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Biosimilars in Emerging Markets

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Abstracts

Biosimilars: Make the most of high risk emerging market opportunities

Emerging biosimilars markets are currently a $5billion opportunity with even more growth potential ahead. Lower drug costs and improved patient access are attractive to governments, insurers and patients too. But with market regulations that are full of loopholes, bias in market access and powerful national champions dominating the field, emerging markets are notoriously difficult to navigate. How can market entrants build a solid team and forge local alliances for success? And what is the single greatest threat to establishing a thriving, competitive emerging market trade in biosimilars?

Report Overview

With detailed country profiles plus insights from local industry executives with real-world experience in today's most attractive emerging markets, Biosimilars in Emerging Markets: Navigating the Challenge offers practical recommendations and success strategies to help protect against the significant risks involved.

Report Features

What you need to know about the patchwork of regulatory developments in key emerging markets: what the rules say, what data is essential and where the gaps are.

In-depth analysis and country profiles for the 6 most attractive emerging markets (Brazil, Mexico, China, India, Russia and Turkey.

Unique 'commercial opportunity versus ease of access' attractiveness ranking for 12 countries including emerging players such as Argentina, Nigeria and

Saudi Arabia.

All the hot-button issues such as biosimilar interchangeability, reference medicines, indication extrapolation and IP rights – and how you can turn them to your advantage.

The current state of play regarding biosimilars market access in the countries attracting the most interest. Will your biosimilar face a price cap? How are drug tenders organised?

Expert recommendations and strategies from industry leaders on how to prioritise and prepare, issues to avoid, tools and resources needed, and what to expect.

Key Benefits

Avoid ‘analysis paralysis’: Get up to speed on the bigger picture and bring together expert views and principles so you can proceed with confidence.

Understand the differences: Approaching multiple emerging markets with a ‘one-size-fits-all’ plan is dangerous. The issues may be similar but success strategies will differ. What is important in each country, and what activities are required to mitigate risk?

Be prepared for the threats: Use expert insight to prepare ahead for the ‘make or break’ factors impacting new market entrants. What must you know before planning your approach?

Know where to focus resources: Build the right team, make better decisions by assessing when and where problems are most likely to arise, and understand which markets best fit with your internal strengths.

Build a targeted strategy: Use specific profiles to dig deeper into market drivers, obstacles, policy, regulatory and IP issues, market access and competitors.

Why the fuss about emerging markets?

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It's no secret that launching biosimilars into emerging markets is a growth opportunity, but this is one area where it really does pay to look before you leap. A clear cut, tried and tested route to success doesn't exist and nobody likes uncertainty. So, are you prepared for a potentially bumpy ride? Have you timed your entrance well? Most importantly, do you have a plan to address the specific challenges you will undoubtedly encounter?

Key Questions Answered By This Report

What barriers to acceptance do biosimilars face?

Which emerging markets are moving with the times, and which are playing catch-up with global gold-standard regulations?

What are the critical success factors and key steps for market entry and funding?

How big is the gap between rules and practice?

When are the best times to play on price or quality?

How can quality biosimilars be differentiated from competitors?

How will originators and local companies challenge new entrants?

How can local partners boost market access and build strong payer relationships?

What does the right team look like, and what skill sets are critical?

Expert Views

The experts interviewed for this report all have in-depth experience of biosimilars in today's emerging markets. To enable them to express candid views, all were offered the option to remain anonymous.

Director, international biosimilars company

Director, international biosimilars company

Manager, India-based generics manufacturer

International regulatory affairs consultant

Biosimilars Unit Director, Indian biotechnology company

Commercial Strategy Director, India-based biotech

Market Access Director, Brazilian biotech

Dr. Xavier Tello, Regulatory Affairs Consultant, Mexico

3 Key Quotes

“IP is becoming an issue now in emerging markets. The multinationals are making all the ‘old hat arguments’ about extrapolation and switching from 10 years ago.” Biosimilars Unit Director, Indian biotechnology company

“The key trend in the next five years is that markets like Russia, China or India will have more clarity on biosimilars regulation. Secondly the role of local players will increase – we have seen this already in India and Russia, and we anticipate that in China too.” Director, international biosimilars company

“How will emerging-market companies evolve in terms of market size? For sure, the multinationals could set up production in a low-cost country, but local clout can make a difference and that is why we value local players [in our alliances].” Biosimilars Unit Director, Biotechnology company

Who Would Benefit from This Report?

Biosimilar manufacturing companies

Research libraries within multi-nationals

Market access teams

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Intellectual property professionals

Regulatory affairs departments for specific markets

Government affairs professionals

Brand marketing departments facing biosimilar competition

Senior leadership teams looking at investment in emerging markets

Content Highlights

Executive Summary

Overview: biosimilars in the emerging world

A small market with enormous potential

Regulations in emerging markets are maturing, but are not harmonised

Timeline of first publication of national or supra-national biosimilars guidelines

Map of emerging biosimilars markets by level of regulatory development

No consensus on classifying reference products or biosimilars naming

Approval steps in biosimilars registration

Extrapolation of indications is still a concern for emerging markets

Post-marketing surveillance exposes the gap between rules and practice

Biosimilars in the age of economic chauvinism

Product pipeline data show a thriving emerging-market industry

Pipeline of biosimilar monoclonal antibodies in emerging markets

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Pipeline of non-monoclonal antibody biosimilars in emerging markets

In market access, biosimilar players face different challenges to originators

Funding & pricing attributes of leading emerging markets

Time to market is a major challenge, even where abbreviated pathways are available

Market access timelines for pharmaceuticals in emerging markets

Regional profiles

Latin America

Biosimilars Country Profile: Brazil

Biosimilars drivers & resistors in Brazil

Healthcare Policy

Regulatory and intellectual property issues

Market access

Competitive Landscape

Outlook

Biosimilars Country Profile: Mexico

Biosimilars drivers & resistors in Mexico

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Competitive Landscape

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Regional profile: Asia

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Biosimilars Country Profile: India

Biosimilars drivers & resistors in India

Healthcare Policy

Regulatory and intellectual property issues

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Outlook

Other key emerging markets

Biosimilars drivers & resistors in Russia

Healthcare Policy

Regulatory and intellectual property issues

Market access

Competitive Landscape

Outlook

Biosimilars drivers & resistors in Turkey

Healthcare Policy

Regulatory and intellectual property issues

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Outlook

Recommendations

Prioritising emerging biosimilars markets

Opportunity vs. access in emerging biosimilar markets

Critical success factors

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