I-MAK FACT CHECK

Pfizer

Calling out I-MAK Misinformation

A strong system of intellectual property (IP) protection provides the incentives necessary to achieve sustainable scientific advancement. The laws governing the protection of IP are essential to fostering innovation and any proposed changes based on misinformation puts into jeopardy these critical incentives. Below are some of the inaccurate statements posted by the Initiative for Medicines, Access, and Knowledge (I-MAK), regarding Lyrica® (pregabalin), with the corresponding truth.

I·MAK

No generic Lyrica approved or "on the market".[1]

Source: I-MAK's Lyrica website, available at https://www.i-mak.org/lyrica/, accessed on July 12, 2023.

FALSE

FACT

In July 2019, the FDA approved **9 generic** versions of Lyrica.[2]

FDA NEWS RELEASE

FDA approves first generics of Lyrica

For Immediate Release: July 22, 2019

https://www.fda.gov/news-events/press-announcements/fda-approves-first-generics-lyrica

I·MAK

"The main compound patent [of Lyrica] expired in 2013, but secondary patents … gave Pfizer six additional years of patent protection…"[3]

Source: I-MAK's Lyrica "Fact Sheet," available at https://www.i-mak.org/wp-content/uploads/2020/11/LyricaFactSheet_85x11.pdf

FALSE

FACT

The main compound patent of Lyrica expired on **June 30, 2019** and was not extended 6 years by "secondary" patents.[4]

I·MAK

"Lyrica was set to go off-patent at the end of 2018... But Pfizer had filed and was issued patents for an additional twenty year period on a controlled-release formulation of the product (Lyrica CR). ...With these patents, Pfizer's hold on the market will remain..."[5]

Source: I-MAK, *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices,* pp. 9-10, *available at* https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf

FALSE

FACT

Lyrica and Lyrica CR are 2 different products. The availability of a Controlled Release option, Lyrica CR, did not change the fact that generic versions of original Lyrica were available as soon as it went off-patent in 2019.[6]

I·MAK

Lyrica had "**42 years** of monopoly from granted patents".[7]

Source: I-MAK's Lyrica website, available at https://www.i-mak.org/lyrica/, accessed on July 12,2023.

FALSE

FACT

Lyrica had market exclusivity for **14.5 years** (2004-2019), and during that time it faced competition from several medicines that treated the same indications.[8]

SOURCES

1.

https://www.i-mak.org/lyrica/

2.

FACT

FDA News Release: FDA Approved First Generics of Lyrica (July 2019)

3.

https://www.i-mak.org/wp-content/uploads/2020/11/LyricaFactSheet_85x11.pdf

4.

FACT

USPTO Website: Applications for patent term extension and patent terms extended under 35 U.S.C. § 156 (Lyrica Patent No. 6,197,819), last visited Aug. 1, 2023; and Pfizer Press Release: Pfizer Receives Six Months Pediatric Exclusivity for Lyrica (pregabalin), Nov. 2018, available here.

5.

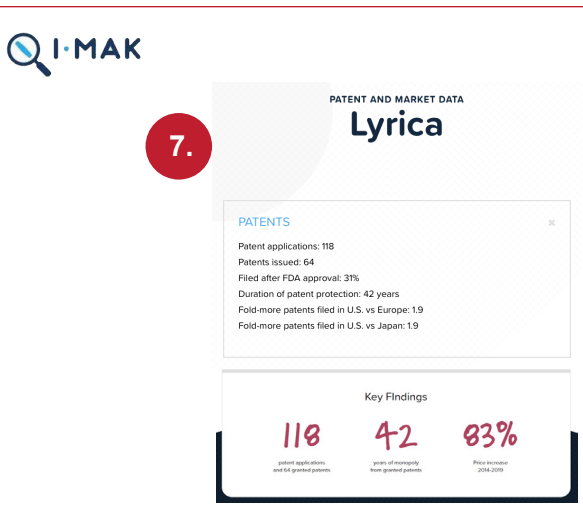
https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf

FACT

6.

FDA News Release: FDA Approved First Generics of Lyrica (July 2019); see also, for example, Amneal Pharmaceuticals, Inc. - Amneal Announces Launch of Generic Lyrica® (22 July 2019), Dr. Reddy's Laboratories announces the launch of Pregabalin Capsules in the U.S. Market | Business Wire (30 July 2019), Rising Pharmaceuticals Announces the U.S. Launch of a Generic Version of Pregabalin Capsules | Business Wire (19 July 2019).

7.



https://www.i-mak.org/lyrica/

FACT

8.

FDA News Release: FDA Approved First Generics of Lyrica (July 2019); Lyrica is indicated for Neuropathic pain associated with diabetic peripheral neuropathy (DPN); Postherpetic neuralgia (PHN); Adjunctive therapy for the treatment of partial onset seizures in patients 4 years of age and older; Fibromyalgia; Neuropathic pain associated with spinal cord injury, *see* Highlights of Prescribing Information (Lyrica); *see also* Highlights of Prescribing Information (Cymbalta), initial U.S. approval in 2004, indicated for, in part, diabetic peripheral neuropathy (DPN) and fibromyalgia; and Highlights of Prescribing Information (Qutenza), initial U.S. approval in 2009, indicated for the management of neuropathic pain associated with postherpetic neuralgia (PHN).

As of December 5, 2023, I-MAK has corrected it's website to reflect the availability of generic versions of Lyrica; however, the remaining inaccurate information has not been addressed by the organization.