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WE PUSH THE BOUNDARIES OF TREATMENT

MANAGED ENTRY AGREEMENTS AND INNOVATIVE PAYMENT MODELS ACROSS EUROPE

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Real world experience in the use of Managed Entry Agreements and innovative payment models across Europe

CRA Charles River Associates

Study Objectives and Methodology

Background and Objectives: Charles River Associates (CRA) assisted EFPIA in the development of a report outlining the use and impact of managed entry agreements (MEAs) from the perspective of payers and companies, particularly in EU10 (Belgium, Czech Republic, England and Wales, France, Germany, Italy, the Netherlands, Portugal, Spain and Sweden) with a focus on outcomes based agreements.

- An expert review of the approach and findings was undertaken by Professor Lieven Annemans

Methodology:

Literature review

- Current understanding of MEAs and lessons for the survey and interviews from previous studies

Survey with companies

- Conducted a survey on the trends, number, types and implementation, common TAs

Interviews with stakeholders

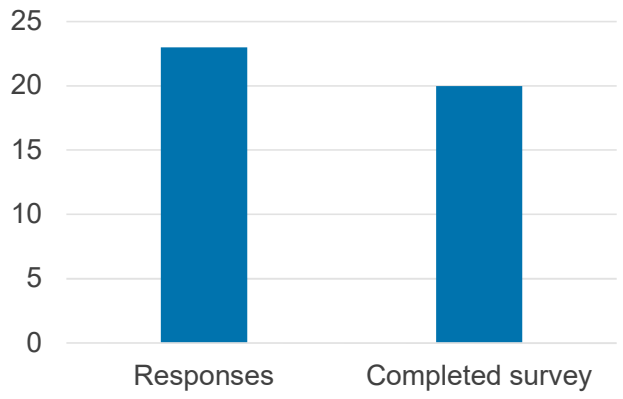
- Conducted interviews to understand benefits, barriers to use and lessons learnt with MEAs

Managed Entry Agreements

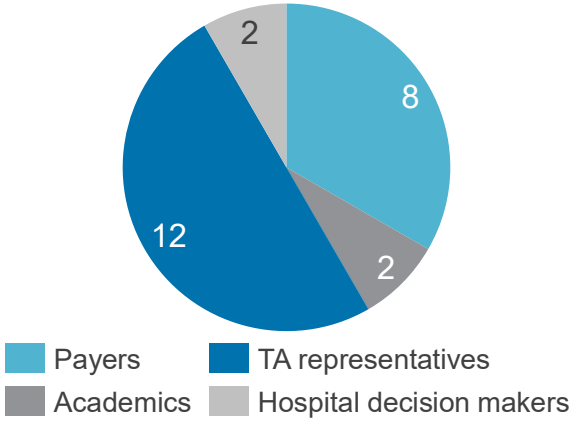
Financial Based Agreements	Outcomes Based Agreements
Market share	No-pay for non-respondent
Pricing by channel	Population outcome agreement
Price volume	Coverage with evidence development
Free initiation	
Capitation	

Hybrids

Survey Responses



Interview program



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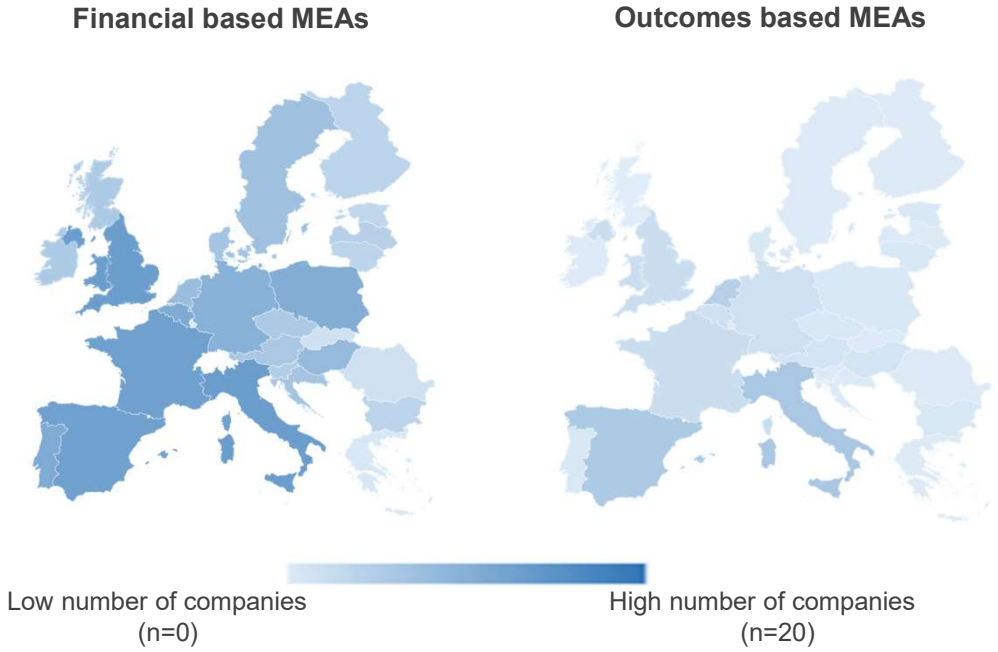
Trends: Number and types of national & regional MEAs across 10 EU countries (2015 – 2017)

- Financial based MEAs are more commonly used than outcomes based MEAs
- Companies (n=20) reported 54 national & regional level outcomes based MEAs initiated in the years 2015 – 2017 across the 10 focus EU countries
- Common types of outcomes based MEAs:
  - 60% are no-pay for non-responder, a third of which are based in Italy
  - A third are coverage with evidence development
  - Population based outcome agreements represent only a small proportion of all agreements
  - Consistent with the interview findings, some companies indicated that over 50% of all outcomes based MEAs were hybrid agreements

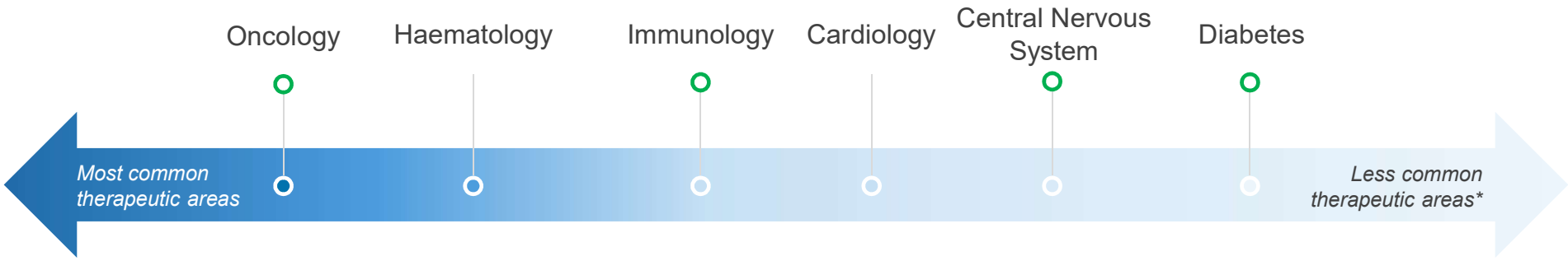
Number of companies with national/regional financial based MEAs (2015 – 2017)



Note: A company can set up multiple MEAs in the period 2015 – 2017. Countries that have regional level MEAs include England and Wales, Italy, Spain, Sweden, and the Netherlands. In Germany, MEAs are negotiated and contracted with individual sick funds rather than at the national level, here categorised as regional, and are usually implemented following the first year of free pricing.

Trends: Common therapeutic areas for national & regional level outcomes based MEAs (2015 – 2017)

- We asked companies about the most common therapeutic areas for products with outcomes based MEAs across the 10 study markets – 8 companies provided a response
  - Oncology appears to be the most common therapeutic area. This is followed by haematology and immunology, though there might be overlaps between the three areas (e.g. immuno-oncology)
  - These findings are similar to the therapeutic areas mentioned during the interviews and in previous studies

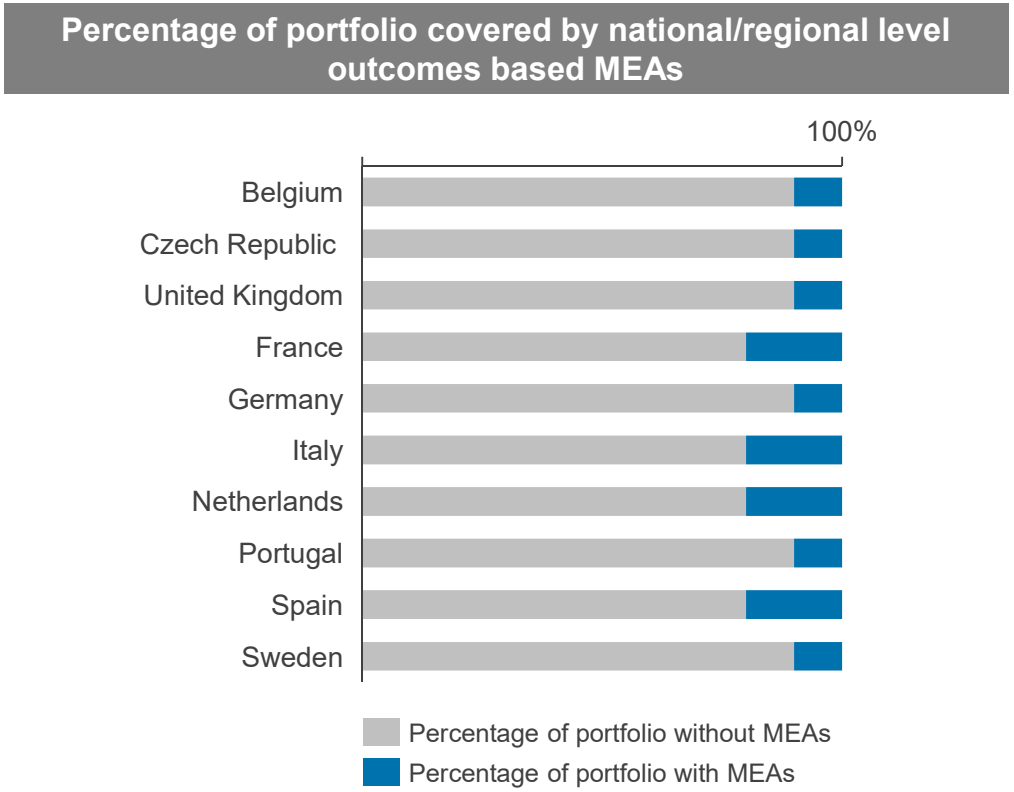


Notes: ○ = mentioned by previous studies as common therapeutic areas (EMiNet, Ferrario et a.,I 2017, Gerkens et al., 2017; Gonçalves et al., 2016) ; * Osteoporosis and Orphan medicines were also mentioned.

Trends: Percentage of portfolio covered by national & regional level outcomes based MEAs (2015 – 2017)

- Portfolio coverage:
  - 13 companies reported that less than 10% of their portfolio was covered by outcomes based MEAs across the EU10
  - A few companies reported that a higher percentage of their portfolio was covered by outcomes based MEAs in France, Italy, Spain and the Netherlands

- Timeline for implementation:
  - In the majority of EU 10 countries, national & regional level outcomes based MEAs occur at the point of market entry
  - In Germany, Spain and the Netherlands, it is commonly the case that national & regional level outcomes based MEAs are initiated during the product lifecycle



Note: In Germany, outcomes based MEAs are negotiated and contracted with individual sick funds rather than at the national level, here categorised as regional, and are usually implemented following the first year of free pricing.

Benefits: Interviewees believed outcomes based MEAs provided benefits to all stakeholders involved

Payers and the industry agreed that outcomes based MEAs deliver the following key benefits:

Top 4 commonly cited benefits

1. Accelerated and wider access to innovative treatments
2. Cost savings in treatment and decreased budget silos
3. Managing uncertainty around the effectiveness/cost-effectiveness of the product
4. Re-evaluation that might lead to sustained reimbursement based on RWE

Other perceived benefits for:

Payers/Providers	Patients and Physicians	Manufacturers
• Value-based HC decision making • Management of combination therapies • Sustainability (controlling budget impact)	• Improve outcomes and disease management for money paid • Opportunity to update treatment guidelines	• Facilitate competition as classes develop • Allow for confidentiality • Allow for marketing of products relying on limited CT data (e.g. phase II)

Note: The input from academics and hospital decision makers was aggregated with that of payers.

Barriers: Stakeholders agree that lack of registries and administrative burden are amongst the key barriers

Payers and the industry agreed on the following key barriers:

Top 4 commonly cited barriers

Lack of efficient IT systems or uniform national databases

High administrative burden on HCPs to report in registries

Low quality of the data collected

Patient data confidentiality

Other perceived barriers:

Data availability	Administration	Others
• Insufficient evidence to prove the pre-agreed end-points • Manufacturers cannot access data in registry	• Lack of human or financial resources	• Low level of collaboration amongst stakeholders • Alignment on the outcomes to be collected • Uncertainty of what happens after the expiry of the MEA

Note: The input from academics and hospital decision makers was aggregated with that of payers.

Success Factors: Stakeholders agree that low administrative burden and alignment amongst stakeholders will enable future use

Payers and the industry agreed on the following success factors and key enablers to the use of outcomes based MEAs:

Top 4 commonly cited success factors

Keep the agreements simple

Identify all relevant outcomes and uncertainties from the start

Keep the administrative burden to a minimum

Appropriate use according to therapy area through combination of outcomes and financial elements

Other perceived success factors:

Negotiation process	Data collection and administration	Others
• Align on a common goal and ensure buy in from all stakeholders • Ensure terms under the agreement match health expectations • Ensure trust amongst stakeholders during the negotiation process	• Base data collection on existing CTs • Allow sufficient time for data collection and ensure consistent data reporting • Allow sufficient human and financial resources • Ensure access to appropriate (IT) infrastructure	• Use horizon scanning techniques to prepare incoming therapies • Collaborate with all relevant stakeholders to achieve common vision • Implement multi-company agreements to minimise admin

Note: The input from academics and hospital decision makers was aggregated with that of payers.

What do these findings mean for the practical use of outcomes based MEAs?

Issue	MEA solution
Budget Uncertainty: Management of budget impact	**Financial agreements:** PVAs, budget caps, dose caps, discounts, and price-match with comparator, free initiation
Value Uncertainty: Management of value for money (utilisation to optimize performance)	**Outcomes agreements:** • No-pay for non-responder – pay for performance type of agreement, linked to clinical outcomes • Coverage with evidence development – conditional reimbursement for limited time with parallel collection of additional evidence on drug effectiveness, whereby reimbursement decisions updated post assessment of new evidence • Though less common, population outcomes agreement
Clinical Uncertainty: Management of uncertain or unacceptable clinical effectiveness and/or cost-effectiveness	

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Key Conclusions

- In many markets the use of outcomes based MEAs is increasing and is expected to be important in the future, with common therapy areas being oncology, and rare diseases in general
- Both financial and outcomes based MEAs are useful instruments if used in a way that is suitable to the therapy area, otherwise they might lead to additional administrative burden
- Most stakeholders agree that outcomes based agreements bring benefits to payers, patients and the industry. The types of benefits vary across payers/policymakers and countries depending on their level of experience
- Companies are willing to engage in these agreements, but the availability of infrastructure for data collection can be a challenge
- For outcomes based MEAs to succeed, payers and manufacturers should keep the agreements simple, align from the beginning on the types of outcomes measured, and ensure that data collection systems are in place

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