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PharmaPoint

**FIBROMYALGIA –
GLOBAL DRUG FORECAST AND MARKET ANALYSIS
TO 2023**

Executive Summary

Fibromyalgia: Key Metrics in Seven Major Pharmaceutical Markets, 2013–2023	
2013 Epidemiology	
Prevalent population	23.7 million
Treated population	4.8 million
2013 Market Sales	
US	$1,479.4m
5EU	$149.7m
Japan	$151.8m
Total	**$1,780.9m**
Pipeline Assessment	
Number of drugs in Phase I–II	4
Number of first-in-class drugs	0
Most Promising Pipeline Drugs	**Peak-Year Sales**
Lyrica CR (Pfizer)	$253.1m
TNX-102 SL (Tonix Pharmceuticals)	$241.4m
DS-5565 (Daichii Sankyo)	$296.7m
TD-9855 (Theravance Biopharma)	$186.8m
Key Events (2013–2023)	**Level of Impact**
Eli Lilly's Cymbalta patent expiry in the US (2013), 5EU (2014), and Japan (2018)	↓↓↓
Pfizer's Lyrica patent expiry in the US (2018), 5EU (2014), and Japan (2022)	↓↓↓
Forest Laboratories/Actavis' Savella patent expiry in the US (2023) and France (2022)	↓↓↓
Launch of Pfizer's Lyrica CR in the US (2016)	↑↑↑
Launch of Tonix Pharmaceutical's TNX-102 SL in the US (2017)	↑↑
Launch of Daiichi Sankyo's DS-5565 in the US (2018) and 5EU (2019)	↑↑↑
Launch of Theravance Biopharma's TD-9855 in the US (2019)	↑↑
2023 Market Sales	
US	$1,641.2m
5EU	$124.2m
Japan	$147.1m
Total	**$1,912.5m**

Source: GlobalData
5EU = France, Germany, Italy, Spain, and UK; 7MM = US, 5EU, and Japan

The table presents the key metrics for fibromyalgia in the seven major pharmaceutical markets (7MM), which are the US, France, Germany, Italy, Spain, the UK, and Japan, during the forecast period from 2013–2023.

Minimal Growth is Expected for the Fibromyalgia Market from 2013 to 2023

Fibromyalgia therapeutic sales growth over the forecast period from 2013 to 2023 is expected to be minimal, at an overall Compound Annual Growth Rate (CAGR) of 0.72%. GlobalData estimated that the fibromyalgia market across the 7MM was valued at approximately $1.8 billion in 2013, the baseline year of the forecast period, and will grow to approximately $1.9 billion by 2023.

The major drivers of the growth of the fibromyalgia market during the forecast period are:

- The introduction of late-stage pipeline therapies, which consist of reformulations of the currently available treatments, and "me-too" products. These will be priced at a premium to the currently marketed therapies

- The increasing prevalent cases of fibromyalgia

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The major barriers to the growth of the fibromyalgia market during the forecast period are:

- The patent expirations of the branded drugs that are approved for the treatment of fibromyalgia in the US and Japan, and are prescribed off-label in the 5EU (France, Germany, Italy, Spain, and the UK). The entry of generic versions of these key drugs will have a negative impact on the revenues of the available branded drugs as well as the pipeline products, following their introduction

- The lack of late-stage pipeline therapies in development, particularly in the 5EU and Japan

- Concerns regarding the reduction of healthcare costs as part of government austerity measures, particularly in Europe, which will impede market growth

Figure below illustrates the global sales for fibromyalgia by region during the forecast period.

Global Fibromyalgia Sales by Region, 2013–2023

Source: GlobalData
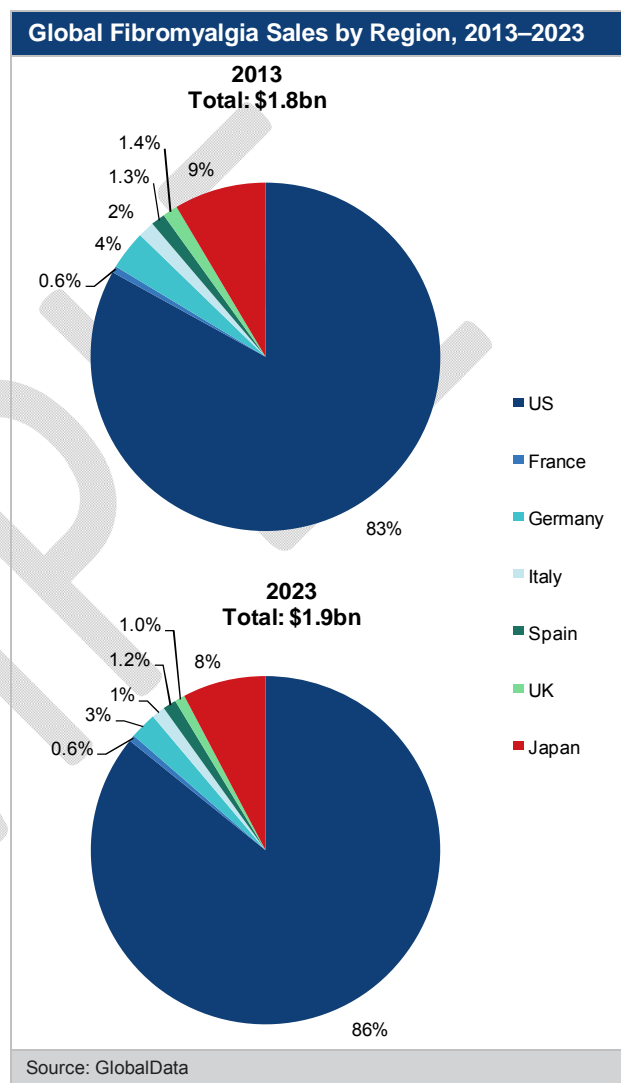
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New Drugs with Improved Efficacy, Safety, and Convenience to Expand the Fibromyalgia Pipeline

In 2007, Pfizer's Lyrica (pregabalin) was the first drug to secure approval by the Food and Drug Administration (FDA) for the treatment of fibromyalgia, and was subsequently approved in Japan in 2012. Following on from this were the FDA approvals of Eli Lilly's Cymbalta (duloxetine) in 2008, and Forest Laboratories/Actavis' Savella (milnacipran) in 2009. While none of these therapies has been approved for fibromyalgia in the 5EU, they are available for other indications, and are therefore prescribed as off-label therapies. Lyrica, Cymbalta, and Savella currently lead the fibromyalgia market in terms of sales across the 7MM. In addition to these products, there are a limited number of other treatments available, including antidepressants, anti-epileptics, opioids, and muscle relaxants, which are mainly genericized and are used off-label.

Since the launch of the three leading treatments, the fibromyalgia market has been fairly inactive in terms of the entry of new therapies. Of the leading players, only Pfizer has decided to keep its stake in the market by developing a follow-up reformulation product, which is a controlled-release (CR) version of Lyrica (Lyrica CR). Over the forecast period, the three branded products will be exposed to severe sales erosion from generic competitors. Further jeopardizing the position of these mature brands will be the launch of other late-stage pipeline

products, which are aimed at improving their efficacy, safety, and convenience profiles. Another drug reformulation in development is Tonix Pharmaceutical's TNX-102 SL, which is a lower-dose formulation of the widely-used cyclobenzaprine. A number of "me-too" therapies are also on the horizon, including Daiichi Sankyo's anti-epileptic, DS-5565, and Theravance Biopharma's antidepressant, TD-9855.

Figure below provides an analysis of the company portfolio gap in fibromyalgia during the forecast period.

Company Portfolio Gap Analysis in Fibromyalgia, 2013–2023

Source: GlobalData
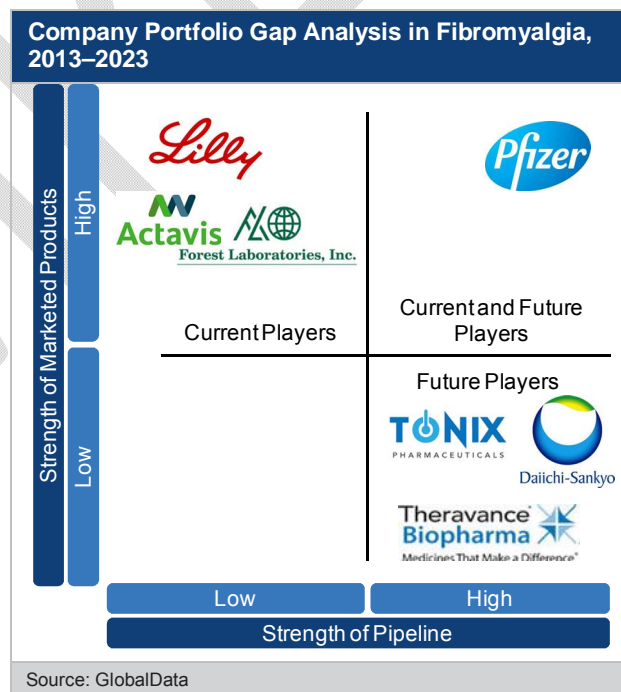
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Limited Number of Approved Products in the Fibromyalgia Market

The fibromyalgia landscape is not yet well-established, with only a handful of drugs being accessible to patients. Of these drugs, three are approved in the US, one in Japan, and none in the 5EU. Consequently, there is a high level of off-label usage of these products, particularly in the 5EU. Off-label drug usage raises reimbursement issues, particularly in the 5EU, which has created an urgent need for the approval of new fibromyalgia therapies. Furthermore, the currently approved drugs for fibromyalgia have modest efficacy and/or safety, underscoring the need for more efficacious and safer therapies that have advantages over the existing treatments.

This clinical unmet need may be addressed by the four products (reformulations and "me-too" products) that have the potential to launch by 2023; however, not all of these products will be commercialized across all the 7MM. Although they lack novelty, it is hoped that these new therapies will provide a wider range of treatments with better efficacy, safety, and convenience profiles. Therefore, the level of unmet need in the fibromyalgia market landscape during the forecast period will continue to be relatively high.

Major Opportunities for New Entrants

By the end of the forecast period in 2023, an additional four products will have been added to the fibromyalgia arena. All four will be launched in the US, only one in the 5EU, and none in Japan. Some of these products are reformulations of existing products, while others are "me-too" products. Ultimately, the companies developing these drugs are using these strategies with the aim to offer safer and more effective therapies in order to address the significant unmet need in treating fibromyalgia patients. The majority of these companies are emerging players in the fibromyalgia market, and are hoping to gain a share of the market.

Although the range of available fibromyalgia therapies is currently limited, the late-stage pipeline will not be able to greatly expand the treatment options in all 7MM. On the other hand, the early-stage clinical trials may be able address this issue by providing novel therapies. Given the low level of research activity in this disease area, there are considerable commercial opportunities available for drug developers.

Pipeline Products Will Leave the Fibromyalgia Landscape Relatively Untapped

Although the potential introduction of new therapies will narrowly increase the treatment choices for fibromyalgia, the launches of different products in different countries (four in the US, and one in the 5EU) will mean that some countries, such as the 5EU and Japan, will see minimal change in the physician adoption rate. Furthermore, these therapies are not expected to revolutionize the fibromyalgia market, given that by the time the reformulations of the existing products

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(Lyrica CR and TNX-102 SL) are launched and established, there will be inexpensive generic equivalents available. While the "me-too" therapies (DS-5565 and TD-9855) may gain a better share of the market, this will depend on the timing of their entry, such that TD-9855, being the last product to enter the US market during the forecast period, will face intense competition for patient share. Daiichi Sankyo's DS-5565 is the only product with potential commercialization in both the US (2018) and 5EU (2019) fibromyalgia markets. GlobalData forecasts that its combined sales will secure its position as the highest-selling pipeline agent by 2023, with sales reaching approximately $296.7m.

Figure below provides a competitive assessment of the late-stage pipeline agents in fibromyalgia during the forecast period.

Competitive Assessment of Late-Stage Pipeline Agents in Fibromyalgia, 2013–2023

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

Source: GlobalData
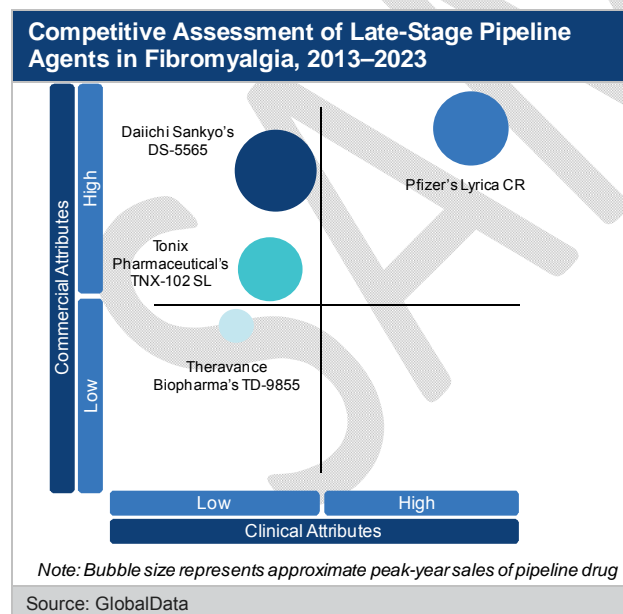
What Do Physicians Think?

Physicians interviewed by GlobalData acknowledged that more effective and safer medications are needed for the fibromyalgia patient population, as well as the fact that the approval of new drugs is a high unmet need in the 5EU.

"We need to have treatments that can address [the] different components [of the disease] more precisely. Like I said, sleep modes and so on, because they're critical [to address] for chronic pain disorder; particularly sleep is one of the most critical ones."

US Key Opinion Leader

"The available drugs are in no way perfect; they have side effects. The effect sizes, at least in the clinical trials, are very low, so there is proof that they improve—that they improve the pain, that they improve depression, sleep, and so [on], but to a small degree....So, there is a need for [more] effective drugs."

OUS Key Opinion Leader

"[If the pipeline drugs receive approval], it would be much easier [for reimbursement] — yes. That would solve a big problem."

OUS Key Opinion Leader

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"We have no authorization, [no] official authorization, for using specific drugs in fibromyalgia. We are able — allowed to use general pain treatments, and so forth."

OUS Key Opinion Leader

"I also hope [that the manufacturers of] pharmaceuticals would provide higher quality and [more] affordable drugs soon."

OUS Key Opinion Leader

In terms of new drugs for fibromyalgia, physicians had mixed views about the reformulation of Lyrica as a CR agent, and expressed concerns about the effect of Lyrica CR's pricing on their prescribing patterns.

"I would prefer the controlled-release [formulation of Lyrica] because of the pharmacokinetics…, but it's a price issue, and I'm not sure the pricing would — the benefits will make up [for] the increased cost for this [drug]."

US Key Opinion Leader

"I don't know whether I would view that [Lyrica CR] as a sort of a major advancement."

OUS Key Opinion Leader

"I think it's [Lyrica CR] a good idea. Again, pregabalin has been a time-tested drug. And yes, one daily dose will be useful in terms of [improving] compliance of the patients. [However,] it would depend on the cost."

OUS Key Opinion Leader

"I'm not sure how much better it [Lyrica CR] will be than the simple Lyrica, but it should be at least as good. It should be easier to use, maybe better-tolerated because of the slow release."

OUS Key Opinion Leader

Physicians were also unsure of the beneficial effects that another reformulation, that of cyclobenzaprine (TNX-102 SL), would have on their patients.

"Yes, I'm not so sure. I mean, I have never had any problems with low-dose cyclobenzaprine [that I would want] to prescribe this [reformulation] without a particular formulary condition. So, I'm not sure [I would prescribe it]. I'm really not."

US Key Opinion Leader

"I think, in general, it [the reformulation of cyclobenzaprine] makes it easy for folks. I don't really have a strong feeling about the route of administration. I guess I'm thinking more about its mechanism, and the mechanism makes sense."

US Key Opinion Leader

In addition, physicians said they believed that there is room for the introduction of "me-too" products to the fibromyalgia market.

"Yes, there are markets [for 'me-too' drugs], particularly if they have slightly different effects and different side effects compared to Lyrica."

US Key Opinion Leader

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"If this was an alpha-2-delta ligand that either has fewer side effects than pregabalin or has a higher effect size in treating pain and sleep disorder—yes, there would be room [for it in the market]."

OUS Key Opinion Leader

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2 Introduction

2.1 Catalyst

The fibromyalgia market is relatively new and is not yet well- established. Three drugs currently dominate the sales across the seven major markets (7MM) (US, France, Germany, Italy, Spain, UK, and Japan), and form the core treatment options — Lyrica (pregabalin), Cymbalta (duloxetine), and Savella (milnacipran) — which are all approved in the US, while only Lyrica is approved in Japan. Since these drugs are also available in the 5EU (France, Germany, Italy, Spain, and the UK) for other indications, they are prescribed as off-label therapies for fibromyalgia. Apart from these drugs, a handful of other genericized products are also used off-label, including antidepressants, anti-epileptics, opioids, and muscle relaxants. Since the launch of Lyrica, Cymbalta, and Savella, the fibromyalgia market has remained static in terms of the entry of new therapies. Although the currently available products can provide an effective treatment regimen, there are ample opportunities for the development of new treatment choices that can expand the medications that are available to patients and provide improvements in efficacy, safety, and compliance. By 2023, the market will have entered a new phase with the patent expiries of the currently leading drugs and the introduction of four potential promising late-stage pipeline products: a reformulation of Lyrica, called Lyrica CR; a reformulation of cyclobenzaprine, called TNX-102 SL; an anti-epileptic, DS-5565; and an antidepressant, TD-9855. These new products will help drive market growth and offset some of the effects of the patent expiries of the leading brands during the forecast period.

2.2 Related Reports

- GlobalData (2015). EpiCast Report: Fibromyalgia – Epidemiology Forecast to 2023, May 2015, GDHCER080-15

- GlobalData (2015). Insomnia – Global Drug Forecast and Market Analysis to 2023, February 2015, GDHC107PIDR

- GlobalData (2014). Neuropathic Pain – Global Drug Forecast and Market Analysis to 2023, April 2014, GDHC003PIDR

- GlobalData (2014). Major Depressive Disorder – Global Drug Forecast and Market Analysis to 2023, April 2014, GDHC003PIDR

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2.3 Upcoming Related Reports

- GlobalData (2015). General Anxiety Disorder – Global Drug Forecast and Market Analysis to 2024

Appendix

11.8   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.

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