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High Potency Active Pharmaceutical Ingredients (HPAPIs)

The fastest growing market segment in the pharmaceutical industry

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ABSTRACT: The High Potency Active Pharmaceutical Ingredients (HPAPIs) market is the fastest growing segment in the pharmaceutical industry globally. The selective targeting characteristics of these compounds are highly deployed in the treatment of cancer, and the HPAPIs market is mostly driven by the growth in the oncology therapeutics market worldwide. North America and Europe together hold more than eighty percent of the global HPAPIs market. Since a lot of investment, expertise and stringent specification standards are required for its production, the contract manufacturing of these high potency compounds is increasing. A lot of pharmaceutical companies are investing or expanding into the production of HPAPI compounds.

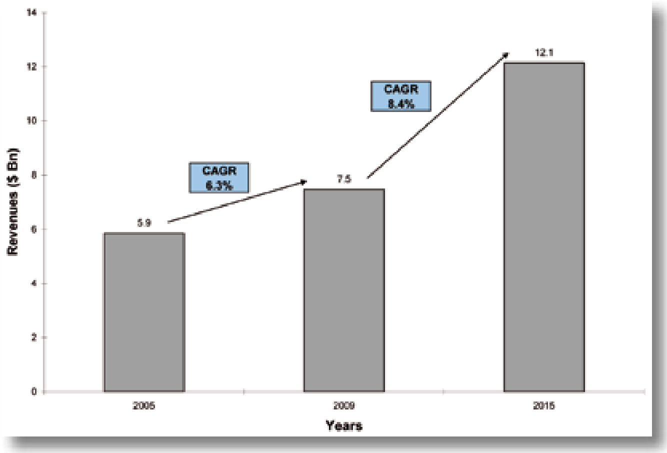
INTRODUCTION TO THE HPAPI

High Potency Active Pharmaceutical Ingredients (HPAPIs), although a niche segment of the API market, is the fastest growing segment. Typically, an API is classified as an HPAPI if it has an occupational exposure limit at or below 10 micrograms per cubic meter of air. HPAPI compounds are known for their ability to target the diseased cells more precisely and selectively than other APIs. They are highly effective at much smaller dosages and hence, much more efficient in the cure of some diseases than other non potent APIs. On the basis of synthesis route, the HPAPIs can be synthetic or biotech. While synthetic HPAPIs hold a dominating share of 85 percent in the global market, the use of biotech HPAPIs is gradually increasing as the research and development work on the use of biological molecules for many therapies is gaining pace. On the basis of customer base, the HPAPIs can be generic or branded. Since a large number of HPAPI compounds are under patent, around 81 percent of the HPAPIs are branded globally. However, the generic HPAPIs market is growing at a fast rate.

GLOBAL HPAPIs MARKET OVERVIEW

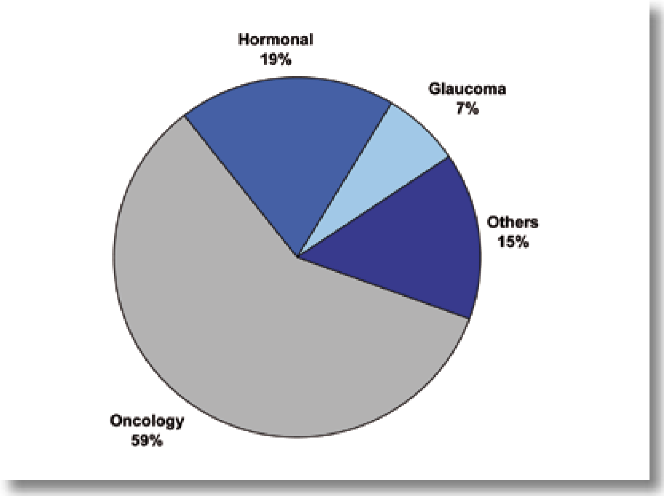
The global HPAPIs market was $7.5 billion in revenue terms in 2009, which forms 10 percent of the overall API market globally. The share of HPAPIs in the overall API market is growing very fast. The global HPAPIs market will grow at a CAGR of 8.4 percent to 2015 with the major growth driver being the anti-cancer drug market which is itself growing at a CAGR of 12.6 percent globally. The selective targeting property of HPAPIs is widely deployed in the treatment of cancer. HPAPIs are also increasingly being used in the form of Antibody Drug Conjugates (ADCs) which is an important and effective breakthrough in cancer treatment. ADCs are a combination of monoclonal antibodies and biologically active drugs.

They combine the unique targeting ability of monoclonal antibodies and the cancer-killing ability of cytotoxic drugs. Highly potent anti-cancer drugs are efficient as they target cancers while minimizing the drug's exposure to the healthy tissues.



Hormonal drugs are also an important category where HPAPIs are increasingly used. A significantly emerging category is glaucoma. In addition to this, HPAPIs are also increasingly finding a role in the treatment of some other diseases as a lot of therapies are moving towards a highly targeted approach.

The applications are emerging in cardiovascular drugs, central nervous system drugs and musculoskeletal drugs. Also, certain high potency analgesics use HPAPIs. Certain gynecological and cosmetic applications of HPAPIs are also observed to be emerging.



Several pharmaceutical companies are recognizing the strong growth potential in the global HPAPIs market. Some companies are considering investing in new HPAPIs production facilities, while others are planning the expansion of their production capacity of HPAPIs in order to meet the fast growing demand.
In the case of HPAPIs, captive manufacturing is very expensive and requires a lot of safety and handling specifications. This is the reason that many drug formulating companies are closing their captive facilities and outsourcing the manufacturing of HPAPIs to the contract manufacturers to benefit from the latter's competency and expertise. The outsourcing of HPAPIs manufacturing is growing in India and China due to the cost advantage. The trend of outsourcing is also growing in the Eastern European countries as the cost of manufacturing in North America and Western Europe is comparatively higher.

"The global HPAPI market is set to grow at a CAGR of 8.4% from 2009 to 2015"

HPAPIs REGIONAL MARKETS

North America, having a highly developed and regulated pharmaceutical industry, holds the largest market for HPAPIs with a dominating share of 45.6 percent in the global market in 2009. Cancer is the second leading cause of death, after cardiac diseases, in the North American region. Cancer therapy drugs have the largest share in the $3.4 billion North American HPAPIs market, and show the strongest growth of any therapeutic category in the region's pharmaceutical industry.
The growth rate of oncology drugs in North America in 2009 was 16.5 percent, and is estimated to be the same in the years to come. The changing lifestyle and older age diseases is also high in this region and is growing at a rate of 6 to 7 percent. Driven by these factors, the HPAPIs market in North America will be growing at a CAGR of 6.6 percent to 2015.

Oncology is the primary driver for the HPAPI demand.

The US has the dominating market share of 93.7 percent. Though coming up strongly, Canada is currently a much smaller market. The key companies holding market share in the North American HPAPIs market are AMPAC Fine Chemicals, SAFC, Teva, Cambrex Ferro, Bristol Myers Squibb and Carbogen Amcis.
Europe is the second largest market for HPAPIs with a share of 35 percent, currently standing at $2.5 billion in 2009. Cancer being responsible for around 25 percent of deaths in Europe, together with the fast growing lifestyle and older age diseases, will drive the demand for HPAPIs in Europe by 8 percent to 2015. The largest market in Europe is the UK with a 22 percent share in the regions' HPAPIs demand, followed by Germany with 15 percent and France with a 10 percent share. The market in Eastern European countries is fast growing with a current share of 26 percent. Bristol Myers Squibb, Bayer Schering and Boehringer Ingleheim are major companies in the HPAPIs segment in Europe. Other companies important in the European HPAPIs market are Sanofi Aventis, Aptuit, Teva, Novasep, Carbogen Amcis and Omnichem among others.
With a share of 9.3 percent in the global demand, the Asia Pacific market for HPAPIs was $697m in 2009. Asia is certainly the fastest growing market for the HPAPIs compounds in the world. Healthcare standards are rising very rapidly in Asian economies, especially China and India. The market for oncology drugs in Asia Pacific is growing at a rate close to 20 percent. The growth in the generic sector HPAPIs is also giving a boost to the Asian market as the number of producers is also growing. The Asia Pacific HPAPIs market will grow at a CAGR of 15.4 percent between 2009 and 2015. The Asia Pacific demand is dominated by Japan as the healthcare standards and adaptability to new drugs are the highest in Japan when compared to other Asia Pacific countries. With a market of $502m, Japan held a dominating share of 72 percent in the region's demand for HPAPI in 2009. India had a share of 11 percent and China, 10 percent. The reason for higher market share in India as compared to China is the better adaptability and acceptance of new drugs in India. In China, the expenditure on healthcare is controlled and restricted to a large extent. Market for HPAPIs is growing very strongly in both these countries. Other Asia Pacific countries which are showing significant growth in this market are South Korea and Australia. Innovators like Bristol Myers Squibb, Pfizer and AstraZeneca operate in the Asia Pacific region. Carbogen Amcis, with a new manufacturing facility in India, holds a significant share of the Asia Pacific HPAPIs market. Aptuit, Hovione, Eisai Ltd., Asymchem, Arch Pharmalabs, Nicholas Piramal, Ranbaxy and Dr. Reddy's Laboratories are other important manufacturers of HPAPIs in this region.

LEVERAGING MARKET GROWTH POTENTIAL

The manufacturing of HPAPIs compounds is not an easy task. The facility requires large investments and very stringent safety and handling specifications. Recognizing the strong growth potential in the global market, a number of companies are preparing themselves for the big run. Some companies are considering investing in new HPAPIs production facilities, while others are planning expansion of their existing production capacities of HPAPIs to meet the fast growing demand.
SAFC Pharmaceuticals has invested close to $75m to expand the capacity of its St. Louis, Missouri facility for the production of highly potent drug conjugates in the past few years. This facility has also acquired a thind party certification for the safe handling of potent drug substances. The company is also building a new commercial-scale HPAPIs facility at Madison with an investment of around $30m. Albany Molecular Research Inc. (AMRI) plant in Rensselaer, New York, has recently acquired a thind party certification for HPAPIs production. The API manufacturer, Ash Stevens is planning to expand its facility at Riverview, Michigan, by 20 percent to incorporate manufacturing of HPAPI compounds. The contract manufacturing company, AMPAC Fine Chemicals (AFC), has been producing HPAPIs for various companies in its

commercial-scale HPAPIs production facility in Rancho Cordova, California. Cambrex is also emerging as a strong player with its facility at Charles City, Lowa in the US, and is also considering investing in Europe for manufacturing HPAPIs. Patheon Inc. is investing to add dedicated high potency and controlled substance manufacturing to its facility in Manati, Puerto Rico. In June 2008, US-based Pharmatek completed the construction of a new facility for the high-potency manufacturing of oral dosage forms.

"North America and Europe together hold more than 80% of the global HPAPI market"

Carbogen Amcis, a part of the India-based Dishman group, is emerging as a very serious company in the high potency segment. Carbogen Amcis currently has a facility in Bubendorf, Switzerland. The company has set up one of the world's largest HPAPIs facilities at Bavla, India which will cater to the cytotoxic and non-cytotoxic highly active substances. This has involved an investment between $15m and $18m by the group. The operations of this facility are expected to help the company's HPAPIs business generate more than 35 percent of its revenues. Nicholas Piramal International Ltd. (NPIL) has also recently invested to upgrade its facility in the UK for HPAPIs. The company has an HPAPIs contract manufacturing facility at Grangemouth, Scotland. Ben Venue, a part of Boehringer Ingelheim, is investing $139m in a new manufacturing plant for producing high potency compounds.

The French company Novasep has installed a new HPAPIs plant at its facility in Le Mans, France with an investment of €8m. This has helped the company to double its HPAPIs production capacity. This enhanced capacity of the company is aimed at meeting the increasing demand for the multiple chemistry and the purification of HPAPIs. This facility recently acquired a thind party certification for its potent compound safety and handling program. Helsinn, a Switzerland-based contract manufacturer operates two plants at its Biasca facility in Switzerland for the manufacture of HPAPIs.

The UK-based API manufacturer and formulator company, Aesica, has expressed plans to double its HPAPIs capacity at its Queenborough, the UK plant, in order to leverage upon the rapidly growing demand. Companies like Bayer Schering, Bristol Myers Squibb, Sanofi Aventis, Lonza and Teva Pharmaceuticals, Pfizer and Merck Pharmaceuticals have been in the HPAPIs business for a number of years. Inspite of a number of HPAPIs suppliers present in the global market, the demand is currently much higher than the supply. The competition is expected to increase in the future although the demand for HPAPIs will also be increasing.

NOTES

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