

OF ATMP'S IN THE HEALTHCARE SYSTEM - PAYER VIEW



BUNDESVERBAND

ADVANCING THE DELIVERY OF ATMP'S TO
PATIENTS
7TH ANNUAL REGULATORY CONFERENCE, EBE

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DISCLAIMER

Mr. van Lente, Director EU-Affairs, is employee of health insurer AOK, Germany

Member of GKV-SV

Member of ESIP

Member of MEDEV

Participating in MoCa

11 regional AOKs with
26.044.106 insured

(1. August 2017)

Market share 35,21 %

1.274 Branch Offices

Revenues 2016: 84,7 Bn. Euro

Expenditures 2016: 83,7 Bn. Euro



Views expressed here are those of the presenter and must not be the formal position of AOK

ATMPS: PROMISE FOR PATIENTS - CHALLENGE FOR HEALTH SYSTEM

- Potential to substantially improve patient relevant outcomes
- Health Insurance is there to pay for effective (cost-effective) care for their insured
- Challenge: uncertainty at the moment of marketing authorization
 - Effectiveness
 - Side effects
 - Relapses
 - Patient groups
 - Budget impact

FACING THE PROBLEM OF UNCERTAINTY AT THE MOMENT OF MA

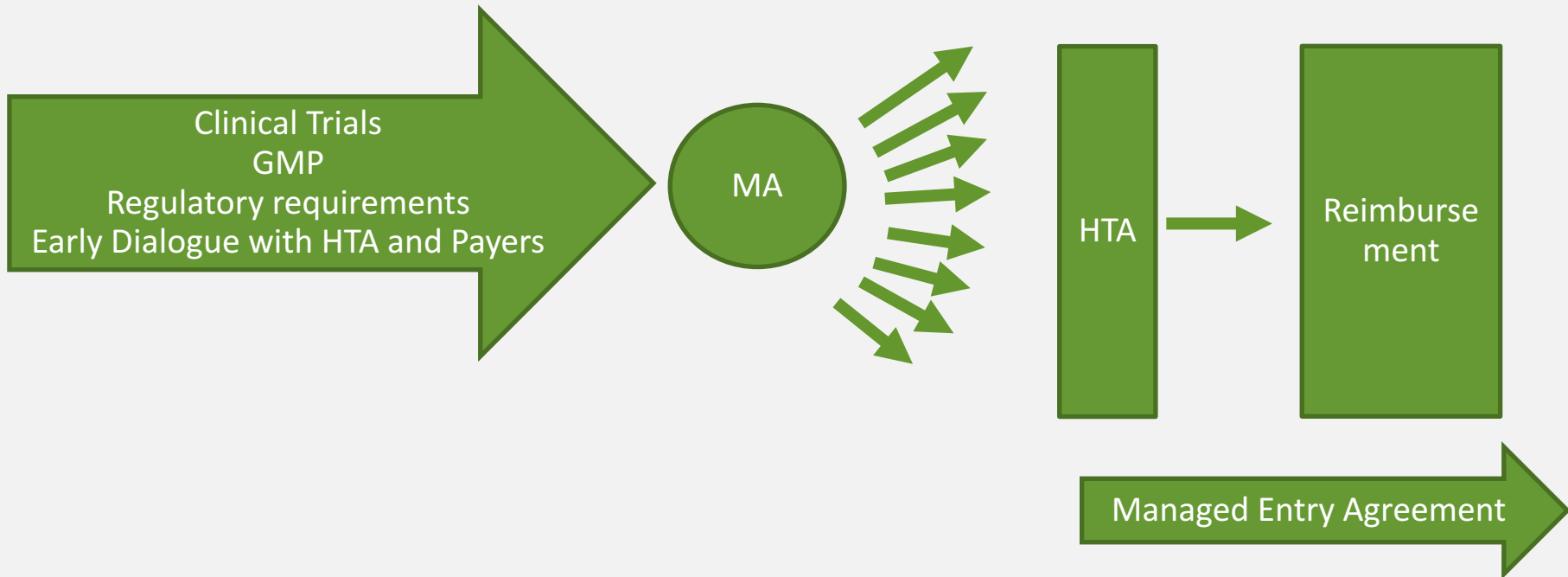
- We need post marketing evidence generation (e.g. through Managed Entry Agreements, MEAs)
- Elaborate adequate study design
- Identify the source for data: registries, routine data, combination
- Transparency of the results is needed to avoid waste of resources

HTA and Reimbursement are a national competence

Access requires affordability for patients and health systems

Challenges pre MA

Challenges post MA



REIMBURSEMENT AND PRICING - GENERAL PRINCIPLES

- Real innovations covering a real unmet medical need must be rewarded with a good price
- Price might be flexible, dependent on the evidence of the additional benefit
- Value of a new product can be reflected in the price
- Prices should reflect public financing of R&D

New Pricing models are needed

Options:

1. Pricing reflecting patient relevant outcomes (value)

Determine Value: added benefit for patients + cost savings in the system

Determine Innovation Score: unmet medical need, magnitude of added benefit

Price = costs of R&D + production + marketing + (Value x Innovation Score)

2. Rebates: price-volume, etc.

3. Outcome-based: Risk sharing, P4P, etc.

Problems with definition and monitoring of outcomes

4. Annuity payments:

Do not help in an environment of a continuously entry of new ATMPs on the market

HEALTH SYSTEMS MUST ADJUST ITS MECHANISMS

- Early dialogue to agree on evidence needed for reimbursement and pricing decisions
- New legal framework for hospital settings
- Legal framework for Competence Center and post marketing studies
- (More) convergence in HTA is possible

Thanks for your attention



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