Spending wisely – the challenges of decision-making for expensive medications in Austria

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The opinions expressed here and any errors are exclusively mine.
The Challenges Facing Payers

- Determining the “added-value” of expensive specialty medicines as a starting point for price negotiations
  - New oncology products
  - Orphan medicinal products
  - Personalized medicines – are we prepared?

...and some Potential Solutions

- From managed introduction to MoCA
- Healthcare reform in Austria – optimizing access and efficiency
- Biosimilars in Austria

Music by Gaetano Donizetti, Lyrics by Felice Romani, First Performance 1832
http://en.wikipedia.org

Dulcamara:
Come buy of me this great specific
Which to you all I cheap will sell
This cures the apoplectical
The asthmatical, the paralytic
The dropsical, the diuretical
Consumption, deafness, too
The rickets and the scrofula…
Orphan Medicinal Products 2009 - 2013: No of Products

<table>
<thead>
<tr>
<th>Year</th>
<th>Anzahl Produkte</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>64</td>
</tr>
<tr>
<td>2010</td>
<td>79</td>
</tr>
<tr>
<td>2011</td>
<td>91</td>
</tr>
<tr>
<td>2012</td>
<td>98</td>
</tr>
<tr>
<td>2013</td>
<td>106</td>
</tr>
</tbody>
</table>

Orphan Medicinal Products 2009 - 2013: Costs per reimbursed package (RP) for OMP vs all products

<table>
<thead>
<tr>
<th>Year</th>
<th>Costs per PP</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>20.53</td>
</tr>
<tr>
<td>2010</td>
<td>20.73</td>
</tr>
<tr>
<td>2011</td>
<td>20.90</td>
</tr>
<tr>
<td>2012</td>
<td>21.33</td>
</tr>
<tr>
<td>2013</td>
<td>21.50</td>
</tr>
</tbody>
</table>

Source: Maschinelle Heilmittelabrechnung
### Yearly Cost of Orphan Drugs per Patient

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Minimum</strong></td>
<td>€ 1,251</td>
</tr>
<tr>
<td><strong>Median</strong></td>
<td>€ 32,242</td>
</tr>
<tr>
<td><strong>Maximum</strong></td>
<td>407,631</td>
</tr>
</tbody>
</table>

Estimating the budget impact of orphan medicines in Europe: 2010 - 2020
Carina Schey (carina@gmasoln.com)
Tsveta Milanova (tmilanova@celgene.com)
Adam Hutchings (adam@gmasoln.com)
Orphan Drugs: Possible Solutions

• Any solution needs to address a) indication creep and b) rising prices
• Rethink the OMP definition
• Higher standards for market exclusivity
• Separate drug development from market exclusivity and reimbursement.
• Companies: Provide a means of demonstrating how increased prices reflect extra development costs
• Payers: create dynamic reward mechanisms that allow for adjustment of costs as additional information is made available
• Societal conversation about the ethical underpinning of approaches to orphan drugs is needed, coupled with discussions about willingness to pay
Models to optimize managed entry include Horizon Scanning and post launch monitoring

Industrial drug development

Phase II  Phase III  Approval  Phase IV

Ref: Wettermark, Godman, Eriksson et al 2010
MoCA concept and Pilot Project

DG Enterprise & Industry - Process on Corporate Responsibility in the field of Pharmaceuticals

Working Group on **Mechanism of coordinated access to orphan medicinal products**

Member States:
- Austria, Belgium, Estonia, Finland, France, Hungary, Italy,
- Malta, Netherlands, Portugal, Spain.

Other stakeholders:
- EPF/Eurordis, CPME, ESIP, AIM, EFPIA, EuropaBio, Eucope,
- EU Commission, Eminet
The Scope of this Project

- to provide real access to a real solution for real patients with real unmet medical needs
- to identify possible options for the creation of a mechanism of coordinated access to OMPs,
- based on:
  - a voluntary,
  - non-legislative,
  - non-regulatory and
  - non-binding collaboration
among stakeholders who are willing to work together
A MoCA Pilot is Learning by Doing

- Horizon Scanning - Company and Payers get together on a voluntary basis. Payers are volunteers from the MEDEV group (see www.ESIP.org)

- They discuss further development of the product

- They discuss the parameters for determining the (added) value of the product, based on the Transparent Value Framework

- Based on the results of these discussions, reimbursement is facilitated in the individual countries of the consortium

- Company and product are kept confidential
## The Transparent Value Framework

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Lower Degree</th>
<th>Medium Degree</th>
<th>High Degree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Available Alternatives/Unmet Need, including non-pharmaceutical treatment options</td>
<td>yes, new medicine does not address unmet need</td>
<td>yes, but major unmet need still remains</td>
<td>no alternatives except best supportive care - new drug addresses major unmet need</td>
</tr>
<tr>
<td>(Relative) Effectiveness, Degree of Net Benefit (Clinical Improvement, QoL, etc. vs. side effects, societal impact, etc.) relative to alternatives, including no treatment</td>
<td>incremental</td>
<td>major</td>
<td>curative</td>
</tr>
<tr>
<td>Response Rate (based on best available clinically relevant criteria)</td>
<td>&lt;30%</td>
<td>30-60%</td>
<td>&gt;60%</td>
</tr>
<tr>
<td>Degree of Certainty (Documentation)</td>
<td>promising but not well-documented</td>
<td>plausible</td>
<td>unequivocal</td>
</tr>
</tbody>
</table>
Conclusions

1. Timely and sustainable patient access to treatments needs us to work together to align on challenges and to explore solutions

2. All relevant stakeholders must be involved: patients, payers, industry, HTA bodies...

3. Early engagement with a multilateral payer forum at a minimum:
   - Develop awareness and understanding for a programme
   - “Design in” payer-driven elements to the clinical design

4. A positive experience and a solid foundation for building further in the future

5. Companies are invited to participate