Diabetes Therapeutics Market in India to 2018
Rapid Uptake of DPP-IV Inhibitors, GLP-1 Agonists and Expanding Insulin Segment to Drive Growth
GBI Research Report Guidance

- Chapter two summarizes the scope of the report.
- Chapter three gives an overview of DM, looking at the types, diagnostic tests and treatment pattern.
- Chapter four gives an in-depth insight into conventional and emerging drug classes increasingly being used for the management of diabetes.
- Chapter five comprises detailed epidemiology of DM and treatment usage patterns.
- Chapter six gives the anti-diabetes market figures and forecasts until 2018, with revenue segmentation by OADs and insulin, along with the cost of therapy and forecast for DM treatment.
- Chapter seven analyzes the economic burden of DM and associated complications in the country.
- Chapter eight gives a detailed account of major drivers and restraints affecting the domestic anti-diabetes market.
- Chapter nine discusses the existing unmet needs in the diabetes therapeutics market.
- Chapter 10 covers the R&D product pipeline and profiles novel molecules.
- Chapter 11 includes case studies highlighting recent events in the diabetes space.
- Chapter 12 discusses the major trends and issues in the Indian anti-diabetes market.
- Chapter 13 gives an overview of top players in the domestic anti-diabetes market.
- Chapter 14 discusses the major strategic consolidations in the domestic market that have taken place in the last four years.
Diabetes Therapeutics Market in India to 2018 - Executive Summary

The Indian diabetes therapeutics market is one of the fastest growing market segments in India. A growing patient population and increased demand for effective medication are offering both domestic and Multinational Companies (MNCs) promising opportunities.

Growing Diabetes Population in India Offers Lucrative Opportunities

With approximately XX million diabetics in 2011, India presents a promising opportunity for pharmaceutical companies with anti-diabetic product portfolios. India, after China, is the XX diabetes capital of the world. As per the International Diabetes Federation’s (IDF’s) estimation, the diabetes population in the country is expected to reach approximately XX million by 2030 (IDF, 2011a). It stood at XX million in 2007, XX million in 2010 and is projected to grow at a Compound Annual Growth Rate (CAGR) of XX% from 2011 to XX million by 2018.

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Source: GBI Research; IDF, 2011a

The number of patient with diabetes, predominantly type 2 diabetes, continues to increase at an alarming rate, mainly attributed to sedentary lifestyles, the adoption of Westernized culture and increased longevity. This offers many promising opportunities to pharmaceutical companies in terms of launching new anti-diabetic therapies and offsetting the loss of revenues and market share, if any, in the established markets.
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2 Diabetes Therapeutics Market in India to 2018 - Overview

Diabetes Mellitus (DM) is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action or both. DM is often associated with long-term damage, dysfunction, and failure of various organs especially the eyes, kidneys, nerves, heart and blood vessels.

India currently has the XX largest diabetes population in the world, expected to reach XX million by 2030, making it one of the fastest growing segments in the country (IDF, 2011a).

Type 2 DM accounts for approximately XX% of all cases of diabetes and generally manifests in adults. Its prevalence has increased over the last few years and has become a growing concern for healthcare authorities and the government.

Increased disease awareness, lifestyle modifications and compliance in terms of prescription medications will at least partly restrain disease prevalence. The emergence of new therapies such as Dipeptidyl Peptidase-4 (DPP-4) inhibitors and Glucagon-like Peptide-1 (GLP-1) agonists, among others, are likely to see patients receiving treatment early and intensify market competition.

Amidst the evolving Oral Anti-Diabetic (OAD) landscape, metformin and its combinations are likely to remain the mainstay of type 2 DM therapy. Effective insulin analogs such as ultra-long-acting insulin and oral insulin formulations are expected to hit the market in the future, creating increased demand for insulin in the forecast period.

2.1 Diabetes Mellitus - A Global Overview

- An estimated XX million people, or XX% of the world’s population (XX-XX years) live with diabetes, expected to reach XX million by 2030 (IDF, 2011a).
- Of the overall diabetes population, XX-XX% is type 2 diabetics, and the remaining XX-XX% is type 1 diabetics.
- China, with XX million diabetes patients, is the world capital of diabetes (IDF, 2011a).
- India, with XX million diabetes patients, is the XX world capital of diabetes, and the figure is expected to reach to XX million by 2030 (IDF, 2011a).
- Approximately XX% of diabetics live in low and middle-income countries.
- Almost XX% of cases are undiagnosed (IDF, 2011a).
- Approximate diabetes healthcare expenditure was $XX billion in 2011, representing XX% of overall healthcare expenditure (IDF, 2011a).
6 Diabetes Therapeutics Market in India to 2018 - Revenue Forecasts

6.1 Introduction

The Indian anti-diabetics market, which is growing at a double-digit growth rate, is very promising and offers many lucrative opportunities to domestic and overseas players. GBI Research’s analysis reveals that the overall anti-diabetes market in India was worth $XXm in 2011. Although this represents a small portion of the global anti-diabetics market, GBI Research estimates that market will witness significant growth at a CAGR of XX% between 2011 and 2018, to attain sales of $XXm in 2018.

The type 2 diabetes therapeutic market, with a share of approximately XX% by value, dominated the overall Indian anti-diabetes market in 2011. The OADs and insulin segments of the type 2 diabetes therapeutics market accounted for XX% and XX% respectively in the same year.

Key drivers of the diabetes therapeutics market in the forecast period will be the large and growing diabetes population, rising obese and geriatric populations and rapid market adoption of drugs from classes such as DPP-4 inhibitors, GLP-1 agonists and others. Low treatment-seeking and diagnosis rates, poor compliance, rising healthcare costs and an increasingly competitive market are some of the key hurdles that must be overcome. Nevertheless, the drivers outweigh the restraints and with the changing treatment usage pattern during the forecast period, the anti-diabetes market in India will witness significant growth.

Figure 6: Diabetes Market, India, Anti-diabetic Revenue Forecast ($m), 2004-2018

![Graph showing diabetes market revenue forecast from 2004 to 2018 with CAGR calculation for 2004-2011 and 2011-2018]

Source: GBI Research; IDF, 2011

Table 10: Diabetes Market, India, Anti-Diabetic Revenue ($m), 2004-2011

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Source: GBI Research; IDF, 2011

Table 11: Diabetes Market, India, Anti-Diabetic Revenue Forecast ($m), 2011-2018

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Source: GBI Research, IDF, 2011
10 Diabetes Therapeutics Market in India to 2018 - Product Pipeline Analysis

The rising global DM epidemic, especially in China and India, has fueled research in the pharmaceutical industry. Many new drugs and drug combinations are under investigation which could possibly evolve as better treatment options.

The R&D product pipeline for DM is strong and dominated by OAD agents. There are over XX molecules which are in the mid-to-late stages of clinical trials and being studied either as a monotherapy or combination therapy.

Although OAD agents, particularly metformin as the mainstay of treatment for type 2 DM, their undesirable side effects have driven the pharmaceutical industry to pursue molecules with better efficacy and safety profiles which could prove the next blockbusters.

The following figure depicts the R&D product pipeline by stage of clinical development.

![Figure 10: Diabetes Market, India, Product Pipeline by Phase, 2012](image)

Source: GBI Research’s Proprietary Clinical Trials Database [accessed November 29, 2012]

Analysis of the R&D product pipeline for diabetes reveals that the majority of the molecules (XX%) are in Phase III, followed by XX% in Phase II. Phase I, Phase II/III and Phase I/II accounted for XX%, XX% and XX% of the overall R&D pipeline respectively.

Paradoxically, the type 2 diabetes market, crowded with many generics and branded generic drug products, is being seen as a significant growth opportunity for newly patent-protected products owing to high prevalence, the progressive nature of the disease and considerably high unmet need.

Of overall R&D pipeline molecules, more than XX% are being studied for the treatment of type 2 DM. This includes molecules from various novel drug classes such as SGLT inhibitors, DPP-4 inhibitors, GLP-1 agonists and new insulin formulations.

The product pipeline comprises molecules from the new therapeutic classes such as DPP-4 inhibitors, SGLT inhibitors and GLP-1 agonists, which are expected to be strong competitors in the near future.

The R&D product pipeline consists of many first-in-class molecules such as dapagliflozin, empagliflozin, canagliflozin and others and a number of me-too molecules such as alogliptin, syncria and lixisenatide, Bydureon (biobetter of Byetta).

Oral insulin (IN-105 from Biocon) and ultra-long-acting insulin preparation (degludec form Novo Nordisk) are noteworthy examples of new products in the insulin segment.

To conclude, the R&D product pipeline is inundated with many combination products belonging to various OAD classes. Should they be approved, intense competition for market share is expected, as they would target the same patient population.
15 Diabetes Therapeutics Market in India to 2018 - Appendix

15.1 Market Definitions

Prevalence population: The prevalence population is the estimated number of people at any given point of time who are affected by diabetes.

Diagnosed population: The diagnosis population refers to the number of people that have been diagnosed with diabetes.

Prescription rate: The prescription population refers to the number of people that are on medication for diabetes.

Total healthcare expenditure: The sum of expenditure on healthcare and healthcare-related items.

Out-of-pocket healthcare expenditure: Healthcare costs that are not covered by insurance; such as deductibles, coinsurance, co-payments, and non-covered expenses.

Essential drugs: According to the WHO, essential drugs are those that satisfy the primary healthcare needs of the population.

Biosimilars: Biosimilars are new versions of branded biologics that are approved after patent expiries of innovator products.

Biobetters: Biobetters are defined as biologic therapies that have the same targets as the originator therapy but that have been improved, either in the form of safety, efficacy, tolerability or dosing regimen.

15.2 Abbreviations

- API: Active Pharmaceutical Ingredient
- ATP: Adenosine Triphosphate
- BMS: Bristol-Myers Squibb
- CAGR: Compound Annual Growth Rate
- CDSCO: Central Drugs Standard Control Organization
- DBT: Department of Biotechnology
- DM: Diabetes Mellitus
- DPCO: Drugs Price Control Order
- DPP-4: Dipeptidyl Peptidase-4
- EMA: European Medicines Agency
- FDA: Food and Drug Administration
- FPG: Fasting Plasma Glucose
- GDM: Gestational Diabetes Mellitus
- GDP: Gross Domestic Product
- GIP: Glucose-dependent Insulinotropic Peptide
- GIT: Gastrointestinal Tract
- GKA: Glucokinase Activator
- GLP: Glucagon-like Peptide
- GSK: GlaxoSmithKline
- ICMR: Indian Council of Medical Research
- IDDM: Insulin-Dependent Diabetes Mellitus
- IDF: International Diabetes Federation
• IFG: Impaired Fasting Glucose
• IGT: Impaired Glucose Tolerance
• MNC: Multinational Corporation
• MSD: Merck Sharp & Dohme
• NIDDM: Non-Insulin Dependent Diabetes Mellitus
• NLEM: National List of Essential Medicines
• OAD: Oral Anti-Diabetic
• OGTT: Oral Glucose Tolerance Test
• OTC: Over The Counter
• PGIIME: Postgraduate Institute of Medical Education and Research
• PPAR: Peroxisome Proliferator-Activated Receptor
• PPG: Postprandial Plasma Glucose
• SGLT: Sodium-Glucose Transport Protein
• SU: Sulfonylurea
• TZD: Thiazolidinedione
• WHO: World Health Organization

15.3 Bibliography


15.4 Research Methodology

GBI Research’s dedicated research and analysis teams consist of experienced professionals with a pedigree in marketing, market research, consulting backgrounds in the medical devices 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.

15.4.1 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 decided 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.

• 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 medical industry, with its databases updated on a daily basis.

The coverage is further streamlined and strengthened with additional inputs from GBI Research’s expert panel (see below).

### 15.4.2 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, scientific journals and other technical literature
- Internal and external proprietary databases
- Relevant patent and regulatory databases
- National government documents, statistical databases and market reports
- Procedure registries
- News articles, press releases and webcasts specific to the companies operating in the market

### 15.4.3 Primary Research

GBI Research conducts hundreds of primary interviews each 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 the market size, market trends, growth trends, competitive landscape and future outlook
- Helps in validating and strengthening the secondary research findings
- 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, marketing/product managers, market intelligence managers and national sales managers
- Hospital stores, laboratories, pharmacies, distributors and paramedics
- Outside experts: Investment bankers, valuation experts, research analysts specializing in specific medical equipment markets
- Key Opinion Leaders: Physicians and surgeons specializing in different therapeutic areas corresponding to different kinds of medical equipment.
15.5 Therapeutic Landscape

The revenues are arrived at by utilizing the GBI Research market forecasting model. The annual cost of therapy for each indication is arrived at by considering the cost of the drugs, dosage of the drugs, and the duration of the therapy.

The generic share of the market for each indication is obtained by calculating the prescription share for generic drugs and the respective cost of treatment.

The treatment usage pattern, which includes quantitative data on diseased population, diagnosed population and treated population, is arrived at by referring to various sources, as described below.

The marketed drugs section contains an overview of the drugs, their mechanism of action, efficacy and safety issues related to the drugs. The drugs profiled in this section are chosen based on estimated revenues and their mechanism of action.

GBI Research uses the epidemiology-based treatment flow model to forecast the market size.

Epidemiology-based Forecasting

The forecasting model used at GBI Research makes use of epidemiology data gathered from research publications and primary interviews with physicians to represent the treatment flow patterns for individual diseases and therapies. The market for any disease segment is directly proportional to the volume of units sold and the price per unit.

\[
\text{Sales} = \text{Volume of units sold} \times \text{Price per unit}
\]

The volume of units sold is calculated based on the average dosage regimen for that disease, the duration of treatment, and the number of patients who are prescribed drug treatment (the prescription population). The prescription population is calculated as a percentage of the population diagnosed with a disease (the diagnosis population). The diagnosis population is the population diagnosed with a disease expressed as a percentage of the diseased population. The prevalence of a disease (diseased population) is the percentage of the total population who suffer from a disease/condition.

Data on diagnosis rate and prescription rate, if unavailable from research publications, are gathered from interviews with physicians and are used to estimate the patient volumes for the disease under consideration. Therapy uptake and compliance data are fitted in the forecasting model to account for patient switching and compliance behavior.

To account for differences in patient affordability of drugs across various geographies, macroeconomic data such as inflation and GDP, and healthcare indicators such as healthcare spending, insurance coverage and average income per individual, are used.

Annual cost of treatment is calculated using product purchase frequency and the average price of the therapy. Product purchase frequency is calculated from the dosage data available for the therapies, and drug prices are gathered from public sources.

The epidemiology-based forecasting model uses a bottom-up methodology, and makes use of estimations in the absence of data from research publications. Such estimations may result in a final market value that is different from the actual value. To correct this ‘gap’, the forecasting model uses triangulation, with the help of base year sales data (from company annual reports, internal and external databases) and sales estimations.
Analogous Forecasting Methodology

The analogous forecasting methodology is used to account for the introduction of new products, patent expiries of branded products, and the subsequent introduction of generics. Historic data for new product launches and generics penetration are used to arrive at robust forecasts. The increase or decrease of prevalence rates, diagnosis rate and prescription rate are fitted into the forecasting model to estimate the market growth rate.

The proprietary model enables GBI Research to account for the impact of individual drivers and restraints in the growth of the market. The year of impact and the extent of impact are quantified in the forecasting model to provide close-to-accurate data sets.

Diseased Population

The diseased population for any indication is the prevalence. The prevalence rates are usually obtained from various journals, online publications, sources such as the World Health Organization (WHO) or associations and foundation websites for that particular disease.

Diagnosis Population

Out of the patients who undergo diagnostic tests to confirm a disease, only a few people get diagnosed with the disease. This number as a percentage of the treatment-seeking population is the diagnosis rate. The diagnosis population is primarily driven by the sensitivity of the diagnostic tests, state-of-the-art technology, patient access to these diagnostic tests, and cost of the diagnostic tests.

Prescription Population

For any disease, multiple treatment options exist. For example, in cancer treatment various treatment options such as surgery, radiation therapy and drug therapy are available. The prescription population is defined as the number of patients who are prescribed drug therapy. This is calculated as a % of the diagnosis population. The prescription population is primarily driven by the age at which the disease is diagnosed, the disease stage, patient health and the cost of drug treatment.
15.5.1 Market

The treatment usage pattern and annual cost of treatment has been factored in while deriving the market size.

Forecasting Model for Therapeutic Areas

<table>
<thead>
<tr>
<th>Disease Population</th>
<th>GBI Research Market Sizing Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Population</td>
<td>743,335,048</td>
</tr>
<tr>
<td>Qualifying condition 1 (Age/Sex/Occupation etc)</td>
<td>1,784,484</td>
</tr>
<tr>
<td>Qualifying condition 2 (Age/Sex/Occupation etc)</td>
<td>0.2%</td>
</tr>
<tr>
<td>Prevalence tissue valve disease</td>
<td>1,784,484</td>
</tr>
<tr>
<td>Diagnosed population</td>
<td>1,784,484</td>
</tr>
</tbody>
</table>

Treatment Flow Patterns

| Treatment Seeking Rate (Symptoms/Dis Awareness) | 89% |
| Diagnosis Rate (Clinical and Diagnostic Tests) | 75% |
| Prescription Rate (Physician Perception, Treatment Effectiveness) | 70% |

Fulfillment

| Availability | NA |
| Willingness to Use (Patient Perceptions) | NA |
| Ready to Use (Surgery eligibility, Reuse etc) | NA |

Affordability at Price

| HE as % of GDP spend | |
| Average Income (per individual) | |
| Patient Out-of-pocket Budget (Annual) | |
| Budget allocation to one-time surgery | |
| Budget allocation to other health needs | |
| Average Payor Coverage | |
| Patient Liability | |
| Target Price (820% pat lab) | |
| ASP for Cost of Therapy | |

TOTAL PATIENT VOLUMES

| Product Purchase Frequency | 1 |

TOTAL UNIT VOLUMES

| Pricing per Unit | $ 18,000 |
| Inflation | |
| Price Decrease due to competition | |

Market Value

Source: GBI Research

The above figure represents a typical forecasting model constructed by GBI Research. As discussed previously, the model is built on the treatment flow patterns. The model starts with the general population, then diseased population as a percentage of general population, and then follows the treatment-seeking population as a percentage of the diseased population, and the diagnosed population as a percentage of the treatment-seeking population. Finally, the total volume of units sold is calculated by multiplying the treated population by the average dosage per year per patient.

Articles are used from research journals and agency publications, such as the International Diabetes Federation, the Diabetic Association of India, Diabetes India.com, Journal of the Association of Physicians of India, Indian Journal of Medical Research, International Journal of Diabetes in Developing Countries and Diabetes Research and Clinical Practice. The marketed drugs section is constructed from company websites and internal databases.
15.6 Geographical Landscape

The geographical landscape of the report comprises India.

15.7 Pipeline Analysis

This section provides a list of molecules at different stages in the pipeline for various indications. The list is sourced from internal databases and validated for the accuracy of phase and mechanism of action at clinicaltrials.gov and company websites. The section also includes a list of promising molecules, which is narrowed down based on the results of the clinical trials at various stages and the novelty of the mechanism of action.

15.8 Competitive Landscape

Profiles of leading players are provided, along with an overview of key products marketed by the companies for various indications.

GBI Research aims to cover all major M&A, licensing deals and co-development deals related to the market. This section is sourced from the companies’ websites and internal databases.

15.8.1 Expert Panel Validation

GBI Research uses a panel of experts to cross-verify its databases and forecasts.

GBI Research’s expert panel comprises marketing managers, product specialists, international sales managers from medical device companies, academics from research universities, and key opinion leaders from hospitals.

Historic data and forecasts are relayed to GBI Research’s expert panel for feedback and adjusted in accordance with their feedback.

15.10 Disclaimer

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