The table above provides the key metrics for asthma in the seven major pharmaceutical markets (US, France, Germany, Italy, Spain, UK, and Japan) and Australia during the forecast period from 2013–2023.

**Asthma Market Will Reach $23.1 Billion by 2023**

GlobalData estimates the 2013 sales for asthma at approximately $15.9 billion across the eight markets covered in this report. The US contributed 64% of these sales, generating an estimated $10.1 billion. This is mainly due to the much higher prices of asthma medications in the US and the lack of generic inhalers for asthma in this market.

By the end of the forecast period in 2023, asthma sales in the seven major markets (7MM) and Australia are expected to grow to $23.1 billion at a Compound Annual Growth Rate (CAGR) of 3.8% over the 10-year period. The class of fixed-dose combinations (FDCs) of inhaled corticosteroids (steroids) and long-acting beta-agonists (ICS/LABAs) is the leading drug class in terms of market value and currently captures almost half of the total asthma market; however, its market share will shrink to 23% as targeted biologics for the treatment of severe asthma enter the market over the forecast period and start dominating this space, growing from 8.7% to 32% of the total asthma sales. The uptake of these novel drugs will be a major driver of the asthma market growth and will offset the dip in sales caused by Singulair’s (montelukast) recent patent expiry and the patent expiry of numerous short-acting beta-agonist...
(SABA), ICS, and ICS/LABA products by 2017. The US market will grow in size somewhat faster than the other markets — at a CAGR of 4.2% — due to a faster increase in the asthma prevalence and a delay in the surge of generic competition in this market. In 2023, the US will represent 66% of the total market, stealing a little piece of market share from all the other countries.

Major drivers for the growth of the asthma market over the forecast period will include:

- The uptake of novel targeted biologic agents and once-daily ICS and ICS/LABA therapies
- Strong brand loyalty and difficulty replicating inhaler devices, which will soften the impact of generic erosion
- The growing number of patients suffering from difficult-to-treat asthma, who do not respond to the standard therapies and will therefore be prescribed the novel biologic therapies

Major barriers to the growth of the asthma market will include:

- Generic erosion of the leading brands for asthma treatment, such as Advair (fluticasone propionate/salmeterol) and Symbicort (budesonide/formoterol fumarate)
- Underdiagnosis of asthma, which represents a significant barrier to asthma market growth
- Increasing pressure for cost-effectiveness across all markets, which will limit the pricing of new products, and in some cases, prevent their reimbursement

The figure below provides the sales for asthma in the US, 5EU, Japan, and Australia from 2013 to 2023.
Companies are Increasing Their Focus on Severe Asthma by Developing Personalized Biologic Therapies

Historically, five large pharmaceutical companies had a strong presence in the asthma market: GSK, Merck, AstraZeneca, Teva, and Boehringer Ingelheim. Roche, in partnership with Novartis, is also one of the current leaders in this space due to the companies’ targeted biologic therapy, Xolair (omalizumab), which has recently achieved blockbuster status. Overall, GSK currently has the world’s most successful respiratory drug portfolio, dominated by the multibillion-dollar Advair. Advair’s patent cliff is not expected soon, despite the patent expirations for both the drug formulations and the Diskus device over the forecast period, due to the difficulties in copying the device and the strong brand loyalty defining the asthma market dynamics. In addition, GSK has Advair’s follower, Breo Ellipta (fluticasone furoate and vilanterol), ready to take over the domination of this market.

Unlike inhalers, oral drugs are much easier to copy, and Merck’s blockbuster drug, Singulair, is currently suffering massive generic erosion. GlobalData expects Merck to be increasingly less focused on respiratory diseases and to lose its leading role in the asthma space due to its relatively weak pipeline, which is focused mainly on immunotherapies.

Future leaders during the forecast period will include GSK, with its Ellipta franchise and rich pipeline; AstraZeneca, which possesses the largest pipeline portfolio of targeted biologic therapies; Roche, with its marketed and pipeline portfolio, which is focused only on targeted biologic therapies, coupled with the company’s expertise in producing companion diagnostic tests; Teva, with its wide range of proprietary delivery systems, which will capitalize on long-established off-patent therapies; and Boehringer Ingelheim, with its potential blockbuster, Spiriva (tiotropium bromide), in a new inhaler device. Sanofi and Regeneron currently do not market any asthma medications, but have partnered to develop a promising targeted biologic therapy, dupilumab, which may earn the companies a significant position within the asthma space.

Companies are trying to penetrate or dominate the asthma market using two main approaches. One approach is developing drugs with different delivery devices to capitalize on long-established off-patent therapies; two, introducing biologics, in particular, interleukin inhibitors, to treat severe uncontrolled asthma. The second approach is clearly reflected in the late-stage asthma pipeline, which consists mainly of targeted biologic therapies. This indicates the beginning of a new era in asthma treatment, where we will see a clear shift toward personalized medicine for the treatment of severe asthmatics.
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The figure below provides an analysis of the company portfolio gap in asthma during the forecast period.

There is a Large Unmet Need for the Treatment of Severe Persistent Asthma Refractory to Standard Therapies

Asthma symptoms can be controlled in the majority of patients using the current standard therapies, which are mainly based on combinations of ICSs, SABAs, ICS/LABAs, and oral leukotriene modifiers. ICSs, alone or in combination with LABAs, are the gold-standard therapy for mild to moderate asthma patients. Nevertheless, in around 5–10% of people with asthma, the disease remains symptomatic and inadequately controlled. Therefore, there are considerably high unmet needs within the indication, which are both clinical and environmental in nature, and are all interrelated. Overall, these needs mainly reflect the high level of heterogeneity of the disease, the lack of patient compliance with the standard therapies, and the high cost of medications for asthma treatment. In addition, there is a lack of diagnostic tools to provide a reliable diagnosis of asthma in young children.

The major obstacle to achieving successful treatment in severe asthmatics is the high level of heterogeneity of the disease. It is now clear that severe asthma is not a single disease, but rather, consists of several clinical phenotypes, each having a unique underlying pathological pathway. Therefore, to address this difficult population of patients, there is a need for therapies that specifically target subgroups of asthma patients whose disease pathogenesis is mediated by a specific pathway.

The Market Entry of Novel Biologics Will Improve the Treatment Landscape for the Difficult-to-Treat Asthma Population

Over the last 10 years, the understanding of asthma pathogenesis has significantly improved, and as a result, we are seeing a major shift in the potential treatment approaches to severe asthma. The current late-stage asthma pipeline is dominated by biologics that target various inflammatory pathways in specific patient subpopulations. They include anti-interleukin (IL)-5 antibodies (GSK’s Bosatria, Teva’s Cinquil, and AstraZeneca’s benralizumab), anti-IL-13 antibodies
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(Roche’s lebrikizumab and AstraZeneca’s tralokinumab), an anti-IL-4/IL-13 antibody (Regeneron/Sanofi’s dupilumab), and an anti-M1 antibody (Roche’s quilizumab). Although the subpopulations that these drugs are targeting are limited in size, these novel agents will begin to fulfill the important unmet need for a personalized approach to the treatment of severe asthma patients.

Despite the fact that the drugs in late-stage development for asthma will fulfill a portion of this large unmet need, the treatment of patients with severe asthma who remain uncontrolled with the standard therapies will likely remain a challenge, and a significant growth opportunity will persist for new patented products. In addition, the understanding of the various phenotypes of severe asthma and the identification of additional biomarkers for each of these phenotypes is improving, which will open a large window of opportunity for additional personalized treatments. Issues will, however, remain regarding the enormous cost of biologics. A cheaper small-molecule therapy that would target the subpopulations of severe asthmatics would represent stiff competition to the drugs that are currently in late-stage development for asthma.

Novel therapies that are delivered by the next-generation inhalers, such as GSK’s ICS therapy, fluticasone furoate, and ICS/LABA therapy, Breo Ellipta, will fulfill some unmet needs, due to their more convenient dosing. These drugs may lead to somewhat improved patient compliance; however, the need for better compliance will remain considerably large over the forecast period, which is partially due to the high cost of medications for asthma. There is a big window of opportunity for novel drugs that would have even more convenient dosing or cheaper inhaler devices.

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

![Competitive Assessment of Late-Stage Pipeline Agents in Asthma, 2013–2023](image)

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

Source: GlobalData
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What Do Physicians Think?

The key opinion leaders (KOLs) interviewed for this report highlighted the need for a personalized approach to asthma treatment, which would ideally lead to complete resolution of the disease. The current standard medications, such as ICS and ICS/LABA therapies, tackle only symptoms; KOLs do not expect that novel drugs from these classes will fulfill this need. The biologics in development will somewhat address these issues, but only in a very small portion of asthmatics, and they will be very costly.

“We have to define certain phenotypes who respond to different specific asthma drugs.”

Out-of-US Key Opinion Leader

“I don’t think we can expect some particular advantages from any new ICS or from new ICS/LABA combinations.”

Out-of-US Key Opinion Leader

“I would like to see asthma drugs that are able to get patients away from asthma. Complete resolution of the inflammation. That would be very nice. We don’t have it, but it would be nice.”

US Key Opinion Leader

“[The anti-interleukin drugs in development], those are strong. These could be very good targets to treat [the] asthma condition, but we have to see the efficiency rate, for instance, whether it is higher than Xolair, better than Xolair, or even less expensive. And also, if it can change the natural course of [the] disease.”

Out-of-US Key Opinion Leader

“Anti IL-5 is useful in a very tiny proportion of asthmatics — the ones who have eosinophil inflammation despite high doses of steroids, and this is a very, very small population of patients, and even in those patients, the effects of anti IL-5 are quite small; they reduce exacerbations, but they don’t improve lung function or symptoms, so they are not suitable as a stand-alone therapy.”

Out-of-US Key Opinion Leader

Some KOLs also indicated that more accurate diagnosis of asthma in children is a large unmet need, as it would allow for the proper treatment of young children with respiratory symptoms. In addition, asthma is also underdiagnosed in adults.
“Very early in life, in the first three years of life or so, there is a high incidence of asthma; maybe a third of young children in this age group in the United States have had it at least once, and many have had recurrent wheezing, and many of those do not go on to have asthma. Some who do are underdiagnosed at that age, and some who don’t are overdiagnosed at that age. As you go up the scale, asthma is more underdiagnosed than overdiagnosed in older children and adolescents.”

US Key Opinion Leader

“There is an additional issue at all age groups…, because asthma [treatment] has incurred an increase in insurance rate[s], so more physicians are reluctant to give a diagnosis of asthma, even if they think that there is asthma and [they] treat them [asthma patients] accordingly.”

US Key Opinion Leader
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2 Introduction

2.1 Catalyst

The asthma market saw very slow growth over the past decade, as it has become saturated with relatively efficacious standard therapies, such as short-acting beta-agonists (SABAs), inhaled corticosteroids (ICSs), inhaled corticosteroids and long-acting beta-agonists (ICS/LABAs), and leukotriene modifiers, and has also been facing increasing generic competition. However, the launch of seven novel targeted biologic agents and once-daily ICS and ICS/LABA therapies delivered by the next-generation inhalers will strongly drive the market growth over the next 10 years. The biologic agents will not only reshape the market growth, but will also mark the beginning of a new era of a personalized approach to asthma treatment. The realization that asthma is a very heterogeneous disease is highly reflected in the rich assortment of these targeted therapies in the late-stage pipeline. Despite the fact that the size of the patient pool that these drugs are targeting is limited, these novel agents will start to fulfill the important unmet need for the treatment of severe asthma patients.

Further developments in the understanding of asthma pathophysiology and its various phenotypes, as well as the identification of additional biomarkers for these phenotypes, will open a large window of opportunity for drug developers to design even better personalized therapies and tackle the largest unmet needs, such as an effective therapy for severe asthmatics who do not respond to the current standards of care.

2.2 Related Reports


2.3 Upcoming Related Reports

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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.

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