Sandoz emerges stronger by injecting more urgency

Growing in emerging markets and offering differentiated drugs such as injectables and biosimilars lie at the heart of Sandoz' strategy, chief executive officer Jeff George told Aidan Fry.

Jeff George

A year into the job, Sandoz' chief executive officer Jeff George is reasonably satisfied with the company's progress over the past 12 months. Having resolved problems at Sandoz' oral-dose facility in Wilson, North Carolina, the US business is growing again. Significant strides have also been made in strengthening the firm's pioneering market position in biosimilars as well as in expanding in emerging markets. And towards the end of this year, Sandoz gained a strong platform for injectable oncology drugs by paying €925 million (US$1.30 billion) for Austria's Ebewe Pharma.

Speaking exclusively to **Generics *bulletin***, George – who took over leadership of Sandoz from Andreas Rummelt on 1 December last year – said 2009 had been a "turnaround year" for the company. "Things are certainly heading in the right direction after the changes we've made in the past 12 months," he insisted, adding that the company now had a greater sense of urgency.

George pointed out that while Sandoz had achieved just 1% sales growth in local currencies during 2008 (**Generics *bulletin***, 13 February 2009, page 6), the company had just recorded three consecutive quarters of 4% local-currency growth. "Clearly, we'd like to grow significantly faster than 4%," he admitted, but stressed that such advances were broadly on a par with Sandoz' peers once acquisitions and proprietary brands had been stripped out.

"From a bottom-line perspective, our performance has been even better this year," he observed. Operating efficiencies raised Sandoz' third-quarter operating margin by one-and-a-half percentage points to 16.9% (**Generics *bulletin***, 30 October 2009, page 4).

George said that shortly after accepting the position he had identified four strategic priorities for Sandoz in 2009. These were driving turnover growth by launching differentiated products and expanding in emerging and untapped markets; strengthening Sandoz' management and organisation; significantly reducing production and operating costs; and instilling the company with a greater sense of urgency and accountability.

Among the products through which Sandoz is seeking to differentiate itself is its unique portfolio of biosimilars – the triumvirate of Omnitrope (somatropin), Binocrit (epoetin alfa) and Zarzio (filgrastim).

"Our total biosimilar sales rose by 76% in the third quarter, so we're up at 68% growth to date this year in local currencies," George revealed. He pointed out that Sandoz had earlier this year launched the first-ever biosimilar in Japan and had also obtained approval for Canada's first subsequent-entry biologic with Omnitrope (**Generics *bulletin***, 1 May 2009, page 1).

In the EU, Sandoz' biosimilars were gaining traction, George noted. "For Omnitrope, our market share is 9% in Italy and about 7% in France," he said. "But the more important thing is to look at how the business is performing overall given the investments we're making into it, and I can say it's doing well."

George said success with biosimilars would have to be measured on a case-by-case basis given that development programmes could cost between US$70 million and US$150 million. "There are not that many players that can make those investments. But we feel the future benefits are there, not just for Sandoz but also in savings for patients and payers," he argued.

Discussing Sandoz' strong progress with biosimilars in Germany, George hailed the German government's support which had, for example, lifted the biosimilar share of the accessible epoetin market to 40% by volume. "They recognise the significance of the opportunity and have driven it more than we've seen in other markets where's there's been less government intervention," he stated. "Quite simply, Germany gets it on biosimilars."

In Australia – where Omnitrope has been on the market since November 2005 – the human growth hormone was gaining market share, George said. And in the US, Omnitrope sales were picking up after the firm recruited Merck-Serono's former endocrinology marketing director Mike Castagna as vice-president of biologics sales and marketing this spring. While Omnitrope's US market share remained in the "low single digits", George said Sandoz was "seeing a nice trend". "We're doing significantly more business on a month-by-month basis than we were even four to six months ago," George revealed.

A recent event held in Tokyo for the Japanese launch of Somatropin BS was attended by more than 40 journalists, as well as by leading endocrinologists (**Generics *bulletin***, 8 July 2009, page 15). "The impression I got from that meeting was that we need to do a great job of marketing the product around its safety and efficacy," George remarked. "Often a paediatric endocrinologist will not switch, so it's naïve patients that we're looking to bring on board," he added.

A focus on reputation and quality was equally important for the rest of Sandoz' business in Japan, George stressed, adding that both the Sandoz and Novartis brand names were crucial in this regard. "We have to make sure all of our people in Japan act as brand ambassadors," he stated. This year, he said, Sandoz was on track to launch around a dozen generics in Japan.

Not only the Novartis brand name, but also the parent group's technical expertise, was an invaluable asset for Sandoz' biosimilars business, George stressed. "For example, when we recently had a question on a particular immunogenicity assay that we're running, we were able to go to Tim Wright at the Novartis Institutes for BioMedical Research in Boston, US, and have him and his team help us out," George explained. Moreover, he added, Sandoz would look to collaborate with Novartis Pharma when the brand unit had marketing expertise in a relevant therapeutic field.

The "deep pockets" of the Novartis group, George noted, had also given Sandoz the freedom to spend almost €1 billion on Ebewe's oncology portfolio and pipeline (**Generics *bulletin***, 1 June 2009, page 1).

"Oncology was an area in which we only had a

minor presence. This had been through the work we had done with Ebewe and a couple of other partners," George admitted. "When we looked at who ideally should be our partner in this area, Ebewe had been top of our list for a couple of years," he added.

The appeal of the Austrian firm was not only its existing pipeline of 15 marketed injectable cancer drugs such as doxorubicin and paclitaxel. It was also its pipeline covering a wave of oncology patent expiries for molecules including docetaxel, gemcitabine and irinotecan. "It's not easy to build – and secure approval for – cytotoxic manufacturing capacity," George highlighted, adding that he envisioned Ebewe's €190 million business producing double-digit sales growth.

Ebewe is to become a standalone global oncology injectables business unit with its own reporting lines, operating in a similar way to Sandoz' biosimilars and anti-infectives businesses. The unit will be led by Ebewe's former chief executive Friedrich Hillebrand from the Austrian firm's headquarters in Unterach (**Generics *bulletin***, 16 October 2009, page 5).

One element that is consistent for all of Sandoz' differentiated products – be they biosimilars, oncology agents or respiratory drugs – is a focus on delivery systems. For example, George said the firm's Omnitrope pen device developed with Becton Dickenson had been well received in the US. "Only Teva rivals Sandoz in terms of our breadth of capabilities," he claimed.

Partnerships for respiratory drugs

In the respiratory field, George highlighted Sandoz' partnerships in the respiratory sector. The company has a deal with UK-based inhalation specialist Vectura, to which it recently made a US$6 million milestone payment for a combination asthma and chronic obstructive pulmonary disease (COPD) generic which uses the UK firm's GyroHaler dry-powder inhaler device. This followed a milestone payment linked to EU rights made in April 2009.

Sandoz launched salbutamol in several European markets during the third quarter of this year, including in Belgium, the UK and certain countries in central and eastern Europe. "In the UK, we have reached about a 5% market share," George observed.

But opportunities were not limited to partnerships Sandoz had formed, George pointed out. The generics business was currently assessing how it could capitalise on Novartis' US$115 million takeover last year of Californian pulmonary drug-delivery expert Nektar.

Describing the respiratory market as a "mid-term play" for Sandoz, George saw substantial rewards ahead. "Three-quarters of a global inhaler market worth US$20 billion – mainly covering asthma and COPD – faces patent expiry by 2015," he stated.

While Sandoz' closest rivals have in recent years bolstered their respiratory offering by acquiring – Teva through its purchase of Ivax, and Mylan via its takeover of Merck KGaA's Dey unit – the German firm has to date pursued an organic growth strategy. George recently opened a €47 million extension to Sandoz' Aeropharm manufacturing site in Rudolstadt, Germany, which serves as a centre of excellence for inhalation drugs (**Generics *bulletin***, 4 September 2009, page 14).

Commenting on Sandoz' progress in Germany under country head Helmut Fabry, George expressed his satisfaction that the local 1A Pharma, Hexal and Sandoz brands were "performing well ahead of the market." In the first nine months of 2009, Sandoz registered local-currency sales growth of 5% in Germany compared to an average 4% downturn in the country's generics market.

Region	Nine-month sales (US$ millions)	Reported change (%)	Local-currency change (%)
Europe	3,075	-11	+4
US	1,311	-1	±0
Asia, Africa, Australasia	575	+1	+11
Canada and Latin America	389	-7	+9
Sandoz	**5,350**	**-7**	**+4**

Figure 1: Breakdown by region of Sandoz' sales totalling US$5.35 billion in the first nine months of 2009 (Source – Novartis)

"Germany is a very important market for us. We have the number one position with a 28.6% share, and our closest competitor, Ratiopharm, is about 12 points lower than us with 16% or 17%," he remarked.

In particular, George highlighted how the firm's low-cost 1A Pharma brand had moved into third place in the German generics market, behind its sister firm Hexal and its rival Ratiopharm. "Like our rivals, we wondered how the German tenders would impact us," George said. "We decided that a broad portfolio across three brands would give us a significant advantage."

The Hexal brand was "focused on having the biggest portfolio" in the German generics market and offered a wide range of specialist drugs with a full-line service, George explained. The Sandoz banner signifies competence in neurology, urology and pain management, and it has also been expanding its OTC presence.

Through its minimal cost base, 1A Pharma was ideally placed to lead the company's participation in the tenders being run by Germany's health insurance funds, George pointed out. Sandoz took the biggest share of the contracts for 63 molecules that Germany's largest fund, the AOK, awarded from 1 June this year (**Generics *bulletin***, 15 May 2009, page 12).

The volume growth being delivered by 1A Pharma was at lower margins that the rest of Sandoz' business in Germany, George acknowledged. However, he stressed, the low-price brand was vital to the firm's strategy in Germany. "We expect strong headwinds in the German market going forward, as more and more tenders are rolled out," he said.

Discussing Sandoz' overall performance in Europe – where local-currency sales growth was 4% in the first nine months of 2009 (see Figure 1) – George said the firm had been losing market share in France over recent years. "We decided we needed a new start in France," he said. Sandoz recently recruited Frédéric Collet from Ciba Vision to head the French business, reporting to Western European head Nick Haggar.

The French operation was now concentrating on building stronger relationships with wholesalers and buying groups, George said. It had already been turned around, he added, having introduced fentanyl patches in September. This had been followed by launches of clopidogrel and filgrastim in October.

While the French generics market still had huge scope to expand, George believed, the same was at least as true of Italy. He pointed out that Sandoz had earlier this year strengthened its position in Italy by striking a deal with Milan-based company Mipharm.

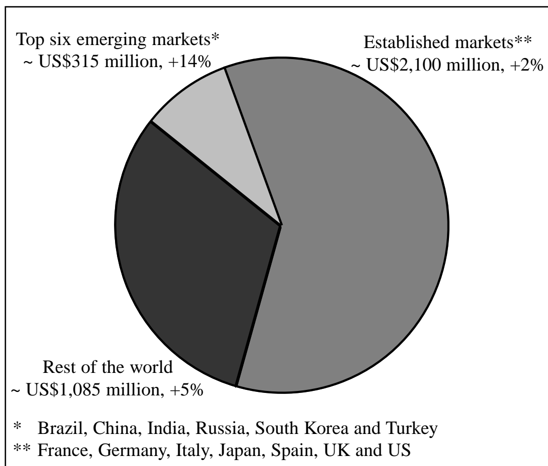

Figure 2: Breakdown by market type – as defined by Novartis – of Sandoz' turnover of US$3.50 billion in the first half of 2009, with changes in local currencies (Source – Novartis)

"With this move, Sandoz will be even better able to leverage its existing presence in speciality generics," he said. "It will add a broad range of dermatology and gynaecology products while also strengthening our OTC portfolio," George explained.

While south European markets have considerable scope to increase local generic penetration, George – who was previously head of emerging markets for Novartis Pharma – is particularly excited by the opportunities on offer in markets such as Asia and Latin America. Sandoz' top six emerging markets represent around a tenth of its turnover (see Figure 2).

"One of the things we've got to do is to drive our growth, particularly in Asia but also in Latin America, the Middle East, Turkey and Africa," he stressed. "These will be hugely important markets for us, and we're already growing quite significantly in many of them."

"In Asia-Pacific, we are growing at double the market average, and have achieved a 20% sales rise to date this year," George highlighted. This regional growth, he added, included a 21% sales gain in China and a 26% advance in Japan.

Speaking just before he left for a business trip to China, self-confessed Sinophile George said expanding in China was a "huge priority" for Sandoz. However, he recognised that this would not be easy.

"They've got about 5,000 low-cost, low-price – and often low-quality – manufacturers in China that make it difficult for multinational companies to compete," George observed. In meetings with officials including China's minister of health, George said he was calling for more refined quality standards and pricing that reflected quality markers such as proven bioequivalence.

Using its local production facility in Guangzhou, Sandoz was aiming to tie the integrity of its brand to differentiated products, especially injectables, he said.

In Latin America, Sandoz had a presence in Argentina, Brazil and Mexico, George said, but he admitted the firm was not one of the biggest players. However, he added, this meant that Sandoz had a considerable opportunity to grow in the region.

"The first step for me was to ensure we had the right leader. I interviewed a number of top candidates from the generics industry, but I ultimately went with someone from the originator side – Oscar Ferenczi, a 20-year Merck & Co veteran who had run Brazil for them," he said (**Generics *bulletin***, 25 September 2009, page 26). In emerging markets, he pointed out, the border between branded generics and originals was blurred.

"I've really been looking to upgrade the talent of our organisation on the commercial side," George said, pointing out that five out of seven of Sandoz' regional heads had joined since October 2008.

"But before I brought in a few people," he said, "I had to create a structure that was more aligned to our customers. We had one aggregate region that covered Asia-Pacific – from China to Australia – Latin America, Russia, Brazil and Canada," he said. Furthermore, Middle East and Africa were included in the western Europe region, which was managed from corporate headquarters in Germany. The revised commercial structure, George said, was "closer to customers".

The Middle East, Africa and Turkey is now a separate region run out of a Dubai office headed by Roger Bassoul, who had managed North African markets for George at Novartis Pharma. George also brought in Peter Goldschmidt from leading Novartis Pharma in south-east Asia to head up Sandoz' operations in central and eastern Europe that generated over €1 billion in annual turnover.

Former Barr US head Christine Mundkur was recruited by George within weeks of his move to Sandoz. Her first task was to lead a recovery in the US business (**Generics *bulletin***, 16 January 2009, page 6).

"Christine and her team are doing a nice job of turning the business around," insisted George, who pointed out that the US business had now posted two consecutive quarters of sales growth following double-digit declines in three of the four quarters in 2008.

"One of the things we've got to do is to drive our growth, particularly in Asia but also in Latin America, the Middle East, Turkey and Africa"

More launches in US this year

"We've had more US launches to date this year than in the whole of 2008," he observed. Several more launches can be expected over the coming months after the Wilson facility passed a re-inspection by the US Food and Drug Administration.

Among the most important launches in 2009 was the first-to-market introduction of tacrolimus, which remains the only generic rival to Astellas' Prograf immunosuppressant (**Generics *bulletin***, 4 September 2009, page 23). "Our version's market share is now up to 35%," George noted.

Vertical integration through Sandoz' anti-infectives unit had helped the firm to be first with tacrolimus, but George said he had no plans for the company to pursue commodity active pharmaceutical ingredients (APIs). Noting that Teva had started out as an API producer and Mylan had bought bulk-drugs specialist Matrix, George said such a "capital-intensive, low-margin business" was not very attractive for Sandoz. Given the overcapacity in the global API industry, it would be better for Sandoz to retain its flexibility in sourcing raw materials, he maintained.

Improved sourcing is a key element of the Project Compete initiative through which George is seeking to improve Sandoz' margins. "Before I came on board, functional operating costs were growing at around 10% in local currencies, versus sales ahead by just 1%," he said. "Clearly, that was not sustainable."

"One of the realities of our industry is price erosion of around 10% over the past few years," he observed. "That means we typically have to recreate well over half of our operating profit each year just to stand still."

Regarding development costs, George said the firm's historic spending levels of around 9% of turnover were higher than at any of its peers. "I wanted to see what bang were we getting for our buck," he explained (**Generics *bulletin***, 1 May 2009, page 7).

"Over the past 12 months, I've encouraged a greater customer focus in how we go about our day-to-day business, increased accountability and performance management, and instilled a greater sense of urgency in everything we do," summarised George. **G**