

Hospira sets ball rolling on push towards globalisation

Expanding its generic injectables portfolio outside the US and pushing into emerging markets are among key strategies of Hospira's new head, Mike Ball. Aidan Fry reports.



Mike Ball

Five months into his tenure as Hospira's chief executive officer, Mike Ball has hardly spent any time behind his desk at the US-based injectables specialist's headquarters in Lake Forest, near Chicago. Instead, the former Allergan president has travelled the world, hearing first-hand from customers and employees about Hospira's strengths and weaknesses.

"What I found," Ball stated during a recent investors' day, "was a US-centric company with tremendous international opportunities. And those global opportunities are even bigger and easier to get at than I had initially thought." In 2010, Hospira generated more than three-quarters of its Specialty Injectable Pharmaceuticals (SIP) sales – and four-fifths of its group turnover – in the Americas region, which consists mainly of operations in the US and Canada, as well as smaller businesses in Brazil and Mexico.

Ball – who took over from Chris Begley at the end of March (*Generics bulletin*, 18 March 2011, page 1) – said Hospira was the world's leading generic injectables company, with an 18% share of those markets in which it competed. That share of the US\$12 billion global generic injectables market in which it had a presence generated annual sales of US\$2.2 billion.

But Ball outlined three ways in which Hospira could more than double to US\$28 billion the market available to the company (see Figure 1). Assuming that the firm maintained its 18% market share, he noted, Hospira would add US\$2.8 billion to its generic injectables turnover, taking the total to around US\$5 billion.

Firstly, he said, Hospira should ensure molecules that were authorised in at least one developed market should become part of the firm's portfolio in its other top-10 markets. This would open up a further US\$5 billion of opportunities, he believed. Secondly, obtaining marketing authorisations for off-patent injectable

products that the company did not currently sell would add US\$6 billion to the available market. And thirdly, he added, tapping into emerging markets presented a further potential market worth US\$5 billion.

Ball observed that Hospira's SIP business marketed 138 generic molecules in the US, nearly 100 in Australia – many acquired with Mayne – and more than 80 in Canada. But the respective figures were barely 40 in the UK, just 18 in France and a meagre 11 in Japan.

Similarly, ensuring that Hospira developed and marketed those off-patent molecules that it had neglected to date would make better use of the firm's global footprint, Ball argued. "When we span out of Abbott, we went for the low-hanging fruit," he acknowledged.

Turning to rapidly-growing emerging markets, Ball said Hospira would look for merger and acquisition opportunities to build critical mass quickly. "We need to get into these emerging markets and ride this wave," he insisted, highlighting the growing affluence of the middle classes in many of these countries.

Conducting "tuck-in acquisitions" in emerging markets will be a goal for Hospira throughout the five-year plan that Ball outlined to investors. For the next couple of years, much of the firm's focus will be on investing in its SIP generics and biosimilars pipeline on a global scale, while also remedying manufacturing issues for both its injectable drugs and its Medication Management Systems (MMS) infusion-pumps business.

Between 2013 and 2015, marketing authorisations would start to flow through in non-US markets, Ball said, while the US operation should see its first biosimilar launches. Furthermore, a 100,000 sq m sterile drugs facility that Hospira was building in Vizag, India, would come online. The facility would ensure that beyond 2015 Hospira remained a low-cost injectables player, benefitting from cross-selling synergies with its US\$1.0 billion MMS pumps business in hospitals, Ball insisted. "We will also be one of the top three companies in the world for biosimilars," he promised.

Chief scientific officer Sumant Ramachandra stressed that Hospira was already biosimilar market leader with Retacrit (epoetin zeta) in Europe and Nivestim (filgrastim) in Australia. He claimed Retacrit held around half of the European Union (EU) market for short-acting erythropoietin biosimilars, which in turn accounted for 18% of total EU erythropoietin sales. Biosimilars, including Nivestim, made up a third of the EU's filgrastim market.

Drawing on clinical safety and efficacy data that had been generated in Europe would be crucial as Hospira looked to launch biosimilars in the US, Ramachandra believed, as would capitalising on alliances with partners including Celltrion, Human Genome Sciences and Stada. The firm had not waited for a US biosimilars pathway to emerge, but had already sought advice from the US Food and Drug Administration (FDA), he said.

Hospira's US epoetin candidate is due to enter Phase III clinical trials before the end of this year (see

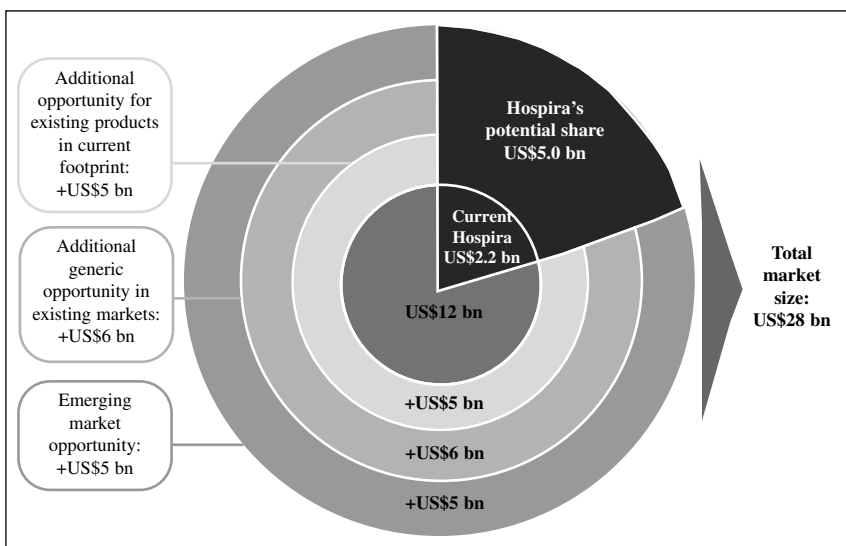


Figure 1: Hospira's current share of the US\$12 billion generic injectables market in which it competes, with its potential share of US\$28 billion markets in which it could compete (Source – Hospira)

page 16). At the same time, a global Phase I study into an internally-developed monoclonal antibody (mAb) is set to start. A Phase I US filgrastim trial is underway, while a global pegfilgrastim programme is at a similar stage.

In total, Hospira's biosimilars pipeline comprises 11 molecules, including two internal projects that overlap with the eight products covered by a licensing deal signed two years ago with South Korea's Celltrion (*Generics bulletin*, 16 October 2009, page 13).

Celltrion's global development programmes for infliximab – the active ingredient in Janssen's Remicade treatment for rheumatoid arthritis – and trastuzumab, which forms the basis of Roche's Herceptin breast-cancer drug, are in Phase III trials (see page 19).

Looking at Hospira's small-molecule generics portfolio, Anil D'Souza – corporate vice-president of global marketing and corporate development – said the firm was working on 72 molecules with a local market value of US\$16 billion. That pipeline represented 623 potential new-to-country launches – 475 in Europe, the Middle East and Africa (EMEA); 77 in the Asia-Pacific region; and 71 in the Americas.

"Around 71% of Hospira's overall US\$16 billion pipeline is scheduled for launch over the next five years," D'Souza commented (see Figure 2). Oncology drugs accounted for about 30% of the pipeline measured by number of molecules, but well over half its value (see Figure 3), he revealed, adding that Hospira's US\$400 million takeover of Orchid's injectables business had given the group a robust roster of antibiotic candidates.

"We are not growing satisfactorily in EMEA," admitted regional head Svend Andersen. Weaker MMS sales cut total turnover in the region by a tenth to US\$489 million last year, although SIP sales were 4.1% stronger at US\$283 million (*Generics bulletin*, 11 February 2011, page 6). "Lately, we've been more aggressive and gained significant volume increases for key molecules," Andersen stressed, adding that setting up business clusters and switching from salesforce-based to key-account marketing was improving efficiency. "We are using a distributor model for emerging markets so as not to dilute our resources or focus," he added.

Andersen's Asia-Pacific counterpart, Tim Oldham, said Australia – the home of the Mayne Pharma business that Hospira acquired in 2007 – accounted for more than half of sales in the region. These had totalled US\$291 million last year. The Australian operation, he said,

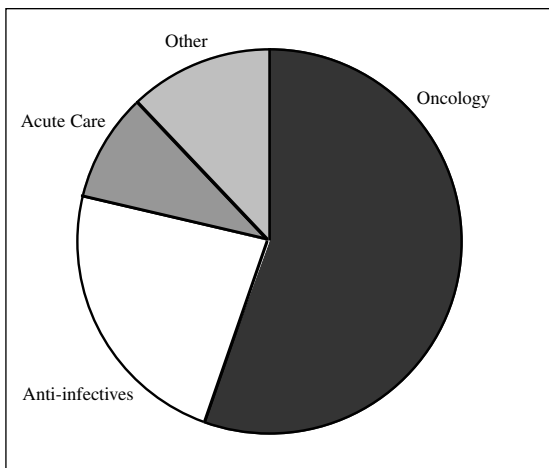


Figure 3: Value of therapeutic categories in Hospira's US\$16 billion small-molecule generics pipeline (Source – Hospira)

would press ahead with its recent record of differentiated, first-to-market launches that had included the oncology agent docetaxel (*Generics bulletin*, 11 February 2011, page 1) and the biosimilar Nivestim (*Generics bulletin*, 8 April 2011, page 21).

"In Japan and Korea, we will establish local alliances to penetrate the generic injectables market," Oldham pledged, adding that Hospira would focus initially on its differentiated oncology range. In China, he continued, a new management team that was based in Shanghai would look for acquisitions and partnerships.

Differentiating generics would also be key in the US, maintained Americas head Tom Moore, who pointed to examples including the firm's single-vial formulation of docetaxel and its first-to-market gemcitabine solution (*Generics bulletin*, 2 September 2011, page 19). For biosimilars, Hospira's North American units would seek to capitalise on synergies with their small-molecule oncology offerings and to "import the leadership position and market experience" of the EMEA operation.

Moore said Hospira's Canadian business would aim to "bridge the gap" with the firm's SIP portfolio in the US; while in South America, the company would look to establish a manufacturing base for injectable drugs and devices, probably through acquisition.

Manufacturing problems in the US – primarily at its Rocky Mount site in North Carolina – had severely compromised Hospira's performance and customer-service levels, admitted Jim Hardy, senior vice-president of operations. Having issued a warning letter last year (*Generics bulletin*, 7 May 2010, page 6), the FDA had identified further problems during a recent re-inspection of the plant, he revealed. A new facility-management team was working closely with the agency, but rectifying the FDA's complaints – along with issues with its MMS pumps – was likely to take two to three years and cost US\$200-US\$250 million, Hardy stated.

The 100,000 sq m facility that Hospira was building in Vizag, India, would alleviate pressure on US sites such as Rocky Mount, he maintained. "At present, 90% of Hospira products are sourced from a single plant," he observed, adding that Vizag's annual capacity of more than 500 million vials was scheduled to come on stream in 2014. The Indian site would offer low-cost, flexible manufacturing that would help Hospira to compete in tender markets, he promised.

Hospira expects manufacturing efficiencies and a better product mix to raise its adjusted group gross margin from 42.5% last year to above 45% by 2016. The compound annual growth rate (CAGR) for sales between 2011 and 2016 is forecasted in the mid- to high-single digits, comprising mid-single digits in the Americas, low teens in EMEA and low- to mid-teens in the Asia-Pacific region.

Ball insisted Hospira had all the major elements in place to "fix the foundation and turbocharge growth", thereby securing a leading position in the hospital channel. "We have no great need to change our strategy, we simply need to globalise it," he insisted.

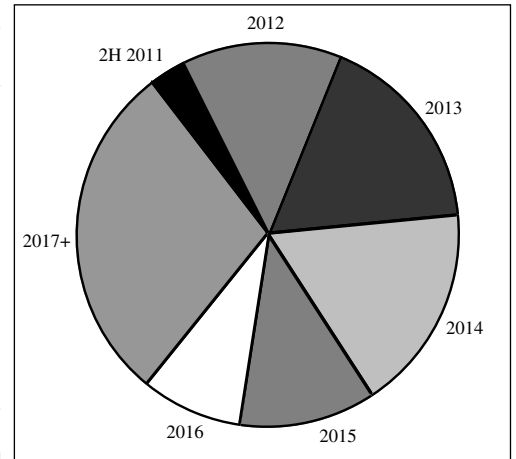


Figure 2: Prospective launch dates for Hospira's US\$16 billion small-molecule generics pipeline (Source – Hospira)

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