



Raising Awareness of Fibromyalgia Syndrome

Press release 23 April 2009

**Second blow for millions of Fibromyalgia Syndrome sufferers
as European Medicines Agency rejects another drug**

European sufferers of a painful chronic condition called Fibromyalgia Syndrome have received a second severe blow with the news that Pfizer's Lyrica has been refused marketing approval as a treatment for the condition.

This comes after the Committee for Medicinal Products for Human Use (CHMP) at the European Medicines Agency (EMA) also rejected a similar application for the drug Cymbalta (Duloxetine hydrochloride) back in October.

There are currently no specifically approved treatments for Fibromyalgia Syndrome (Fibro) in Europe.

Lyrica (generic name Pregabalin) was the first drug to get FDA approval in the USA for the treatment of Fibro, way back in 2007. Since then two other drugs – Cymbalta and Savella – have also been approved by the FDA as treatments for Fibro in the USA.

Lyrica has been an EMA authorised treatment since July 2004 and has marketing approval as a treatment for neuropathic pain (pain from nerve damage), epilepsy in patients who have partial seizures and generalised anxiety disorder.

Pfizer applied for a change to the marketing authorisation so that Lyrica could be officially indicated as a treatment for Fibromyalgia Syndrome and marketed for this purpose. The CHMP refused this change, citing as reasons that they were concerned that the benefits of Lyrica in treating Fibro had not been shown either in the short or long term and that they were concerned that the safety and effectiveness of Lyrica had not been shown in patients from the EU.

FibroAction founder Lindsey Middlemiss commented today:

"FibroAction are disappointed to learn of the refusal by the CHMP to allow the clinical indications of Lyrica to be extended to include Fibromyalgia Syndrome. The millions of people with Fibromyalgia Syndrome across Europe desperately need the help that a properly approved drug would bring.

FibroAction is a charity registered in England and Wales (registered charity number 1125957)

FibroAction (company number 6662336) is a company registered in England and Wales

whose registered office is at 46 The Nightingales, Newbury RG14 7UJ.



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It is concerning that the CHMP are saying that they will not look at data gathered from outside the EU. This insular view seems extraordinary given that Pfizer presented them with data concerning the use of Lyrica as a treatment for Fibro in over 3,000 patients. Most drug trials for Fibro are done in the US as the climate for research into this complex condition is better over there. Does this mean that no drugs will be able to get approval in the EU as treatments for Fibro?"

This second negative response from the CHMP is likely to perpetuate the myth that because no drugs have marketing approval in the EU for Fibromyalgia Syndrome, there are no treatments available for the condition. Because Pregabalin already has EMEA authorisation, it is available on prescription if a doctor considers that it is an appropriate treatment. This is also true of many other treatments for Fibro, some of which are already widely used.

Fibro is a debilitating, chronic condition whose main symptoms are widespread chronic pain, hypersensitivity to pain and chronic fatigue. Despite the high numbers of sufferers (between 1.2 and 2.7 million people in the UK alone), awareness of the condition, and the knowledge and treatments available for it, is very low, even amongst medical professionals, and many patients are left to suffer alone.

For more information see www.fibroaction.org

ENDS



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Further information:

- **Fibromyalgia Syndrome (Fibro)** is also referred to as Fibromyalgia, FMS and FM. Fibromyalgia is pronounced Fy-bro-my-AL-gee-ah. FibroAction prefer the abbreviation, Fibro, as it is easy to pronounce, spell and remember.
- The estimate of 1.2 and 2.7 million people with Fibro in the UK is based on internationally recognised prevalence statistics of 2-4.5% of the population. The prevalence of Fibro in the UK has historically been hugely under reported.
- FibroAction (registered charity number 1125957) was set up in April 2008.
- FibroAction is an incorporated charity and as such is also a company registered in England and Wales (company number 6662336).
- FibroAction aims to educate people about Fibromyalgia Syndrome (Fibro), including people with Fibro, healthcare professionals and the general public, as well as providing support to patients.