

IDENTIFYING THE KEY DRIVERS AFFECTING THE REIMBURSEMENT OF THERAPEUTIC VACCINES IN THE EU5 USING A WEB-BASED PORTAL TO ENGAGE PAYERS

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INTRODUCTION

The global market for therapeutic vaccines has witnessed significant growth in the last decade (e.g. anti-cancer, hepatitis B); however, the overall cost, stringent regulatory policies and initial capital investment associated with therapeutic vaccines present a challenge to payers. This research was completed to identify how HTA processes are likely to evolve over the next 5-10 years to address the challenges associated with therapeutic vaccines and to understand the key drivers that will support favorable pricing and reimbursement outcomes in the EU5 markets.

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 for vaccines in France, Germany, Italy, Spain and the UK; MAT engaged 5 payers per country.

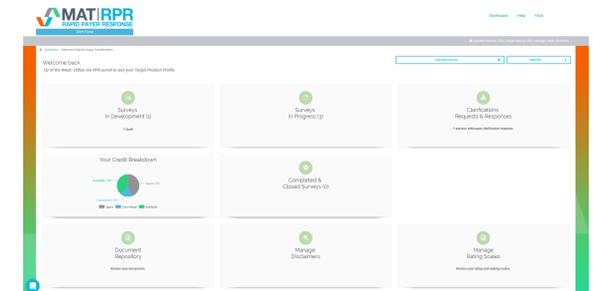


Figure 1: The Rapid Payer Response™ portal

Payer profiles included former members of the department of Health and JCVI (Joint Committee of Vaccine and Immunization) 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.

RESULTS

What are the key drivers that support favorable pricing and reimbursement outcomes for therapeutic vaccines in the EU5 markets?

Across all EU5 markets, the efficacy and safety of the vaccine, and the use of appropriate biomarkers were the most important clinical drivers influencing reimbursement.

- Cost effectiveness and real-world evidence (RWE) were considered to be particularly important by payers in the UK and Italy.
- Quality of life data was acknowledged to be an important parameter by payers in the UK, Germany and Italy.
- Compliance and adherence were important parameters in the UK, but considered less important by payers in the other scope markets.
- Convenience of administration was considered to be of lower importance overall.

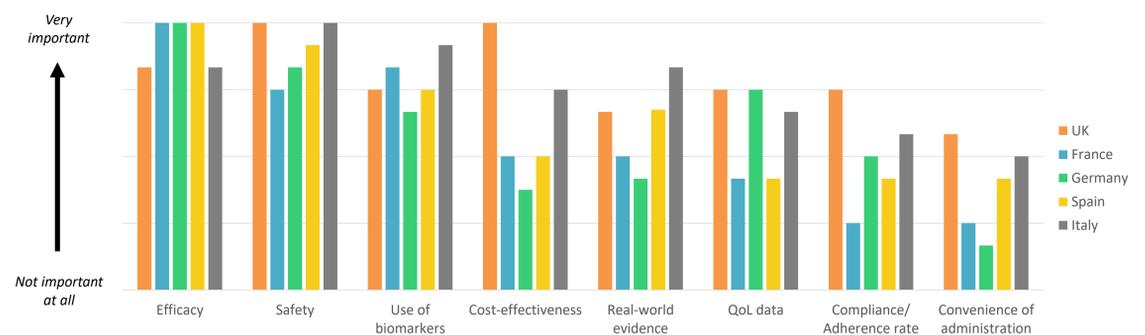


Figure 2: The key clinical drivers considered to have the greatest impact on reimbursement decision-making for therapeutic vaccines in EU5 markets

In addition to the clinical drivers specified above, payers also acknowledged that external or indication-specific factors will influence reimbursement and pricing outcomes, primarily:

- the level of unmet need
- the size of the eligible patient population
- willingness-to-pay based on national/regional budget constraints.

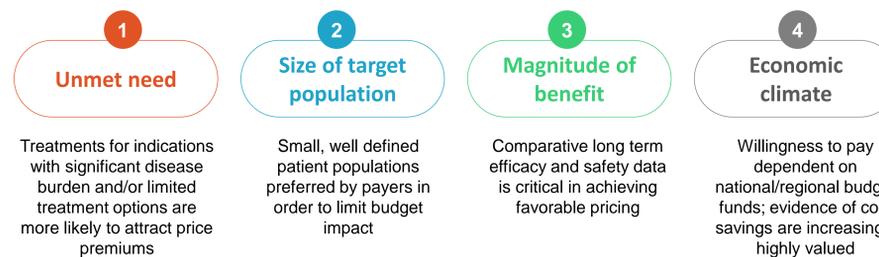


Figure 3: The key attributes associated with favorable pricing and reimbursement outcomes for therapeutic vaccines in EU5 markets

Payers acknowledged that favorable pricing and reimbursement outcomes would be most likely in a scenario where a therapeutic vaccine can demonstrate substantial clinical benefit in an indication with a small and well-defined patient population, that has limited treatment options.

How are HTA processes likely to evolve to address the challenges associated with therapeutic vaccines?

Uncertainties surrounding the clinical benefit of therapeutic vaccines and identifying the eligible patient population represent key challenges to reimbursement decision-making; payers highlighted the difficulty in understanding the long-term effect of therapeutic vaccines compared to existing treatments. This uncertainty, in combination with the expected high cost of treatment, means that payers are increasingly concerned about the budget impact associated with novel therapeutic vaccines. Payers also acknowledged the mindset that many still associate vaccines with disease prevention rather than treatment.

Over the next 5-10 years, payers predict that agency processes will evolve with an aim to mitigate these uncertainties:

- HTA evaluation processes will remain heavily focused on the efficacy and safety of therapeutic vaccines; cost effectiveness data will become increasingly important in decision making.
- In order to mitigate the uncertainty associated with identifying the most appropriate patients for treatment, payers expect there to be greater use of diagnostic biomarkers to target patients.
- Payers expect risk sharing or procurement models to become more prevalent for funding/coverage.
- Endorsements in clinical guidelines and real-world evidence are also expected to support favorable pricing and reimbursement outcomes.

CONCLUSIONS

It is becoming increasingly important to understand payer awareness and perceptions regarding therapeutic vaccines in order to meet expectations around evidence requirements and pricing. This research has highlighted that payers associate therapeutic vaccines with a high level of uncertainty, both regarding the long-term clinical benefit and the overall budget impact. Favorable pricing and reimbursement outcomes are therefore more likely in indications with limited and well-defined patient populations. In addition to strong comparative trial data, long-term follow up and RWE is recommended to demonstrate how clinical trial outcomes translate in clinical practice.