Active Pharmaceutical Ingredients (APIs) Market in Asia Pacific to 2017

Increasing Penetration in China and India Coupled with Low Cost Manufacturing to Fuel Regional Growth
GBI Research Report Guidance

The coverage in this report is as follows:

- Chapter three contains a discussion of the Contract Manufacturing Organizations (CMO) trend in Asia-Pacific, the importance of CMOs and growth drivers for CMOs in the API manufacturing industry.

- Chapter four contains the market overview and API revenue forecasts for Asia-Pacific. The chapter includes API classification based on synthesis routes, and the respective drivers and restraints of the Asia-Pacific API industry. This section also includes synthetic and biotech API revenue analysis by country, and classification of synthetic and biotech APIs by customer base.

- Chapter five contains the API market overview and revenue forecast for Japan. The chapter includes revenue trends and share analysis by product types and by therapeutic categories, classification of APIs by customer base, in-depth analysis of revenue trends and revenue share analysis. This section also contains details about the revenue share analysis by therapeutic applications.

- Chapter six contains the API market overview and revenue forecast for China. The chapter includes revenue trends and share analysis by product types and by therapeutic categories, classification of APIs by customer base, in-depth analysis of revenue trends and revenue share analysis. This section also contains details about the revenue share analysis by therapeutic applications.

- Chapter seven contains the API market overview and revenue forecast for South Korea. The chapter includes revenue trends and share analysis by product types and by therapeutic categories, classification of APIs by customer base, in-depth analysis of revenue trends and revenue share analysis. This section also contains details about the revenue share analysis by therapeutic applications.

- Chapter eight contains the API market overview and revenue forecast for India. The chapter includes revenue trends and share analysis by product types and by therapeutic categories, classification of APIs by customer base, in-depth analysis of revenue trends and revenue share analysis. This section also contains details about the revenue share analysis by therapeutic applications.

- Chapter nine contains the appendix of the report, illustrating the methodology, research process and important definitions included in the report.
Executive Summary

Asia-Pacific Active Pharmaceutical Ingredients Market Revenue Expected to Grow, with a Healthy CAGR of XX% During the Forecast Period 2011-2017

The total revenue generated by the Asia-Pacific Active Pharmaceutical Ingredients (APIs) market was $XXm in 2011, which is expected to increase with a healthy CAGR of XX% during 2011-2017, to generate revenues of $XXm in 2017. Major demand growth in the region’s market is expected to come from the biotech and generic sectors. India and China in particular are expected to contribute high growth for the region’s APIs market. The increasing elderly population, improving healthcare standards and changing lifestyles in these countries will drive the demand, which will be supported by increasing per capita income and increasing healthcare penetration.

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2  Introduction

Active Pharmaceutical Ingredients (APIs), also known as bulk drug substances, are defined as any substance or mixture of substances intended to be used in the manufacture of a drug or any medicinal product that, when used in the production of a drug, become an active ingredient of the drug or medicinal product. The API is then suspended in excipients to make it into the desired dosage form. This active substance is responsible for the therapeutic effect of the drug, and the efficacy of a drug entirely depends upon the concentration and composition of the API.

APIs are used at a number of stages of pharmaceutical development. This includes stability sample testing, general analytical testing and method development, as Good Manufacturing Practice (GMP) APIs in clinical trials, and as source materials for manufacturing marketed drugs. In this report, both the merchant and captive API markets are considered.
4.8 Asia-Pacific Revenue Share Analysis by Product Types

On the basis of product type, the APIs market in Asia-Pacific was divided into two categories; the synthetic market and the biotech market. The synthetic market, being the traditional market, had the highest revenue share in the Asia-Pacific market in 2011, accounting for XX% of API market revenues. The biotech market held a share of XX% in the API market revenues in 2011. Biopharmaceuticals have recently gained importance on a commercial scale because of their better exclusivity and revenue growth opportunities. The biotech market is expected to increase its revenue share in the APIs market during the forecast period.

The following figure illustrates the API market revenues share based on product type in the Asia-Pacific market in 2011.

![Figure 9: APIs Market, Asia-Pacific, Revenue Share by Product Types (%), 2011](image)

The following table provides the API market revenues and revenues share based on product type in the Asia-Pacific market in 2011.

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Revenue ($m)</th>
<th>Share (%)</th>
</tr>
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<tbody>
<tr>
<td>Synthetic Market</td>
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<td>Biotech Market</td>
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<td>Total</td>
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4.10.3 Asia-Pacific Biotech Market Revenues and Forecasts to 2017

Biotech APIs generated revenues of $XXm in 2005 in the Asia-Pacific region. The biotech APIs market suffered from low growth in the first two years due to high fluctuations in domestic currencies of Asia-Pacific markets. However, from 2008 onwards biotech API market revenues have registered year-on-year growth of more than XX% for each year, and reached $XXm by 2011 in the Asia-Pacific region. All major countries in Asia-Pacific have contributed towards the growth of the biotech APIs market in the region. Japan has established a regulatory pathway for biologics, while countries such as India and China have increased R&D and production facilities dedicated for biosimilars.

The figure given below illustrates the API market revenues generated and API market revenue growth rates for biotech pharmaceuticals in the Asia-Pacific market during 2005-2017.

![Figure 16: Biotech Market, Asia-Pacific, Market Revenues (\$m and %), 2005-2017](image)


The biotech APIs market in the Asia-Pacific region is expected to have revenues of $XXm by 2017, with a CAGR of XX% during 2011-2017. Patent expiries during the forecast period would increase the biosimilars demand in the Asia-Pacific region, and better exclusivity is expected to drive the sale of biologics. All major countries in the Asia-Pacific region are expected to increase their demand for biosimilars, whereas biologics will witness limited growth.
The table given below provides the API market revenues generated by biotech pharmaceuticals in the Asia-Pacific market during 2005-2017.

<table>
<thead>
<tr>
<th>Year</th>
<th>Revenue ($m)</th>
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<tbody>
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<td>2005</td>
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<td>2006</td>
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<td>CAGR (2005-2011)</td>
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<td>CAGR (2011-2017)</td>
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5.4 Japan APIs Market by Customer Base

5.4.1 Japan Synthetic Market Revenue by Customer Base and Forecasts to 2017

Japanese synthetic APIs generated market revenues of $XXm in 2005, which increased with a CAGR of XX% during 2005-2011 and reached $XXm in 2011. The domestic currency fluctuations against USD were a major cause of high fluctuations in revenues in USD terms.

Within the synthetic APIs market, innovative APIs were dominant and contributed XX% of national API revenues in 2011. Japanese innovative API revenues increased from $XXm in 2005 with a CAGR of XX% during 2005-2011, to reach $XXm in 2011. However, the Japanese government has recently indicated plans for increasing the generic penetration level in the Japanese market. With increased support from the government, the Japanese generics market contributed XX% of revenues generated by the synthetic segment in 2011. In revenue terms, generic API revenues in Japan increased from $XXm in 2005 with a CAGR of XX% during 2005-2011, and reached $XXm by 2011.

The following figure illustrates the synthetic API market revenues based on consumer segments in Japan during 2005-2017.

Figure 25: Synthetic Market, Japan, Market Revenues by Customer Base ($m), 2005-2017

Japanese synthetic market revenues are expected to grow with a very low CAGR of XX% during 2011-2017, to reach around $XXm in 2017. The high maturity level of the Japanese pharmaceutical market and increasing competition from biopharmaceuticals are the major reasons for slow growth expectations surrounding the synthetic API market revenues.

Within the synthetic APIs market in Japan, revenues from generic APIs are expected to increase with a high growth rate. Increasing medical costs have been pushing the Japanese government to support the generic pharmaceutical market, causing better growth in generic API revenues than in the innovative APIs market. Revenues generated by the innovative market are expected to reach around $XXm by 2017, while the generic market is expected to generate revenues of $XXm by the same point.
The following table provides details of the synthetic API market revenues based on consumer segments in the Japanese market during 2005-2017.

Table 19: Synthetic Market, Japan, Market Revenues by Customer Base, $m, 2005-2017

<table>
<thead>
<tr>
<th>Year</th>
<th>Innovative Market ($m)</th>
<th>Generic Market ($m)</th>
<th>Synthetic Market ($m)</th>
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</thead>
<tbody>
<tr>
<td>2005</td>
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<td>2017</td>
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<tr>
<td>CAGR (2005-2011)</td>
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<td>CAGR (2011-2017)</td>
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</tbody>
</table>

6.4.2 China Synthetic Market Revenue Share Analysis by Customer Base

The Chinese synthetic APIs market has been dominated by generic APIs. The revenue share of generic APIs in the synthetic APIs market in China was XX% in 2005, which increased to XX% in 2011. Due to the comparatively weak IPR protection framework, producers of branded drugs have been hesitant over Chinese market entry. This gave great opportunities for the cost effective generics market to gain dominance in the national synthetic market. The revenue share of the innovative market decreased during the historic period, from XX% in 2005 to XX% in 2011.

The following figure illustrates the revenue share analysis for the synthetic API market in China, by consumer segment, for 2005, 2011 and 2017.

![Synthetic Market, China, Revenue Share Analysis by Customer Base](image)

Source: GBI Research Pharmaceutical Market Database (July 26, 2012), CPA

Patent expiries of some blockbuster drugs and the cost effectiveness of generic drugs are factors that are expected to further drive the generic APIs market growth in China, increasing the revenue share of generic APIs to XX% in the Chinese synthetic market by 2017. However, relatively slow growth in the innovative APIs market is expected to shrink its revenue share to XX% in 2017.

The following table provides the revenue share analysis for the synthetic API market in China, by consumer segment, for 2005, 2011 and 2017.

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Generic Market</td>
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<tr>
<td>Innovative Market</td>
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<tr>
<td>Synthetic Market</td>
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</table>

Source: GBI Research Pharmaceutical Market Database (July 26, 2012), CPA
9 Appendix

9.1 Abbreviations

ABLE - Association of Biotechnology Led Enterprises
API - Active Pharmaceutical Ingredients
CMO - Contract Manufacturing Organizations
CAGR - Compound Annual Growth Rate
CPA - Chemical Pharmaceutical Generic Association
EBTC - European Business and Technology Centre
FDA - Food and Drug Administration
GMP - Good Manufacturing Practice
IPR - Intellectual Property Right
KIHSA - Korea Institute of Health and Social Affairs
KPMA - Korea Pharmaceuticals Manufacturers Association
KPTA - Korea Pharmaceuticals Traders Association
MHLW - Ministry of Health, Labour and Welfare
R&D - Research and Development
USD - United States Dollar (or American Dollar)

9.2 Bibliography


- Speciality Chemicals Magazine (February, 2012). “India outruns them all - India is the real growth giant in the APIs market, while Italy and Spain still have a role to play. So says a new report by the CPA”. Chemical Pharmaceutical Association, Italy. Available from: http://www.specchemonline.com/articles/view/india-outruns-them-all [Accessed July 27, 2012].
9.3 Market Definitions

‘Asia-Pacific’ refers to Japan, China, South Korea and India; all other countries in Asia-Pacific are considered under ‘Rest of Asia-Pacific’.

9.4 Methodology

GBI Research’s dedicated research and analysis teams consist of experienced professionals with marketing, market research and consulting backgrounds in the pharmaceutical industry and advanced statistical expertise.

GBI Research adheres to the codes of practice of the Market Research Society (www.mrs.org.uk) and the Strategic and Competitive Intelligence Professionals (www.scip.org).

All GBI Research databases are continuously updated and revised.

9.4.1 Coverage

The objective of updating GBI Research’s coverage is to ensure that it represents the most up to date vision of the industry possible.

Changes to the industry taxonomy are built on the basis of extensive research of company, association and competitor sources.

Company coverage is based on three key factors: market capitalization, revenues and media attention/innovation/market potential. This can be further supported by the following:

• An exhaustive search of 56 member exchanges is conducted and companies are prioritized on the basis of their market capitalization.
• The estimated revenues of all major companies, including private and governmental, are gathered and used to prioritize coverage.
• Companies which are making the news, or which are of particular interest due to their innovative approach, are prioritized.

GBI Research aims to cover all major news events and deals in the petrochemical industry, updated on a daily basis.

9.4.2 Secondary Research

The research process begins with exhaustive secondary research on internal and external sources being carried out to source qualitative and quantitative information relating to each market.

The secondary research sources that are typically referred to include, but are not limited to:

• Company websites, annual reports, financial reports, broker reports, investor presentations and US Securities and Exchanges Commission (SEC) filings.
• Industry trade journals and other literature.
• Internal and external proprietary databases.
• National government documents, statistical databases and market reports.
• News articles, press releases and webcasts specific to the companies operating in the market.
9.4.3 Primary Research

GBI Research conducts hundreds of primary interviews a year with industry participants and commentators in order to validate its data and analysis. A typical research interview fulfills the following functions:

- It provides first-hand information on market size, market trends, growth trends, competitive landscape, and future outlooks for markets and sectors
- It helps in validating and strengthening secondary research findings
- It further develops the analysis team’s expertise and market understanding
- Primary research involves email interactions, telephone interviews and face-to-face interviews for each market, category, segment and sub-segment across geographies

The participants who typically take part in such a process include, but are not limited to:

- Industry participants: CEOs, VPs, business development managers, market intelligence managers and national sales managers,
- Outside experts: investment bankers, valuation experts, research analysts and key opinion leaders specializing in petrochemicals markets.

9.4.4 Expert Panel Validation

GBI Research uses a panel of experts to cross-verify research and forecast methodologies and drive its analytical content.

The GBI Research expert panel comprises marketing managers, product specialists, international sales managers from petrochemical companies; academics and geologists from research universities, consultants from venture capital funds and distributors/suppliers of petrochemicals goods and services.

9.6 Disclaimer

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