

Anti-Obesity Medications Market

Market Insights

*What Perspectives
for Pharma Companies*

Smart Pharma Consulting proposes a method for a preliminary but documented evaluation of drug markets, illustrated by the analysis of the Anti-Obesity Medications market by 2030

Introduction

Context

- Obesity – defined by a BMI¹ ≥ 30 kg/m² – is a major risk factor for several chronic diseases such as heart diseases and stroke, which are the leading causes of death
- The rate of obesity keeps on growing, becoming a major global public health issue, incl. in low-income countries
- The Anti-Obesity Medications (AOMs) market is making a fresh start with the launch of GLP-1 RAs², showing significantly higher weight loss vs. former drugs
- The AOMs market is expected to show the highest growth rate, by 2030, ahead of the Anti-Cancer Drugs market

Objectives

- The objectives of this study are to:
 - Propose a “Quick & Robust” method to evaluate drug market potentials, through the case of AOMs
 - Share insights regarding the potential development of the adult AOMs market, incl. its drivers and limiters
 - Exhibit the important heterogeneity of current and future AOMs market sizes, depending on the most recent published estimates
 - Assess the attractiveness of this market segment for pharma companies, over the 2023 – 2030 period

Methodology

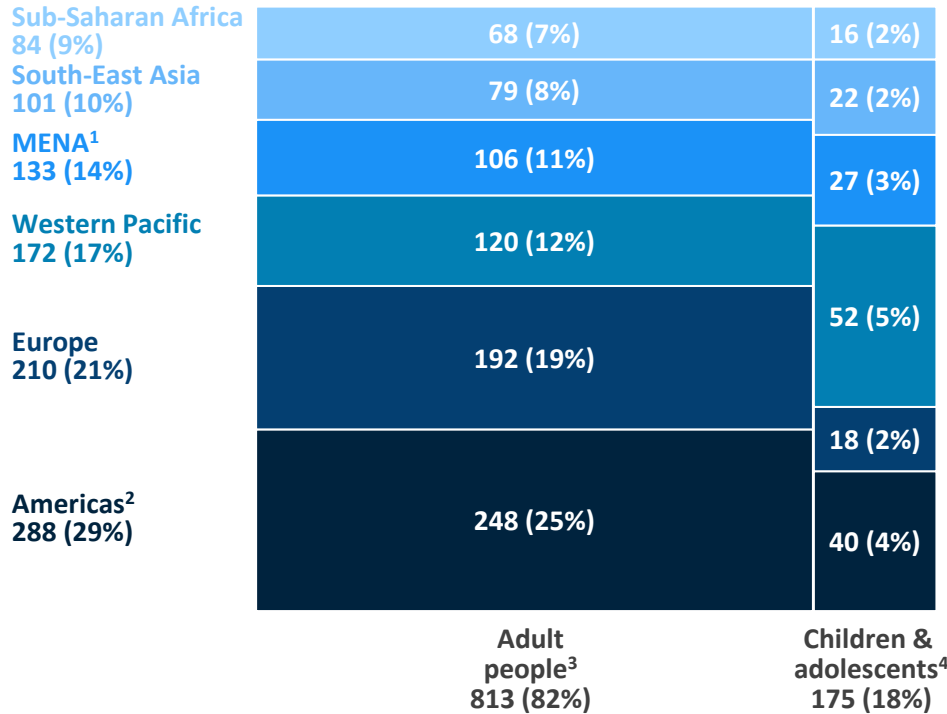
- Literature search re. healthcare environment of obesity (epidemiology, health policies, competition, customers) at a global level
- Building of a forecasting model
- Development of assumptions re. the adult AOMs market
- Global adult AOMs market sales estimates (2023 – 2030)
- Analysis of key market drivers and constraints, and implications for pharma companies

The worldwide prevalence of obesity amongst adults should rise from 16% in 2020 to 21% in 2030, with significant discrepancies between regions

Epidemiology by region

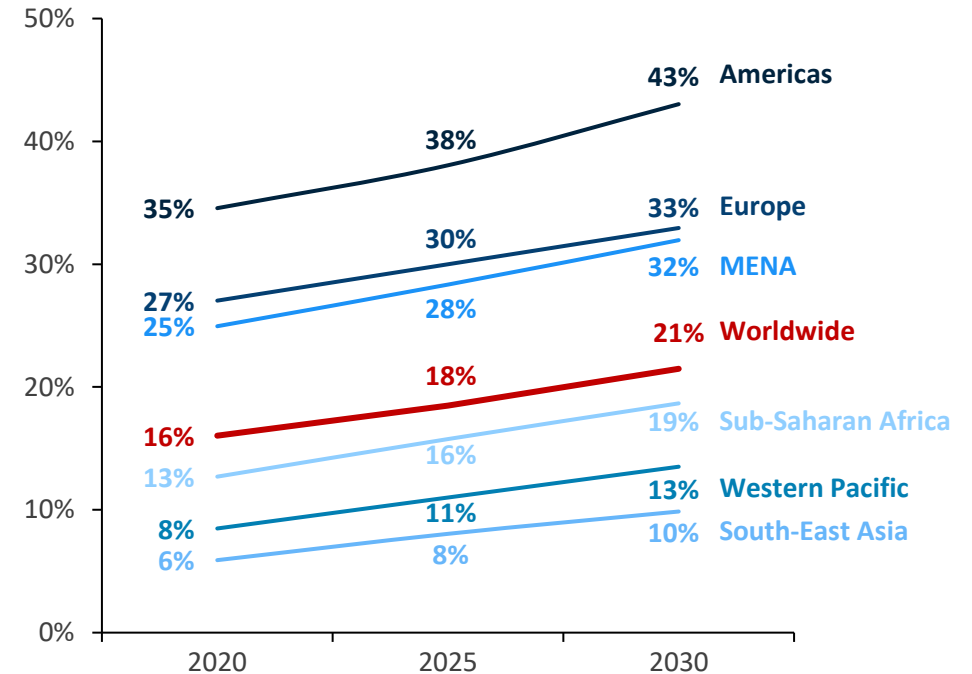
Prevalence of obesity (2020)
All people (in millions)

Total number of people with obesity*: 988 million



Projected trends (2020 – 2030)
Adults only (as a percentage of population)

Adult people with obesity
(as a percentage of adult population)



* Adults with a BMI ≥ 30 kg/m² and children and adolescents with a +2SD above median growth reference (as defined by the WHO classification)

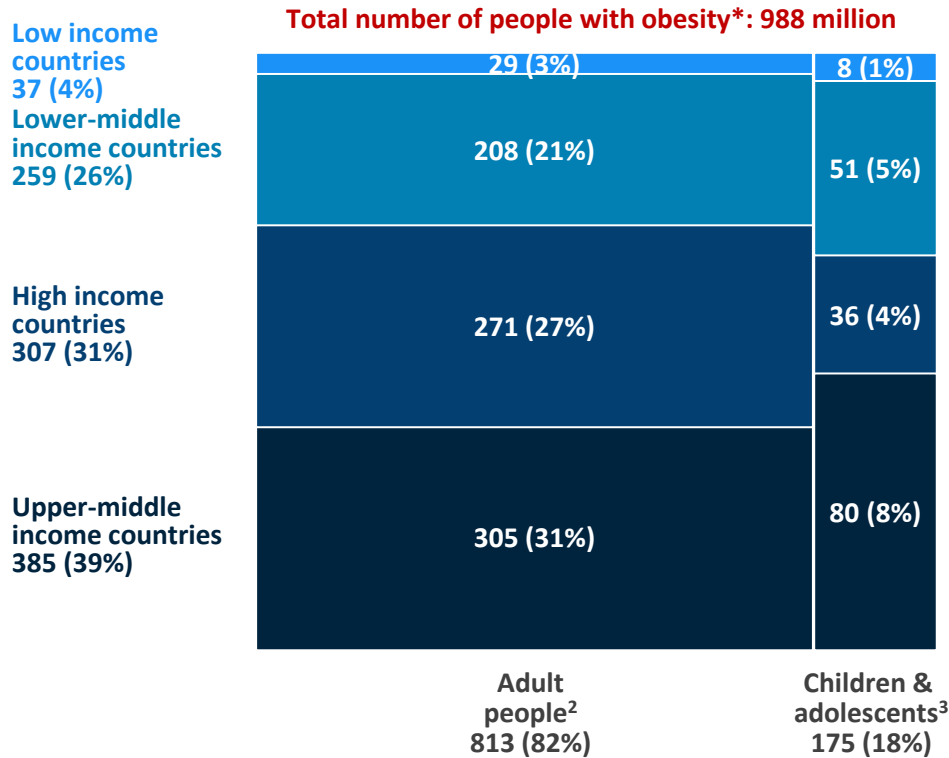
Sources: World Obesity Atlas, World Obesity Federation (March 2023) – Smart Pharma Consulting analyses

¹ Middle East and North Africa – ² North, Central and South America – ³ People aged 20 years and over – ⁴ People aged from 5 to 19 years

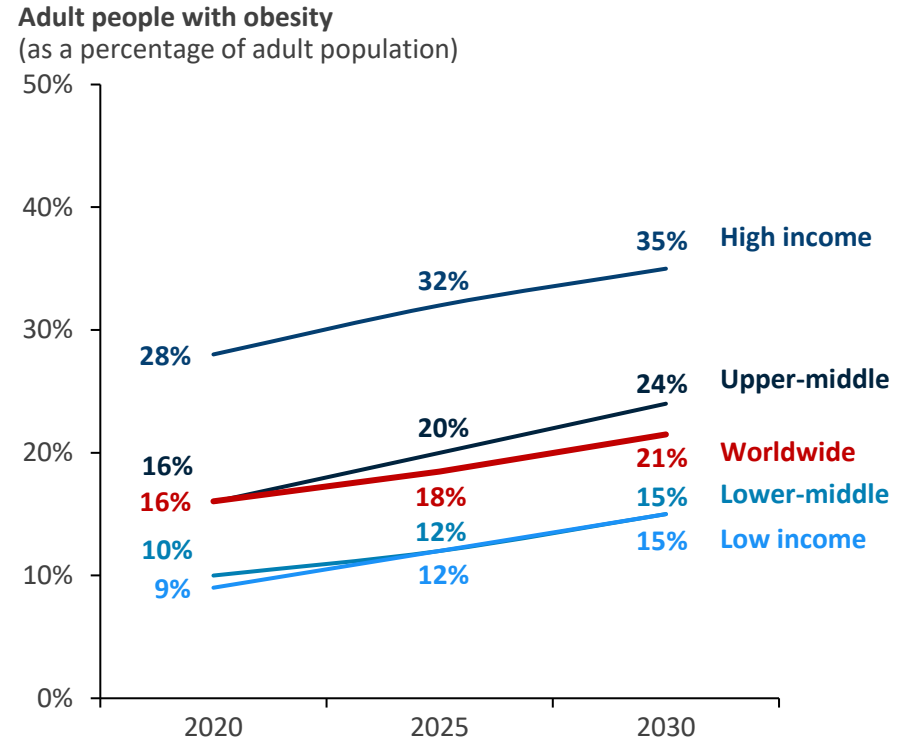
The 2030 projected prevalence of obesity amongst adults is higher in high income countries (35%) than the worldwide average (21%)

Epidemiology by level of income¹

Prevalence of obesity (2020)
All people (in millions)



Projected trends (2020 – 2030)
Adults only (as a percentage of population)



* Adults with a BMI ≥ 30 kg/m² and children and adolescents with a +2SD above median growth reference (as defined by the WHO classification)

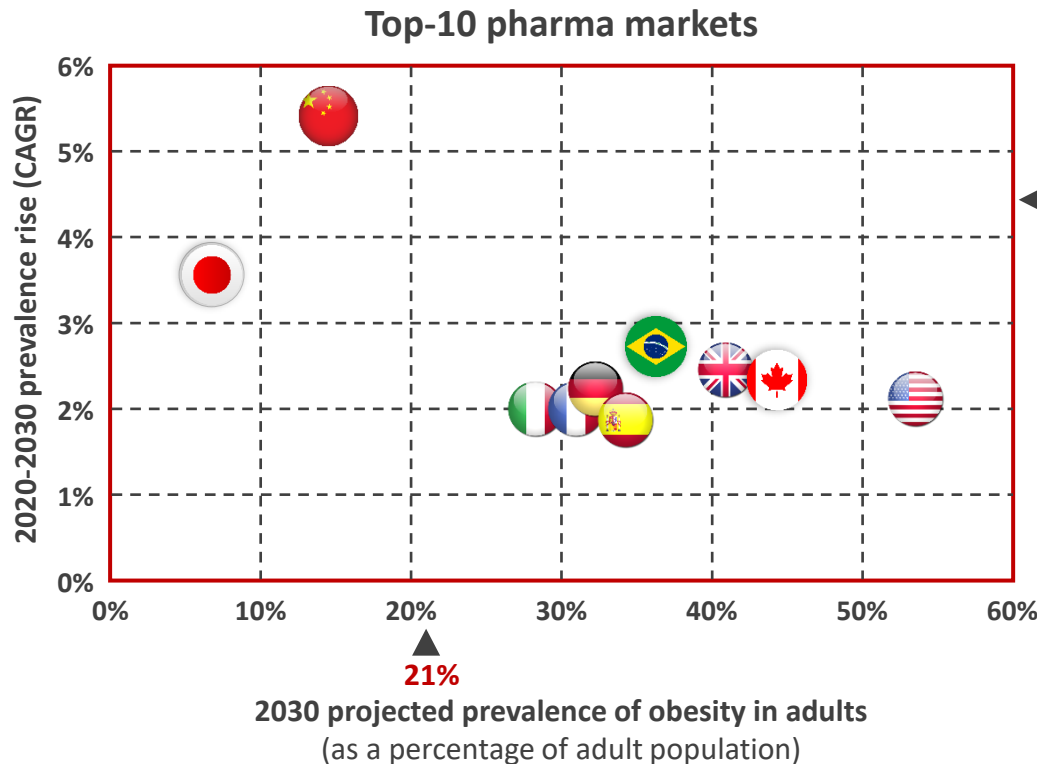
Sources: World Obesity Atlas, World Obesity Federation (March 2023) – Smart Pharma Consulting analyses

¹ Depending on the 2023 gross national income per capita, as defined by the World Bank – ² People aged 20 years and over – ³ People aged from 5 to 19 years

The AOMs market should be mainly driven by the USA,
where ~53% of adults are expected to have a BMI ≥ 30 kg/m² by 2030

Epidemiology by country

Projected trends in the prevalence of obesity* (2020 – 2030)



- By 2030, the global prevalence of obesity should increase by 4.4% on average per year and reach up to 21% of the global adult population
- The 2030 projected prevalence is higher in most top-10 pharma markets than the worldwide average due to high-income countries' lifestyle (e.g., consumption habits, sedentary):
 - USA has the highest projected prevalence of obesity (53% of adults by 2030) followed by Canada (44%), UK (41%) and Brazil (36%)
 - EU-4 countries¹ have projected prevalence rates ranging from 28% to 34% of adults
 - Japan and China have the lowest projected prevalence rates (7% and 14%, respectively)

* Adults with a BMI ≥ 30 kg/m²

Sources: World Obesity Atlas, World Obesity Federation (March 2023) – IQVIA Institute (January 2023) – Smart Pharma Consulting analyses

¹ Germany, France, Italy and Spain

Multiple pharmacological and non-pharmacological solutions can be considered; the efficacy of the latter being harder to prove and often associated with each other

Main existing solutions to fight obesity

Non-pharmacological solutions^a

- **Food regimen** are numerous and must be personalized to effectively impact the weight (e.g., paleolithic diet, intermittent fasting)
- **Physical activity** increases the energy expenditure as well as the mental and emotional well-being of obese people
- **Thermal cures** have biological, physical and sociable positive effects and are usually accompanied by a food diet and educational content
- **Cognitive behavioral therapy** (CBT) is considered as the 1st line treatment for eating disorders (e.g., goal setting, stimulus control)
- **Gastric balloon** method consists in placing a balloon in the stomach and then fill it, so that the person feels full faster
- **Bariatric surgery**¹ leads to significant weight loss through a physical modification (e.g., a sleeve gastrectomy removing a part of the stomach)

Pharmacological solutions^b









- **Peripherally acting drugs** are lipase inhibitors, which reduce the intestinal absorption of fat (e.g., orlistat²)
 - **Centrally acting drugs** act on the central nervous system (e.g., phentermine/topiramate³, bupropion/naltrexone⁴, lorcaserin⁵...)
- Some anti-depressants are also used against obesity (e.g., fluoxetine)
- **Mimicking drugs** mimic intestinal hormones, naturally released after eating, to send the brain the signal of satiety (e.g., semaglutide⁶ and liraglutide⁷ mimic the GLP-1⁸ hormone, tirzepatide⁹ mimics the GLP-1 and GIP¹⁰ hormones)

Sources: ^a "Pharmacologic Therapy for Obesity", US National Library of medicine (August 2022) –
^b "Pharmacotherapy of obesity: an update on the available medications and drugs under investigation",
 EClinicalMedicine (August 2023) – Smart Pharma Consulting analyses

¹ Surgery is only used for severe cases (BMI > 40) or when an obesity-related condition such as diabetes can be improved through the weight loss – ² Xenical/Alli – ³ Qsymia – ⁴ Contrave / Mysimba – ⁵ Belviq – ⁶ Wegovy –
⁷ Saxenda – ⁸ Glucagon-Like Peptide-1 – ⁹ Zepbound – ¹⁰ Glucose-dependent Insulinotropic Polypeptide

The main products on the market are centrally-acting drugs and mimicking drugs, with a higher proven efficacy of the two latest entrants on the market

Marketed AOMs

Drug name	Zepbound	Wegovy	Imcivree	Saxenda	Contrave / Mysimba ¹	Qsymia	Belviq	Xenical / Alli
INN	Tirzepatide	Semaglutide	Setmelanotide	Liraglutide	Bupropion / Naltrexone	Phentermine / Topiramate	Lorcaserin	Orlistat
Mechanism of action	GLP-1 RA ² / GIP RA	GLP-1 RA agonist	MC4 ³ RA	GLP-1 RA	MC4 RA	Sympathomimetic / GABA R modulation	Serotonin 3C RA	Lipase inhibitor
Type	Mimicking drugs	Mimicking drugs	Centrally acting drugs	Mimicking drugs	Centrally acting drugs	Centrally acting drugs	Centrally acting drugs	Peripherally acting drugs
Pharma company								
FDA / EMA approval	2023 / 2023	2021 / 2022	2022 ⁴ / 2022	2014 / 2015	2014 / 2015	2012 / not yet approved	2012 ⁵ / not yet approved	1999 / 1998 ⁶
Weight loss (%) ⁷	20.9 %	14.8 %	7.9 %	8.0 %	6.1 %	8.6 %	5.0 %	< 5%
































Note: Phentermine on its own (Adipex, Lomaira) is used as an appetite suppressant – Other products are commercialized, e.g., amfepramone, phendimetrazine

Sources: “Novel Anti-Obesity Therapies and their Different Effects and Safety Profiles: a critical overview”, US National Library of medicine (June 2023) – EMA – FDA – Smart Pharma Consulting analyses


¹ Contrave in the EU and Mysimba in the RoW – ² Receptor Agonist – ³ Melano Cortin-4 – ⁴ Supplemental indication for obesity due to Bardet-Biedl Syndrome – ⁵ Withdrawn from the market in 2020 and active lawsuit since 2021 due to suspicions of increased risks with cancer – ⁶ Initially introduced by Roche as a Rx-bound drug under the brand name Xenical – ⁷ Clinically proven

Multiple Phases II and III clinical trials are running,
with Lilly and Novo Nordisk being the most advanced companies

AOMs in development

Phase II	Phase III
<p>Maridebart cafraglutide  </p>	<p>Retatrutide  </p>
<p>Dapiglutide  </p>	<p>Survodutide   </p>
<p>LB54640   </p>	<p>Cagrilintide + semaglutide  </p>
<p>CT-388   </p>	<p>Semaglutide  </p>
<p>CT-868   </p>	<p>Orforglipron  </p>
<p>Danuglipron  </p>	<p>Mazdutide   </p>
	<p>Bimagrumab  </p>

Sources: clinicaltrials.gov – Smart Pharma Consulting analyses

 Oral form  IV form

Amongst the Anti-Obesity Medications in Phase II development stage, maridebart cafraglutide from Amgen has shown, to date, the best results

AOMs in development – Phase II

Maridebart cafraglutide



- **GIP RA¹ / GLP-1 RA**
- **14.5%** weight reduction after 12 weeks² (Phase I – June 2023)
- Phase II study (estimated completion date: January 2026)

Dapiglutide



- **GLP-1 RA / GLP-2 RA**
- **4.3%** weight reduction after 4 weeks² (Phase I – June 2022)
- DREAM Phase II study (estimated completion date: August 2024)

LB54640



- **MC4 RA**
- Phase I study completed in July 2022
- An ongoing Phase II study in patients with genetic obesity (estimated completion date: December 2025)

CT-388



- **GLP-1 RA /GIP RA**
- **8.4%** weight reduction after 4 weeks on patients with type 2 diabetes (Phase I – October 2023)
- Ongoing Phase I/II study in people with and without type 2 diabetes

CT-868



- **GLP-1 RA /GIP RA**
- For overweight and obese patients with Type 1 and type 2 diabetes
- No disclosed results from Phase I study
- Ongoing phase II study (started in October 2023)

Danuglipron



- **GLP-1 RA** (oral form)
- **8% to 13%** weight reduction after 32 weeks (Phase IIb results disclosed by Pfizer in December 2023)
- An improved once-daily form is to be tested in 2024, after high rates of side effects seen with the twice-daily form

Sources: clinicaltrials.gov – Respective company’s announcement as of January 2024 – Smart Pharma Consulting analyses

¹ Receptor Agonist – ² In overweight and obese adults – ³ Rhythm Pharmaceuticals acquired the global licensing rights of LB54640 in January 2024 – ⁴ Roche acquired Carmot Therapeutics in Dec. 2023

Several of the Anti-Obesity Medications in Phase III have reached more than 15% weight loss results

AOMs in development – Phase III

Retatrutide



- GLP-1/GIP/Glucagon RA¹
- 24.2%** weight reduction² over 48 weeks (Phase II – June 2023)
- Ongoing phase III study: TRIUMPH-2 trial (2023 – 2026)

Survodutide



- GLP-1/Glucagon RA
- 19.0%** weight reduction² after 46 weeks (Phase II – June 2023)
- 3 ongoing phase III studies: SYNCHRONIZE-1, -2, - CVOT³

Pemvidutide



- GLP-1/Glucagon RA
- 15.6%** weight reduction² over 48 weeks (MOMENTUM) (Phase II – November 2023)
- Altimmune is looking for a partner to start a phase III study and launch the product

Cagrilintide + semaglutide



- Amylin / Calcitonin RA (CagriSema)
- 15.6%** weight loss over 32 weeks (Phase II – August 2023)
- Ongoing phase III study: REDEFINE 2 trial (2023 – 2025)

Semaglutide (oral form)



- GLP-1 RA
- 15.1%** weight loss² over 68 weeks (Phase III: OASIS 1 trial – published in August 2023)

Orforglipron



- GLP-1 RA
- Up to **14.7%** weight reduction² after 36 weeks (Phase II – June 2023)
- Ongoing phase III study: ATTAIN-1 (2023 – 2027)

Mazdutide



- GLP-1/Glucagon RA
- 7.0%** weight reduction² over 24 weeks in Chinese patients (Phase II – December 2023)
- Phase III GLORY-1 completed & phase III GLORY-2 ongoing

Bimagrumab^{4,5}

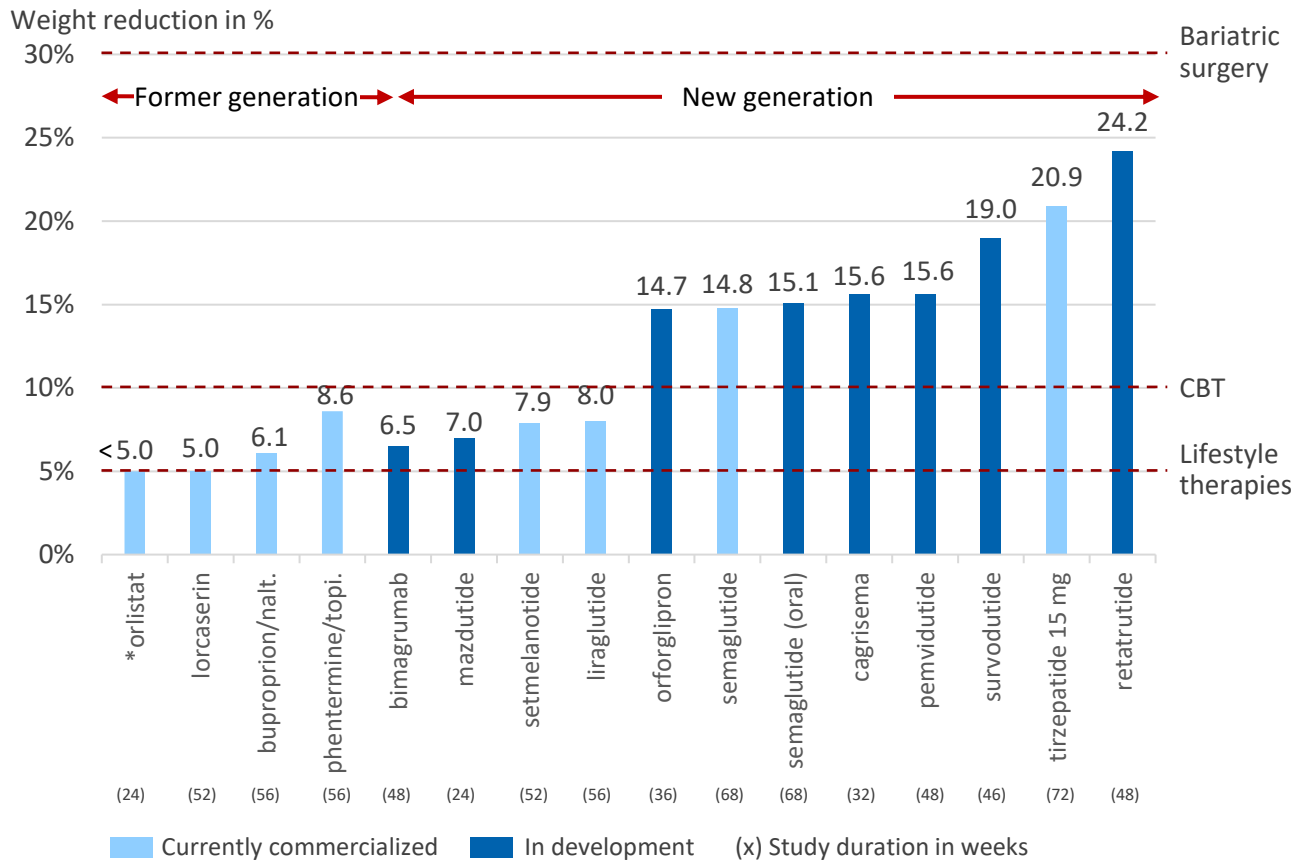


- Activin II RA
- 6.5%** weight reduction² after 48 weeks (Phase II – January 2021)
- No ongoing phase III study, to date in obesity

Note: An ongoing Phase II study of S-309309 – a Monoacylglycerol AcylTransferase 2 (MGAT2) inhibitor is developed by Shionogi. Expected results in April 2024

Retatrutide from Lilly has shown the highest weight loss results, being more than twice as effective as CBT¹ and approaching the efficiency of bariatric surgery

Efficacy of AOMs²



- **Former generation** of AOMs provides < 9% weight loss:
 - Peripherally acting drugs: less than 5%* weight loss for orlistat (Xenical / Alli)
 - Centrally acting drugs: from 5.0% weight loss for lorcaserin (Belviq) to 8.6% weight loss for phentermine/ topiramate (Qsymia)
- **New generation** of AOMs has demonstrated variable results, ranging from 6.5% to 24.2% weight loss:
 - Liraglutide (Saxenda): 8.0% weight loss
 - Semaglutide (Wegovy) was the most effective anti-obesity drug until the arrival of tirzepatide (Zepbound)
 - Five drugs currently in Phase III clinical trials have shown to be more effective than semaglutide to reduce weight
 - Retatrutide clinical results are close to that obtained with bariatric surgery

* Estimated after Orlistat clinical trials results that have been expressed as a reduction in kg and not in %

Obesity is tackled through national prevention campaigns in the USA, but the lack of HCPs trainings and the limited coverage of AOMs should hamper their growth

Healthcare environment (1/3)

USA



- The government has launched **national campaigns** about the importance of balancing food intake with exercise (e.g., Play Hard campaign) and about nutrition education (e.g., Food Stamp campaign)
- **HCPs lack training** to provide **recommendations** to obese people, with only 40% of overweight or obese people receiving HCP counseling on weight loss^a
- Multiple **patient associations** and **NGOs** address obesity, specializing on different categories (age, level of income, ethnicity, etc.)
- **Coverage** of AOMs **by private health insurance** companies is at least **possible** while in the **public** it is either **spotty**, as in Medicaid, **or prohibited**, as in Medicare, though some select Medigap and Medicare Advantage plans for retirees do
- Members of Congress have introduced the **Treat and Reduce Obesity Act of 2023** (H.R. 4818 and S. 2407) that **would allow Medicare to cover AOMs** which would result in greater use by Medicare enrollees
- Many **health plans paid** for by **large employers will cover Wegovy** and **Zepbound**, although they may require that patients try a rigorous diet program and/or cheaper drugs first
- Semaglutide (**Wegovy**), liraglutide (**Saxenda**¹), and tirzepatide (**Zepbound**) are **approved for obesity in adults**
- As of September 2023, the **street price** for **Wegovy** was **\$1,349 for 4 weeks**, but **discounts** are **granted** to **public** and **private insurers**; and **patients** can benefit from **coupons**
- The **outcomes** of the **SELECT study**, showing a **20% reduced risk of major cardiovascular events** such as **heart attacks** or **strokes** when obese **patients** are **treated by Wigovy**, will **put pressure** on insurance companies to **cover obese patients** with **associated co-morbidities**
- **Novo Nordisk expects** to obtain from the FDA a **label extension based on the SELECT study** outcomes by end of 2025

Sources: "The Challenges and Opportunities associated with reimbursement for obesity pharmacotherapy in the USA", PubMed (2015) – "Public Health Considerations regarding Obesity" US National library of medicine (June 2023) – ^a "HCP counseling for weight management behaviours among adults with overweight or obesity", BMJ (Nov. 2020) – Smart Pharma Consulting analyses

¹ Also approved for adolescents aged 12 to 17 by the FDA (December 2020) and the EMA (March 2021)

The coverage of AOMs by public and private health insurance systems in major European countries by 2030, could be introduced but partially, considering the high budget impact

Healthcare environment (2/3)

Europe

Germany



- **No national strategy nor prevention program** re. obesity
- Since February 2023, the German Minister of Nutrition fights to ban advertising of sugar, salt and fat-content food for children
- Creation of the **German Obesity Alliance** in 2020¹
- By law, public health insurance schemes cannot **reimburse** the so-called “**lifestyle drugs**” as Anti-Obesity Medications
- **Wegovy** is available since 2023 for a 4-week cost of **USD 328** for the 2.4 mg dosage

France



- Several **preventive governmental** actions, incl. reimbursed health checks and follow-ups for obese children
- **37 centers specialized** in obesity and **multiple associations**
- **Wegovy** benefited from an **early access scheme** (July 2022 – October 2023) with strict conditions² and a coverage by the National Health Insurance Fund
- **Wegovy** has been **considered as providing no clinical added value** (CAV) by the Transparency Committee in December 2022³

UK



- The **NICE**⁴ produced several official **guidelines on prevention, weight loss treatments and surgery** since 2014
- **Access to Wegovy** under a **two-year pilot**⁵ program implemented by hospital specialists for patients with a BMI >35 and one obesity-related condition (e.g., diabetes, high blood pressure) which will give access to around **35,000 obese patients**
- **Pharmacy chains** (e.g., Boots, Superdrug) charge private patients for **Wegovy 2.4 mg from USD 256** for a four-week treatment

Italy



- **Best practices policies** for a healthier food environment exist, but obesity is **not a major topic** for the government
- Obesity-focused **facilities are heterogeneously present** in the country, with few facilities in highly prevalent regions
- **Patient associations** fight especially against **child obesity**
- AOMs are **not reimbursed** in Italy by the National Healthcare system

Sources: Countries' national Healthcare systems' websites – “Confronting obesity in Germany”, The Economist Intelligence Unit (2016) – NICE clinical guidance on obesity (July 2023) – Smart Pharma Consulting analyses

¹ Includes patients, HCPs, insurance companies and drug manufacturers to change awareness of, and attitude towards obesity in the society – ² For people with a BMI >35, complementary to a low-calory diet and an increase in physical activity, if a nutritional therapy did not result in the patient losing more than 5% of their weight in 6 months – ³ The positive results from the SELECT cardiovascular outcomes trail (August 2023) will lead to a reassessment of Wegovy – ⁴ National Institute for Health and Care Excellence – ⁵ Zepbound could join the program too

In China, India and Brazil, it is unlikely that AOMs will be reimbursed, even partially, due to the general economic context and the existing healthcare cost coverage systems

Healthcare environment (3/3)

Rest of the World

China^a



- Chinese people have **higher percentages of body fat** and **rates of cardiovascular risk factors** and all-cause mortality than the western population at given BMI levels
- The government has made **obesity prevention a priority** in its national healthcare blueprint, known as “Healthy China 2030”
- Active role of the **academic community** with the creation of the **Obesity Prevention & Control Section** in 2021
- **Liluping** (benaglutide), a locally developed **GLP-1 RA¹** has been **approved in 2023**, as well as a **copycat version of Saxenda** (liraglutide) which is **marketed at ~USD 123 per month**

India



- Implementation by the government of a “**fat tax**” on food and beverage considered to have “a high amount of fat”^b
- In 2021, **74% of Indians** are **unable to afford a healthy diet**^c
- **Saxenda is available**, **Wegovy is expected in 2026**, and **Sun Pharma** develops **utreglutide**, a **long-acting GLP-1 RA**

Japan^d



- Japan has **one of the lowest adult obesity rates** in the world (4.5%)
- **National programs to prevent obesity through education**
- The “**metabo law²**”, introduced by the Ministry of Health in 2008, aims at helping citizens live a healthier lifestyle by achieving a **mandatory waistline** of 85 cm for women and 90 cm for men
- **Adult obesity** includes **BMI > 25**, due to physiological differences between Asian and Western metabolisms
- **Most patients** will pay **30% of medical expenses for Wegovy**, which has been approved in March 2023 and will be launched from February 22, 2024, at **USD 289** for 2.4 mg for 4 weeks³

Brazil^e



- Proposal of a strategy for “the **prevention and care**” of **childhood obesity** in Oct. 2023 (Proteja strategy)
- **Approval of Wegovy in early 2023** by the Brazilian Health Regulatory Agency (ANVISA) for **adolescents and adults**
- Wegovy is **not reimbursed** in Brazil

Sources: ^a “The serious challenge faced by Chinese children and adolescents”, US National library of medicine (July 2023) – ^b “Fat taxation in India”, Health Promotion Perspectives (2020) – ^c Regional Overview of food security and nutrition, FAO (Dec. 2023) – ^d “Japanese data from the ACTION-IO study”, US National library of medicine (Nov 2020) – ^e “Analysis of the elaboration and proposal of a Brazilian intersectoral strategy for the prevention and care of childhood obesity”, Cad Saude Publica (Oct. 2023) – Smart Pharma Consulting analyses

¹ Receptor Agonist – ² It includes an objective to decrease obesity rate by 25% in 17 years, and failure to meet the goals results in a fine, called the “fat tax”, paid by the regions – ³ Access will be limited to patients with a BMI >27 and suffering from at least two obesity related diseases, or having a BMI > 35

Prevalence, medical needs, economic and social impacts are so important, that the arrival of new effective and safe AOMs are speeding up the market growth, despite their high prices

AOMs market drivers and limiters (2023 – 2030)

Market Determinants	Driving Factors	Limiting Factors
Health Authorities (Policy-markers – Public payers)	<ul style="list-style-type: none"> Obesity is a public health burden having an economic (e.g., absenteeism) and social (e.g., exclusion) impact Obese-related risks of chronic diseases (e.g., cardio-vascular diseases, hypertension, cancer¹, type-2 diabetes, depression, sleep apnea, arthritis) and premature death² Political pressure to better support the obese population 	<ul style="list-style-type: none"> Budget constraints of public healthcare coverage systems No strong evidence re. the positive impact of AOMs on total healthcare costs relative to obese patients Non reimbursement / partial reimbursement and/or limited reimbursement to a subset of the obese population
Customers (HCPs – Patients – PAGs – Private payers)	<ul style="list-style-type: none"> Increasing prevalence due to population ageing and a larger number of people with unhealthy and sedentary lifestyles Increase in population awareness re. severe chronic diseases related to obesity Rising disposal income, healthcare expenses and awareness for AOMs, especially in Asian countries (e.g., India, China) 	<ul style="list-style-type: none"> High costs to be beard by patients or insurance companies (e.g.; ~USD 17,537 street price³ p.a. for Wegovy in the USA) Medium-low persistence (e.g., 60% of dropouts within a year under Wegovy^a) Appetite for non-pharmacological solutions (e.g., gyms, exercise, diet plans, compliance for surgical procedures) Off-label prescriptions of same molecules indicated for T2D⁴
Competitors (Pharma companies)	<ul style="list-style-type: none"> Increase of the offer contributing to raise HCP and patient awareness Development of more effective and safer AOMs favoring earlier adoption, better adherence and longer persistence New coming AOMs leading to increasing price competition and consequently market expansion in volume Oral forms that would be more cost-effective 	<ul style="list-style-type: none"> Adverse events induced by AOMs (e.g., gastro-intestinal disorders with GLP-1 RAs⁵) Medications that speed up the metabolism and suppress the appetite are risky and can lead to high blood pressure, increase in heart rate, lung and heart problems Supply limitations that should extend into 2024 and 2025 Counterfeit drugs that may put at risk patients and represent a loss of income for original manufacturers

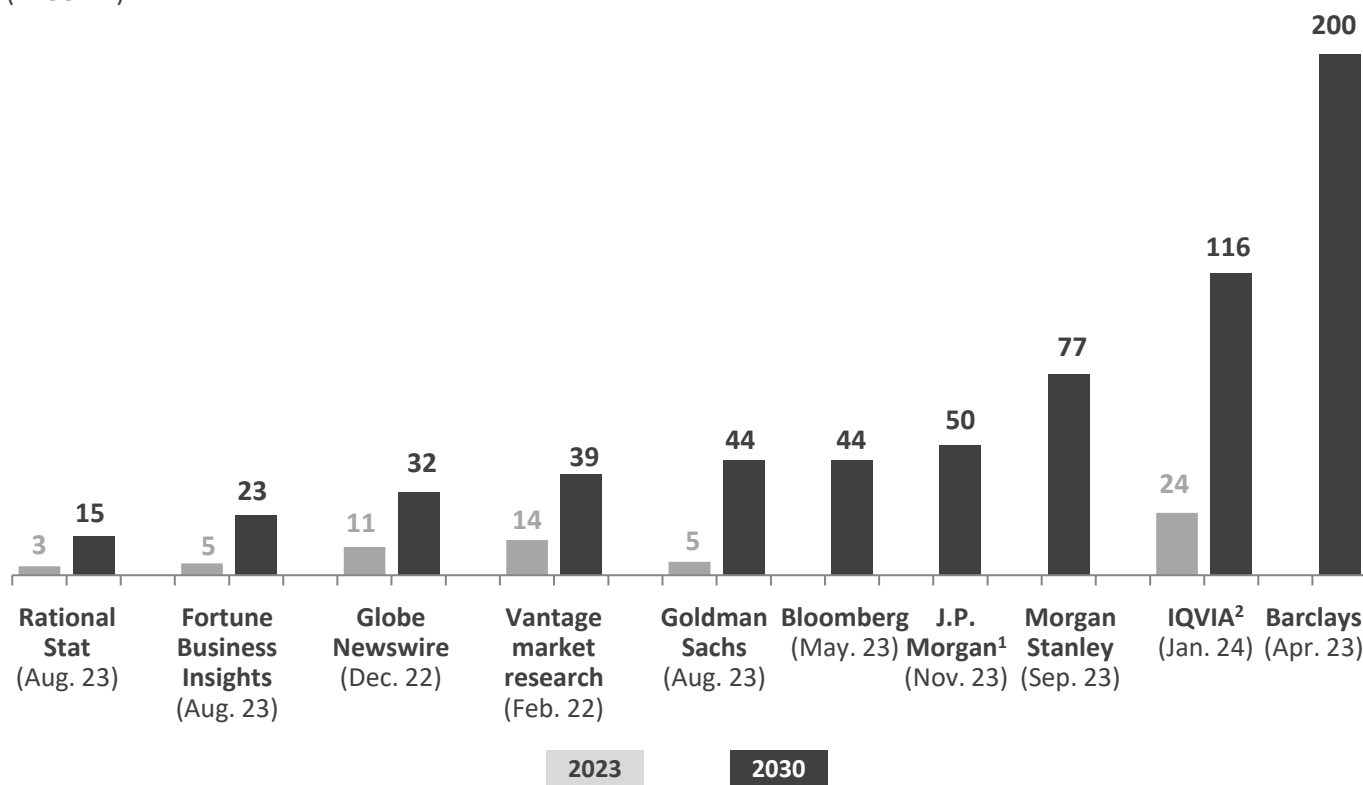
Sources: ^aH. Gasoyan et al., Obesity (Silver Spring, Dec. 2023) – Smart Pharma Consulting analyses

¹ Centers for Disease Control and Prevention (CDC) estimated in 2021 that more than 650,000 obese-associated cancers occur in the USA per year –² The WHO considers that more than 2.8 million people are dying each year because of their obesity –³ Without considering the Wegovy savings card (a type of coupon) or the discounts granted to insurance companies –⁴ These products have the same active pharmaceutical ingredient (e.g., semaglutide) but are marketed under different names and prices with different coverage status (e.g. Ozempic for T2D (type 2 diabetes) and Wegovy for obesity) –⁵ Receptor Agonists

Various sources, recently published, estimate the AOMs market from USD 15 B to USD 200 B by 2030, showing a very high variance with assumptions most often poorly documented

AOMs market sales estimates (2023 – 2030) – Open Access Data

AOMs market sales
(in USD B)



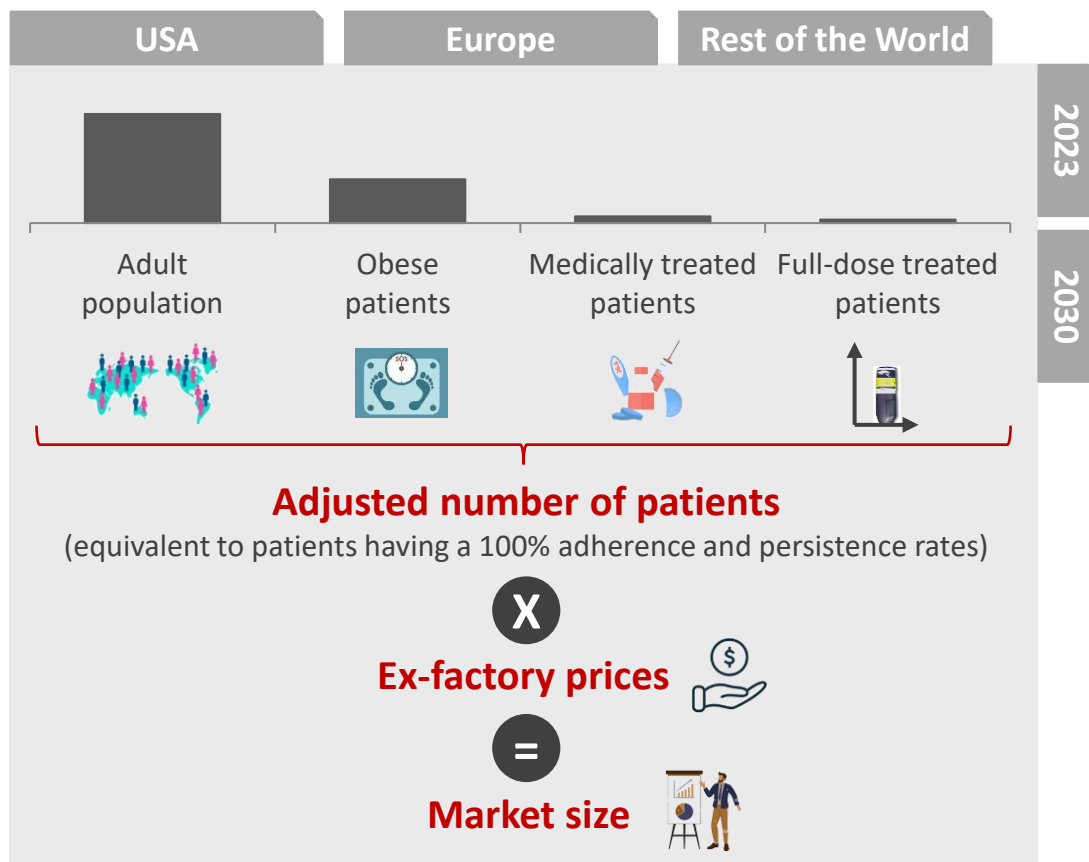
- Open access data show a significant variance, with a global obesity market estimated to range, by 2030, from USD 15 B to USD 200 B
- The rationale behind the assumptions made is most often poorly documented whether in volume (e.g., prevalence of obesity, share of obese patients medically treated, patient adherence to treatment) or in price
- Amongst the 10 recent reports that have been reviewed, 4 present a 2030 forecast without specifying the starting point in 2023

Sources: Desk research (January 2024) – Smart Pharma Consulting analyses

¹ USD 100 B forecast by 2030, driven equally by diabetes and obesity usage – ² Extrapolated from 2028 estimates

Smart Pharma Consulting estimated the number of equivalent full-dose treated patients and then translated it in value, based on net price assumptions by region over the 2023–2030 period

AOMs market sales estimates (2023 – 2030) – Methodology



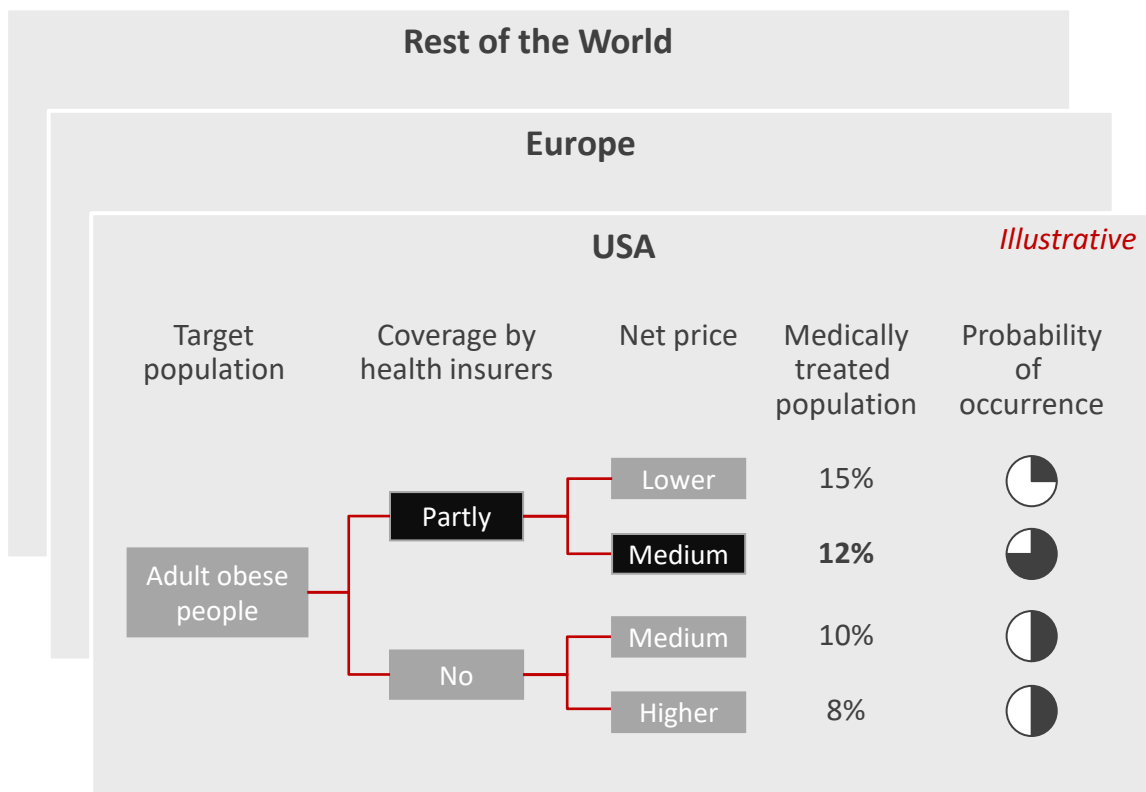
- Only adult people with a BMI ≥ 30 kg/m² have been considered by Smart Pharma Consulting, in line with WHO’s definition of obesity
- Population projections are based on OECD¹ statistics
- Prevalence projections are adapted from the Atlas of the World Obesity Federation² (March 2023)
- Number of medically treated patients are estimated after multiple sources (e.g., IQVIA, market players’ investor communications, investment funds)
- Number of full-dose³ medically treated patients are estimated by combining adherence and persistence rates by analogy with results of various real-world studies carried out with semaglutide in obesity and in T2D⁴, and with other drugs in chronic diseases⁵
- Ex-factory prices have been estimated, net of rebates granted to patients, public and private health insurers or other intermediaries
- Several scenarios have been considered according to reimbursement status and net pricing strategy

Sources: Smart Pharma Consulting analyses

¹ Organization for Economic Cooperation and Development – ² Organization representing professional members of the scientific, medical and research communities from over 65 regional and national obesity associations – ³ Adjusted number of patients as if their adherence and persistence rates were 100% – ⁴ Type-2 diabetes – ⁵ Crohn disease, rheumatoid arthritis, psoriasis, hypercholesterolemia, hypertension

The AOMs market growth by 2030 will strongly depend on their coverage status by health insurance organizations, pharma companies pricing strategy and patients' willingness to pay

AOMs market sales estimates (2023 – 2030) – Scenario building principle



- The ramp up of the AOMs market over the 2023 – 2030 period will be strongly dependent on the following inter-related variables – per country:
 - The degree of coverage by public and/or private health insurers
 - The net price granted by pharma companies to these organizations and/or to patients
- The coverage of AOMs can be:
 - Limited to the most severe cases¹
 - Restricted to patients having failed to respond to non-pharmacological and/or cheaper medications
 - Limited in duration (e.g., one year)
 - Conditional upon patients' enrolment in a journey²
 - Capped in term of reimbursement level³
- The net price by country and over time will depend on:
 - Coverage policy of health insurance organizations⁴
 - Payers' sensitivity to price
 - Competitive intensity of pharma companies on price
 - Balance between supply and demand

Sources: Smart Pharma Consulting analyses

¹ E.g., BMI > 35 + one risk factor – ² Such as a specific Patient Support Program to ensure the proper usage and adherence of obese patients to AOMs, and thus optimize their clinical outcomes and value – ³ Per pack in percentage or in absolute terms, or for a certain treatment duration – ⁴ Their position could evolve with additional studies demonstrating a reduction of risk factors associated to obesity with the new generation AOMs and/or a positive budget impact

The base case scenario has been built on the assumption of a partial coverage of AOMs in the USA, a very limited one in Europe and no reimbursement in the rest of the world¹

AOMs market sales estimates (2023 – 2030) – Base case scenario description

USA

- The percentage of adult obese patients medically treated will grow from 4% to 12% over the period due to increasing awareness re. the disease
- The coverage of AOMs by private and public health insurers will be partial, but should increase over the period, especially with the confirmation of the positive cardio-vascular outcomes of

Wegovy (SELECT trial) and with the expected morbidity and mortality reduction of Zepbound (SURMOUNT-MMO trial)

- The net price will remain moderately high
- The net price has been set based on the 2023 situation and its evolution has been estimated at +3.8% p.a., based on historical trends

Europe

- The reimbursement of AOMs in Europe will be strictly limited to the most severe obese patients (e.g., BMI > 35 + one risk factor)
- The reimbursement would occur for a limited duration (e.g., 6 to 12 months) and if patients adhere to a strict weight reduction program
- The net price will be moderately low compared to the US and will decrease by ~-2% p.a.

Rest of the World

- AOMs should not be reimbursed, excepting in Japan, over the period due to the budget impact and/or the social perception of obesity
- The net price will be moderately low, and close to the average European price, as Novo Nordisk, and Lilly are unlikely to enter in a price war
- The net price of manufacturers should decrease by ~-2% p.a.

Preliminary estimates	USA		Europe		Rest of the World		Worldwide		
	2023	2030	2023	2030	2023	2030	2023	2030	
Adult population (in millions)	257	271	710	719	4,326	4,808	5,293	5,798	
Adult obese ¹ patients (in millions) (% of adult population)	118 (46%)	142 (52%)	204 (29%)	237 (33%)	602 (14%)	867 (18%)	924 (17%)	1,246 (21%)	
Medically treated adult obese patients ² (as a % of adult obese patients)	4.4 (4%)	17.0 (12%)	4.0 (2%)	19.0 (8%)	6.0 (1%)	26.0 (3%)	14.4 (2%)	62.0 (5%)	
Full-dose treated patients p.a. ³ (in millions) (adjustment factor in % of treated patients)	1.5 (35%)	6.0 (35%)	1.5 (38%)	7.2 (38%)	1.0 (16%)	4.1 (16%)	4.0 (28%)	17.3 (28%)	
Full-dose treated patients by generation of AOMs (in millions) (% of the total)	New generations ⁴	0.5 (35%)	4.2 (70%)	0.2 (10%)	4.3 (60%)	0.0 (1%)	0.8 (20%)	9.3 (54%)	
	Former generations	1.0 (65%)	1.8 (30%)	1.3 (90%)	2.9 (40%)	1.0 (99%)	3.3 (82%)	8.0 (46%)	
Ex-factory prices p.a., net of rebates ⁵ (in USD)	New generations	9,100	11,825 ⁶	2,861	2,484 ⁷	2,861	2,484 ⁸	7,639	6,688
	Former generations	792	1,029 ⁶	307	267 ⁷	189	164 ⁸	419	395

Most likely scenario based on collected insights and follow-on analyses carried out by Smart Pharma Consulting

The current high level of uncertainties requires to treat these figures with caution and to carry out regular updates

The share of obese adults medically treated worldwide should rise from ~2% in 2023 to ~5% in 2030, with new generation of drugs accounting for ~54% of patients in 2030 (+36 pts vs. 2023)

AOMs market sales estimates (2023 – 2030) – Base case assumptions*

Preliminary estimates		USA		Europe		Rest of the World		Worldwide	
		2023	2030	2023	2030	2023	2030	2023	2030
Adult population (in millions)		257	271	710	719	4,326	4,808	5,293	5,798
Adult obese ¹ patients (in millions) (% of adult population)		118 (46%)	142 (52%)	204 (29%)	237 (33%)	602 (14%)	867 (18%)	924 (17%)	1,246 (21%)
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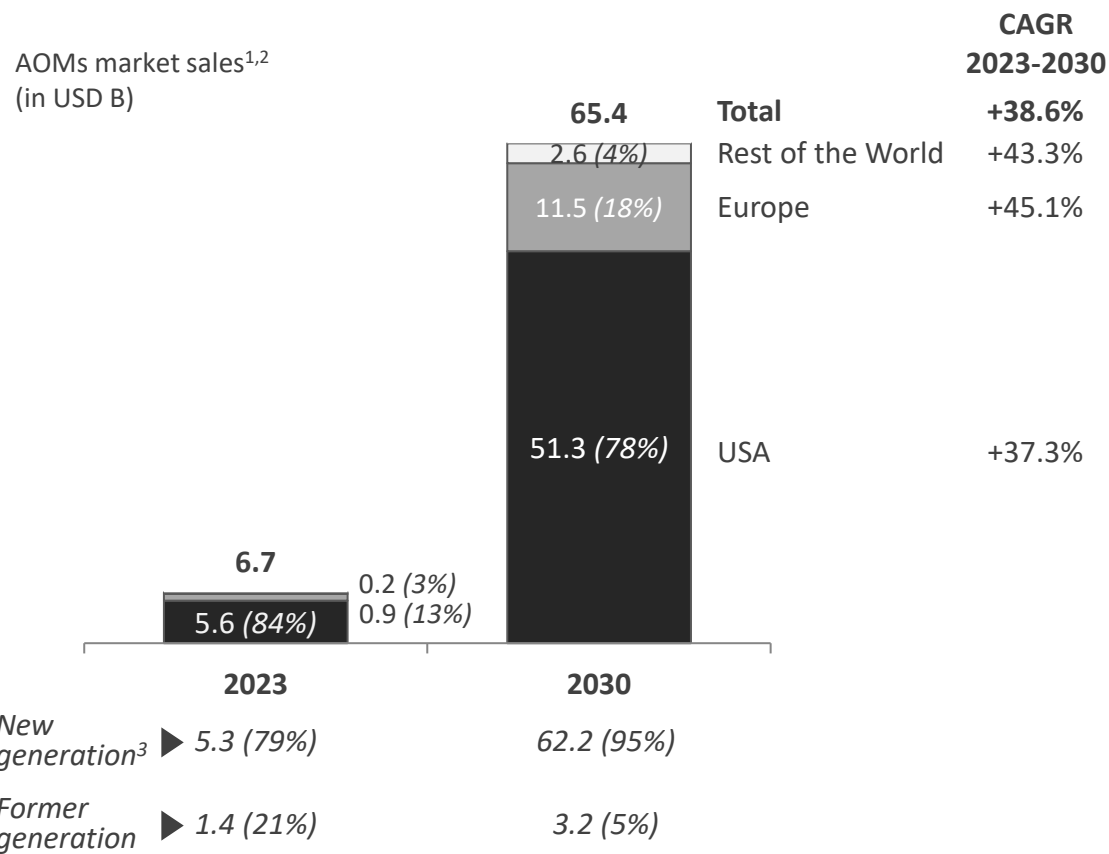
* Most likely scenario based on collected insights and follow-on analyses carried out by Smart Pharma Consulting. The current high level of uncertainties requires to treat these figures with caution and to carry out regular updates

Sources: OECD population statistics (Jan. 2024) – World Obesity Federation (Jan. 2024) – Market players’ websites (Jan. 2024) – PubMed (Jan. 2024) – Atonra (Nov. 2022) – Estimating the cost of new treatments for diabetes and obesity, American Enterprise Institute (Sep. 2023) – Smart Pharma Consulting estimates

¹ People with a BMI ≥ 30 kg/m² – ² Excluding patients treated for type 2 diabetes – ³ Adjusted number of patients as if their adherence and persistence rates were 100% – ⁴ GLP-1 RAs indicated for obesity and other new generation AOMs being developed – ⁵ Rebates to patients (e.g., coupons), public and private health insurers or other intermediaries – ⁶ +3.8% CAGR over 2023-2030 – ⁷ -2.0% CAGR over 2023-2030

According to Smart Pharma Consulting, The AOMs market should reach ~ USD 65 B by 2030 with a +39% CAGR vs. 2023 and be mainly driven by Wegovy and Zepbound; and the US demand

AOMs market sales estimates – Base case results



- By 2030, the obesity market is expected to reach USD 65.4 B at ex-factory prices before VAT and net of rebates to patients, public payers, private insurers and other intermediaries, representing a +38.6% CAGR over the 2023-2030 period:
 - USA should account for 78% of the market, with sales increasing from USD 5.6 B in 2023 to USD 51.3 B in 2030 (+37.3% CAGR)...
 - ... Followed by Europe, whose sales should reach USD 11.5 by 2030 (+45.1% CAGR)
 - The rest of the world should account for ~4% of the global market, with sales reaching USD 2.6 B by 2030
- Market growth should be mainly driven by new generation of anti-obesity medications (e.g., Wegovy, Zepbound) which should account for 95% of the market in net value by 2030

* Most likely scenario based on collected insights and follow-on analyses carried out by Smart Pharma Consulting. The current high level of uncertainties requires to treat these figures with caution and to carry out regular updates

Sources: Smart Pharma Consulting estimates

¹ Excluding patients treated for type 2 diabetes – ² Net ex-factory sales after rebates to patients (e.g., coupons), public payers, private insurers or other intermediaries and before VAT – ³ GLP-1 RAs indicated for obesity and other new generation AOMs being developed

The AOMs market offers huge sales perspectives for the first-comers – Novo Nordisk and Lilly – provided they match the supply with the demand and get significantly covered by health insurers

Worldwide AOMs market perspectives for Pharma companies

Opportunities to seize

- The number of obese adults should rise from 924 million in 2023 to 1,246 million in 2030 (i.e., +35% over the period)
- Obesity being associated with mortality, severe and costly events, governments would be forced to facilitate patients’ access
- Obese people demand for effective and well-tolerated AOMs is huge and increasing
- Clinical outcomes of new AOMs¹ with 15% or more weight loss, and a pretty good safety profile should meet most of obese patients needs
- Demonstrated reduction in MACEs² associated with weight loss reinforces the value of these new AOMs³ and the probability for public and private health insurers to cover their cost



Challenges to address

- The AOMs market growth will remain hampered by insufficient production capacities for Wegovy and Zepbound, that are estimated to last up to 2026, and possibly beyond
- The off-label Rx of Ozempic (semaglutide) and Mounjaro (tirzepatide) registered for diabetes, will cannibalize Wegovy and Zepbound respectively, due to price and/or coverage status differences
- Newcomers would have to offer a minimum weight reduction of 18-20%, a good safety profile, while demonstrating positive cardiovascular outcomes through CVOT⁴ data to gain market share
- The pricing strategy of pharma companies will be essential to determine the coverage level of AOMs by health insurers and the magnitude of obese patients’ access

Sources: Smart Pharma Consulting analyses

¹ Such as retatrutide, tirzepatide, semaglutide – ² Major Adverse Cardiovascular Events – ³ As demonstrate in mid-2023 with the results of the SELECT study carried out with Wegovy of Novo Nordisk. Lilly is currently investigating the effect of tirzepatide on the reduction of morbidity and mortality in obese adults (SURMOUNT-MMO trial) – ⁴ Cardio-Vascular Outcomes Trials

According to our current insights and analyses, the worldwide AOMs market could reach USD ~65 B* in 2030, with more than ~80% of it captured by Novo Nordisk and Lilly

Key Takeaways

- The worldwide AOMs market is preliminary evaluated at USD ~65 B* in 2030

- 1.25 B adult obese people are expected in 2030 (+35% vs. 2023)



- 78% of sales in value will come from the USA and 18% from Europe

- Novo Nordisk and Lilly insufficient level of production to meet AOMs demand cannot be fixed before 2026



- Health, social and economic burden of obesity will urge policy makers and payers to facilitate patients' access

- The pricing strategy of pharma companies will be instrumental on the magnitude of patients' access



- ≥15% weight reduction, good tolerability and evidenced prevention of MACE¹ are a prerequisite for newcomers

- Novo Nordisk (Wegovy) and Lilly (Zepbound) will take the lion's share on the 2023 – 2030 AOMs market, knowing that most promising AOMs currently in phase II or III development will not reach the market before 2028 – 2029

* Most likely scenario based on collected insights and follow-on analyses carried out by Smart Pharma Consulting. The current high level of uncertainties requires to treat these figures with caution and to carry out regular updates

Consulting firm dedicated to the pharmaceutical sector operating in the complementary domains of strategy, management and organization

Market Insights Series

- The Market Insights Series has in common to:
 - Be well-documented with recent facts and figures
 - Highlight key points to better understand the situations
 - Determine implications for key stakeholders
- Each issue is designed to be read in 15 to 20 minutes and not to exceed 24 pages

Anti-Obesity Medications Market

What Perspectives for Pharma Companies

This paper gives an overview of the Anti-Obesity Medications (AOMs) market and is structured as follows:

- Obesity epidemiology (by region, income and country)
- Existing pharmacological and non-pharmacological solutions
- Efficacy of AOMs
- Healthcare environment (USA – Europe – Rest of the World)
- AOMs market drivers and limiters
- AOMs market sales estimates (2023 – 2030)

Smart Pharma Consulting Editions



- Besides our consulting activities which take 85% of our time, we are strongly engaged in sharing our knowledge and thoughts through:
 - Our teaching activities in advanced masters (ESSEC B-school, Paris Faculty of Pharmacy)
 - Training activities for pharma executives
 - The publication of articles, booklets, books and expert reports

- Our publications can be downloaded from our [website](#):
 - 41 articles
 - 77 position papers covering the following topics:
 1. Market Insights
 2. Strategy
 3. Market Access
 4. Medical Affairs
- Our research activities in pharma business management and our consulting activities have shown to be highly synergistic
- We remain at your disposal to carry out consulting projects or training seminars to help you improve your operations

Best regards

Jean-Michel Peny