OBESITY - GLOBAL DRUG FORECAST AND MARKET ANALYSIS TO 2022
Executive Summary

The following table provides a summary of the key metrics for obesity therapeutics in the nine major pharmaceutical markets (US, France, Germany, Italy, Spain, UK, Japan, Brazil, and Canada) during the forecast period from 2012–2022.

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>2012 Epidemiology</strong></td>
</tr>
<tr>
<td>Prevalent population</td>
</tr>
<tr>
<td>Treated population</td>
</tr>
<tr>
<td><strong>2012 Market Sales</strong></td>
</tr>
<tr>
<td>US</td>
</tr>
<tr>
<td>5EU</td>
</tr>
<tr>
<td>Japan</td>
</tr>
<tr>
<td>Brazil</td>
</tr>
<tr>
<td>Canada</td>
</tr>
<tr>
<td>Total</td>
</tr>
<tr>
<td><strong>Pipeline Assessment</strong></td>
</tr>
<tr>
<td>Number of drugs in Phase I–II</td>
</tr>
<tr>
<td>Number of first-in-class drugs</td>
</tr>
<tr>
<td><strong>Most Promising Pipeline Drugs</strong></td>
</tr>
<tr>
<td>Victoza (liraglutide/Novo Nordisk)</td>
</tr>
<tr>
<td>Contrave (buproprion / naltrexone) (Orexigen / Takeda)</td>
</tr>
<tr>
<td><strong>Key Events (2012–2022)</strong></td>
</tr>
<tr>
<td>Launch of Victoza in 2014</td>
</tr>
<tr>
<td>Launch of Belviq (lorcaserin) in 2013</td>
</tr>
<tr>
<td>Patent expiry of Qsymia (phentermine/topiramate) in 2019</td>
</tr>
<tr>
<td><strong>2022 Market Sales</strong></td>
</tr>
<tr>
<td>US</td>
</tr>
<tr>
<td>5EU</td>
</tr>
<tr>
<td>Japan</td>
</tr>
<tr>
<td>Brazil</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

Source: GlobalData

SEU = five major European countries (France, Germany, Italy, Spain, and UK)

Sales for Obesity Therapy Expected to Increase 2012–2022

The obesity market generated approximately $407m in global sales in 2012. Over the next 10 years, this market is expected to grow to reach $8.4 billion, with major growth occurring in the main obesity markets, such as the US, Canada, and Brazil.

Some of the main drivers of growth are expected to be:

- New therapies with greater efficacy and better clinical trial results
- The growing population of overweight and obese patients needing pharmacological intervention
- The rise in obesity-related comorbidities has fueled the medical community’s increasing awareness of obesity as a disease with life-threatening implications.
- The obesogenic environment, with ease of access to calorie-laden foods and lifestyles that minimize physical activity.
Executive Summary

Some of the main barriers to growth are expected to be:

- Government oversight and regulatory restrictions and challenges
- Decreased healthcare spending due to austerity measures
- Physician and patient perceptions, and reluctance to treat with pharmacotherapy due to associated safety concerns and risks
- The complexity inherent in the multiple pathways underlying obesity continues to hinder the development of safe and tolerable agents that promote sufficient weight loss.

The following figure shows the global sales for obesity by region during the forecast period.

Companies Focus on Efficacy-Driven Solutions in the Revival of This Market

The obesity space has seen little activity in the past decade due to a pharmacological history of modest efficacy, poor tolerability with dangerous side effects, and limited healthcare coverage, which have all contributed to the failure of the commercial success of anti-obesity drugs. Recently, however, there has been a revival of this market space, as a couple of companies have released drugs that challenge these limitations, bringing this disease to the forefront of public concern. There has not been a historical major player in this indication space. Smaller biotech companies, such as Vivus, which markets Qsymia, and Arena Pharmaceuticals, which has recently launched Belviq in conjunction with Eisai, are the norm in this indication revival. Big Pharma is most likely to enter this space by acquiring one of these smaller biotechs, or by expanding the type 2 diabetes portfolio to include the obesity indication.

The message the industry is trying to convey is that obesity is a disease that needs pharmacological intervention. A treatment-based regimen offers patients a supplementary option to lifestyle changes in managing their weight. Efficacy will always remain at the forefront of these challenges, and many companies are moving towards combination therapy in their developmental trials to elicit greater weight loss. Another hurdle that is related to drug efficacy is the reimbursement challenges of third-party payers.
Executive Summary

Obesity drugs are costly and in the past have not shown a significant weight change, and are thus not included in most standard health benefits plans. The high out-of-pocket costs for patients are a great deterrent in the uptake of these drugs and are a big reason why compliance is low. Pharmaceutical companies must work with third-party payers to ensure that the price of obesity drugs is not prohibitive for patients.

The following figure provides a company portfolio gap analysis in obesity during the forecast period.

The Need for More Novel Therapies Defines the Obesity Market

The overall level of unmet need in the obesity drugs market is very high, with inefficiencies at every level of the payer-prescriber-patient relationship, representing good opportunities for the pharmaceutical and medical devices industries to provide solutions. The current range of pharmacological interventions suffers from a paucity of options, and those drugs that are available offer only modest efficacy and have problematic side effect profiles. The few therapy options are Xenical (orlistat), which is the only approved pharmacological agent in the seven major markets (7MM), Canada, and Brazil, along with phentermine, Qsymia and Belviq, which are available solely in the US. There has been a severe shortage of novel therapies, as pharmaceutical companies are wary of the challenges they face in achieving regulatory approval. In countries outside the US, physicians have only Xenical. More commonly, they resort to medications indicated for other conditions due to various clinical and environmental restrictions and because of the unpleasant side effects of this product. This market is highly underserved and in need of innovative drugs and devices to fill the gap.
Executive Summary

Reimbursement and Disease Perception Are Long-Standing Barriers to Market Growth

Unmet needs in the obesity drugs market will persist even after the launch of late-stage pharmacological agents and devices. In addition to the need for an intervention offering efficacy superior to that of the currently-marketed and late-stage pipeline products, the perception of obesity as a lifestyle disease that is not suited to therapeutic intervention will continue to hamper market growth. While the launches of novel drugs will drive up the drug treatment rate during 2012–2022, it will remain extremely low across the countries profiled in this report. Another market barrier that is closely tied to disease perception is the lack of reimbursement for obesity drugs by third-party payers, including both private and public payers, both in the US and by public health systems throughout the rest of the world. Although companies that have launched novel drugs have worked with payers to gain reimbursement for their products and will continue to do so, we anticipate that limited reimbursement will constrain the market during the next decade.

More Efficacious Drugs Will Reinvigorate the Market

With the changing tide of opinion on the treatment of obesity and the upcoming launches of novel drugs and devices, we anticipate that the prescribing of obesity drugs will increase over the next 10 years, driving an increase in the overall market size. While the drug-treated population will continue to comprise just a fraction of the total prevalent obese population, even a slight uptick in the drug treatment rate will translate to substantial market growth. The two drugs that will have the greatest impact on the size of the market are Victoza and Belviq. Victoza’s advantage, in addition to its efficacy, lies largely in the fact that it is marketed for the treatment of type 2 diabetes by Novo Nordisk, a leader in the metabolic disorders space. It is already used off label by high-prescribing bariatricians and endocrinologists, and it benefits from familiarity among both these specialists and the primary care physicians (PCPs) who will prescribe it for obesity. Belviq’s advantage lies in its novelty: unlike Vivus’ Qsymia and the two drugs being developed by Orexigen, it is a novel molecular entity, rather than a combination of existing therapeutic options.
Executive Summary

The following figure provides a competitive assessment of the late-stage pipeline agents in obesity during the forecast period.

**Competitive Assessment of Late-Stage Pipeline Agents in Obesity, 2012–2022**

**Clinical Attributes**

- Low
- High

**Commercial Attributes**

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

Source: GlobalData

What Do the Physicians Think?

The key opinion leaders (KOLs) interviewed for this report shared their insights into the trends within the obesity market. The primary concerns within this market remain the need for medications that adequately address the clinical unmet needs in the overweight and obese population, such as the efficacy and safety of the therapy. Another major unmet need is the lack of reimbursement for these often costly medications, which prohibits patient access.

“The problem, presently, is that there are no drugs with relatively good efficacy. If there is a better treatment without indesirable side effects, patients would be ready to pay the associated costs!”

EU key opinion leader, May 2013

“As far as orlistat is concerned, it has been around for a long time now — it’s really quite a safe drug, but…most people who take it have some side effects from the GI tract. It isn’t a very effective medicine anyway. It gives 2.8 kilograms more weight loss than a placebo for six months, which is not a very big amount of weight.”

US key opinion leader, March 2013

“[Orlistat] is not reimbursed, so obesity or weight loss is not an accepted indication for reimbursement of drug treatment.”

EU key opinion leader, April 2013

“It’s not been good with Qsymia, as they are not getting much reimbursement. I think I have probably prescribed it at least 30 times, and I think I have only got it covered one or two times. Otherwise, the patients are paying out of pocket.”

US key opinion leader, March 2013
Executive Summary

“The problem is that reimbursement is a decision by the society on what is considered a disease. Obesity is not considered a disease, like diabetes or cardiovascular disease. The perception of [the] treatment of obesity in France is not considered a priority, but rather a luxury, when patients can always go on a diet.”

EU key opinion leader, May 2013

“If medications are reimbursed, the percentage of medication use will increase, but there needs to be studies or research to show that it works.”

EU key opinion leader, May 2013
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Introduction

2 Introduction

The successful treatment of obesity and overweight involves a lifelong effort of making permanent changes in both energy intake and expenditure. And while dietary modifications consisting of low caloric intake and increases in energy expenditure as first-line treatments can produce some results, there are patients who are in need of pharmacological intervention. Patients are referred to pharmacological treatments as a second-line treatment after lack of success with lifestyle modifications. The need for safe and efficacious pharmacotherapy is thus clear when the worldwide trends are tipping the scales toward an obesity pandemic. The shortcomings of the current pharmacological therapies are limiting in that their efficacy is modest, producing a loss of only 5–10% of total body weight; their tolerability profiles are generally poor; and they are usually recommended only for short-term use, which is ineffective for a chronic condition such as obesity. At present, there are three prescription drugs available for long-term weight management: Xenical (orlistat), an older-generation drug, and two drugs that were approved in mid-2012, Qsymia (phentermine/topiramate) and Belviq (lorcaserin), after more than a decade-long hiatus. However, there is uncaptured value in this market space, and the potential for the emergence of a blockbuster drug that could effectively treat the overweight and obese population is great.

For many patients who have not had success with exercising, dieting, or pharmacotherapy, surgical intervention is the final option and offers a potential solution; however, patients are reluctant to opt for surgery because it can be extremely invasive and is not easily reversible, if at all. Approximately 20 million Americans qualify for insurance coverage for bariatric surgery, yet only 200,000 opt to have it done. In lieu of invasive bariatric surgery and ineffective pharmacotherapy, many patients are now turning to device implantation as a safe and effective adjunct to a lifestyle change program to promote healthy weight loss. Only a small percentage of patients utilizing pharmacotherapy options ever successfully lose excess body weight by taking these drugs, and many of them have undesirable side effects. As a result, the med-tech industry is striving to take market share from the pharmaceutical industry. All but three marketed pharmaceuticals that were once available have been discontinued due to lack of efficacy.
Introduction

2.1 Catalyst

Obesity is an escalating public health problem with an increasing prevalence worldwide, and it has become a well-known threat to public health (WHO, 2013d). Due to problems regarding cardiovascular and psychiatric safety, past therapies for the treatment of obesity have been withdrawn from the market, which has resulted in greater scrutiny and regulation for companies wanting to enter this market space. As a result, this has been a slow-moving market for the last 10 years, and it has only recently begun to undergo a revival as new medications have begun to enter this area in the US, such as Qsymia in September 2012, and Belviq in June 2013. These two medications will bring attention to the massive potential of this market space. Over the forecast period, other therapies, both new molecular entities (NMEs) as well as established drugs seeking label expansion, such as Novo Nordisk’s Victoza (liraglutide), will also enter the market and catalyze a shift in the treatment algorithm.

In addition to pharmacotherapy, medical devices represent a growing segment of the obesity market. As medical device safety and efficacy has improved, along with reduced manufacturing costs, improved implantation methods, and ever-amassing clinical experience, increasing numbers of patients are now turning to device implantation for weight loss indications. When used in combination with lifestyle changes, bariatric devices have exhibited notable weight loss results and have generated significant attention worldwide. There are a number of devices in the industry, which take very different approaches to weight loss, and some market segments are more mature than others. Overall, however, the obesity medical device industry is expected to experience significant growth in the coming years, driven by physician adoption, patient awareness, and increased device efficacy.
2.2 Related Reports

- Obesity Medical Devices – Global Pipeline Analysis, Competitive Landscape, and Market Forecasts to 2018, May 2013, GDME001MFR
- Bariatric Surgery Devices – Global Pipeline Analysis, Competitive Landscape, and Market Forecasts to 2018, July 2012, GDME0152MAR
- GlobalData (2013). Type 2 Diabetes – Global Drug Forecast and Market Analysis to 2022, July 2013, GDHC54PIDR

2.3 Upcoming Related Reports

- GlobalData (2013). Dyslipidemia – Global Drug Forecast and Market Analysis to 2022, December 2013, GDHC46PIDR
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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