

A Datamonitor report

Pricing and Reimbursement in the US: Innovation and robust pharmacoeconomic analysis are key

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Use this report to...

Review P&R trends in the US, based on Datamonitor analysis and primary research conducted with key stakeholders in the industry

Providing you with:

- **Identification** of the pressures facing the drugs industry and examination of the implications for pricing and reimbursement
- **Overview** of the US healthcare market, focusing on identifying key pricing and reimbursement stakeholders
- **In-depth analysis** of global pricing and reimbursement controls, examining which are important in the US market both currently and in the future
- **Best-practice recommendations** to help drugs companies capitalize on pricing and reimbursement opportunities to maximize drug ROI

Introduction

The US is the leading global drugs market in terms of sales and profit margin. However, drug companies are facing an unprecedented number of challenges in maintaining revenue growth: fewer drugs are being approved, a wide number of blockbusters are facing patent expiry, and payers are implementing stringent cost-containment policies in the face of sky-rocketing healthcare costs.

With overall healthcare spending set to continue to rise, payers are targeting rising drug costs due to their high visibility and negative press in the US. Cost containment in this area is making pricing and reimbursement increasingly important. As a result, this is contributing to the shift towards prioritizing innovation, and implementing strategies to maximize revenue in the face of a wide range of drug pricing and reimbursement controls.

Key findings and highlights

- US drug developers need to prioritize pricing and reimbursement as an important factor in drug development, and in particular should place significant emphasis on performing robust pharmacoeconomic analysis to strengthen the case for setting a strong launch price and securing adequate reimbursement.
- Drug developers should increasingly focus on securing strong pricing and reimbursement justification before green-lighting me-too drugs. If it is not possible to clearly differentiate the drug, then the developer should carefully assess potential ROI, and consider discontinuing development if necessary to optimize resource allocation.
- To capitalize on changes to the pricing and reimbursement environment, drugs companies must optimize pricing and reimbursement team interaction both internally with other teams such as brand management, and externally with payer decision-makers.

Reasons to buy

- **Review** P&R trends in the US, based on Datamonitor analysis and primary research conducted with key stakeholders in the industry
- **Benchmark** company performance against best practice P&R recommendations to develop stronger P&R strategies
- **Gain** insight into how P&R fits into drug company strategy in the US and identify specific opportunities and threats within this area

For more information...

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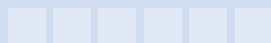


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EXECUTIVE SUMMARY

- **Scope of the report**

OVERVIEW OF THE US DRUGS MARKET: IDENTIFYING WHY PRICING AND REIMBURSEMENT IS IMPORTANT AND WHERE IT FITS IN

- **Introduction: why is drug pricing and reimbursement important?**
- **Pharma is facing a reduction in productivity**
- **Blockbuster patent expiries are also damaging Big Pharma**
- **Pharma pipeline strategy needs to adjust to market demands**
- **Public and private payers exert pressure on profit margins**
 - Pressures on drug developers rise because healthcare expenditure is set to continue to increase
 - Although drugs make up a relatively small percentage of healthcare spending, they are a highly visible target
 - Spending on drugs is set to rise
- **The drugs industry is being squeezed on drug pricing and reimbursement**

THE US HEALTHCARE SYSTEM

- **Introduction**
- **There is a wide range of P&R stakeholders in the US healthcare system**
- **An overview of private and public healthcare in the US**
 - Private healthcare insurance dominates US healthcare provision
 - Public healthcare in the US covers a significant percentage of the elderly and disabled
 - A small but significant percentage of the US population are uninsured
 - A summary of the US Healthcare System

DRUG PRICING IN THE US

- **Introduction**
- **Setting the price for a new drug**
- **An overview of pricing controls**
 - Drug pricing controls in the US
- **An overview of government-led price controls**
 - Cost-plus pricing is not used in the US

- The use of profit controls is more of a European measure than a US strategy
- Implicit reference pricing is set to be incorporated into US cost containment strategies
- Price ceilings are used in the US but are not a key pricing control
- Price cutting and price freezing do not play a significant role in US cost containment
- Linking pricing with Consumer Price Index
- **The use of pharmacoeconomics (PE) in US pricing controls**
 - Using healthcare economics, outcomes research and pharmacoeconomics to justify pricing
 - Methodologies of pharmacoeconomic evaluation
 - The use of pharmacoeconomics in HTAs
 - Issues with pharmacoeconomic analysis
- **Discounts and rebates have a significant impact on US pricing**
 - The use of discounts and rebates in the public arena
 - Private payers in the US
- **Modulating pricing while the drug is on the market**

DRUG REIMBURSEMENT IN THE US

- **Introduction**
- **Reimbursement favours innovation-focused drug development**
- **A wide range of factors influence reimbursement**
 - Controlling doctors budgets is used in Europe but is not widely used in the US
 - Volume and expenditure limitations is not a key reimbursement control in the US
 - Tiered co-pay and formularies are key reimbursement controls in the US
 - Formulary access and Positive/Negative lists are a popular cost containment tool in the US
 - Taxes on reimbursed drugs
 - Some countries require drugs to be included on reimbursement lists of a number of countries before reimbursement is granted
 - Pharmacoeconomics and risk-sharing agreements are increasingly important in the US
 - Step therapy or fail first plays a central role in cost containment in the US
 - The role of restricting pharmacy networks in the US

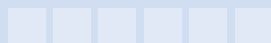
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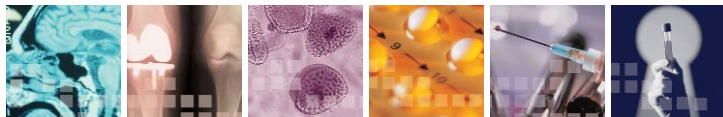
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- Enforcing a switch to OTC status is another reimbursement restriction tool

THE FUTURE OF PRICING AND REIMBURSEMENT IN THE US: BEST PRACTICE RECOMMENDATIONS

- **Introduction**
- **Best practice recommendations**
 - Recommendations focusing on improving how P&R is carried out internally in a company
 - Recommendations focusing on enhancing how the company carries out P&R activities externally in the marketplace
 - Drug-specific recommendations
- **The future of pricing and reimbursement in the US**

APPENDIX : SUPPORTING DATA

TABLES

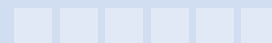
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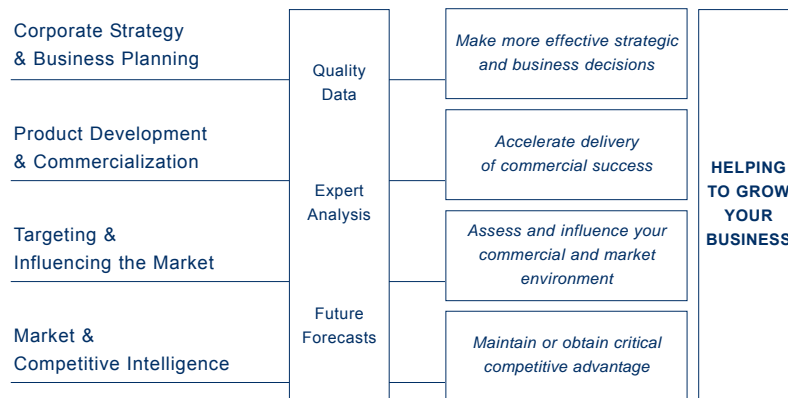
“...If we focus on large market 'me-toos' we will in the short term be probably fairly successful - in the long run, we will be cutting our own throats...”



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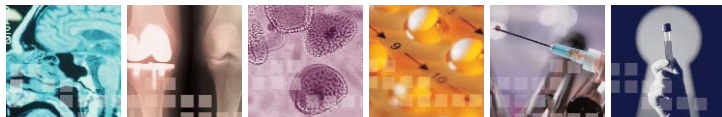
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