# A Post-Authorisation Safety Study (PASS) to Assess the Effectiveness of the Risk Minimisation Measures of Domperidone – Physician Survey

**First published:** 11/11/2016

**Last updated:** 02/04/2024

Study Finalised

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/19694

**EU PAS number**

EUPAS16095

**Study ID**

19694

**DARWIN EU® study**

No

**Study countries**

- [ ] Belgium
- [ ] France
- [ ] Germany
- [ ] Spain
- [ ] United Kingdom

**Study description**

Multi-national, non-interventional cross-sectional study to characterise prescriber's knowledge, understanding and extent of awareness regarding the new safety information for domperidone following the change in SmPC and the distribution of DHPC.Data will be collected through a physician survey to be administered in a group of prescribers, across 5 EU countries with varying prescription volumes: Belgium, France, Germany, Spain and United Kingdom.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Adelphi Real World

- [ ] United Kingdom

**First published:** 22/07/2016

**Last updated:** 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

# Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Taylor-Stokes Gavin

Primary lead investigator

# Study timelines

**Date when funding contract was signed**

Actual: 31/10/2016

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**Study start date**

Planned: 04/01/2017

Actual: 19/01/2017

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**Data analysis start date**

Planned: 01/04/2017

Actual: 03/04/2017

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**Date of final study report**

Planned: 30/06/2017

Actual: 27/06/2017

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Domperidone DUS Collaboration Group

## Study protocol

PASS Study_DUS_Physician Survey_Domperidone_JNJ-17296812-AAA_0005_EDMS-ERI-90221144_8.0.pdf(355.1 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

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Primary data collection

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**Main study objective:**

Assess the awareness of the health care professionals and level of understanding and knowledge detailed in the risk minimisation activities (eg. DHCP) with respect to the safety and risk management of domperidone.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

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

DOMPERIDONE

## Population studied

**Short description of the study population**

Prescribers, across 5 EU countries with varying prescription volumes: Belgium, France, Germany, Spain and United Kingdom.

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**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)

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**

0

# Study design details

**Outcomes**

Characterise prescriber's knowledge, regarding the new safety information for domperidone following the change in SmPC, including:- Indications for domperidone prescribing- Length of treatment- Maximum daily dose- concomitant use of domperidone and other drugs known to prolong the QT-interval or potent CYP3A4 inhibitors- contraindicated conditions- treated population characteristics

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**Data analysis plan**

Descriptive statistics will be used for evaluation and comparison of prescriber knowledge and awareness as measured by the study survey. The study population will be described using demographic characteristics, such as age, sex, specialty, clinical practice type, and country.Continuous variables will be presented using appropriate descriptive statistics, such as mean, median, standard deviation and range. Categorical variables will be described using frequencies.Further stratification by baseline variables may be performed and will be described in the statistical analysis plan.The primary analysis will present the rate of correct answers per question for all countries pooled together. An additional analysis will include the rates of correct answers by country. The proportion of physicians who potentially prescribe domperidone for unapproved indications will be described.

## Documents

**Study results**

Domperidone PASS Study RRA-17004_CSR_Final 27JUN2017.pdf(606.64 KB)

# Data management

## Data sources

**Data sources (types)**

Other

**Data sources (types), other**

Physician Survey - the survey will be conducted using a multiple choice survey via the internet to address the most important safety information in the DHCP and potential off-label use

## 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**

Unknown