UNDERSTANDING THE IMPACT OF REAL WORLD EVIDENCE ON REIMBURSEMENT DECISIONS ACROSS EU5 COUNTRIES USING A WEB-BASED PORTAL TO ENGAGE PAYERS

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INTRODUCTION

Real World Evidence (RWE) studies support RCTs by demonstrating that the trial outcomes are generalizable to clinical practice.

RWE can be used to address uncertainties around disease burden and long-term treatment outcomes, however, significant challenges remain on the optimal method of collecting RWE for use in reimbursement decision making.

This research was completed to understand the impact of RWE on reimbursement decision-making, the current challenges and the future value of RWE across the EU5.

METHODOLOGY

A web-based survey was administered through the Rapid Payer Response™ online portal (RPR®) to 25 payers with experience in HTA and reimbursement decision-making in France, Germany, Italy, Spain and UK; MAT engaged 5 payers per country.

Payer profiles included former members of NICE and the SMC in the UK, ex-CEPS and ex-TC payers in France, ex-GBA and SHI payers in Germany, and both national and regional level payers in Italy and Spain. Responses were collected through RPR® in 5 days and analyzed via Microsoft™ Excel.

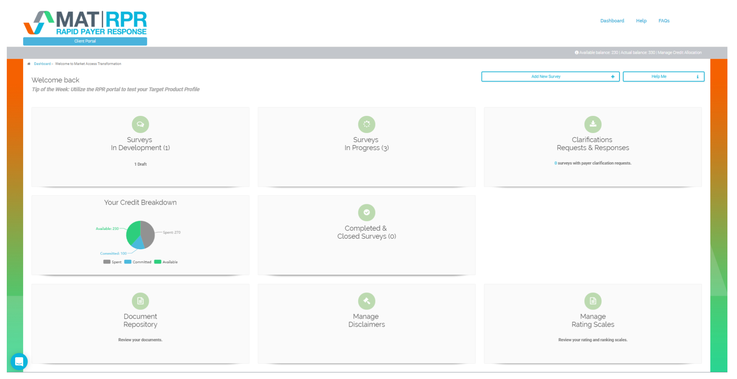

Figure 1: Rapid Payer Response™ portal

RESULTS

How influential is RWE on current reimbursement decision-making?

At the present time, RWE has a moderate impact on decision making in the UK, Spain and Italy and limited impact in Germany and France, with the exception of orphan drug evaluations.

Payers acknowledged that RWE is particularly relevant in markets where patient access schemes and outcomes-based agreements are more prevalent.

Payers considered RWE focused on safety, efficacy, budget impact and health resource utilization to be the most useful data to decision-making.

Country	*Influence of RWE on reimbursement decision-making*
France	• *Limited impact* • *RWE considered low level of evidence by TC, limited influence on SMR/ASMR ratings* • *However, RWE can be used in re-assessments and may have an impact on the renegotiation of product price*
Germany	• *Limited impact* • *RWE is not normally accepted by IQWiG or G-BA; the only exception is the benefit assessment of orphan drugs for which data from registries and observational studies can be used*
Italy	• *Moderate impact* • *Particularly valuable if available at the time of price negotiation; also used to maintain pricing* • *RWE expected to have increased impact in the next 5-10 years*
Spain	• *Moderate impact* • *Valuable supportive data where there is lack of evidence from RCT e.g. orphan drugs* • *Increased influence at the regional/local level compared to national*
UK	• *Moderate impact* • *RWE is utilized in formation of patient access schemes and outcomes-based agreements*

Figure 2: Influence of RWE on reimbursement decision-making in EU5 markets.

What are the key challenges associated with collecting RWE?

Robustness of data was considered by payers across all scope countries to be the most significant challenged associated with RWE studies.

- Payers in France, Germany and the UK also highlighted integrating data from multiple sources and the cost of data collection as key issues in their markets
- Payers in Italy and Spain considered additional challenges to be the lack of standardization of RWE analytics and the difficulties with tracking outcomes for patients with specific biomarkers.

"Decisions are only as good as the data that informs them. Data has to be robust, consistent across systems and different parts of the same system and relatively easy to collect." ***Former Senior Advisor, NICE, UK***

"Depends on the quality of the data collection and bias prevention; data analysis in health care is still at the development stage." ***Former Advisor, AIFA, Italy***

How will the role and impact of RWE to change over the next 5-10 years?

The majority of payers agreed that RWE is likely to become more important to pricing and reimbursement processes over the next 10 years, with greater emphasis on the patient population and the methodology used to collect the data. In particular:

- Increased use of RWE driven by to the growing number of outcomes-based agreements and patient access schemes
- Use of RWE to identify subgroups with improved clinical outcomes, particularly for expensive therapies
- Use of RWE in treatment pathway and guideline development.

CONCLUSIONS

Currently, RWE has a modest influence on EU pricing and reimbursement processes; although not currently a core component of HTA processes, RWE is a key requirement for outcomes-based agreements and price renegotiation. Payers expect the role of RWE to become more influential in the future, both in HTA evaluation processes and the development of treatment guidelines; however payers emphasized that at present there are still concerns regarding the robustness of data collected, lack of standardization and the administrative burden of data collation.

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