Market Access Levers and Barriers for Key Oncology Agents in the EU5: Surveyed Oncologist and Interviewed Payer Insights

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Background

- Healthcare budgets are increasingly tight across the EU5 (France, Germany, Italy, Spain, and the UK), and payers are being more aggressive in their investment in oncology.
- Across each country, payers strive to drive down healthcare costs while ensuring access to high-value treatments, often at the expense of one another. Healthcare budget and policy makers are restricting reimbursement for new therapies, and payers are continually reevaluating and optimizing uptake in a more straightforward manner.
- On the supply side, market access for emerging drugs is fraught with regulatory challenges and optimization hurdles.

Objectives

- To identify the key market access challenges for emerging oncology products in the EU5, and make specific recommendations on how to tackle these challenges.

Methods

- Members of national, regional, and local hospital and health authority (HA) systems, and payers in the five EU5 countries were interviewed.
- Interviews focused on their views about the relative importance of various market access factors in driving uptake.
- Interviewed payers across the EU5 stressed the importance of consultation and feedback from all stakeholders.

Results

- Unapproved payers across the EU5 showed the importance of optimizing clinical trial design in order to secure positive HTA status and approval under local conditions (Figure 1).
- The lack of robust data from pivotal trials that drug X met regulatory standards for SGLT2 and was effective in patients with type 2 diabetes is highlighted.
- The ability to effectively target a well-defined patient population implies a more favorable predictive biomarker was also flagged as a key issue in HTA in the EU and beyond. This greater opportunity for more robust efficacy data, which in turn increases the positive value proposition, translates into a more favorable value proposition for the payer.
- The ability to identify patients most likely to respond to a given therapy is highly important to payers as they make careful decisions on future funding, which are likely to be based on these clinical trial data, since each disease area can vary greatly.
- The growing preference for health outcomes and pharmacoeconomic data in value assessments is one of the key factors driving optimization and uptake (Figure 3).
- Payers in Spain report increasing use of cost-sharing arrangements (CSA), while in the UK, the policy for immediate patient access to new drugs is still under review.
- The overall cost of treatment (e.g., drug cost, administrative costs) and interaction with marketing company are vital to adequately demonstrate added benefit to the payer.
- The cost-containment bar is rising, and cost-containment measures can be aggressive. Consequently, navigating the pre-approval phase can be a key market access lever in this regard. For example, physician diagnosis and prescriber education, non-inferiority studies. But non-inferiority data can have a significant influence on the payer, especially in the federal healthcare markets of Italy, Spain, and the UK.

Discussion

- The cost-containment EU5 healthcare authorities can no longer afford to provide funding for all new agents that pharmacists prescribe. Therefore, the HTA bar is rising steeply, with payers seeking innovation and demonstrable advantages over currently approved treatments.
- Well-designed clinical trials showing robust survival benefits relative to current standards are critical. With the number of new agents now reaching the market, payers will only approve treatments that offer a real advantage.
- Demonstrated cost-effectiveness is imperative.
- The UK is adopting a new real-world evidence (RWE) assessment and cost-effectiveness analysis. Demonstrative cost savings can be a key market access lever for emerging agents.
- Healthcare authorities can no longer be satisfied with the current reactionary response to the use of costly drugs “controversial” or “innovative” that require treatment pre-authorizations and sales restrictions. The EU5 market is moving towards a proactive approach to RWE that will provide a robust framework for ongoing monitoring in real-life of the drug.
- A proactive strategy and highly transparent payment policies can be an essential market access lever. Given the increasing trend towards regional/national formulary variation, payers are reluctant to support premium-priced agents.
- Developers should identify patients most likely to benefit from the drug and develop a more targeted approach. Using evidence-based agents, their clinical trial design, and phase II clinical trials with prospective biomarker analysis can increase their likelihood of validation with the apparently relevant endpoint.
- Comparative diagnostic tests that use surrogate endpoints, such as duration, plasma, and other parameters, which can be used to demonstrate the drug's potential benefit.
- A new risk-sharing scheme can become more prevalent, funding models being designed in which the drug would be available only if a certain level, country-specific legal requirements permitting non-commercial risk-sharing schemes can come into play.
- Effective marketing strategies educating payers and prescribers on the key benefits that new drugs offer will maximize rapid formulation.
- Promoters of emerging agents need to be aware of the substantial delays between marketing authorization at pan European level and the availability of drugs for prescription at the national level. In the federal healthcare markets of Italy, Spain, and the UK, targeting agents and prescribers is key for maximizing drug uptake. (Figure 4).
- The regional/local budgetary variation can limit patient access to new drug costs.
- Manufacturers estimate that patient population size is a key leverage point when drafting an innovative prescribing strategy in countries, further encouraging early pharmacoeconomic evaluation and uptake.

CONCLUSION

The EU5 governments are tightening their healthcare belts. To successfully penetrate pan-European markets, novel oncology agents must demonstrate added benefit to patients in the real world, in order to head off the proliferation of less than optimal therapies. Furthermore, an economic advantage, at least a marketing advantage, must be clearly demonstrated, and to miss the real efficacy mark is not only lead to lost sales, but also loss in credibility, trust, and ultimately difficulty in incorporating the innovations.

References

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15. Manufacturers estimate that patient population size is a key leverage point when drafting an innovative prescribing strategy in countries, further encouraging early pharmacoeconomic evaluation and uptake.