An Evaluation of the Misuse and Abuse of Pregabalin using RADARS® System Programs in the United States and the European Union – 2019

First published: 17/06/2020

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/35868

EU PAS number

EUPAS35867

Study ID

35868

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] United States

Study description

The primary objectives of this evaluation:1) Summarize misuse and abuse data for pregabalin and each comparator within each country for each data source2) Summarize patterns of polysubstance use of drugs for pregabalin and each comparator to assess frequency of joint use of drugs within each country, data source, and time period of interest

Study status

Planned

Research institutions and networks

Institutions

RADARS® System

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Institution

Rocky Mountain Poison & Drug Safety,Denver Health and Hospital Authority

Contact details

Study institution contact

Walker Chris

Study contact

chris.walker@pfizer.com

Primary lead investigator

Walker Chris

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/10/2019

Study start date

Planned: 15/03/2021

Data analysis start date

Planned: 30/03/2020

Date of final study report

Planned: 31/08/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A0081366 Pregabalin Study Protocol V1 08JUNE2020.pdf(379.11 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

A0081366

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

1) Summarize misuse and abuse data for pregabalin and each comparator within each country for each data source

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N03AX16) pregabalin

pregabalin

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

60000

Study design details

Outcomes

Summarize misuse and abuse data for pregabalin and each comparator within each country for each data source, 2) Summarize patterns of polysubstance use of drugs for pregabalin and each comparator to assess frequency of joint use of drugs within each country, data source, and time period of interest

Data analysis plan

The market authorization holder will estimate rates or prevalence estimates for each of the outcomes (non-medical use, misuse, abuse, intentional exposures) by program for pregabalin and comparators within each country using descriptive statistics.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Summarize misuse and abuse data for pregabalin and each comparator within each country for each data source

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No