

---

# Editorial

*Journal of Generic Medicines* (2006) 4, 1–3. doi:10.1057/palgrave.jgm.4950049

In this ‘Global Review of Generic Medicines’ special issue, the authors explore the dynamics of the generics marketplace in several key regions and countries including Europe, the United States, Latin America, Japan and India. The dynamics in each area provides a glimpse of the challenges and the opportunities generics companies face worldwide. As the authors clearly demonstrate, each region is very different with limited direct similarities, but what becomes clear from the articles as a group is that in today’s market, for a generics company to not only survive but also prosper, a global footprint is required.

As Brian Tempest of Ranbaxy writes, the Indian market is emerging as an interesting generics market in its own right. With over 1bn people, and with forecasts suggesting that India will become one of the world’s major economies in the coming decades, it is a generic market that cannot be ignored by outsiders for long. This is also true of a country like China, which may in fact provide even greater opportunities. Today few companies based outside of these countries sell into them as they are dominated by local producers. In India, the largest generics companies are all domestic. In fact, there is not one single global generics company that figures in the top generics companies in these countries. Expanding the list to the top 20 does not improve the picture. Such a market structure cannot be found in any other significant market in the world. The companies based in these countries, especially India, are increasingly focused on expanding internationally and their activity in mergers and acquisitions has increased dramatically in the past several years. Ranbaxy has made a number of acquisitions, including that of RPG from Aventis in France and more recently acquiring Terapia from a financial investor (this author advised Ranbaxy on both of these transactions). Other recent mergers/acquisitions include Dr Reddy’s acquisition of Betapharm in Germany, Sun Pharmaceuticals becoming the majority shareholder in Carraco in the US, and the acquisition of Docpharma by Matrix in Belgium.

The Chinese companies have been less active in mergers and acquisitions to date, stemming from their more limited commercial participation directly in Western markets. The Chinese are only now emerging as key API suppliers globally and finished formulation activities towards export markets is in its infancy. But this is likely to change quickly.

Companies in countries such as India and China dominate the local markets that are very large and growing, providing strong economies of scale to their operations. The domestic market provides a strong base for these companies to consider options in export markets. As a result, these companies are expanding their sights to Western markets. As such, they will be a new force to contend with in the Western markets given their large economies of scale and significant cost advantages.

Within the US, as the paper by Kathleen Jaeger of the US Generic Pharmaceutical Association (GPhA) points out, the generics market remains vibrant with strong growth prospects continuing. But at the same time challenges are also increasing, such as the lack of regulation around authorised generics that is destroying the extra profitability that regulators had previously built in to encourage generics. Additionally, the lack of funding for the Office of Generic Drugs (OGD) is slowing the time to registration and keeping generics off the market. Both of these challenges are underpinned by government regulation. It demonstrates the impact that government regulation, or the lack thereof can have on companies, and the industry as a whole

in a particular market. Even with strong underlying prospects, government regulation could shift the dynamics and cause a significant impact on the strength of a generics company.

The challenges in Europe are just as clear where undoubtedly a need still exists for a less complex and more cohesive market for generics, as Greg Perry of the European Generic Medicines Association (EGA) explains. The EGA is striving to achieve a greater commitment on the part of governments to introduce measures that increase patient access to generic medicines, particularly by reducing the time delays for access to markets and by dealing with market distortions caused by certain regulatory and patent issues as well as improving information on the quality, safety, efficacy and economic advantages of generic and biosimilar medicines for European patients.

As indicated previously, the European generic industry is facing strong competition from India and China, which benefit from low labour and production costs, weaker environmental and patent protection laws, and a growing high-tech scientific base. European generics must also compete with much better-positioned American generics companies, which benefit from a large, unified market fortified by a strong legal and commercial environment designed to favour generic medicines competition. In contrast, the EU generic medicines industry must operate within the constraints and additional costs of solid social, environmental and intellectual property protection, coupled with those generated by a lack of a genuine single market for pharmaceuticals in Europe.

These risks further demonstrate the importance of companies needing to consider taking steps to diversify their regulatory exposure away from any one single country or even region. While, historically, companies in the generics sector predominantly were focused on their home market, the past five years or so has seen a significant increase in cross-border M&A. The trend was led by Teva and Sandoz who have global operations spanning the globe. Increasingly, however, other companies are following this pattern and it is becoming increasingly clear that relying on a purely domestic operation is not maintainable in the long term. The exposure to multiple countries is an important engine of growth but also important as a way of diversifying the regulatory risk faced in any one country.

Access into other markets, however, is also an important way to create additional growth. As the paper by Vera Valente of ProGenericos on the region points out, government regulation in a place like Latin America is a catalyst to the dynamic growth prospects of that particular market. Governments around the world are facing increasing pressure from ballooning healthcare spending, and a ready way to try to take some pressure off is the encouragement of lower-cost generics use. This can create significant growth potential in that segment of a market. For international companies to tap into such growth most readily, they have to have strong local operations in many different countries.

The cost savings to governments by generic substitution of originator medicines are significant — as the paper by Simoens and De Coster details — in a number of European countries. These substantial savings have already been noted by the Japanese Government, which has taken significant steps over recent years to reduce its ever increasing health expenditure in a country with one of the lowest infant mortality rates and highest life expectancy of any in the world as the paper by Osamu Saigusa of the Japan Generic Pharmaceutical Manufacturers Association (JGPMA) points out. The set up of the Japanese healthcare system coupled with the various government funded health insurance programmes that are available means the financial burden on government is considerable. A centrally controlled drug price revision strategy coupled with monetary incentives for doctors and pharmacists who prescribe/substitute for generics means the prospects for brand drugs in this region are poor, while those for generics companies, with the support of government, are much more positive.

Taking the articles as a whole demonstrates the need for companies in the sector to think globally. Indian and other low-cost based companies are emerging into the Western markets directly. The impact of government regulation, both positive and negative, requires companies to establish strong operations in many countries. These drivers push companies to become increasingly global, which in turn forces the remaining local companies to consider their fortunes as well.

The past 2–3 years has witnessed a transformation of the focus of mergers and acquisitions away from strengthening domestic operations to strengthen global operations. As already highlighted above, Indian companies' M&A focus is entirely on ways to tap into Western markets directly. As these companies successfully gain market share, the incumbents will need to consider their own situation. It is untenable, medium-term, for Western focused companies to remain as they are without a strong link into lower cost countries. On this basis, the trend towards globalisation should continue. The tie-ups between lower cost producers and established Western generics companies will only speed up and those proactively seeking partnerships and becoming first-movers will benefit over companies that wait until the competitive landscape has already changed.

*Tommy Erdei*  
*Executive Director,*  
*Healthcare Banking,*  
*UBS Investment Bank,*  
*London, UK*  
*Tel: +44 (0) 207 568 2497*  
*E-mail: [tommy.erdei@ubs.com](mailto:tommy.erdei@ubs.com)*