Implementation of new pharmacovigilance legislation concerning the new adverse drug reactions definition (IMAGINATION)

First published: 20/11/2015

Last updated: 19/06/2024

Study Planned

Administrative details

EU PAS number

EUPAS11628

Study ID

14243

DARWIN EU® study

No

Study countries

☐ Croatia

Study description

Non-interventional, observational study aimed at investigating the level of implementation of pharmacovigilance legislation concerning adverse drug reactions which arise from the use outside the terms of the marketing authorisation, including overdose, off-label use, misuse, abuse and medication errors. Estimated total number of reports included in the study is 1500 cases. Five hundred cases reported at three different time point will be included in the study, before and after the implementation of the EU Directive 2010/84/EU which came into force in Croatia in July 2013, and following the implementation of the “Good practice guide on recording, coding, reporting and assessment of medication errors” which will come into the force in November 2015.

Study status

Planned

Research institutions and networks

Institutions

Department for Pharmacovigilance and Rational Pharmacotherapy, Agency for Medicinal Products and Medical Devices (Phv Department -HALMED)

Croatia

First published: 22/10/2014

Last updated: 19/06/2024

Institution **Regulatory Authority** **ENCePP partner**

Networks

It is being carried out in the collaboration with a research network at the Faculty of Pharmacy and Biochemistry University of Zagreb.

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Viola Macolić Šarinić

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2015

Actual: 01/01/2015

Study start date

Planned: 01/01/2005

Data analysis start date
Planned: 01/01/2015

Date of final study report
Planned: 01/06/2017

Sources of funding

- Other

More details on funding

HALMED

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 type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Policy assessment (The extent of implementation of the new legislation)

Main study objective:

To investigate the level of implementation of pharmacovigilance legislation concerning ADRs which arise from the use outside the terms of the marketing authorisation, including overdose, off-label use, misuse, abuse and medication errors.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

After before study

Population studied

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)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

1500

Study design details

Outcomes

To evaluate and compare the number of individual case safety reports (ICSRs) concerning ADRs which arise from the use outside the terms of the marketing authorisation, including overdose, off-label use, misuse, abuse and medication errors before and after the change in pharmacovigilance legislation, To identify, evaluate and describe ICSR in which suspected medicinal product was used outside the terms of the marketing authorisation, but did not result in harm.

Data analysis plan

The primary endpoint of the study, difference in number of ICSR in which suspected medicinal product was used outside the terms of the marketing authorisation before and after the implementation of the change in pharmacovigilance legislation

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)

Spontaneous reports of suspected adverse drug reactions

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