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Orphan Drug Market Access: Payer Insights 2016

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Abstracts

How to ensure positive payer engagement for orphan drug market access

The explosion in orphan drug approvals and high prices are causing increasing concern to payers.

When there were few orphan drugs for small patient populations the cost was less of an issue. But with the orphan drug bill pushing 10% of drug spending to treat less than 1% of patients, hard questions are being asked and tough choices being made.

The current trends are unsustainable and payers are looking to rein in costs through vigorous HTA assessment, innovative contracting, and higher proof of value. Orphan drug developers need to take seriously the issues payers face and Orphan Drug Market Access: Payer Insights is a “must read” report that shows how positively working with them will have real market access benefits.

Key Features

In-depth interviews reveal the insights of leading payers in the US, France, Germany, Italy, Spain and the UK gained from frontline experience

SWOT of the orphan drug market access landscape in 2016

Graphs and tables defining orphan drug product and developer status

Charts outlining US/EU orphan drug designation process

Case study of NICE rejection of Alexion Pharma’s Kanuma

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At-a-glance summaries of all the main conclusions

Key Benefits

Understand current market dynamics and why the growth in the number of orphan products and the rise in prices is unsustainable

Easily evaluate the players and products that are leading the the orphan drug sector

Review in detail the regulatory incentives and support for orphan drugs in the US and EU-5.

Appreciate how the orphan drug market access landscape in the EU5 countries differ and the challenges which must be overcome at the national level

Assess US payer responses to the growing cost burden of orphan drugs that threatens the free pricing model

Drive payer engagement practices that build supportive relationships

Know how payers view the role patients can play in the orphan drug space.

Key Questions Answered By This Report:

Defining “Orphan”: Is there a need to more narrowly redefine what an orphan drug actually is?

Regulation: Regulatory incentives are driving rare disease drug development but how do they differ in the US and EU and what’s on offer?

EU Reimbursement: EMA approval doesn’t necessarily translate into positive reimbursement at the national level. How is this affecting market access post-approval and where?

US Pricing: Which legal ruling has impacted pricing of orphan drugs in non-orphan indications and why is this a concern to US payers?

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New Working Models: %li%What do payers want in terms of pricing, innovative contracting, post-marketing research and engagement with pharma?

The Patient Voice: What role would payers like to see patient groups take on in orphan drugs?

Expert Views

To ensure candid views were expressed, payer names have been kept anonymous, but each has been selected for their experience and detailed current knowledge of orphan drug issues.

French Payer - Head of the Department of Pharmacy at a major university hospital in Paris and a Professor of Clinical Pharmacy and Biotechnology at the Faculty of Pharmacy at his university. He is President of a national hospital formulary group covering almost all therapy areas, including many that have an ‘orphan’ designation.

German Payer - His role involves managing the drug budget, including negotiating with insurance companies, as well as negotiating the federal state budget for specialty groups. His organisation reimburses orphan drugs and he is a voting member of the Federal Joint Committee on the assessment of orphan drugs.

Italian Payer - The Pharmacy Director of a hospital which is the referral centre for specific metabolic rare diseases with budget responsibility for all of the drugs prescribed in the hospital. She helps physicians identify the most appropriate drugs, particularly in situations where no specific treatments are available for a particular rare condition.

Spanish Payer - The Director of a Pharmacy Service and the Chief of the Pharmacy and Therapeutic Committee at a large teaching hospital in Valencia who has experience in the use, financing, pricing, reimbursement and market access of medications in Spain including orphan drugs

UK Payer - A regional pharmacy payer with a role involving implementation of

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NICE guidelines, allocation of health technology resources and formulary guidelines, reimbursement policy and procedures for Commissioning Groups in hospitals

US Payer 1 - Executive Vice President of a national plan and has responsibility for the oversight of manufacturer relationships, formulary development, reporting and analytics. This includes sitting on committees that review the appropriateness, coverage and contracting for orphan drugs.

US Payer 2 – A senior manager in a large national payer who is a member of the Formulary Pharmacy and Therapeutics Committee and has been engaged in formulary management, specialty injectables, manufacture contracting and benefit designs for 14 years.

US Payer 3 – The Chief Medical Officer and Chair of the Pharmacy and Therapeutics Committee at his organisation. He is responsible for the entire pharmacy budget and is involved in decisions regarding coverage and restrictions on drugs, formulary placement and contracting.

“I don't think it's fair for the payer system to inherit an orphan-like drug price for a non-orphan disease.”

US Payer 1

“We cannot decide at the hospital level to choose between patients. If you have no money to pay for very expensive drugs, the government says, ‘okay, you have to manage the problems yourself.’ But we cannot manage the problems ourselves, because we have a lot of patients coming into the hospitals.”

“I think a good model is having companies which can maybe arrange face to face interviews, advisory forums, payer forums where they have more in-depth, deep-dive discussions. I think there's a few companies doing that. Basically they need to do that more now.” UK Payer

Who will benefit from this report?

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Market access professionals needing to secure orphan drug market entry

MSL teams needing knowledge of orphan drug pricing and reimbursement issues

HEOR teams building value and evidence portfolios for orphan drugs

Brand/KAM teams charged with presenting commercial propositions for orphan drugs to payers

Regulatory affairs professionals tracking orphan drug regulation and incentives

National and regional payers having to negotiate pricing and reimbursement with companies

Health technology experts reviewing the safety, efficacy and value of orphan drugs

Patient advocacy groups wanting to widen market access and availability.

Content Highlights

Market dynamics

Market size and growth forecast

The key players

Regulatory environment

Orphan drug regulation in the US

Orphan drug regulation in the EU

International harmonisation

Incentives for orphan drug development

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