

Payer experience in MoCA*

The European Conference on Rare
Diseases & Orphan Products
Game Changers in Drug Development,
Authorisation and Access
The last cornerstone

*Mechanism of Coordinated Access to Orphan
Medicinal Products

Disclosure of Conflicts of Interest

Anna Bucsics has been involved in MoCA since 2010, first on behalf of the Main Association of Austrian Social Insurance Institutions, and since 2014 as advisor to MEDEV. She is currently Project Advisor to MOCA and has no conflicts of interest to declare.

Acknowledgements

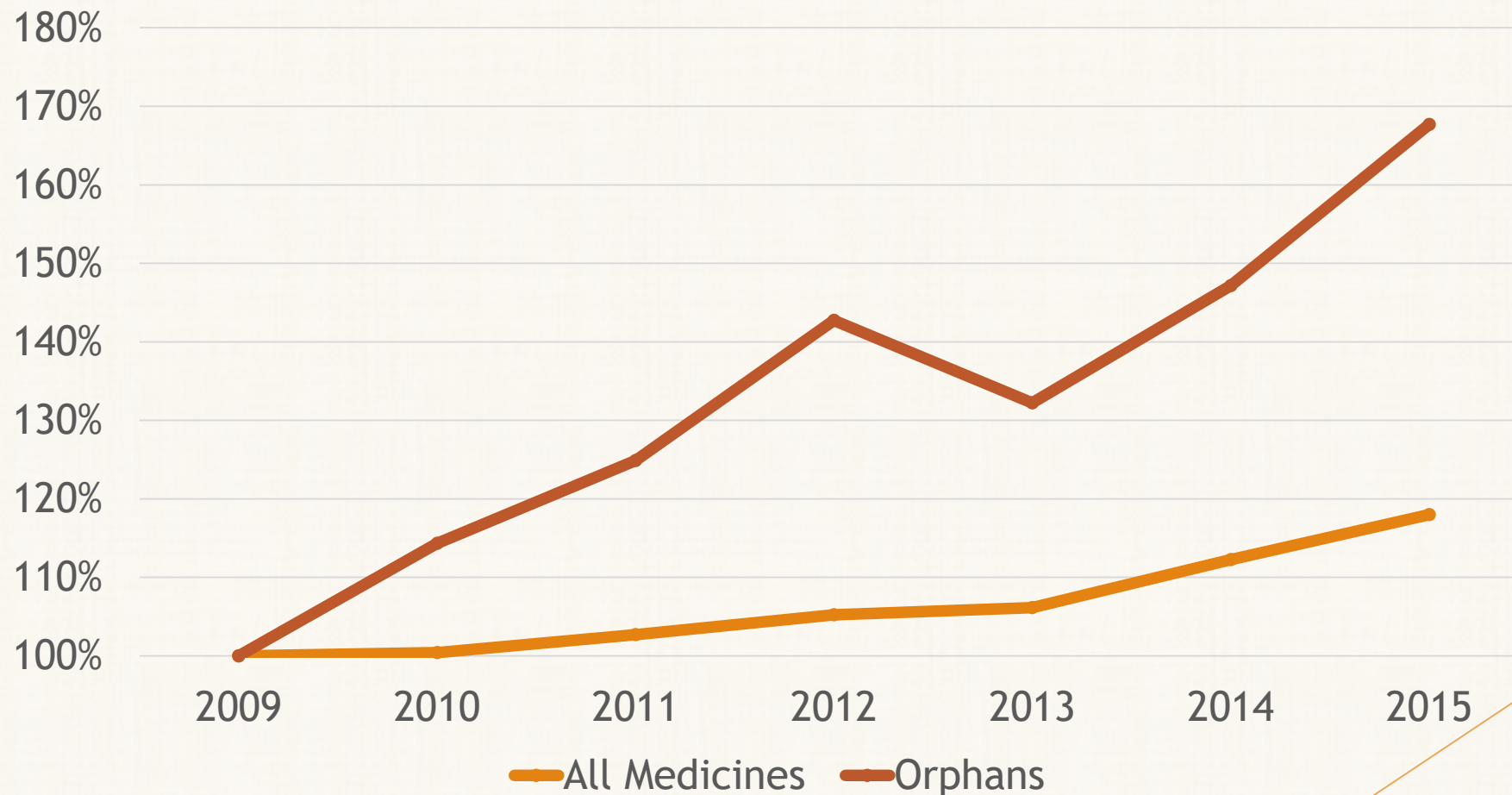
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This presentation represents my views and experiences, and does not necessarily represent the views and positions of the institutions and individuals participating in MoCA.

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Increase in Expenditures for Extramural Medicines in Austria since 2009



The cost of the products has also increased

Year	Average Cost per Prescription for <u>Extramural</u> Medicines in Austria	
	All Products	Orphans
2009	€ 20,53	€ 2 754,31
2015	€ 24,09	€ 3 136,26
Difference 2009-2015	€ 3,56 (+17%)	€ 381,95 (+14%)

A Mechanism of Coordinated access to Orphan Medicinal Products (MoCA)

Aims to facilitate coordinated and improved access to OMPs, based on:

- ▶ a voluntary,
- ▶ non-legislative,
- ▶ non-regulatory
- ▶ non-binding collaboration

among stakeholders who are willing to work together: Patients, Payers and Industry (other stakeholders welcome)

What do we want from MoCA?

Patients:

- ▶ Quicker and broader availability of the Orphan Medicinal Product
- ▶ Increased equity between patients in different EU Member States
- ▶ better and more coordinated follow-up and collection of patient-reported outcomes and real-life experiences.

Payers:

- ▶ Better documentation of added value,
- ▶ more precise budget impact estimates,
- ▶ sharing of expertise, resources and knowledge with other EU Member States,
- ▶ More efficient price negotiations

Companies:

- ▶ More predictable and more rapid uptake of new products
- ▶ Better understanding of payers' expectations

How is it done?

- Expression of interest by a company - brief product overview
- Initial presentation at a MoCA meeting (usually in Brussels)
- Dialogue** continues in a consensually established way
- Final report containing learnings and recommendations: these may concern
 - ▶ Patient numbers and estimates of use
 - ▶ Product delivery/treatment centers
 - ▶ Registries
 - ▶ Ultimately, a framework for negotiations (eg Transparent Value Framework)
- ▶ Confidential and non binding (unless otherwise agreed), „Opt-out“ anytime; currently free of charge for companies



Current Participants

- ▶ **Patients:** represented by EURORDIS and individual patients or patients' organisations relevant to a specific Orphan Medicinal on an ad hoc basis
- ▶ **Payers:** Members of the Medicines Evaluation Committee (MEDEV): volunteers from 13 countries participated in one or more MoCA pilot projects.
- ▶ **Pharmaceutical industry:** Mostly SME's, including startups (industry also represented in Steering Committee)

Pilots since 2014

- ▶ 1 concluded, 7 ongoing, 2 initiated
- ▶ Products: Small molecules, biologicals and advanced therapies
- ▶ Development Stage at initiation: From Phase 2 to post-authorisation

Learnings

- ▶ Better understanding of which outcomes matter to patients and payers
- ▶ Better understanding of payers' needs for decision-making
- ▶ Companies are welcome anytime during the product cycle - but the earlier the better
- ▶ Understanding the challenges of complicated products, eg when a disease is so rare and the treatment so complicated that it will be limited to a few selected “Centers of Expertise” across Europe (similarity with ERNs)

Payer Experience

- ▶ Informal, open discussions on many aspects of the new product and its delivery
- ▶ „heads-up“ on new developments - and their consequences for reimbursement, eg cross-border issues
- ▶ Opportunity to explore new models and to communicate concerns - may prevent future complications
- ▶ Ongoing dialogue and „brainstorming“ together can help in building trust
- ▶ ...but still a bit vague on the specifics...

Challenges - this is why we do it!

- ▶ There is no “single payer voice” - different health care systems, laws, economies, priorities...
- ▶ Complexity of new therapies
- ▶ Designing registries which accommodate the needs of regulators, HTA and payers - and are workable
- ▶ When is the best time to discuss the value of a product?

Way Forward

- ▶ Revised Terms of Reference for a new series of pilots in a more structured and better supported way to generate concrete results and new learnings
- ▶ Avoiding duplication is paramount, but we need more experience to see if MoCA can and should be integrated into other processes or projects at EMA, EUnetHTA, STAMP, etc.
- ▶ EURORDIS and EPF issued a call to EU National Competent Authorities for Pricing and Reimbursement (May 2015), asking for support of MoCA and for a Round Table on Price Negotiations

Read More

<http://www.eurordis.org/content/moca>

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Thank you for your
attention!

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