

The Future of Market Access in Europe

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Abstracts

The Future of Market Access in Europe

The challenges and barriers to market access across Europe continue to be widely debated against the ever-present backdrop of cost-cutting and budgetary pressures. At the same time, the healthcare world keeps on turning and pharma must continue to push forward and ensure the latest drugs reach the patients they are designed for. But what is the current mood amongst payers? How effective are market access strategies in the current climate? And what do the decision-makers on drug usage think today about how the industry is responding to the immense challenges they are facing?

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Executive Summary

Payers and health-technology assessment (HTA) agencies at multiple levels of healthcare systems have a growing influence on market-access conditions for medicines in Europe. The barriers to market access are increasing as health systems address the challenges of sustainability in the face of global trends such as population ageing.

Medicines remain an easy target for cost-cutting, with payers particularly concerned about rising expenditure on orphan drugs, cancer therapies and premium-priced, high-volume medicines such as direct-acting antivirals for hepatitis C. As a result, there is growing encouragement in the EU for closer collaboration between regulatory and HTA functions to support more flexible approaches to drug approval and value assessment. However, payers in the EU5 markets (France, Germany, Italy, Spain and the UK) are unclear about the prospects for more co-operation between stakeholders in market access.

Member states are also embracing pan-European cooperation on HTA procedures, and even pricing and reimbursement, to an unprecedented degree. However, payers see EU-wide harmonisation of HTA procedures as intrinsically limited by national and local priorities in pricing and reimbursement. Nor do they expect much impact on market access from member-state alliances to mitigate drug-price inflation. Larger member states may prefer to rely on superior leverage and negotiate national-level discounts or other cost-sharing arrangements.

Payers expect the UK's pending 'Brexit' withdrawal from the European Union to have little bearing on market access across the EU, beyond some potential disruption to drug supply from changing trade patterns and relocation of the European Medicines Agency.

EU5 payers cite the need for more sophisticated evidence development as a key market-access challenge for the next five years. Real-world data can help to substantiate value offerings in actual clinical practice, enabling payers to adjust drug pricing and reimbursement. They expect pharmaceutical manufacturers to take a more proactive role in evidence generation to demonstrate value at different stages of the product lifecycle.

Payers in the EU5 markets are generally open to performance-based pricing and reimbursement, while pointing out some of the technical and logistical difficulties involved in administering these schemes. They also mostly favour the use of biomarkers and other tools to identify sub-populations most responsive to new medicines. There is scepticism, though, about the willingness of national governments to abandon well-established cost-containment such as external reference pricing, budget caps or tendering.

Biosimilars, along with more encouragement for mainstream generic prescribing

and substitution, are likely to be a critical lever of market access in Europe, both by reducing the costs of biologics and clearing space in drug budgets for the next wave on innovation. Manufacturers will need to work harder, though, to resolve lingering questions around the reliability, interchangeability and pricing of biosimilars.

Medical guidelines and recommendations remain an important element in market-access policy for medicines, although some payers complain that they are not updated quickly enough. Most of the payers interviewed did not see drug-adherence programmes nor other value-added services as a significant component of the market-access package, with some regarding these as veiled marketing tools.

In general, patients were not seen as having a decisive influence on access to medicines through formal contributions to evaluation processes in the EU5 member states. However, patient objections or preferences can have a strong bearing on drug uptake in some circumstances.

HTA procedures already play a significant role in determining market access to medicines both at national and regional/local level. They are expected to evolve incrementally, while budget caps, risk-sharing schemes or price-volume contracts will be imposed in cases where particularly expensive or high-demand new drugs risk overwhelming healthcare budgets.

This report is based on in-depth interviews with 8 payers responsible for drug budgets in EU5 markets (France, Spain, Italy, Germany and the UK).

Research Methodology and Objectives

This report assesses the current mood of payers across Europe and looks at market access barriers, incentives, policies and solutions from both pan-European and national perspectives. The views of each of the expert contributors are backed up with secondary research from a range of sources to provide a unique insight into current market dynamics as well as a view on future developments.

Analysis is based on detailed interviews carried out between July and August 2017 with 8 expert payers based in either France, Germany, Italy, the UK and Spain.

Advisor to the Spanish Agency for Medicines and Health Products (AEMPS) and member of the Inter-Ministerial Pricing Commission (CIPM).

French pharmaceutical-market consultant and former member of the Haute Autorité de Santé.

French hospital pharmacy director and vice-president of formulary drug committee, involved in national health technology assessment, reimbursement and pricing.

Member of Italy's Mediterranean Institute for Transplantation and Advanced Specialised Therapies (ISMETT) and of the Italian Society for Hospital Pharmacy (SIFO).

Head of drug budgeting and reimbursement in Germany.

Head of drug budgeting and reimbursement in Germany.

UK consultant pharmacist, pharmaceutical advisor to regional clinical commissioning group and national expert adviser to the National Institute of Health and Care Excellence (NICE).

UK member of the national heads of medicines management committee and of a regional advisory committee on high cost, low-volume drugs.

Key questions explored in this report include

What EU-wide harmonisation is underway and what impact is it likely to have?

How is the European market-access landscape likely to evolve over the next 5 years?

Which drugs/disease areas are of most concern for payers and why?

What more do payers expect from pharma to help alleviate cost and efficiency pressures?

What is the current feeling regarding performance-based pricing and

reimbursement?

What changes in regulation are expected on a country-by-country basis?

How important is real world evidence to payers and is it influencing decision-making?

What impact is patient input having on market access in individual countries?

How important is tracking and maintaining drug adherence?

What is the current attitude towards traditional market access controls?

What level of impact are biosimilars and generics having on European markets?

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The general mood amongst payers may be far from buoyant, but pharma must still strive to meet their challenges and find more effective ways to help with the relentless problem of drug cost versus finite budget – otherwise everyone suffers, and most of all patients. Market access barriers are always present, but the key to overcoming them is to continue to listen to payers and work together to evolve new ways of working that reflect the changing dynamics of individual healthcare systems. This report gives a unique insight into the latest developments in Europe as well as payers' current views and responses on market access today and going forward.

This report will enable you to

Discover how pan-European convergence in market access is happening and understand more about the potential benefits and likely limitations.

Understand the key differences between each of the healthcare systems in place across France, Germany, Italy, Spain and the UK.

Strengthen your negotiating approach at a local and regional level through deeper insight into the payers' perspective.

Find out what 'value for money' means to payers, and how it is viewed and assessed in individual countries.

Gain up-to-date national insights on the latest developments including new German drug laws and UK Brexit implications.

Ensure your pan-European market access activities and strategies are taking account of the current needs of payers and HTA agencies.

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