Healthcare is a priority but cost becoming unsustainable in mature markets

Source: Economic Intelligence Unit (EIU), August 2011; OECD Health Data 2011; * data until 2008
Agenda

- **Major trends**
- Global medicines spend
- Generic medicines
- Biopharmaceuticals
- Conclusions
Understanding the Major trends to 2016

1. Mature markets facing low growth, more cost containment
2. Europe is under pressure with severe hospital debt and austerity measures
3. Pharmerging markets to have high growth with mixed fortunes for Originators
4. Consolidation within the industry and diversification by originators changing the playing field
5. On patent brand sales to decline as generics aspire to +/- 80% dispensed prescriptions
6. Growth will come from specialist driven markets particularly biologics but with biosimilars making little impact to 2016
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Global Spending on Medicines

Global spending on medicines annually will grow to nearly $1.2 trillion by 2016, as the pharmerging markets, biologics and generics contribute a greater share of spending.

- By 2016, developed markets will decline to 57% of global spending due to patent expiries, slower brand spending growth and increased cost containment actions by payers.
- Pharmerging markets share of spending will increase by 10 percentage points to 30% of global spending over the next five years, as population and economic growth will drive a dramatically higher use of medicines in these markets.
- There will be an accelerated shift in spending to generics; biologic medicines are expected to account for $200-210Bn of global spending, while biosimilars will be between $4-6Bn, or 2% of biologics spending.
- Off-invoice discounts and rebates will represent an estimated $180-190Bn in 2016, which would lower estimated global spending by 15-16% to $995-1,005Bn.
Significant differences in spending per person will remain

- Developed markets, which include countries with the most advanced health systems and economies, and are expected to spend an average of $609 per person in 2016.
- Pharmerging countries, which account for nearly two-thirds of the world’s population, will average $91 in drug spend per capita in 2016.
- Many pharmerging countries have been making significant efforts to cover more of their populations with health insurance and basic medical services; however, millions still have limited access to healthcare, often because they must pay a significant portion of their healthcare costs.

Chart notes
Real spending in 2005$ at variable exchange rates, adjusted for purchasing power parity.
*Region average drug spend weighted by population
Pharmerging Tier 2: Brazil, India, Russia
Pharmerging Tier 3: Argentina, Egypt, Indonesia, Mexico, Pakistan, Poland, Romania, South Africa, Thailand, Turkey, Ukraine, Venezuela, Vietnam.
Rest of Europe excludes Russia, Turkey, Poland, Romania, Ukraine, which are included in pharmerging.

Source: IMS Market Prognosis, May 2012; Economist Intelligence Unit, Jan 2012

The Global Use of Medicines: Outlook Through 2016
Report by the IMS Institute for Healthcare Informatics
The top 20 therapy areas will account for 42% of spending in 2016. Classes with the highest levels of spending on medicines in 2016 are expected to include cancer, diabetes and asthma/COPD.

Overall, the top 20 therapy areas will account for 42% of total spending.

Seven of the top 20 classes are specialty medicines, often with novel mechanisms and improved efficacy, and represent many of the most important and recent innovations in global medicine.

These medicines include breakthroughs for melanoma, prostate cancer, autoimmune diseases, lupus, multiple sclerosis and hepatitis C.

**Chart notes**

Spending in US$ with constant exchange rates. Specialty therapies are products which are often injectables, high-cost, biologic or requiring cold-chain distribution. They are mostly used by specialists, and include treatments for cancer, other serious diseases and often involve complex patient follow-up or monitoring.

Therapy forecasts from IMS Therapy Forecaster adapted by the IMS Institute to represent global forecasts and to include additional classes.

Abbreviations: COPD: Chronic Obstructive Pulmonary Disease; HIV: Human Immunodeficiency Virus; ADHD: Attention Deficit Hyperactivity Disorder.

### Top 20 Global Therapy Areas

<table>
<thead>
<tr>
<th>Therapy Area</th>
<th>Spending 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oncologics</td>
<td>$83-88Bn</td>
</tr>
<tr>
<td>Antidiabetics</td>
<td>$48-53Bn</td>
</tr>
<tr>
<td>Asthma/COPD</td>
<td>$44-48Bn</td>
</tr>
<tr>
<td>Autoimmune</td>
<td>$33-36Bn</td>
</tr>
<tr>
<td>Lipid Regulators</td>
<td>$31-34Bn</td>
</tr>
<tr>
<td>Angiotensin II</td>
<td>$22-25Bn</td>
</tr>
<tr>
<td>HIV Antivirals</td>
<td>$22-25Bn</td>
</tr>
<tr>
<td>Antipsychotics</td>
<td>$22-25Bn</td>
</tr>
<tr>
<td>Vaccines</td>
<td>$19-22Bn</td>
</tr>
<tr>
<td>Immunostimulants</td>
<td>$16-18Bn</td>
</tr>
<tr>
<td>Anti-Ulcerants</td>
<td>$15-17Bn</td>
</tr>
<tr>
<td>Anti-Epileptics</td>
<td>$14-16Bn</td>
</tr>
<tr>
<td>Multiple Sclerosis</td>
<td>$14-16Bn</td>
</tr>
<tr>
<td>Platelet Aggregation</td>
<td>$14-16Bn</td>
</tr>
<tr>
<td>Narcotic Analgesics</td>
<td>$14-16Bn</td>
</tr>
<tr>
<td>Immunosuppressants</td>
<td>$13-15Bn</td>
</tr>
<tr>
<td>Contraceptives</td>
<td>$13-15Bn</td>
</tr>
<tr>
<td>Cephalosporins</td>
<td>$13-15Bn</td>
</tr>
<tr>
<td>Antivirals, excl HIV</td>
<td>$12-14Bn</td>
</tr>
<tr>
<td>ADHD</td>
<td>$12-14Bn</td>
</tr>
</tbody>
</table>
Biologics usage will drive many therapeutic areas increasing the need for biosimilars to manage costs

- Biologics will account for an increased share of spending by 2016, as important clinical advances continue to emerge from research, and patients around the world are treated.
- Spending on biosimilars will increase from $693Mn in 2011 to $4-6Bn by 2016, which represents 2% of biologic spending.
- Adoption is expected to remain modest through 2016, largely because most biologic medicines will stay protected by patents or market exclusivity in many countries.

**Global Biologics Spending**

Source: IMS Consulting Group, May 2012

- **2006**: $93Bn
- **2011**: $157Bn
- **2016**: $200-210Bn

Biologics include single identified components, whole cells, and include some forms of polymers. They can be purified from human, animal, plant or micro-organism sources. Biologics can be produced by recombinant DNA technology or chemically synthesized. Biosimilar products are biologic products approved in a country which has an abbreviated approval process for biologic products that reference an originator biologic in the regulatory submission.
Transformations in Disease Treatment

New medicines will transform patient care in a large number of diseases including cancer, heart disease and central nervous disorders, though significant gaps will remain in several global priority diseases.

- From 2006-2010, 140 NMEs were launched globally, with the developed markets gaining the most from these new product introductions. While few medicines are uniformly available across most countries, the most innovative ones are broadly available, across developed and pharmerging markets, including medicines for treating diabetes, HIV and thrombosis.

- Greater availability of existing and new medicines will transform care as treatments for global priority diseases improve and clusters of new therapies, with existing or novel mechanisms of action, provide more options for patients.

- More new medicines will be launched per year during the next five years, including innovative therapies for Alzheimer’s, autoimmune diseases, diabetes, and a number of cancers and orphan diseases.

- Treatments for priority diseases will improve, but gaps will remain.
Treatment will be transformed by new and existing mechanisms

Between 32-37 innovative products are expected to be launched per year over the next five years.

These developments include new mechanisms of action in several disease states such as Alzheimer’s, autoimmune diseases and various types of cancer, which have the potential to transform disease treatment, though not every therapy will become available or achieve its ultimate clinical aims.

There are also further developments in areas of research where some therapies have already launched including hepatitis C, multiple sclerosis and prostate cancer, which offer the potential to deliver better efficacy, safety or convenient administration.

**Chart notes**
Table includes selected not yet launched New Molecular Entities (NME) expected to be launched by 2016. An NME is the first commercial launch of a novel therapeutic entity. Abbreviations: JAK: janus-like kinase inhibitor; MAb: monoclonal antibody; GLP-1: glucagon-like peptide-1; DPP IV: dipeptidyl peptidase-IV inhibitor; SGLT: sodium-glucose cotransporter inhibitor; HSV: 5-HT2C: immunotherapeutic cancer vaccine, 5-hydroxytryptamine 2C; Xa: Xa coagulation factor inhibitor; NS5A: non-structural protein 5A; HSV: herpes simplex virus; ACS: acute coronary syndrome.

**Source:** IMS Institute for Healthcare Informatics, May 2012
Pharmaceutical growth is expected at 3-6% CAGR up to 2016 with value over US$ 1.1 trillion in 2016*

(* at ex-manufacturer price levels, not including rebates and discounts. Contains Audited + Unaudited data. All CAGR calculations are 5 years

**Source**: IMS Market Prognosis, Apr 2012
Agenda

• Major trends
• Global medicines spend
• **Generic medicines**
• Biopharmaceuticals
• Conclusions
Generics have seen superior double digit growth performance for a number of years

2008-2012: Global Generic Sales

Source: IMS Health, MIDAS, MAT Mar 2012, Rx only. Market Segmentation + LIC countries
US leads generics sales and growth
China’s contribution to growth falling from its earlier highs

Source: IMS Health, MIDAS, MAT Mar 2012, Rx only. Market Segmentation + LIC countries.
Asia-Pac has overtaken European generics market in size

Global Generic Mkt: $172bn +10.8% SU912bn +5.8%

N. America
$55.7bn SU188.9bn
+9.7% +4.6%

L. America
$20.0bn SU65.9bn
+22.2% +11.1%

Europe
$43.1bn SU235.7bn
+5.4% +4.5%

Japan
$5.4bn SU33.3bn
+9.7% +1.2%

Asia/Australasia*
$48.6bn SU364.3bn
+13.0% +6.9%

Africa & ME
$5.1bn SU57.2bn
+11.8% +3.5%

Source: IMS MIDAS MAT Mar 2012. RX only. Market segmentation + LIC markets only. *Japan is a subset of Asia/Australasia not additional
An accelerated shift in spending to generics is expected

- Global brand spending is forecast to increase from $596Bn in 2011 to $615-645Bn in 2016, primarily from developed markets.
- Global generic spending is expected to increase from $242Bn to $400-430Bn by 2016, of which $224-244Bn of the increase is from low-cost generics in pharmerging markets.
- Increased generic spending in developed markets in the next five years will be driven by generic competition due to patent expiries, with some additional increases due to expanded generic use for off-patent molecules.
- In pharmerging markets, generic and local companies will drive most of the increases in spending.

**Global Spending, 2011 and 2016**

<table>
<thead>
<tr>
<th>Global Spending in 2011: $956Bn</th>
<th>Global Spending in 2016: $1,175-1,205Bn</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developed</td>
<td>Pharmerging</td>
</tr>
<tr>
<td>$596Bn</td>
<td>$242Bn</td>
</tr>
<tr>
<td>$627Bn</td>
<td>$194Bn</td>
</tr>
<tr>
<td>$660-690Bn</td>
<td>$345-375Bn</td>
</tr>
</tbody>
</table>

- Brand (53%)
- Generic (35%)
- Other (12%)

**Chart notes**

Spending share in US$ with variable exchange rates. Brands defined using IMS’s proprietary market segmentation methodology and include vaccines, but exclude branded generics. Generics are defined as unbranded generics and branded generics but exclude OTC. Other products include OTC, diagnostics and non-therapeutics.
Factors that have been shown to drive generic utilisation

- Mandatory INN prescribing
- Generic first dispensing and prescribing
- Large price differential between generic and originator
- Reimbursement levels
- Patient Co-payments
- Incentives for dispensing/prescribing generics
Factors that inhibit generic utilisation

- Lack of incentives for pharmacists to dispense
- Lack of margin for wholesalers to distribute
- Preference for brands in certain markets
- Influence of originators
- Across the board price cuts
- Quality concerns
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Biologics growth is nearly double that of total pharma

Putting additional financial pressure on healthcare budgets

Source: IMS Health, MIDAS, MAT 12/2011
In Europe, biosimilar uptake is increasing. Variances reflect differences in local healthcare systems.

Volume per capita as defined daily dose potential of realised market for Biosimilars

Source: IMS Health, MIDAS, June 2011. **IMS data combined hospital and retail audit. * IMS data covers the retail channel only. Greek market driven by Human growth hormone as original brands refuse to supply (parallel exports also a possibility).
Latest trends unlock positive scenarios for biosimilars

**Impact**

- Increasing uptake in EU, with recent acceleration
- New alliances - especially on the BigPharma side - as well as increasing specialization along the value chain
- New guidance on MAbs and Int. B in EU
- US guidance
- Overall macroeconomic framework
- Advent of development of some of the new biosimilars*
- Evolving regulatory framework in Asia and active role of national governments on biosimilars
- Pfizer – Biocon deal called off
- Merck close Bioventures project
- Life cycle and pricing strategies
- Increasing number of competitors
- Extension of Enbrel patent in the US
- Rituxan development issues
- Risk in return on investments (high upfront cost, length of development, uncertain uptake)

**Barrier**

- Risk in return on investments (high upfront cost, length of development, uncertain uptake)
- Increasing number of competitors
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**Driver**

- New alliances - especially on the BigPharma side - as well as increasing specialization along the value chain
- New guidance on MAbs and Int. B in EU
- US guidance
- Overall macroeconomic framework
- Advent of development of some of the new biosimilars*
- Evolving regulatory framework in Asia and active role of national governments on biosimilars

**Timing of impact**

- Short term (2012-14)
- Long term (2014+)

*Infliximab, trastuzumab, rituximab

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*Source: IMS*
Current biosimilars only scratch the surface...among the new TAs, anti-TNF and MAbss are key.
Along with insulins, they account for more than 40% of the overall biologic market.

Source: IMS MIDAS, 12/2011
New biologics represent a threat for budgets but also biosimilars

Patients should expect the latest and most effective therapies so the biosimilar value proposition should include both the originator and follow-on biologics in the same TA.
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Generic Medicines and Biosimilars: key elements in controlling costs and increasing access to medicines

Prevention should always be the starting point

Compliance remains a challenge

Generic medicines represent gold standards

Earlier diagnosis and treatment initiation extends treatment periods

Value to payers and regulators is critical as drugs bill escalates

Government measures must hasten the penetration of generics and biosimilars

Price cuts continue to stifle generic growth

Demand for latest innovations in key therapy areas will increase

Use of disease modifying drugs and biologicals in primary care indications will drive drug costs
One sure thing...

We have to sell more....

..........  

.... for less
Thank you

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