Value of generic medicines
Medicines for Europe / IGBA annual conference
9 June 2016

Medicines for Europe Vision 2020
Our 5 pillars

PATIENTS
QUALITY
VALUE
SUSTAINABILITY
PARTNERSHIP
Pressure on EU budgets
Reduction of healthcare spending

Growth rates of health spending for selected functions per capita, OECD average, 2005-2013

<table>
<thead>
<tr>
<th>Function</th>
<th>2005-09 Average</th>
<th>2009-13 Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient care</td>
<td>2.4%</td>
<td>1.7%</td>
</tr>
<tr>
<td>Outpatient care</td>
<td>3.5%</td>
<td>2.7%</td>
</tr>
<tr>
<td>Long-term care</td>
<td>5.9%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Pharmaceuticals</td>
<td>2.7%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Prevention</td>
<td>-1.8%</td>
<td>-0.3%</td>
</tr>
<tr>
<td>Administration</td>
<td>3.9%</td>
<td>0.8%</td>
</tr>
</tbody>
</table>


An ageing population:
Major EU social and economic challenge

Modern lifestyle and an ageing population increase prevalence of chronic disease

Population Structure by Major Age Groups
EU28, 2014-2080 (percentage of total population)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>2014</th>
<th>2050</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-14 years</td>
<td>18.5</td>
<td>28.7</td>
</tr>
<tr>
<td>15-64 years</td>
<td>66.9</td>
<td>56.5</td>
</tr>
<tr>
<td>65+ years</td>
<td>14.6</td>
<td>15.1</td>
</tr>
</tbody>
</table>

Source: Eurostat Population Statistics
A surge in innovation: Major EU social and economic challenge

Global spending on new brand medicines has more than doubled in 2014 and is 2.6% of global pharmaceutical spending

Source: IMS Health, R&D Focus, May 2015; MIDAS, Q4 2014, constant USD

Global New Brand Spending Growth USD Bn

Generic medicines are key to EU healthcare sustainability

VALUE OF GENERIC MEDICINES

- Increased access to medicines
- Reduction of health inequalities
- Better health outcomes
- Positive Economic impact
- Improved medication adherence
Generic Medicines
A Cornerstone of Healthcare Sustainability

KEY FIGURES ON GENERIC MEDICINES

56% of dispensed medicines
22% of pharmaceutical expenditures
+ 100% patients access to over 500 million patients
- €100 BN less

Manufacturing Europe’s essential medicines
350 manufacturing sites
160,000 employees
7-17% R&D investment of turnover

Still considerable opportunities to increase uptake throughout Europe

Protected and off-patent marked share (volume) by country, June 2015

Source: IMS Health, MIDAS, Q2 2015, retail and hospital channel
Note: Non-original brands and branded generics include copy products in some countries. Generics include INN branded and company branded.
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VALUE OF GENERIC MEDICINES

Generic medicines increase patient access

Twice as many patients treated... without an impact on treatment costs

Evolution of volume, price and treatment cost in seven therapy areas

Selected therapy areas: Hypertension, epilepsy, gastro-intestinal disorders, mental health, high cholesterol and diabetes.
Benefits accrue in different ways across countries

Increased access to medicines delivers long-term benefits to society and to healthcare providers

<table>
<thead>
<tr>
<th>Country</th>
<th>Price (%TD)</th>
<th>Volume (TD#unit)</th>
<th>Treatment Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td>-6%</td>
<td>15%</td>
<td>-7%</td>
</tr>
<tr>
<td>UK</td>
<td>-6%</td>
<td>14%</td>
<td>-31%</td>
</tr>
<tr>
<td>France</td>
<td>-5%</td>
<td>40%</td>
<td>-31%</td>
</tr>
<tr>
<td>Italy</td>
<td>-5%</td>
<td>12%</td>
<td>-9%</td>
</tr>
<tr>
<td>Ireland</td>
<td>-5%</td>
<td>24%</td>
<td>-9%</td>
</tr>
<tr>
<td>Sweden</td>
<td>-6%</td>
<td>108%</td>
<td>-90%</td>
</tr>
<tr>
<td>Spain</td>
<td>-5%</td>
<td>109%</td>
<td>0%</td>
</tr>
<tr>
<td>Czech</td>
<td>-5%</td>
<td>121%</td>
<td>2%</td>
</tr>
<tr>
<td>Austria</td>
<td>-5%</td>
<td>133%</td>
<td>14%</td>
</tr>
<tr>
<td>Slovenia</td>
<td>-5%</td>
<td>132%</td>
<td>-30%</td>
</tr>
<tr>
<td>Poland</td>
<td>-5%</td>
<td>193%</td>
<td>33%</td>
</tr>
<tr>
<td>Slovakia</td>
<td>-5%</td>
<td>237%</td>
<td>9%</td>
</tr>
</tbody>
</table>

Source: IMS Health, MIDAS, Q4 2014; OECD Population statistics

Selected therapy areas: angiotensin II antagonists, anti-epileptics, anti-psychotics, anti-ulcerants, cholesterol regulators and oral anti-diabetics

Generic medicines reduce healthcare inequalities

Cost-efficiency gains

Investment in health

Reduce healthcare expenditure without compromising health outcomes

Improve health outcomes through better patient access without increasing health expenditure

Source: Kaló Z et al. (2014). Investment aspects of generic drug policies in countries with severe resource constraints. Poster presented at ISPOR Annual European Congress in Amsterdam
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**Better adherence will improve health outcomes and lead to a positive economic impact**

Lack of adherence is estimated to cost the European governments €125 billion / year

Avoidable cost for the National Healthcare System

- Additional cost of poor adherence compared to the total healthcare expenditure
- 0.3%
- 14%
- 8.9%
- 2.7%
- Hospital admissions
- Long-term facility admissions
- Emergency Dept. Visits
- Physician Visits


Note: €125bn/year is an A.T. Kearney estimate based on US avoidable cost data
Better adherence will improve health outcomes and lead to a positive economic impact

Appropriate generic medicine policies can improve adherence

Generic medicines positively influence adherence in systems with lower co-payment for generic medicines

The pharmacist’s role in ensuring patient understanding and comfort with medication through accurate information and dialogue is crucial to maximize adherence when substituting

Adherence is linked to patient co-payment*
Italian patients receiving generic amlodipine, with lower patient co-payment, were more adherent compared to branded amlodipine**

Impact of substitution
Adherence of Dutch patients, which have one designated pharmacy, was not influenced by substituting generic hypertensive medicines for a branded medicine**

Generic medicines are key to EU healthcare sustainability

VALUE OF GENERIC MEDICINES

Increased access to medicines
Better health outcomes
Positive Economic impact
Improved medication adherence
Reduction of health inequalities

**Source: EGA market review 2015

Generic payment exists across Europe, including but not restricted to the following countries: Belgium, Bulgaria, Finland, Hungary, Ireland, Italy (regional), Portugal, Romania, Switzerland. (Source: EGA market review 2015)

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Better health outcomes - Hypertension

- Antihypertensive drugs reduce mortality in hypertensive patients
- 50% decrease in hypertension related mortality in DE (1998-2010)
  - Increased access and treatment rates
  - Better medicinal treatment options
  - Smoking reduction
  - Better hypertension control
  - Guideline implementation

Increased cost-effectiveness


Source: IGES based on data in Schwabe/Paffrath (various years)

Better health outcomes - Breast cancer

- Adjuvant endocrine therapies: Over 15 years after treatment start, mortality is reduced by 1/3 and recurrence rates by 40%
- Breast cancer related mortality decreased since late 1980s
  - Improved treatment options
  - Increased access
  - Early detection programs

Decreased cost/QALY


Source: IGES based on data in Schwabe/Paffrath (various years)
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Europe Market Policies
Europe: different P&R policies in countries, regions...

Authorities are taking a short-term approach to cost-containment measures
At the same time, the EU regulatory burden is increasing... with complexity and cost

Generic medicines

- Pharmaco-vigilance Legislation
- Medicines in the environment
- Variations Regulation
- Clinical Trials Regulation
- Falsified Medicines Directive

National + EU level

All European countries are affected by disruption, yet pace and mechanisms differ

- Decision-makers
  - Physician
  - Pharmacy
  - Payen/Key Accounts
- Decision-criteria
  - Scientific, brands
  - Rebates & conditions

- Prices
  - High
  - Low
- Interchangeability
  - Low
  - High

Source: The Boston Consulting Group
Specialty generic medicines and biosimilars to account for 70% of profits by 2020

Projected EU 6 profit pools 2020

<table>
<thead>
<tr>
<th>Technical Barriers</th>
<th>Commercial Barriers</th>
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<tbody>
<tr>
<td>Standard unbranded Gx</td>
<td>Biosimilars</td>
</tr>
<tr>
<td>Specialty Gx</td>
<td>Standard branded Gx</td>
</tr>
</tbody>
</table>

Expect profit growth despite barriers

Expect further profit erosion

Dilemma: 80% of Gx volumes & assets commoditizing but profits are dwindling

Source: Boston Consulting Group (2014)

Analysis covers France, Germany, Italy, Poland, Spain and UK
Still considerable opportunities to increase uptake throughout Europe

Protected and off-patent marked share (value) by country, June 2015

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