium™ © THOMSON REUTERS
Current Trends
Trends of the Market

Arthritis
- 21% of adults (non-institutionalized) in the U.S. (2003)

Cancer
- 23 million suffering worldwide. Estimated of 1.37 million people in the US were diagnosed with cancer in 2005
- about 1 in 3 lifetime risk; 38% of women and 43% of men
- The average cost of cancer treatment is well over $100,000 per person.
- Estimated $280 billion spent on treatment drugs for cancer annually. More than $100 Billions in US

Diabetes
- Estimated 18.2 million people in the United States, or 6.3% of the population (2005)
- 165 million cases worldwide (2003)
- $132 billion spent in direct and indirect costs in America (2002)

Heart Disease
- 25 million adults in the US
US NCE Approvals 2001-2018

Source: Newport Horizon Premium™ © THOMSON REUTERS
Current pipeline activity looks to continue the trend

Source: Thomson Pharma © THOMSON REUTERS
Your future
Typical Organogram
It includes many job opportunities of pharmacists:

- Drug discovery
- Manufacturing
- Marketing
- Medical information
- Product development
- Quality assurance
- Training & development
- Sales
- Regulatory
- Project management
- Health outcomes research
- Legal (e.g. IP)
- Information technology
- Scientific communications
Jobs Opportunities in Pharmaceutical Industry

It includes many job opportunities of pharmacists:

• Patience
• Attention to detail
• Decisiveness
• Independence
• Excellent IT skills
• Numerical skills
• Analytical skills
• Teamworking skills
• Languages
Jobs Opportunities in Pharmaceutical Industry

The interview

• Decide what you want
• Excellent CV
• Be Prepared (from beginning to end)
• Do not lie. Be honest.
• Ask questions.
  – Show interest in the position
  – The company
  – The team
  – The expectations
  – Understand the position offered
Jobs Opportunities in Pharmaceutical Industry

Solution selling

- Focus on other party problems
- Be solution to the problems
- No problems by yourself
thank you!