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.

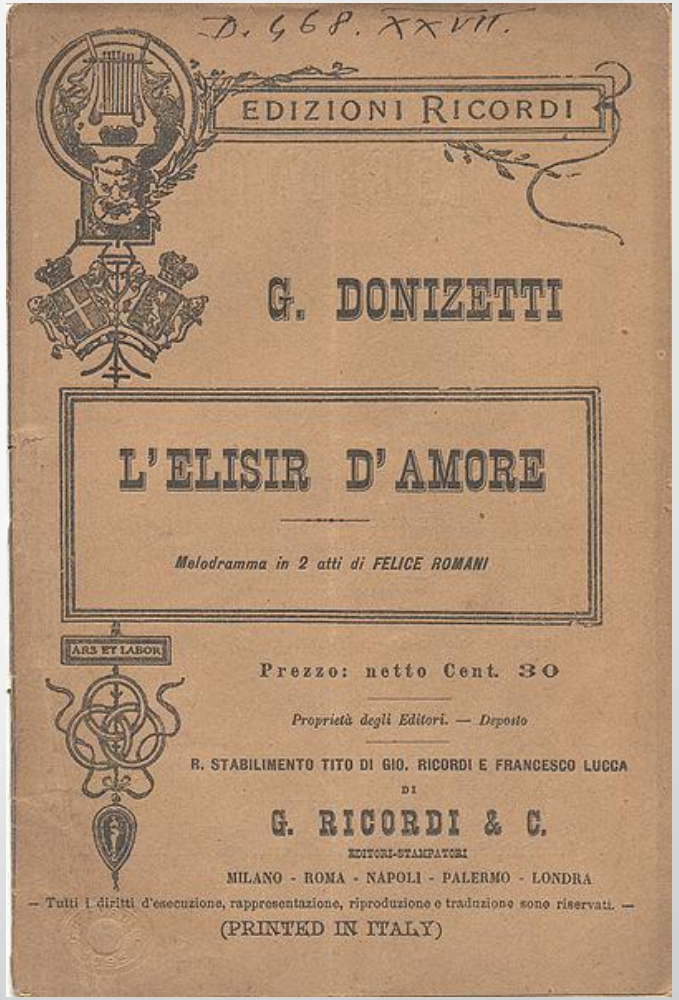
The Challenges Facing Payers

- 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

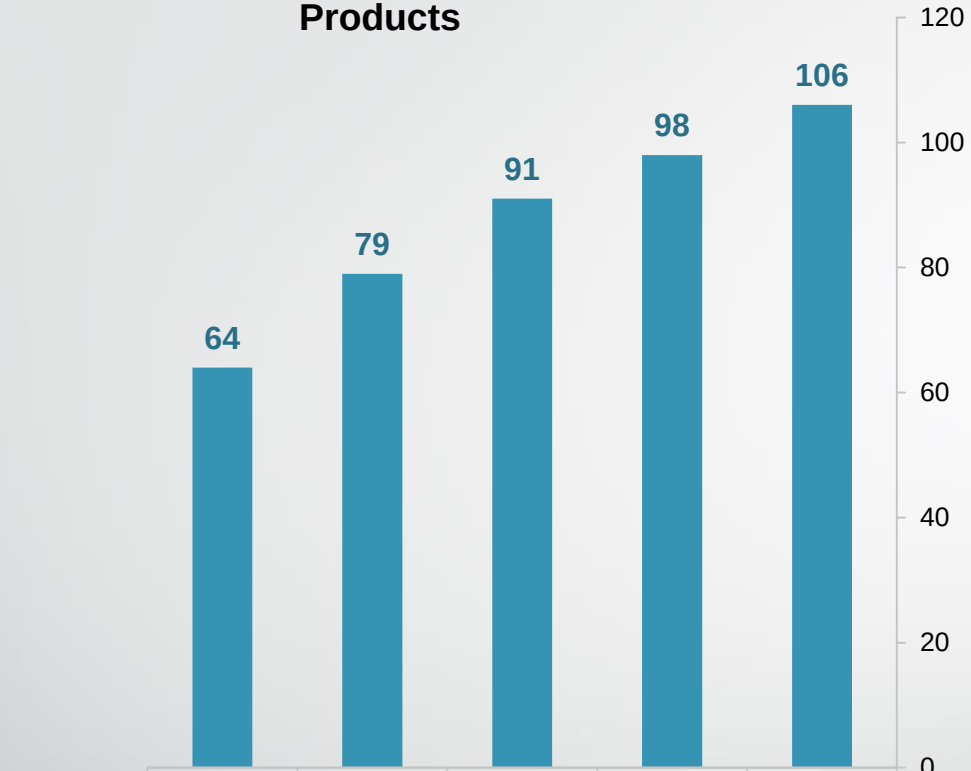
- From managed introduction to MoCA
- Healthcare reform in Austria – optimizing access and efficiency
- Biosimilars in Austria

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…



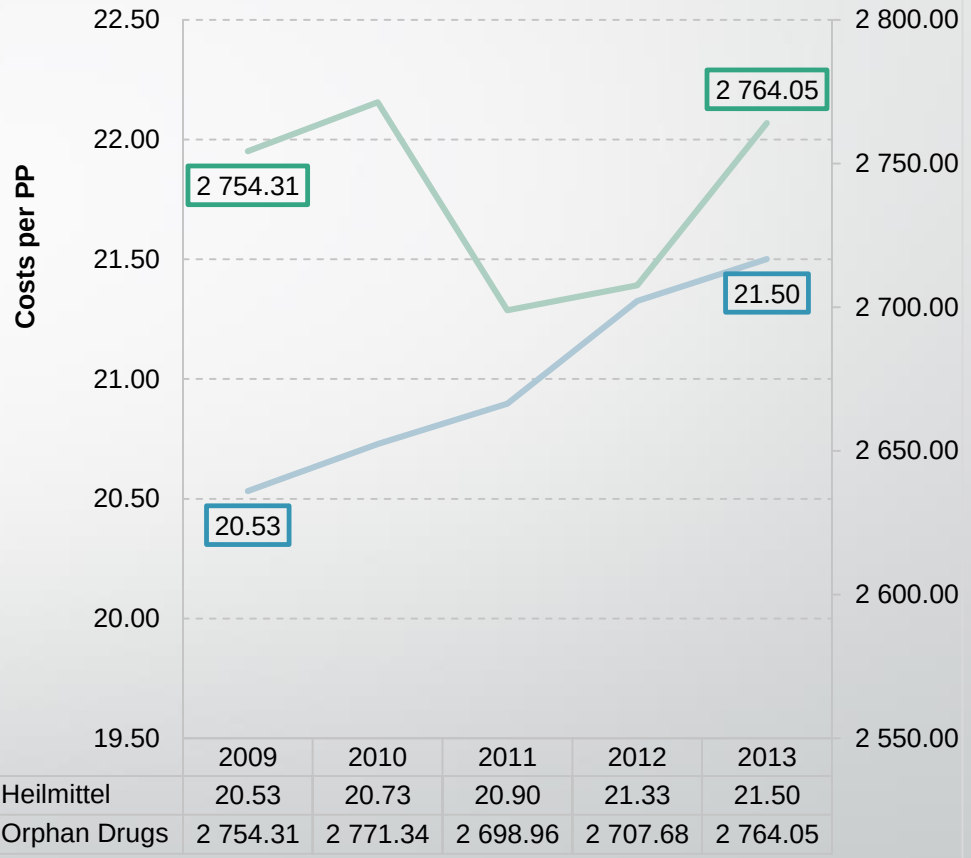
Music by Gaetano Donizetti,
Lyrics by Felice Romani,
First Performance 1832
http://en.wikipedia.org

Orphan Medicinal Products 2009 - 2013: No of Products



Source: Maschinelle Heilmittelabrechnung

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



Source: Maschinelle Heilmittelabrechnung

Yearly Cost of Orphan Drugs per Patient

Minimum	**€ 1 251**
Median	€ 32 242
Maximum	407 631

Estimating the budget impact of orphan medicines in Europe: 2010 - 2020
Orphanet Journal of Rare Diseases 2011, 6:62 doi:10.1186/1750-1172-6-62
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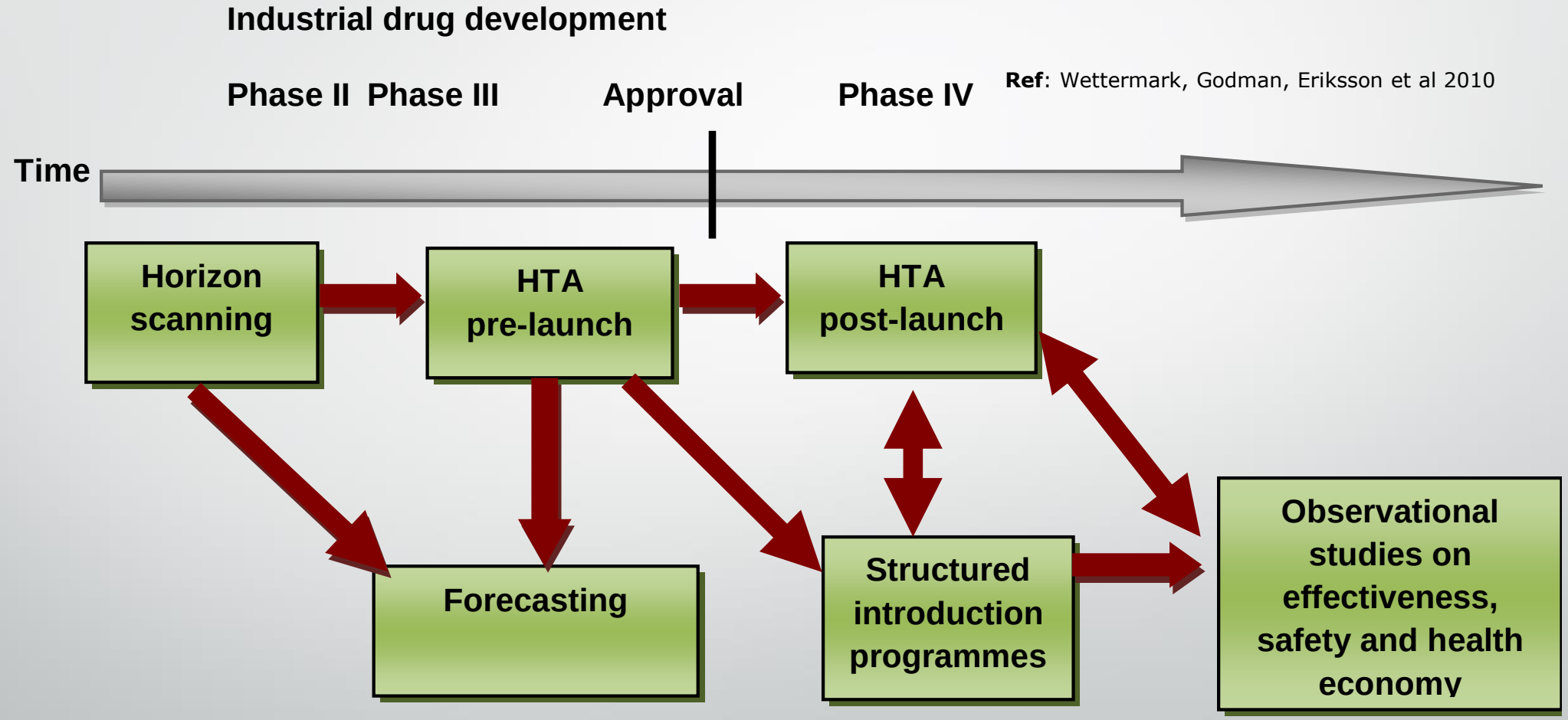
Orphan Drugs: Possble Solutions

- 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



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) avaue 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

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

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