# Drug utilization study of dexamfetamine in European countries (DUS of dexamfetamine)

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# Administrative details

PURI https://redirect.ema.europa.eu/resource/43102
EU PAS number
EUPAS7778
Study ID
43102
DARWIN EU® study
No
Study countries
Denmark

Finland	
Germany	
Ireland	
Netherlands	
Norway	
Spain	
Sweden	
United Kingdom	

# **Study description**

This is a retrospective database analysis to provide data on drug utilization on an annual basis for up to 5 years. Objectives are • to describe how dexamfetamine is prescribed in Europe • to evaluate off-label use in Europe • to collect data on abuse, misuse, overdose, diversion and dependence related to dexamfetamine

### **Study status**

Finalised

# Research institutions and networks

# Institutions



# Contact details

# **Study institution contact**

Dieter Fritsch

Study contact

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# **Primary lead investigator**

Dieter Fritsch

**Primary lead investigator** 

# Study timelines

# Date when funding contract was signed

Planned: 31/10/2014

Actual: 27/04/2016

# Study start date

Planned: 30/09/2015

Actual: 01/05/2016

# Data analysis start date

Planned: 01/06/2016

Actual: 01/06/2016

### Date of interim report, if expected

Planned: 13/11/2018

Actual: 13/11/2018

### Date of final study report

Planned: 31/12/2020

Actual: 14/12/2020

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

Medice

# Study protocol

Dexamfetamine DUS Protocol V2-1 08-09-2015 privacy.pdf(500.86 KB)

# Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

# Methodological aspects

Study type

Study type list

### **Study topic:**

Human medicinal product

### Study type:

Non-interventional study

### Scope of the study:

Drug utilisation

### **Data collection methods:**

Secondary use of data

### Main study objective:

• to describe how dexamfetamine is prescribed in Europe • to evaluate off-label use in Europe • to collect data on abuse, misuse, overdose, diversion and dependence related to dexamfetamine

# Study drug and medical condition

### **Anatomical Therapeutic Chemical (ATC) code**

(N06BA02) dexamfetamine dexamfetamine

# Population studied

### Short description of the study population

For the DUS patients who have been prescribed dexamfetamine at least once during the study period.

A: Identification of reporting sources

Inclusion criteria

- European countries, Denmark, Germany, Netherlands, Norway, UK
- •Review, surveys, chart review, medical records, monitoring,
- Monitoring centers, databases, poison control centers
- Stimulants
- •Abuse, misuse, overdose, diversion and dependence, problem drug use, nonmedical drug use, addiction

Exclusion criteria

- Centers and databases from outside of EU
- Testing methods

B: Identification of information on abuse, misuse, overdose, diversion and dependence associated with dexamfetamine/lisdexamfetamine Inclusion criteria

- European countries, Denmark, Germany, Netherlands, Norway, UK
- •Literature review, surveys, interviews, chart review, medical records, monitoring
- •Dexamphetamine, dextroamphetamine, Dexamfetamine, dextroamfetamine, lisdexamfetamine, lisdexamphetamine, Attentin, Dexamed, Dexedrine, other trade names for dexamfetamine, Elvanse, Vyvanse
- •Abuse, misuse, overdose, diversion and dependence, problem drug use, nonmedical use, addiction

Exclusion criteria

- Reports from outside the EU
- •Only information on methylphenidate, only information on stimulants and amphetamine in general
- •Reports which only describe use of substances where the use of an authorised medicinal product can be excluded (e.g. different galenic formulations)
- Substance use disorder

### Testing methods

### Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 - 27 days)

Infants and toddlers (28 days - 23 months)

Children (2 to < 12 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)

### **Estimated number of subjects**

500

# Study design details

### Data analysis plan

For the DUS, the analysis of databases will be done descriptively. A detailed statistical analysis plan (SAP) will be agreed on prior to the start of the analysis. Information from drug monitoring centers and poison control centers, other databases, literature and internet searches will be summarized per reporting period and compared with the findings from previous reports.

# **Documents**

### Study results

Dexamfetamine DUS Executive Summary on Final Report V1 02-11-2020.pdf (118.77 KB)

### Study, other information

Dexamfetamine DUS Abstract of Final Report DAT V2 25-05-2021 privacy.pdf (110.87 KB)

Dexamfetamine DUS Abstract of Final Report LIT V2 28-05-2021 privacy.pdf (74.37 KB)

# Data management

# Data sources

### Data source(s)

Danish registries (access/analysis)

### Data source(s), other

Deutsche Beobachtungsstelle für Drogen und Drogensucht (DBDD) Germany, TRIMBOS Netherlands, SIRIUS Norway, Department of Health United Kingdom

# **Data sources (types)**

Drug registry

# Use of a Common Data Model (CDM)

# **CDM** mapping

No

# Data quality specifications

# Unknown Check completeness Unknown

# **Check stability**

**Check conformance** 

Unknown

# **Check logical consistency**

Unknown

# Data characterisation

### **Data characterisation conducted**

No