Proposals for Engaging Patients and Healthcare Professionals in Risk Minimisation from an Analysis of Stakeholder Input to the EU Valproate Assessment Using the Novel Analysing Stakeholder Safety Engagement Tool (ASSET)

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Last updated: 03/11/2020

### Administrative details

**EU PAS number** 

**EUPAS35947** 

Study ID

37897

**DARWIN EU® study** 

No

# Study countries Netherlands

#### **Study description**

This study analysis the content of input provided by patient and healthcare professional representatives at the public hearing and dedicated stakeholder meeting for the valproate teratogenicity and risk management assessment by the Pharmacovigilance Risk Assessment Committee (PRAC) at EMA in 2017/2018. The content analysis applies theories on implementation of innovation in healthcare and leads to proposals to be considered by PRAC for piloting in order to enhance their engagement with patients and healthcare professionals with a view to increasing effectiveness of risk minimisation measures. The study is conducted under the PRAC Impact Strategy.

#### **Study status**

Finalised

### Research institutions and networks

### Institutions

### European Medicines Agency (EMA)

First published: 01/02/2024

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Institution

### Contact details

#### **Study institution contact**

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#### **Primary lead investigator**

Priya Bahri

**Primary lead investigator** 

## Study timelines

### Date when funding contract was signed

Planned: 09/03/2017

Actual: 09/03/2017

#### Study start date

Planned: 26/09/2017

Actual: 26/09/2017

#### Data analysis start date

Planned: 06/11/2017

Actual: 06/11/2017

#### **Date of final study report**

Planned: 20/05/2020

Actual: 20/05/2020

## Sources of funding

## Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

## Methodological aspects

## Study type

## Study type list

#### **Study topic:**

Human medicinal product

Disease /health condition

#### **Study type:**

Non-interventional study

#### Scope of the study:

Other

If 'other', further details on the scope of the study

Stakeholder engagement analysis

#### **Data collection methods:**

Secondary use of data

#### Main study objective:

(1) Analyse stakeholder input at public hearing and dedicated meeting for the 2017/18 EU procedure on valproate teratogenicity, (2) Draw proposals for enhancing PRAC engagement.

## Study Design

#### Non-interventional study design

Other

#### Non-interventional study design, other

Theory-based case study with qualitative content analysis

## Study drug and medical condition

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

#### Medical condition to be studied

**Epilepsy** 

## Population studied

#### Short description of the study population

Patient and healthcare professional representatives at the public hearing and dedicated stakeholder meeting for the valproate teratogenicity and risk management assessment by the Pharmacovigilance Risk Assessment Committee (PRAC) at EMA in 2017/2018.

#### Age groups

Adolescents (12 to < 18 years)
Adults (18 to < 46 years)

#### Special population of interest

Pregnant women

#### **Estimated number of subjects**

60

## Study design details

#### **Outcomes**

Stakeholder input content analysis findings and derived proposals for enhancing engagement between regulators, patients and healthcare professionals

#### **Data analysis plan**

Development of content analysis tool based on established theories with coding scheme and rules, testing of tool prior to application, peer examination of research design, data analysis applyig tool and adhering to coding rules

### **Documents**

#### **Study results**

Bahri P, Morales D, Inoubli A, Dogne JM, Straus S\_Valproate hearing ASSET analysis and PRAC engagement proposals.pdf (1.09 MB)

#### **Study publications**

Bahri P, Morales DR, Inoubli A, Dogné JM, Straus SM. Proposals for engaging pat...

## 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 sources (types)** 

Other

Data sources (types), other

Stakeholder input at EMA meetings

Use of a Common Data Model (CDM)

**CDM** mapping

## Data quality specifications

#### **Check conformance**

Unknown

### **Check completeness**

Unknown

### **Check stability**

Unknown

### **Check logical consistency**

Unknown

### Data characterisation

#### **Data characterisation conducted**

No