

Chemical Week

October 20, 2008

High-Potency API Expansion Plans Under Way as Market Soars

Deepti Ramesh in Frankfurt

Several manufacturers are planning to expand operations amid healthy growth in the high-potency active pharmaceutical ingredient (HPAPI) market, CW has learned. However, increasing raw material costs and the need for tougher standards for pharma ingredients, especially for products imported from Asia, are major issues, the manufacturers told CW at the CPhI pharma ingredient exposition, held in Frankfurt earlier this month.

Companies that told CW of HPAPI expansions include Cambrex and Aesica Pharmaceuticals (Newcastle, U.K.). "The high-potency API market is growing at least twice as much as the pharmaceutical outsourcing market," says Steven Klosk, president and CEO of Cambrex. "Cambrex currently manufactures HPAPIs only in Iowa, but we are considering investing in Europe," Klosk says. "Globally, there are only up to seven significant HPAPI players, and so Cambrex would like to tap more into the HPAPI market."

Aesica says it will expand HPAPI capacity at its Queenborough, U.K. plant during the next year. "The Queenborough plant is currently running at full capacity, and we are looking to double the capacity of the plant in the next 12 months," says Robert Hardy, CEO of Aesica. "The demand for HPAPIs is increasing especially from large U.K. and U.S. pharma companies," Hardy says.

Carbogen Amcis (Bubendorf, Switzerland), a subsidiary of Dishman Pharmaceuticals & Chemicals (Ahmedabad, India), announced plans last April to set up one of the largest facilities for HPAPIs worldwide at Bavla, India. The plant will cater to cytotoxic and non-cytotoxic highly active substances (CW, April 14/21, p. 33).

Carbogen Amcis says that more than 20% of its revenues are currently generated from its HPAPI business, and that the new facility will help its HPAPI business to generate more than 35% of revenues during the next two years.

"The HPAPI facility at Bavla will involve an investment of about \$15 million-\$18 million," Rhona McIntyre, European sales manager at Carbogen Amcis tells CW. The plant is scheduled to become operational by mid -2009, McIntyre says.

Dishman and Carbogen Amcis will both use this GMP-compliant HPAPI facility, Dishman says.

API manufacturer Ash Stevens (Detroit) says that it plans to expand capacity by 20% at its Riverview, MI facility by early 2010. The expansion will include increasing HPAPI manufacturing capacity as well as new plant-scale hydrogenation equipment, Ash Stevens says.

Meanwhile, incidents of contamination of the blood-thinning drug Heparin earlier this year have raised quality and consistency issues relating to drug ingredients, particularly

concerning ingredients sourced from China (CW, May 5, p. 33). "By working with organizations such as the European Fine Chemicals Group (EFCG; Brussels) and the Active Pharmaceutical Ingredients Committee (Brussels), BASF is pushing for better global standards for manufacturing pharmaceutical ingredients," Martin Widmann, group v.p./pharma ingredients and services at BASF tells CW.

The EFCG and the International Pharmaceutical Excipients Council of Europe (Brussels) say they have developed a certification proposal for pharmaceutical excipients. "If you want safe medicines, you have to start with safe ingredients," Guy Villax, EFCG board member and CEO of Hovione (Loures, Portugal), told reporters at CPhI press conference. "The manufacture of excipients is neither regulated nor controlled, and currently there is no legal obligation for excipient manufacturers to comply with good manufacturing practices," says Tim Bolke, a member of EFCG's excipients task force. "Therefore, we are developing a certifiable global standard," Bolke says.

Aesica says it opened an office in Shanghai last month to enable the company to source raw materials directly from the country, rather than through agents. "Our customers are wary of intermediates from China, but we will audit the facilities where products will be manufactured," Hardy says.

Cambrex says it is exploring the possibility of manufacturing partnerships in China and India, a move primarily driven by cost concerns. The company says it is considering a model in which the early processing steps would be done in developing countries and the cGMP steps would be done by Cambrex.

Distributor Univar, which sources products from Asia, says it will be "more stringent" with manufacturers in Asia. "Univar will audit the facilities of the manufacturers in Asia," says Matthew Ottaway, European industry manager/pharma and personal care at Univar.

DSM says that it will insist that its Asian suppliers implement rules similar to those followed by DSM at its own facilities. "Many other companies will follow this model in the future," says Hans van Nistelrooij, v.p./new business development at DSM Anti-Infectives.

Another major concern are increasing energy and raw material costs. "Costs have doubled in the last 18 months, which has resulted in an increase in prices of products from between 20% and 25%," says Thomas Frazier, global marketing manager/polyglycols and surfactants at Dow. "Most specialty products will, however, have reasonable price stability by next year," Frazier says.

Saltigo says that it has been trying to combat increasing costs with measures including increased mechanization and efficiency improvements.

Meanwhile, more than 1,700 companies from more than 60 countries exhibited at CPhI, which attracted more than 25,000 attendees, CPhI says.