

# Prescribing of zolpidem in the primary care setting in France, Germany and the UK during 2012. (Prescribing of zolpidem in IMS Germany/France/UK)

**First published:** 07/11/2013

**Last updated:** 19/07/2016

Study

Finalised

## Administrative details

### EU PAS number

EUPAS5106

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### Study ID

14148

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### DARWIN EU® study

No

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### Study countries

 France

 Germany

 United Kingdom

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## Study description

The present study aims to describe the extent and patterns of prescription of zolpidem in the primary care setting in three large EU countries in 2012 in line with the scope of an Article 31 referral. This has been done using the EMA's in-house IMS Health databases. The study includes patients from UK, Germany and France and for these patients the prevalence of zolpidem use in 2012 is stratified by gender and age. The prevalence of low strength (5 mg) and high strength (10 mg) prescribing and by different daily doses prescribed is also reported. In addition new users in 2011 has been characterised and the percentage starting at low/high strength and different daily doses is reported. These new users are followed up and the extent of use 3-6 months after the first prescription is studied.

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### European Medicines Agency (EMA)

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Institution

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Kristian Svendsen

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 16/07/2013

Actual: 16/07/2013

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**Study start date**

Planned: 02/09/2013

Actual: 02/09/2013

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**Data analysis start date**

Planned: 09/09/2013

Actual: 09/09/2013

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**Date of interim report, if expected**

Planned: 30/09/2013

Actual: 30/09/2013

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**Date of final study report**

Planned: 25/10/2013

Actual: 25/10/2013

## Sources of funding

- Other

## More details on funding

There was no specific funding for the project which was conducted using EMA resources.

## Regulatory

**Was the study required by a regulatory body?**

Yes

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

Not applicable

## Methodological aspects

Study type

Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

the prevalence of zolpidem use in 2012 stratified by gender, age, strength and prescribed daily dose. In addition new users in 2011 has been characterised and the percentage and these new users are followed up after 3-6 months

## Study drug and medical condition

**Study drug International non-proprietary name (INN) or common name**

ZOLPIDEM

## Population studied

**Short description of the study population**

All patients receiving a prescription of zolpidem recorded in the IMS Disease Analyser

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**Age groups**

- Term newborn infants (0 - 27 days)
  - Infants and toddlers (28 days - 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - 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)
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### **Estimated number of subjects**

18000000

## Study design details

### **Outcomes**

Prevalence of prescribing in 2012-Stratified on age and gender-Stratified on prescribed strength-Stratified on the prescribed daily doseIncident use in 2011-stratified as above-Percentage having prescribed zolpidem 3-6 months after the initial prescription

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### **Data analysis plan**

Descriptive study design. New user have been defined as patients with no prescription of the drug in question in the previous 12 months before first prescription in the calendar year in question (2011).Age grouping done to isolate elderly aged 65-79 and the very old aged 80 and older. The drug in question will be well captured in primary care databases (internal validity good) and the databases are considered representative for their respective countries (external validity good).

## Documents

## Study results

[zolpidem report final with annex.pdf](#) (833.29 KB)

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## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data source(s)

Disease Analyzer - OMOP

IQVIA Disease Analyzer Germany

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### Data source(s), other

IMS Disease Analyzer United Kingdom

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### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No