PharmaPoint

Lyrica (Epilepsy) – Forecast and Market Analysis to 2022

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GlobalData

Lyrica (pregabalin) Key Metrics in the Nine Major Pharmaceutical Markets	
2012 Market Sales	
US - Lyrica	$33.1m
US – pregabalin generics	$0.0m
5EU - Lyrica	$58.6m
5EU – pregabalin generics	$0.0m
Japan - Lyrica	$26.6m
Japan – pregabalin generics	$0.0m
India and China - Lyrica	$2.7m
India and China – pregabalin generics	$0.3m
Total	**$121.2m**
Key Events (2012–2022)	**Level of Impact**
Patent expiration in the US/EU in 2018/2013	↓↓↓
Entry of newer and efficacious AED's into the market	↓↓
2022 Market Sales	
US - Lyrica	$6.7m
US – pregabalin generics	$5.3m
5EU - Lyrica	$17.4m
5EU – pregabalin generics	$20.7m
Japan - Lyrica	$29.0m
Japan – pregabalin generics	$0.0m
India and China - Lyrica	$4.1m
India and China – pregabalin generics	$0.4m
Total	**$83.5m**
Source: GlobalData	

Sales of Lyrica (pregabalin) in the Global Epilepsy Market

Sales of Lyrica and pregabalin generics are expected to decrease from $121.2m in 2012 to $83.5m in 2022 at a negative compound annual growth rate (CAGR) of 3.7%.

Major drivers of Lyrica and pregabalin generics sales over this forecast period will include:

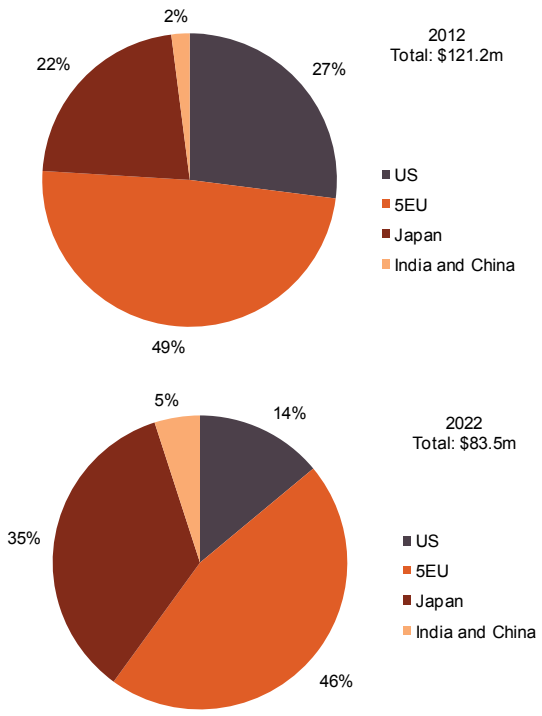
- Benefit from Pfizer's historical strength in marketing

Major barriers of Lyrica and pregabalin generics sales over this forecast period will include:

- Patent expiration in the US in 2018 and EU in 2013
- Entry of newer and more efficacious anti-epileptic drugs (AEDs) into the market.

- The below figure illustrates the sales for Lyrica and pregabalin generics in the seven major markets (US, 5EU, and Japan) and India and China during the forecast period.

Lyrica (pregabalin) Sales for Epilepsy by Region, 2012–2022



Source: GlobalData

Note: Sales figures shown are combined totals for Lyrica and pregabalin generics in each region

What Do the Physicians Think?

- Overall physicians expressed a need for more AEDs and favorable opinions of those in pipeline development.

"Among intractable epilepsy patients, any drug that helps treat an additional segment of them will be used, and because we don't have a basis for using one or another, if it's attractive, it will be used more."

[US] key opinion leader, November 2012

"Brivaracetam is an interesting concept because it's supposed to be "Super Keppra," the follow-on from Keppra. The Phase II studies were very promising, but I think the Phase III were a bit of a disappointment; there might be some methodological issues in terms of some patient selection issues that they have come across. But I think that's one of the more interesting of the new drugs that I'm really wanting to see in clinical practice, particularly if, as the Phase II studies suggested, that some patients who haven't responded to levetiracetam are responders to this drug. So, I think that that's going to be one drug to watch."

[EU] key opinion leader, November 2012

- However, with more than 20 existing AEDs, new ones currently entering the market, and more to come in the future, physicians are unsure of how all these drugs will fit in the treatment landscape, and lack a way to differentiate between them, particularly in terms of efficacy. Also, there are no predictive tools that would guide the choice of treatment from patient to patient.

"We have about 25 AEDs for focal (partial) epilepsy, but which one to choose? Upfront, it's tough to say because we don't have any tests to say, 'this is the lamotrigine patient and this is the levetiracetam patient'."

[EU] key opinion leader, October 2012

- In the future, physicians would like to see distinct new classes of AEDs that target different mechanisms, rather than more of the same drugs that currently dominate the market.

"Do we need the sixth or seventh sodium blocker? Do we need the tenth calcium channel modulator? I think we need new drugs, but more than that, I think we need new classes of drugs which address things differently."

[EU] key opinion leader, October 2012

"If you ask me, my wish list would be disease-modifying drugs that you could use once or twice, once you determine that the person has a tendency for unprovoked seizures, and that would stop the process."

[EU] key opinion leader, November 2012

- Physicians believe that a better understanding of the disease mechanisms in epilepsy will be crucial to developing more effective treatments.

"I would not discourage the development of drugs, but I think we need to change the paradigm. But tochange the paradigm, we need to understand things better, so we need a lot of basic research."

[EU] key opinion leader, November 2012

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2 Introduction

2.1 Catalyst

The epilepsy market has been very dynamic since 2008, with several of the market-leading drugs losing patent protection and experiencing steep sales declines, particularly in the United States, including:

- UCB's Keppra (levetiracetam) (US patent expiry in 2008)
- GlaxoSmithKline's (GSK's) Lamictal (lamotrigine) (US patent expiry in 2008)

However, the decline in global sales of these products was buffered by their recent introduction into the Japanese market, as well as by a slower-than-expected uptake of generics for Keppra in Europe. Both of these former blockbuster drugs have also since been introduced to the market as extended-release formulations that hold exclusivity from generic competition during the forecast period. Levetiracetam (Keppra, Keppra XR, and generics) and lamotrigine (Lamictal, Lamictal XR, and generics) are predicted to remain key players in the clinical arena through the end of the forecast period in 2022, but will face stiff competition in market share from multiple new market entrants.

Since 2008, the epilepsy drug market has seen the approval and market entry of several major products, including:

- Eisai's Banzel/Inovelon (rufinamide)
- UCB's Vimpat (lacosamide)

And within the past two years:

- GSK's Trobalt/Potiga (retigabine/ezogabine) – launched in the EU in 2012; approved in the US in 2011
- Eisai's Fycompa (perampanel) – launched in the EU in 2012; approved in the US in October 2012

Of these new market entrants, Vimpat has experienced the most rapid uptake, providing competition for other sodium channel blockers, which represent the mainstay of epilepsy treatments in terms of mechanism of action (MOA). However, it is set to face patent expiry as soon as 2014, allowing the emergence of lacosamide generics, which will erode Vimpat sales. However, lacosamide as a whole (both Vimpat and generics) will continue gaining in market share during the forecast period, even after patent expiration.

Trobalt/Potiga, which is a potassium channel modulator; and Fycompa, which is an aminohydroxymethylisoxazole propionic acid (AMPA) receptor antagonist, are both new market entrants with novel first-in-class MOAs that offer patients, especially refractory patients, an alternative to the sodium and calcium channel blockers that have dominated the epilepsy treatment market in recent decades. Their safety and efficacy profiles, once tested in clinical practice, will determine their clinical position in the future treatment landscape and their significance as competitive market players.

The drivers for market growth will include the introduction of the newer drugs into the Asian market, particularly in Japan

The drivers for market growth will include the introduction of the newer drugs into the Asian market, particularly in Japan. India and China will also contribute to market growth as their populations obtain increasing access to epilepsy pharmacotherapy. The challenges will be the crowded marketplace, which currently comprises more than 20 antiepileptic drugs (AEDs), with individual drugs struggling to distinguish themselves, particularly in terms of efficacy.

2.2 Related Reports

- GlobalData (2013). Epilepsy – United States Drug Forecast and Market Analysis to 2022. GDHC1038CFR.
- GlobalData (2013). Epilepsy – United Kingdom Drug Forecast and Market Analysis to 2022. GDHC1043CFR.
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- GlobalData (2013). Keppra (Epilepsy) – Forecast and Market Analysis to 2022. GDHC1061DFR.
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- GlobalData (2013). VX-765 (Epilepsy) – Forecast and Market Analysis to 2022. GDHC1072DFR.
- GlobalData (2013). Epilepsy – Current and Future Players. GDHC1005FPR

7.8 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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