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Market Access in the EU5 – a comparative overview

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Abstracts

The sustained and challenging economic environment in the EU has impacted – and is impacting - pharmaceutical companies as never before. But success is still possible for those that understand the new operating environment and can navigate through the changes.

With health expenditure under scrutiny throughout the EU, spending on drugs has been targeted as a key area for cost savings. Now, gaining EU marketing authorisation from the EMA for a new drug is no longer a guarantee of commercial success, and companies must respond to national market conditions where a product must prove not just clinical effectiveness but show real economic advantage and benefits.

A high value market

The main pharmaceutical markets of the EU still rank among the world's best for innovative medicines. The pharmaceutical market value of the top 5 EU markets at ex factory prices exceeded €101,627 million in 2011. Despite health payer encouragement to use generic alternatives, generic drugs accounted for relatively little of the value, for example 30.6% in Germany but only 9.7% in Italy. The challenge facing each country in controlling its drugs bill is illustrated by per capita pharmaceutical expenditure: In France this was €608 while in Spain in was €299.

Drug pricing and reimbursement policies evolve

Countries vary in their response to tackling the funding of drugs and strategies to control the market through drug pricing and reimbursement policies continue to develop. The willingness to act has gone beyond clinician encouragement, voluntary codes and pricing deals. A raft of regulatory changes in Germany, France and the UK will see fundamental changes to drug pricing and reimbursement assessment. For the Pharma

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industry it’s tight, and it’s getting tighter.

Essential market access data and insights are now available in this new report

Using secondary source information, much of which is not available in English, this report, Market Access in the EU5 – a comparative overview, provides a detailed snapshot of the current environment and trends that are influencing market access in the five leading EU markets: France, Germany, Italy, Spain and the UK. A comprehensive overview provides valuable insights and tables of key indicators allowing easy “compare and contrast” assessment. This is followed by country specific sections examining at a national level the current status and future changes to pharmaceutical regulation, pricing, reimbursement in the context of health, demographic and economic trends.

The report answers practical questions

Who are the key decision makers for pricing and reimbursement in the major EU markets?

What are the forthcoming changes with regard to drug pricing systems?

What criteria are assessed for reimbursement decisions and how do these vary country to country?

Does inclusion in the national formulary mean a drug will automatically be available to patients throughout the country?

Are the rules for pricing and reimbursement any different for generics, compared with those for innovative medicines?

Are demographic or economic trends having a real effect on pharmaceutical spending?

Drill down into the issues that are shaping the markets and evaluate

The introduction of formal medico-economic assessments in autumn 2013 in France

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The Amendment to the German AMNOG act and the impact it may have on new innovative medicines

Why companies would be wise to engage with regional government in Italy

The role managed entry agreements play in Spain

The impact of the introduction of value based pricing in the UK in 2014

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Contents

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Healthcare provision

SPAIN

Market access considerations
Regulatory authority: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)
Pricing and reimbursement
Market environment
Demographic and economic indicators
Trends in health and pharmaceutical spending
Healthcare provision

UK

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About

Accessing the major pharmaceutical markets of the European Union (EU) may be more complicated than it first appears. Marketing authorisation for new active substances has been centralised for some years through the European Medicines Agency (EMA). Approval is issued by the European Commission (EC) rather than the EMA, but the EC generally follows the EMA's recommendations and marketing authorisation applies to all EU member states. However, responsibility for the approval of other medicines, such as generics, lies with national regulatory agencies. For the majority of prescription medicines, however, marketing authorisation represents the first hurdle.

In order to achieve success in each of the main EU markets, pharmaceutical companies must develop market access strategies that take into account the regulations and trends within each country. In the current economic climate, government budgets have been squeezed and health payers are driving reforms. While efficacy remains of paramount importance, this is increasingly being balanced with economic considerations and companies will have to provide evidence of cost-effectiveness as well as medical benefit.

Pricing and reimbursement systems continue to evolve and pricing regulation is a growing trend. The introduction of the Gesetz zur Neuordnung des Arzneimittelmarktes (known as the Arzneimittelmarkt-Neuordnungsgesetz or AMNOG) in 2011 ended free pricing in Germany. In the UK, the expected introduction of a value-based pricing system from 2014 will effectively introduce tighter control on the prices on new medicines. In France, new pricing regulations formally introduce medicoeconomic assessment for drugs from October 2013.

Gaining a positive reimbursement decision is crucial for the commercial success of most prescription medicines. A positive outcome to assessment for reimbursement will become increasingly prized as dossiers for new drugs are scrutinised not only at national level, but in Italy and Spain in particular, at regional level, where regional health authorities are responsible for the provision of local healthcare services.

Where the outcome is a negative response for reimbursement, there may still be room for negotiation. Managed entry agreements (MEAs) and patient access schemes may offer a way forward for some medicines, typically involving some form of risk-sharing agreement between pharmaceutical companies and health payers.

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The aim of this report is to provide a snapshot of the current environment and trends that influence market access in the five leading EU markets: France, Germany, Italy, Spain and the UK. Beginning with a regional overview, the report goes on to examine each individual market in more detail. The issues covered include regulation, current pricing and reimbursement systems and expected future changes, MEAs, trends in health and pharmaceutical spending, healthcare provision, and key demographic and economic indicators.

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