



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

20 February 2014  
EMA/174304/2014  
Committee for Medicinal Products for Human Use (CHMP)

## Assessment report

### **Pregabalin Pfizer**

International non-proprietary name: Pregabalin

Procedure No. EMEA/H/C/003880/0000

### **Note**

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.



## Table of contents

<b>1. Background information on the procedure</b> .....	<b>4</b>
1.1. Submission of the dossier.....	4
1.2. Manufacturers.....	5
1.3. Steps taken for the assessment of the product .....	5
<b>2. Scientific discussion</b> .....	<b>5</b>
2.1. Introduction .....	5
2.2. Quality aspects .....	6
2.3. Non-clinical aspects .....	6
2.4. Ecotoxicity/environmental risk assessment .....	6
2.5. Clinical aspects .....	6
2.6. Pharmacovigilance.....	7
2.7. Risk Management Plan .....	7
2.8. User consultation .....	7
<b>3. Benefit-Risk Balance</b> .....	<b>7</b>
<b>4. Recommendations</b> .....	<b>7</b>

## List of abbreviations

CHMP	Committee for Medicinal Products for Human Use
EMA	European Medicines Agency
GAD	Generalised Anxiety Disorder
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
RMP	Risk Management Plan
PSUR	Periodic Safety Update Report

# 1. Background information on the procedure

## **1.1. Submission of the dossier**

The applicant Pfizer Limited submitted on 29 November 2013 an application for Marketing Authorisation (MA) to the European Medicines Agency (EMA) for Pregabalin Pfizer, through the centralised procedure. The eligibility to the centralised procedure was agreed upon by the EMA/CHMP on 24 October 2013.

The applicant applied for the following indications:

- Neuropathic pain

Pregabalin Pfizer is indicated for the treatment of peripheral and central neuropathic pain in adults.

- Epilepsy

Pregabalin Pfizer is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation.

- Generalised Anxiety Disorder

Pregabalin Pfizer is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.

### **The legal basis for this application refers to:**

Article 10(c) of Directive 2001/83/EC – relating to informed consent from a marketing authorisation holder for an authorised medicinal product.

The application submitted is composed of Module 1 administrative information with a letter from a MAH Pfizer Limited allowing the cross reference to relevant quality, non-clinical and clinical data.

This application is submitted as a multiple of Lyrica authorised on 06 July 2004 in accordance with Article 82.1 of Regulation (EC) No 726/2004.

### ***Information on Paediatric requirements***

Not applicable.

### ***Information relating to orphan market exclusivity***

### ***Similarity***

Not applicable.

### ***Scientific advice***

The applicant did not seek scientific advice at the CHMP.

### ***Licensing status***

Lyrica was given a Union marketing authorisation on 06 July 2004.

## **1.2. Manufacturers**

### **Manufacturer responsible for batch release**

Pfizer Manufacturing Deutschland GmbH  
Betriebsstätte Freiburg  
Mooswaldallee 1  
D-79090 Freiburg  
Germany

## **1.3. Steps taken for the assessment of the product**

The Rapporteur and Co-Rapporteur appointed by the CHMP were:

Rapporteur: Johann Lodewijk Hillege

Co-Rapporteur: Bruno Sepodes

- The application was received by the EMA on 29 November 2013.
- The procedure started on 22 December 2013.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 30 January 2014. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 30 January 2014.
- The joint Assessment Report has been circulated to all CHMP members on 17 February 2014.
- During the meeting on 20 February 2014, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to Pregabalin Pfizer.

## **2. Scientific discussion**

### **2.1. Introduction**

This application has been submitted as an informed consent application in accordance with Article 10c of Directive 2001/83/EC as amended.

Accordingly, the MAH of the reference product, Lyrica has provided consent to allow access to

Module 2 to Module 5 of the initial dossier and any subsequent post-marketing procedures submitted, assessed and approved. The complete assessment history of Lyrica is available on the EMA website.

The proposed indication for Pregabalin Pfizer is the same as the approved indication for the reference product.

Pregabalin Pfizer application, as opposed to Lyrica, does not include oral solution.

## ***2.2. Quality aspects***

Since this application is an informed consent of the Lyrica application, the quality data in support of the Pregabalin Pfizer application are identical to the up-to-date quality data of the Lyrica dossier, which has been assessed and approved (including all post-marketing procedures).

## ***2.3. Non-clinical aspects***

Since this application is an informed consent of the Lyrica application, the non-clinical data in support of the Pregabalin Pfizer application are identical to the up-to-date non-clinical data of the Lyrica dossier, which has been assessed and approved (including all post-marketing procedures).

## ***2.4. Ecotoxicity/environmental risk assessment***

Since this application is an informed consent application, the medicinal product subject to this application is intended to be administered at comparable dose levels and for indications that were already approved in the Union for Lyrica. Based on the assumption that Pregabalin Pfizer hard capsules are intended to substitute for identical products on the market, the approval of the product does not result in an increase of the total quantity of the active ingredients released into the environment. This justification is considered acceptable and in accordance with the Guideline on the environmental risk assessment of medicinal products for human uses (EMA/CHMP/SWP/4447/00).

## ***2.5. Clinical aspects***

Since this application is an informed consent of the Lyrica application, the clinical data in support of the Pregabalin Pfizer application are identical to the up-to-date clinical data of the Lyrica dossier, which have been assessed and approved (including all post-marketing procedures). No additional clinical studies have been submitted.

## **2.6. Pharmacovigilance**

### **Detailed description of the pharmacovigilance system**

The CHMP considered that the Pharmacovigilance system as described by the applicant fulfils the legislative requirements.

## **2.7. Risk Management Plan**

The submitted Risk Management Plan (version 10), is identical to the latest reviewed RMP for Lyrica (version 9.1). Therefore, no additional assessment has been necessary.

The CHMP, having considered the data submitted in the application, is of the opinion that no additional risk minimisation activities are required beyond those included in the product information.

## **2.8. User consultation**

A justification for not performing a full user consultation with target patient groups on the package leaflet has been submitted by the applicant and has been found acceptable for the following reason:

The Patient Information Leaflet for the reference product, Lyrica, was the subject of a user testing study, which was completed successfully in 2008. A copy of the final readability report for Lyrica has been provided.

As the Patient Information Leaflet for Pregabalin Pfizer is identical (with the exception of the product name) to that of the reference product, the user testing of the Patient Information Leaflet for the reference product can be taken to apply equally to Pregabalin Pfizer.

## **3. Benefit-Risk Balance**

Since this application is an informed consent of the Lyrica application, the CHMP considered that the benefit/risk ratio for Pregabalin Pfizer is identical to that of Lyrica.

## **4. Recommendations**

### ***Outcome***

Based on the CHMP review of data on quality, safety and efficacy, the CHMP considers by consensus that the risk-benefit balance of Pregabalin Pfizer in the treatment of epilepsy, neuropathic pain and Generalised Anxiety Disorder is favourable and therefore recommends the granting of the marketing authorisation subject to the following conditions:

***Conditions or restrictions regarding supply and use***

Medicinal product subject to medical prescription.

***Conditions and requirements of the Marketing Authorisation***

- **Periodic Safety Update Reports**

The marketing authorisation holder shall submit periodic safety update reports for this product in accordance with the requirements set out in the list of Union reference dates (EURD list) ) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal.

***Conditions or restrictions with regard to the safe and effective use of the medicinal product***

- **Risk Management Plan (RMP)**

The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the Marketing Authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

If the dates for submission of a PSUR and the update of a RMP coincide, they can be submitted at the same time.

***Conditions or restrictions with regard to the safe and effective use of the medicinal product to be implemented by the Member States.***

Not applicable.