

# Generics Series: Generics Trends in the Seven Major Markets and Beyond

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## Providing you with:

- **An overview** of key events which have impacted on the generics industry in the seven major markets
- **An insight** into the strategic trends employed by the industry to sustain growth in an increasingly competitive environment
- **An introduction** to the emerging markets, as the next frontier for industry growth
- **An outline** of how recent M&A activity has altered the generics industry landscape

### *Use this report to...*

*Identify the issues are impacting on the generics industry in the seven major markets*

# Introduction

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Based on generics use, the seven major markets may be divided into mature (the US, Germany and the UK) and immature (France, Italy, Spain and Japan) markets, both of which present different challenges, making the fast-growing, high-value emerging markets a tantalizing prospect. In addition to market expansion, acquisition and closer innovator ties represent key strategies for industry growth.

Looming patent expiries and empty pipelines have prompted several innovators to edge into the generics market, by acquisition or collaboration, marking a substantial shift in the innovator-generic dynamic. However, the two contingents have come under fire for entering into agreements which could lead to delayed generics market entry in both the US and Europe. Drug cost-cutting measures, which in the past have driven generics use in more mature markets, and are now beginning to work against the industry in Germany and the UK, forcing a change in strategy.

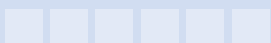
## Key findings and highlights

- The global generics market is growing, however it will be the immature and emerging generics markets which will increasingly drive growth, as competitive pressures in the more mature markets intensify, and make sustaining revenue growth more difficult here.
- Consolidation continues to be a crucial strategy for generics industry growth, with recent M&A activity having reinforced the position of some companies, whilst bolstering the ranking of others. The magnitude of acquisitions has also increased, and given current economic conditions, such high price-tags may not be sustainable.
- The increasingly close relationship between generics and branded companies—feared by regulators to delay generics market entry in some cases—has reached an extreme in the recent acquisitions of generics companies by innovators, a response to the pressures the latter are under.

## Reasons to buy

- **Identify** the issues are impacting on the generics industry in the seven major markets
- **Understand** why the emerging markets are increasingly a target for generics companies
- **Identify** the key strategic trends for the generics industry in the future

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## EXECUTIVE SUMMARY

- **Scope of the report**
- **Key findings**

## TRENDS IN THE GENERICS MARKET

- **Consolidation - size, spread, and (drug) supply**
  - Acquisition of Barr allows Teva to extend its lead
  - Mylan still assimilating Merck Generics acquisition
  - Acquisitions to come
- **Convergence between generics companies and innovators**
  - Daiichi Sankyo's acquisition of Ranbaxy
  - Pfizer moves beyond own-generics
  - Sanofi-Aventis bags Zentiva
  - GlaxoSmithKline inching into emerging markets via generics
- **Innovator-generic company deals under increasing scrutiny**
  - Reverse payments in US
  - EU Commission undertakes dawn raids, to gather settlement data

## THE MATURE GENERICS MARKETS

- **The US market - reaching the outer limits of growth**
  - Wal-Mart reinforces its position in the generics prescription market by targeting the mail order pharmacy sector
  - Generics drive from insurers and PBMs
  - ANDA approval times on the increase
  - Generic erosion in the US
- **Germany - on the road to becoming a commodity market**
  - AOK relaunches more competitive drug tenders
  - DAK tenders under scrutiny
- **The UK - reimbursement changes will impact on generics use**
  - Mandatory pharmacist substitution to be introduced

## THE IMMATURE GENERICS MARKETS OF EUROPE

- **Italy experiences setback following bioequivalence issues**
- **Spain remains a tough market**
  - Teva expands presence in Spain through Bentley acquisition
  - Zydus Cadila moves into Spain

## • **France - generics use driven by state and pharmacists**

- Generics penetration has increased for a subset of drugs
- Pharmacists are driving generics use
- Wholesaler discounts larger for generics
- Reference pricing has contributed to growth in generics use

## JAPAN POISED FOR GROWTH

- **Japan's generics market - international interest mounting**
  - Reforms to promote generics use
  - Impact of new form prescriptions
  - Quality over price
  - Improving generics distribution should promote uptake
  - Boost to cardiovascular drug generic switch
  - Impact of the generics drive
  - Influx of multinationals as Japanese generics market looks set to grow

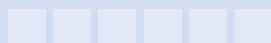
## EMERGING MARKETS ARE THE NEXT FRONTIER

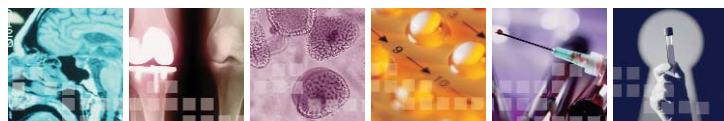
- **Growth opportunities in emerging markets**
  - Central and Eastern Europe - the time to enter is now
  - Latin America - generics use to continue to grow
  - Asia - driving growth of the pharma industry in the future, but unlikely to be a goldmine for generics
  - Middle East and North Africa - easy pickings for foreign entrants?
- **Companies looking to enter emerging markets**
  - Teva looking east
  - Sandoz's growth driven by emerging markets
  - Mylan looking to be a top three player in CEE
  - Stada establishing itself through a combination of organic and inorganic growth
  - Actavis has acquired its way into emerging markets
  - Indian generics companies continue to expand aggressively

## BIBLIOGRAPHY

- **Publications and online articles**
- **Conference literature**
- **Datamonitor resources**

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## APPENDIX

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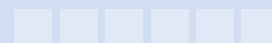
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*“...The competitive pressures that have driven generics companies to move from the initially profitable mature generics markets into immature ones, have been instrumental in the current shift towards emerging markets...”*

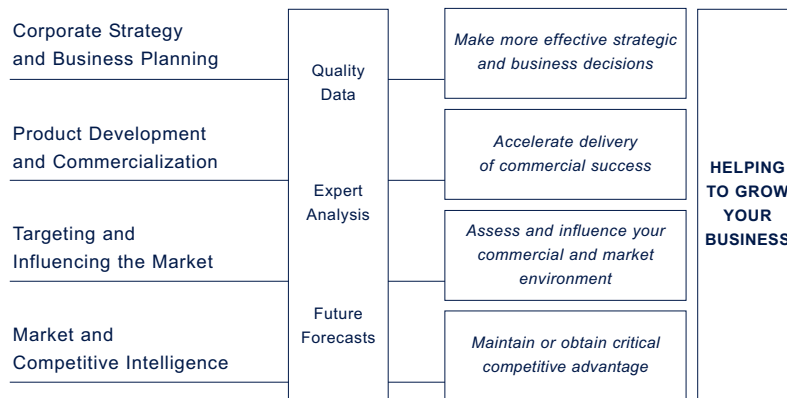


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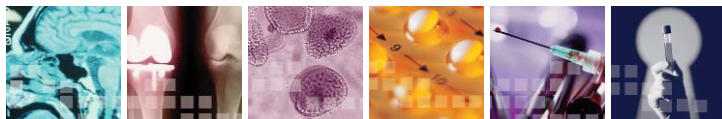
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### **Mylan Inc. (incl. Merck KGaA Generics): PharmaVitae Generics Profile**

Analysis of Mylan's corporate strategy, marketed branded and generic portfolio, pipeline potential and financial position in 2006. Includes analysis of the impact of Mylan's recent acquisition of Merck KGaA's generics business

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