US pressures making life tough for leading lights

Most of the world's leading generics and biosimilars players are suffering from severe pricing pressure in the US. But by no means are all companies struggling for growth, as the latest Generics bulletin global ranking shows. Aidan Fry reviews the results.

Upon completing their merger last month, Amneal and Impax highlighted how combining had created "the fifth-largest generics business in the US". By virtue of the importance of the US market, the deal also propels the new company – which operates under the Amneal name – into the top 20 generics and biosimilars players worldwide, according to a ranking compiled by **Generics *bulletin***.

By joining forces, Amneal and Impax expect to generate not only double-digit sales and profits growth as they deliver on a pipeline of around 150 abbreviated new drug applications (ANDAs) pending approval and 135 active development projects, but also annual cost synergies of about US$200 million within three years. Within days of merging, Amneal started to deliver on that promise by announcing plans to close Impax' main US facility in Hayward, California, and transfer production to the group's "lower-cost facilities in the US and India" (**Generics *bulletin***, 18 May 2018, page 3).

Amneal is far from alone in looking for ways to alleviate the severe pricing and margin pressure it is experiencing in its core US market as a result of a consolidated customer base and accelerated approval timelines at the US Food and Drug Administration (FDA).

Teva has been aggressively pruning its US portfolio to eliminate low- or negative-margin products at the same time as it has already cut more than 6,000 of the total 14,000 staff positions it intends to remove around the world. Between announcing a restructuring plan under new chief executive Kåre Schultz in December and announcing first-quarter results in early May this year, the Israeli group also announced 10 plant closures.

"We are not in the business of volume, we are in the business of profitability," Schultz told investors, although he stressed that Teva would avoid disruptions to supply in the US. North America commercial head Brendan O'Grady explained that Teva had given each of its major US customers a list of products it specifically wanted to address. "About 80% of those products we will get out of and they will move on to other suppliers, and on about 20% of the products we will see an increase in price," he disclosed.

Despite Teva's US difficulties – the firm's North American Generics sales tumbled by 23% in the first quarter of this year (**Generics *bulletin***, 11 May 2018, page 4) – the Israeli group remains the world's leading generics and biosimilars company, according to our ranking. Teva reports OTC sales as part of its Generics business segment, while its closest challengers, Mylan and Novartis' Sandoz, similarly do not split out non-prescription products. Therefore, our ranking includes OTC products – which are typically off-patent – within the same group as prescription generics and biosimilars.

On that basis, Teva narrowly leads ahead of Mylan, which recently bolstered its OTC offering, especially in Europe, through its takeover of Sweden's Meda in August 2016. The full-year impact of the Meda deal was largely responsible for Mylan's 8% rise in group turnover to US$11.9 billion last year (**Generics *bulletin***, 9 March 2018, page 3), while Teva benefitted from incorporating Actavis' Anda distribution business from the fourth quarter of 2016.

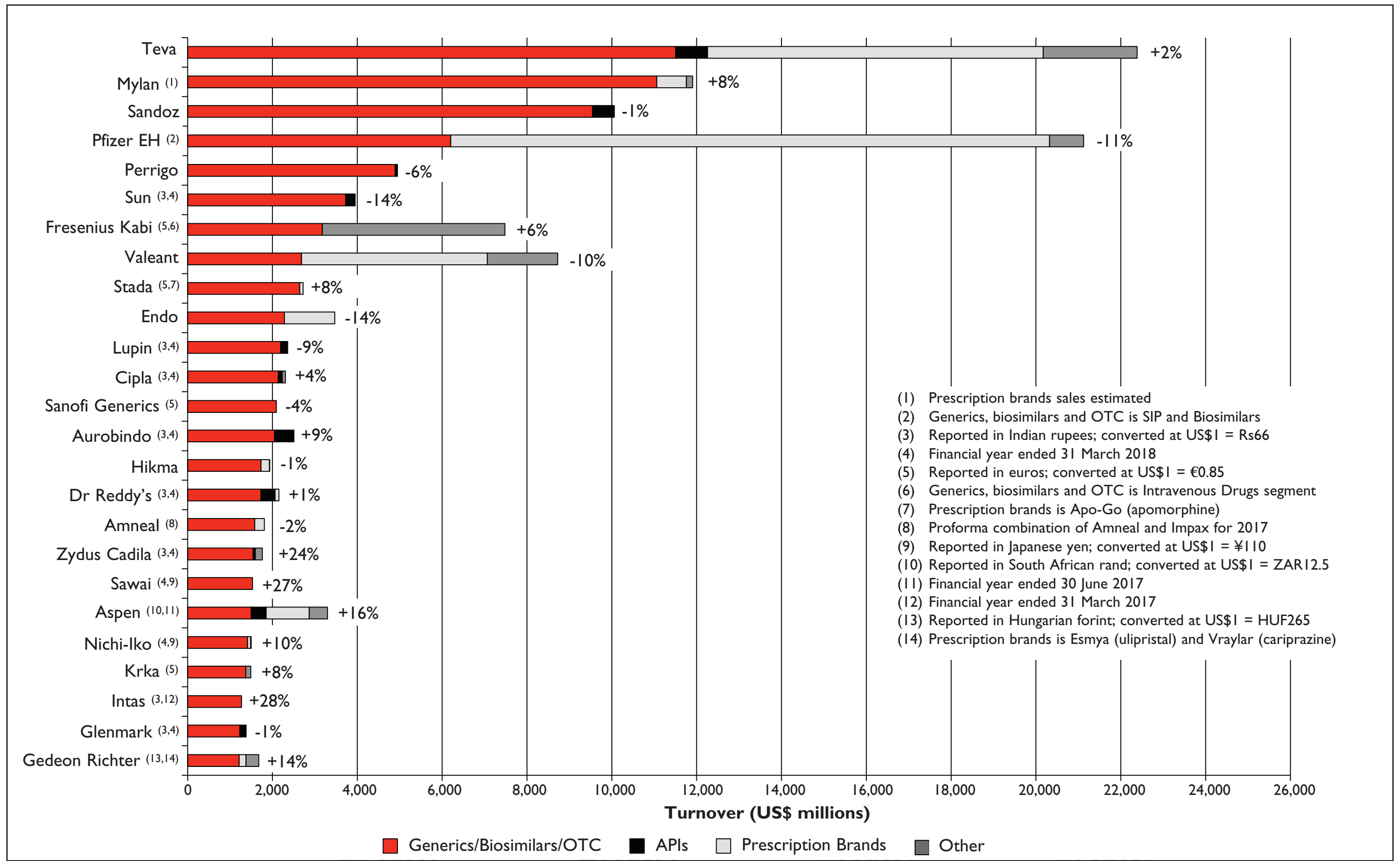
Exceptions to downward sales trend

For many of the remaining top-10 players in our rankings that did not receive a sales boost from recent transactions, the tough US competitive landscape was reflected in declining group turnovers (see Figure 1). Two exceptions to that trend – Germany's Fresenius Kabi and Stada – do at least as much business in Europe as in North America.

Kabi had intended to strengthen its position in the US injectable and intravenous generics arena by agreeing a US$4.75 billion deal to take over local firm Akorn. But after suggestions emerged that Akorn may have breached FDA data-integrity requirements in its regulatory filings, the German group first opened an independent investigation, and then in late April this year said it was terminating the takeover deal (**Generics *bulletin***, 27 April 2018, page 1). Akorn sued in a Delaware chancery court, arguing that Kabi was experiencing "buyer's remorse", which prompted the German group to allege fraud and violation of both data-integrity and current good manufacturing practice (cGMP) requirements (**Generics *bulletin***, 11 May 2018, page 3). The trial in that litigation will start on 9 July.

Stada enjoyed broad sales growth last year, despite the disruption caused by the protracted saga of a takeover bid by private-equity investors Bain Capital and Cinven. With the deal finally completed – and the private-equity owners seemingly happy to sit on their majority share (**Generics *bulletin***, 11 May 2018, page 6) – chief executive officer Claudio Albrecht recently announced a growth strategy that includes investing over €100 million (US$125 million) into biosimilars over the next three years (**Generics *bulletin***, 16 March 2018, page 5). Albrecht is also looking for takeover targets in the UK, in Central and Eastern European countries such as Poland, and in the Middle East and North Africa (MENA) region (**Generics *bulletin***, 16 March 2018, page 1).

Despite being predominantly in private hands, Stada is included in our rankings by virtue of having disclosed detailed annual financial figures. Other privately-owned players that do not disclose precise sales figures – such as Alvogen, Apotex, Chemo and Polpharma, as well as Grupo NC, the parent group of Brazil's EMS – are excluded. Also left out are state-owned entities for which transparent financial data is lacking, and corporations that group any generics activities into a wider mature brands or established products segment that also includes off-patent brands. G



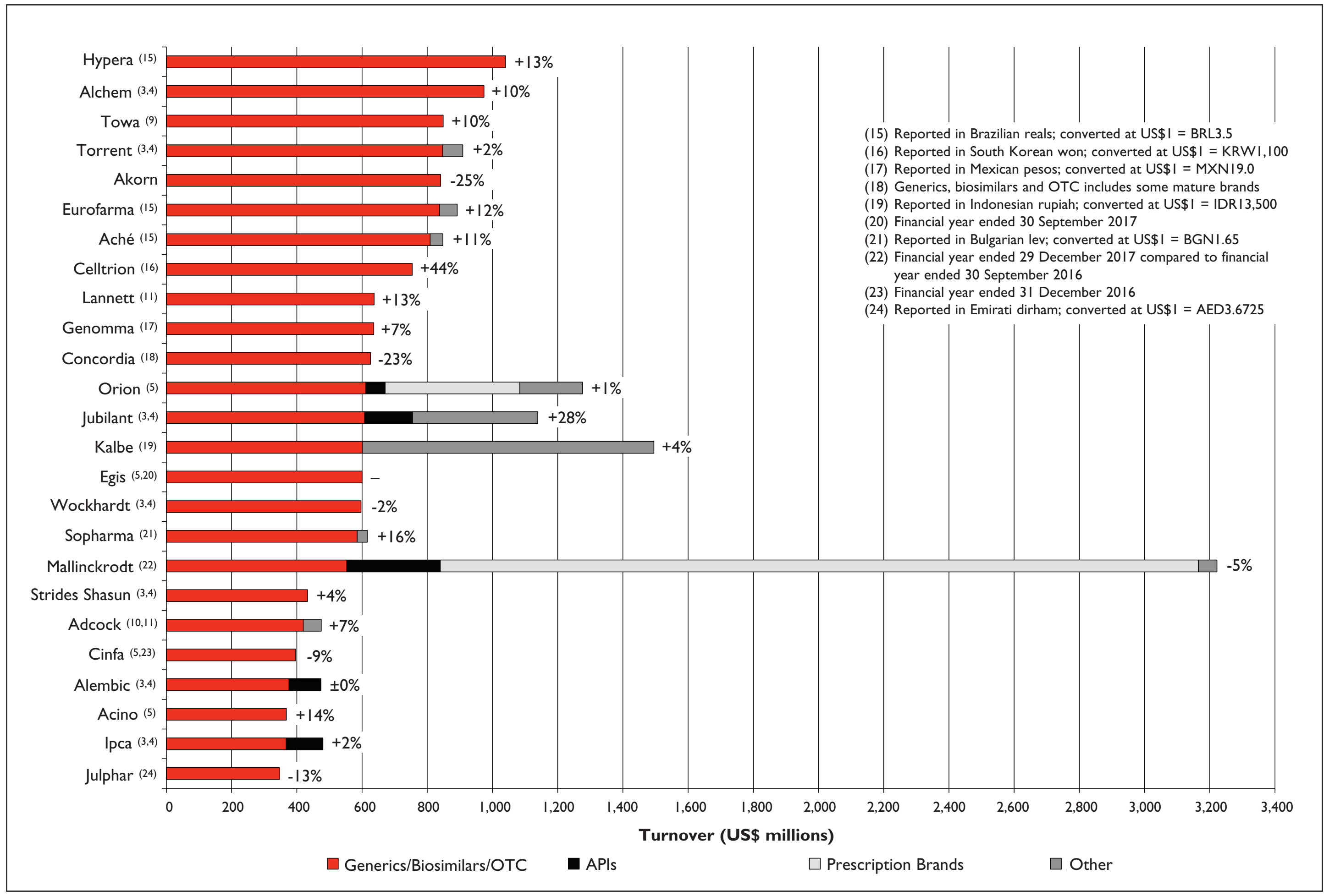


Figure 1 (above) and Figure 2 (right): Generics companies which reported annual global generics/biosimilars/OTC turnover of more than US$1 billion (above) and more than US$225 million (right). Figures have been quoted for the 2017 calendar year where possible, showing total growth compared with the previous year. Results not reported in US dollars have been converted at the rates shown, but growth figures are as reported. Business breakdowns are mostly according to companies' own definitions (Source – Company reports)

COMPANIES