MANUFACTURING

Medichem in Malta makes potent APIs

Spanish manufacturer Medichem has opened a high-potency active pharmaceutical ingredients (HPAIs) unit at its facility in Hal Far, Malta, to supply bulk drugs to the generics industry. "Our expansion to the HPAI field will allow Medichem to offer a broader product portfolio to our customers. Today, 25% of new drugs in development are highly potent, and we expect this tendency to keep growing," commented the company's chief executive officer, Ervin Veszprémi.

Equipped with development laboratories and 10-litre and 20-litre reactors, the unit will make generic highly-potent compounds for oncology and musculoskeletal treatments based on hormones, narcotics and retinoids. It is scheduled to become operational in the second half of this year.

Benefits from patent situation

The firm highlighted Malta's "unique patent situation" allowing it to develop and produce HPAIs in advance of patent expiry. "This legal intellectual-property framework allows Medichem to offer first-to-market opportunities to its customers worldwide," stated the company.

Medichem's Malta plant is one of two of the company's facilities that have been inspected by the US Food and Drug Administration (FDA). The other is located in Spain, where the firm's sister company, Combino Pharm, specialises in developing, manufacturing and marketing generic finished-dose formulations.

BUSINESS STRATEGY

Norway's Navamedic seeks sharper focus

Focusing on niche therapeutic areas rather than commodity medicines and selling more of its own products rather than distributing for other suppliers are among the ways in which Norway's Navamedic plans to enhance its profits and strengthen its business strategy.

Prioritising a smaller group of products and strengthening its position in the Nordic region are also important elements of "a more focused strategy going forward", the firm stated.

"A broad and general approach to the generics market has not worked for Navamedic," the firm acknowledged, "causing the company to suffer delays in reaching the expected size and profitability." Since gaining entry to the generics sector in 2010 through a deal with Aspen (**Generics *bulletin***, 5 March 2010, page 5), Navamedic has built a generics business that in 2013 generated an operating profit of NKr1.25 million (US$0.20 million) on sales of NKr152 million (**Generics *bulletin***, 4 April 2014, page 6).

As "one of a few with a pan-Nordic distribution and competence network", the firm said it would aim to capitalise on its regional expertise, noting that the Nordic market represented almost 80% of the firm's sales. Along with a "highly selective approach to portfolio expansion" and increasing the proportion of products that Navamedic would own itself – rather than distributing for others – the Norwegian firm said it would also bolster growth "through acquisitions of products or minor companies".

BUSINESS STRATEGY/ANNUAL RESULTS

Vivimed lines up DMF filings

Vivimed Labs plans to strengthen its generic active pharmaceutical ingredients (APIs) portfolio by filing five or six new drug master files (DMFs) in the US by the end of March 2015. The Indian company operates three API facilities in Mexico and Spain through its Uquifa bulk-drugs division headed by Mark Robbins, along with seven finished-dose sites in India.

"Vertical integration" of APIs and finished dosage formulations (FDFs) plays a key part of Vivimed's strategy to "move up the value chain". The company expects "significant growth opportunities" in the regulated generic markets having recently started shipping formulations to the US from its facility in Alathur, India.

As part of Vivimed's strategy, it will also continue targeting "new geographies" such as the Commonwealth of Independent States (CIS) region, where the firm recently obtained approval from the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PICs) to export finished dosage forms.

Sales by Vivimed's Healthcare division, which houses its APIs and FDF operations, advanced by 26.8% to account for over two-thirds – or Rs.9.37 billion (US$156 million) – of total group turnover that rose by 21.3% to Rs.13.6 billion in the firm's financial year ended 31 March 2014. The Indian firm said it generated around 85% of Healthcare turnover from highly-regulated markets. Specialty Chemicals, such as personal and home-care products, made up the remainder of group turnover.

The Healthcare segment's earnings before interest and tax (EBIT) decreased by 8.5% to Rs645 million, reducing its EBIT margin by 2.7 percentage points to 6.9%. The group's EBIT margin fell by 1.6 points to 10.9%.

MANUFACTURING

Tianjin receives warning letter

Failure to maintain adequate records of major equipment use, conduct adequate change control with regards to production of intermediates and active pharmaceutical ingredients (APIs) or to review and investigate product deviations at an API plant in Tianjin, China, have caused Tianjin Zhongan Pharmaceutical to receive a warning letter from the US Food and Drug Administration (FDA).

The letter dated 10 June follows an inspection undertaken by the US agency in late September last year. Noting that the Chinese firm should submit a corrective action plan "to ensure adequate investigations are conducted for all deviations", the FDA said this should include hiring qualified personnel to perform investigations and improving deviation-investigation procedures.

Tianjin currently produces 10 major bulk chemicals at the facility, including metronidazole, nifedipine and caffeine, which have an annual value of approximately RMB250 million (US$40.2 million). Around 90% of its products are exported.

IN BRIEF

ANI PHARMACEUTICALS has signed an exclusive licensing and supply deal with **Dexcel Pharma** for an undisclosed abbreviated new drug application (ANDA) in the US. Noting that Dexcel had submitted the ANDA – for a product that generates combined branded and generic sales of around US$80 million per year in the US – the firms said Dexcel would be responsible for obtaining US Food and Drug Administration (FDA) approval and manufacturing the drug, while ANI would market and distribute it in the US.