TYPE 2 DIABETES - GLOBAL DRUG FORECAST AND MARKET ANALYSIS TO 2022 – EVENT-DRIVEN UPDATE
Executive Summary

**Type 2 Diabetes: Key Metrics in 10 Major Pharmaceutical Markets**

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<tr>
<th>2012 Epidemiology</th>
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<tbody>
<tr>
<td>Prevalent Population</td>
<td>188.6 million</td>
</tr>
<tr>
<td>Treated Population</td>
<td>119.6 million</td>
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<table>
<thead>
<tr>
<th>2012 Market Sales</th>
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<tbody>
<tr>
<td>US</td>
<td>$16.4bn</td>
</tr>
<tr>
<td>5EU</td>
<td>$5bn</td>
</tr>
<tr>
<td>Japan</td>
<td>$2.5bn</td>
</tr>
<tr>
<td>China</td>
<td>$2.4bn</td>
</tr>
<tr>
<td>India</td>
<td>$1.5bn</td>
</tr>
<tr>
<td>Brazil</td>
<td>$320m</td>
</tr>
<tr>
<td>Total</td>
<td>$28.1bn</td>
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**Pipeline Assessment**

| Number of drugs in Phase I–II | 155 |
| Number of first-in-class drugs (Phase III) | 1 |

**Most Promising Pipeline Drugs**

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<thead>
<tr>
<th>Most Promising Pipeline Drugs</th>
<th>Peak-Year Sales</th>
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<tr>
<td>Albiglutide (GSK)</td>
<td>$1.2bn</td>
</tr>
<tr>
<td>LY2409021 (Eli Lilly)</td>
<td>$1.1bn</td>
</tr>
<tr>
<td>Insulin peglispro (Eli Lilly)</td>
<td>$911m</td>
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**Key Events (2012–2022)**

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<th>Level of Impact</th>
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<tr>
<td>Actos patent expiry worldwide in 2012</td>
<td>↓↓↓</td>
</tr>
<tr>
<td>BMS/AstraZeneca’s Bydureon launch in 2012</td>
<td>↑↑↑</td>
</tr>
<tr>
<td>Sanofi’s Lantus goes off patent in 2014</td>
<td>↓↓↓</td>
</tr>
<tr>
<td>GSK’s albiglutide launch in 2014</td>
<td>↑↑↑</td>
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**2022 Market Sales**

<table>
<thead>
<tr>
<th>2022 Market Sales</th>
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<tbody>
<tr>
<td>US</td>
<td>$38.8bn</td>
</tr>
<tr>
<td>5EU</td>
<td>$9.2bn</td>
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<td>Japan</td>
<td>$4.3bn</td>
</tr>
<tr>
<td>China</td>
<td>$9.2bn</td>
</tr>
<tr>
<td>India</td>
<td>$5.0bn</td>
</tr>
<tr>
<td>Brazil</td>
<td>$1.3bn</td>
</tr>
<tr>
<td>Total</td>
<td>$67.7bn</td>
</tr>
</tbody>
</table>

Source: GlobalData.

Sales for Type 2 Diabetes by Region 2012–2022

This report focuses on type 2 diabetes pharmaceuticals in seven major markets (US, France, Germany, Italy, Spain, UK, and Japan) and three emerging markets (China, India and Brazil). These 10 markets will be referred to as the global market. The global type 2 diabetes pharmaceutical market in the 2012 base year was $28.1 billion, including both branded and generic drugs. Branded products alone accounted for $19.2 billion across the 10 markets. At 58% of the overall type 2 diabetes market, the US is clearly the dominant market, totaling $16.4 billion in branded and generic pharmaceutical sales. This is due to the much higher prices of pharmaceuticals in this country and due to the high diagnosed prevalence. The next-largest individual market is Japan, at 9% of the worldwide type 2 diabetes market, totaling $2.5 billion. The 5EU countries make up 18%, while emerging markets, including India, China and Brazil together, account for 15% of the total market.
Executive Summary

Over the forecast period, emerging markets will grow in size most rapidly, due to a dramatic increase in the prevalence and diagnosis of type 2 diabetes, which are attributed to increased life expectancy and lifestyle changes that have occurred through rapid economic growth. Uptake of branded drugs will also increase in these markets due to fast growth of the middle class. Sales in the US will grow by about 9% per year over the forecast period. The European and Japanese markets will also increase steadily; however, cost constraints in Europe and the slow regulatory process in Japan will slightly limit growth in these regions.

The table below presents the drivers and barriers in the global type 2 diabetes market during the forecast period.

<table>
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<th>Type 2 Diabetes Market – Drivers and Barriers, 2012</th>
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<tr>
<td><strong>Drivers</strong></td>
</tr>
<tr>
<td>The most important driver of growth in the type 2 diabetes marketplace will be a dramatic increase in the prevalence and the diagnosis of the disease.</td>
</tr>
<tr>
<td>The rise in type 2 diabetes-related comorbidities has fueled the more aggressive approach in the treatment and the use of multiple-drug therapies.</td>
</tr>
</tbody>
</table>

Source: GlobalData
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Corporate Shift in Focus from Therapeutic Value Towards Competitive Pricing

Historic leaders in the type 2 diabetes space include Novo Nordisk, Bristol-Myers Squibb, Sanofi, Novartis, GlaxoSmithKline, Merck, Eli Lilly and Takeda; AstraZeneca and Boehringer Ingelheim have recently entered the space through the formation of partnerships. All of these companies have had or will have blockbuster drugs in this space. Takeda and GlaxoSmithKline faced a large patent cliff in 2012 with the loss of market exclusivity for their blockbuster drugs, Actos and Avandia, respectively. Avandia’s patient share dropped sharply even before the patent cliff due to its adverse effects. Takeda is compensating for Actos’ loss of patent protection by strengthening its diabetes portfolio through partnerships, but also by developing some novel, first-in-class molecules. Novo Nordisk, Sanofi and Eli Lilly are all facing patent expiry for their blockbuster insulin analogs (Novolog, Lantus and Humalog, respectively) this and next year in 2013 and 2014, and will suffer erosion to biosimilars from around 2015, when presumably all the regulations for biosimilar insulin production will be in place. The companies are undertaking different strategies, whereby they either go on the offense or defense, to address this problem. Eli Lilly already has a Lantus biosimilar in late-stage development, which will be a strong competitor to Sanofi’s Lantus, while Sanofi is developing a superior version of its own product Lantus and also a fixed-dose combination of Lantus and Lyxumia in order to protect its own franchise. Sanofi is also stepping up its biosimilar insulin development program and expects to have two projects in clinical development soon, which are likely to be versions of Eli Lilly’s Humalog and Novo Nordisk’s Novolog. Only Novo Nordisk does not have a biosimilar insulin strategy, which reflects its existing portfolio of novel insulin analogs in development.

Future leaders during the forecast period will include Novo Nordisk, AstraZeneca, Merck, Eli Lilly/Boehringer Ingelheim, Takeda, and Johnson & Johnson. All of these companies have late-stage pipeline products or very recently marketed products that have the potential to strengthen significantly the companies’ current portfolios. Novo Nordisk will remain the market leader in the type 2 diabetes market overall, and particularly in the insulin market, with its several insulin analogs marketed or in development, and its current blockbuster from the GLP-1 class, Victoza. AstraZeneca will be the fastest growing company in the type 2 diabetes space and may become the second-largest player with its two potential blockbusters: first-to-market (in the EU and China) SGLT-2 inhibitor Forxiga, and first-to-market once-weekly GLP-1 agonist Bydureon. AstraZeneca has the potential to run shoulder to shoulder with Merck, which will continue capitalizing on its blockbuster Januvia throughout the forecast period.
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The type 2 diabetes market is very mature, marked by a late-stage pipeline filled with me-too drugs. Some companies, such as Sanofi, have started focusing on price rather than on therapeutic value. Sanofi’s recently marketed drug Lyxumia was launched at a heavy discount to its rival GLP-1 agonists, BMS’ Byetta and Novo Nordisk’s Victoza. Lyxumia is the fourth-to-market GLP-1 product with low level of differentiation in the GLP-1 space, and thus Sanofi had to offer a competitive price in order to win market share. With health systems in many markets facing cost pressures today, this is likely a strategy that other companies will adopt with their me-too drugs that are in late-stage development. However, some companies, like Eli Lilly, are embracing a new business model, discarding the traditional blockbuster approach and instead focusing on highly individualized solutions for patients.

The figure below provides an analysis of the company portfolio gap in type 2 diabetes for the forecast period.

Current Therapies Leave Unmet Needs in Type 2 Diabetes Market

The type 2 diabetes therapeutics market is crowded with many generics and branded generic drug products, comprising several classes of treatment options. Nevertheless, owing to the increasing prevalence and progressive nature of the disease, there are considerably high unmet needs within the indication. Overall, these unmet clinical needs are interrelated and they include improved durability of treatment, a better balance of efficacy of glycemic control with cardiovascular safety, hypoglycemia avoidance, and tolerability and ease of compliance.
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The table below lists the prominent unmet needs in the type 2 diabetes market, along with a numerical value to depict the level of attainment of these needs in different markets (1 = low attainment, 5 = high attainment). The table also ranks the relative importance of each of the unmet needs on a scale of low, moderate, or high.

<table>
<thead>
<tr>
<th>Unmet Need</th>
<th>Current Level of Attainment</th>
<th>Relative Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early efficacy</td>
<td>4</td>
<td>Low</td>
</tr>
<tr>
<td>Sustainable efficacy</td>
<td>1</td>
<td>High</td>
</tr>
<tr>
<td>Safety</td>
<td>2</td>
<td>High</td>
</tr>
<tr>
<td>Patient awareness</td>
<td>2</td>
<td>High</td>
</tr>
<tr>
<td>Physician education</td>
<td>4</td>
<td>Low</td>
</tr>
<tr>
<td>Compliance</td>
<td>2</td>
<td>High</td>
</tr>
<tr>
<td>Diagnosis rate</td>
<td>1</td>
<td>High</td>
</tr>
</tbody>
</table>

Source: GlobalData, based on primary research interviews

Entry Opportunities for Type 2 Diabetes Market Access

All currently available treatments for type 2 diabetes are initially effective and reduce complication rates, but they lack the ability to maintain glycemic control in the long term because of the progressive nature of pancreatic β-cell dysfunction; this represents one of the highest unmet needs in the type 2 diabetes space. As the late-stage pipeline is dominated by me-too drugs and by drugs belonging to novel classes that are not very different from the marketed classes, most of the unmet needs will remain unfulfilled in the foreseeable future. Therefore, this market has a significant growth opportunity for new patent-protected products.

Molecules in the earlier stages of development, Phase II or earlier, employ various novel mechanisms of action. These early-stage drug classes include 11-beta-hydroxysteroid dehydrogenase (11b-HSD) type 1 inhibitors, G protein-coupled receptor 119 (GPR119) agonists, glucokinase activators, ranolazine, fructose-1,6-bisphosphatase inhibitors, protein tyrosine phosphatase 1B inhibitors, carnitine palmitoyltransferase 1 inhibitors, acetyl CoA carboxylase 1 & 2 inhibitors, salicylate derivatives, and a number of other novel agents that may hold promise for fulfilling some of the unmet needs in type 2 diabetes. In order to address the biggest unmet need in type 2 diabetes, new drugs must address the problem of insulin resistance, as this is the root of the disease, but they must do this while offering a strong cardiovascular safety profile and not causing weight gain, which is currently the biggest problem with insulin sensitizers such as TZDs.

DPP-4 Inhibitors and GLP-1 Receptor Agonists Will Still Dominate the Market in 2022

During the 10-year forecast period, we anticipate that the type 2 diabetes market will not experience a fundamental shift in the classes of drugs that are preferred by physicians. Rapid uptake of drugs from the novel class of SGLT-2 inhibitors will
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occur; however, DPP-4 inhibitors and GLP-1 receptor agonists will continue dominating the non-insulin type 2 diabetes space because SGLT-2 inhibitors will often be used as a third-line treatment. GLP-1 receptor agonists will experience the fastest growth of all classes (CAGR of 13.4%), due to their weight-loss effects and their novel once-weekly administration, which is preferable to the standard once- or twice-daily therapies. Three me-too drugs from the GLP-1 class will reach the market over the forecast period: GSK’s albiglutide, Eli Lilly’s dulaglutide and Novo Nordisk’s semaglutide. They are all once-weekly therapies like BMS’ currently marketed Bydureon, but they have a somewhat better clinical profile in terms of convenience. As albiglutide will reach the market first among these three upcoming agents, it will gain a significant market share and achieve sales of $1.2 billion by 2022. Upcoming DPP-4 inhibitors, such as Merck’s MK-102 and Takeda’s trelagliptin, will also only offer an advantage in terms of convenience, with once-weekly instead of once-daily administration. This advantage will not give them as much of an edge as it would in the injectable GLP-1 space, as DPP-4 inhibitors are oral drugs. Merck’s MK-3102 will achieve sales of $591m by 2022. One distinguished and quite unique feature of the type 2 diabetes market, illustrative of the rapid growth expected in this disease area, is its ability to support multiple key growth drivers in single drug classes, and therefore all of the upcoming me-too drugs will gain certain share of this huge market, particularly with the novel ADA/EASD treatment guidelines which push for patient-tailored approaches.

The only first-in-class drug in late-stage development (in preparation for Phase III trials), Eli Lilly’s LY2409021 (glucagon receptor antagonist), will achieve great success. Until January 2014, there was an additional first-in-class drug in late-stage development, Takeda’s fasiglifam; however, the company terminated its trial due to concerns with liver safety, leaving the global type 2 diabetes Phase III pipeline completely void of any first-in-class molecules. Therefore, Eli Lilly’s LY2409021 may be the only drug with a novel mechanism of action to reach the type 2 diabetes market within the next five years. This drug does not address the crucial issue of insulin resistance, but it employs a novel mechanism of action and could be used as an add-on therapy. LY2409021 will likely reach sales of over $1 billion by 2022. Another first-in-class drug in the late stage, Roche’s aleglitazar (dual PPARα/γ agonist), has also been retracted very recently from its Phase III trials, which will alter the future of the type 2 diabetes competitive landscape, leaving more room for other new entrants to gain market share.

The ultra-long-acting insulin analog, Eli Lilly’s insulin peglispro, will also reach sales of almost $1 billion in 2022. The drug’s clinical profile (long duration of action and efficacy in achieving weight loss) would typically enable it to become a big blockbuster drug; however, it will face stiff competition from another ultra-long-acting insulin
Executive Summary

analog, Novo Nordisk’s Tresiba, and also from the biosimilars of the currently established long-acting insulin analogs.

Competitive Assessment of Late-Stage Pipeline in Type 2 Diabetes, 2012–2022

<table>
<thead>
<tr>
<th>Commercial Attributes</th>
<th>Clinical Attributes</th>
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<tbody>
<tr>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>Novo’s NPH–Tresiba</td>
<td>Eli Lilly/Boehringer Ingehelm’s insulin analogue</td>
</tr>
<tr>
<td>Eli Lilly/Boehringer Ingehelm’s insulin analogue</td>
<td>AstraZeneca’s exenatide</td>
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<td>AstraZeneca’s exenatide</td>
<td>Takeda’s zipagliflozin</td>
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<tr>
<td>Takeda’s zipagliflozin</td>
<td>Chugai’s tofogliflozin</td>
</tr>
<tr>
<td>Chugai’s tofogliflozin</td>
<td>Astellas Pharma’s lixisenatide</td>
</tr>
<tr>
<td>Low</td>
<td>High</td>
</tr>
</tbody>
</table>

Note: Bubble size represents the approximate peak year sales of pipeline drug.

Source: GlobalData.

What Do the Physicians Think?

“I think that [the number of] people needing a second and third drug is going to increase dramatically in the next 10 years and that we will just see those numbers go up, up, up. Two things are going to drive that up. One is the expectation that we’ll treat these people fairly aggressively to get their A1c down to around 7 to 7.5. The target appears to be moving based on a few of the studies, but we are not going to tolerate people after 8.5 and 9 like we used to. That’s going to drive it, and second is that most people are not going to have a control over lifestyle, they are going to continue to overeat and under-exercise and they are going to see their weight continue to go up and therefore their need for more medications will go up with it. So I think [in this] the market, the sky is the limit on how much the market is going to be.”

Key Opinion Leader, April 2013

“I think over the next 10 years the long-acting GLP-1 receptor agonist therapies will increase the most, because now you know the companies will be developing once-a-week treatments… Longer-acting preparations, if they are proved to be effective and safe, will be used more and more because they really do have a benefit in weight loss.”

Key Opinion Leader, April 2013

“Weight change direction or level and the risk of hypoglycemia, these are strong determinants for the choice of the drug today or in the future even more.”

Key Opinion Leader, April 2013

“My biggest challenge [with type 2 diabetes] has been the lack of long-term efficacy; that the disease is complicated, the disease is resilient, and most of the agents are not potent enough to get everybody under control long enough. So, lack of efficacy and having therefore to combine medications has been my biggest challenge.”

Key Opinion Leader, April 2013
“We have SGLT-2 inhibitors, we have the long-acting GLP-1 receptor agonists, DPP-4 inhibitors, and this will be quite a choice now for physicians to find the right drugs or right combination of drugs.”

Key Opinion Leader, April 2013

“The SGLT-2s and the dual PPARs are probably going to have a better impact long-term... the things that increase insulin secretion, somewhat are similar to the sulfonylureas, they are going to have hypoglycemic events, or they are going to cause people to gain weight, or they are going to burn the pancreas out... I am much less impressed with them than I am with the SGLT-2s and the dual PPARs.”

Key Opinion Leader, April 2013

“The whole concept of individualization of therapy is very important; it is something that we practiced for a long time. Each patient is different. We have to give quite a combination of drugs to each patient depending on various factors.”

Key Opinion Leader, April 2013

“I think the use of metformin [first-line therapy] will not change. I think it will continue, but the use of sulfonylureas will decline... I think they will be gradually replaced by newer therapies, some available now, some will be available later in the future.”

Key Opinion Leader, April 2013

“The endocrinologist recognized that being overly conservative can hurt the patients, so in other words if you say that there is no long-term data for new drug that can prevent complications, you can’t wait. I am not going to wait for 10 years for randomized controlled trials to show me that injection will dispel. If I know that it prevents complications, I am happy. We are not going to have 300 randomized controlled trials checking all possible combinations because now it’s so many combinations of drugs you could test. So, me and other colleagues, what we have been doing really for years is that we know what works and we know what doesn’t work ... we know that we don’t have data but we really need to prescribe certain therapies without data, knowing what the advantages are. I think that the newer guidelines fully acknowledge the reality, that’s what endocrinologists are doing, I think the guidelines didn’t set up anything new, they are just catching up with what physicians are doing already.”

Key Opinion Leader, April 2013
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Introduction

2 Introduction

2.1 Catalyst

The American Diabetes Association’s 73rd Scientific Sessions, held in June 2013, represented an opportunity for the major industry players with a stake in the type 2 diabetes market to showcase their diabetes drugs’ latest results. In particular, Eli Lilly presented new data on its investigational drugs, dulaglutide and empagliflozin, as well as confirmed its development and regulatory timescale for biosimilar insulin products, including a version of Sanofi’s Lantus. Another key takeaway from the ADA sessions was Sanofi’s encouraging data on its Lantus follow-on product, aimed at protecting its Lantus franchise.

While the global type 2 diabetes market is crowded with inexpensive generics and marked by a pipeline filled with me-too drugs, GlobalData expects this market to undergo substantial growth between 2012 and 2022, more than doubling over this period. The main driver of this enormous expansion will be the dramatic increase in disease prevalence, which is attributable to increased life expectancy and an increasingly sedentary and stressful lifestyle. The second largest driver will be the physicians’ efforts to delay disease progression and reduce the costly burden of diabetic complications through the use of combination therapies and novel branded drugs. In the emerging markets in particular, uptake of branded drugs will increase due to rapid economic growth.

Despite the high number of marketed therapies, this market is still experiencing large unmet needs and it has a significant growth opportunity for new patent-protected products. Metformin will remain the first-line therapy for type 2 diabetes due to physicians’ familiarity with it and the availability of long-term data, but the usage of sulfonylureas, another front-line therapy, will gradually be replaced over the next 10 years by novel therapies with improved side-effect profiles. The battle for second- or third-line therapy will involve DPP-4 inhibitors, GLP-1 receptor agonists, SGLT-2 inhibitors and other upcoming novel therapies. Of all currently marketed classes, GLP-1 receptor agonists will experience the fastest growth due to their weight-loss effects and the skyrocketing epidemic of obesity. With the recent therapeutic guidelines putting emphasis on a patient-tailored approach in treating type 2 diabetes, pharmaceutical companies will achieve considerable success with their me-too drugs. In the future, companies may choose to focus not on blockbuster medicines, but rather on niche drugs that are aimed at smaller groups.
Introduction

In December 2013, two major events occurred that will shape the future of this market:

AstraZeneca announced an agreement under which it will acquire the entirety of BMS’ interests in the companies’ diabetes alliance

Takeda terminated a Phase III trial of fasiglifam due to concerns with liver safety, making Eli Lilly’s LY2409021, a glucagon receptor antagonist, the only first-in-class product in the late-stage development pipeline.

2.2 Related Reports

- GlobalData (2013). Obesity – Global Drug Forecast and Market Analysis to 2022, October 2013, GDHC50PIDR.
Appendix

11.7 About GlobalData

GlobalData is a leading global provider of business intelligence in the Healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports and forecasts. Our analysis is supported by a 24/7 client support and analyst team.

GlobalData has offices in New York, Boston, London, India and Singapore.

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