Impact of medicines regulatory interventions in Europe: a systematic review focusing on unintended consequences, data used and methodology

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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/47826

EU PAS number
EUPAS47825

Study ID
47826

DARWIN EU® study
No

Study countries
Austria
Belgium
Bulgaria
Croatia
Cyprus
Czechia
Denmark
Estonia
Finland
France

Germany
Greece
Hungary
Iceland
Ireland
Italy
Latvia
Liechtenstein
Lithuania
Luxembourg
Malta
Netherlands
Norway
Poland
Portugal
Romania
Slovakia
Slovenia
Spain
Sweden
United Kingdom

Study description
The goal is to perform a comprehensive assessment of studies that evaluate the impact of pharmacovigilance regulatory interventions in the European Economic Area (EEA), focusing on identifying unintended consequences and highlighting the methodology and data used.

Study status
Ongoing

Research institution and networks

Institutions

Division of Pharmacoepidemiology & Clinical Pharmacology (PECP), Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University

Netherlands
First published: 01/03/2010
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23/05/2024
Institution

Educational Institution ENCePP partner

Contact details

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Study timelines

Date when funding contract was signed
Planned:
01/09/2021
Actual:
01/09/2021

Study start date
Planned:
01/01/2022
Actual:
13/12/2021

Date of final study report
Planned:
31/01/2023

Sources of funding

- Other

More details on funding

Utrecht University

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

Main study objective:
The goal is to perform a comprehensive assessment of studies that evaluate the impact of pharmacovigilance regulatory interventions in the European Economic Area (EEA), focusing on identifying unintended consequences and highlighting the methodology and data used.

Study Design

Non-interventional study design
Systematic review and meta-analysis

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
0

Study design details

Data analysis plan
We will perform descriptive analysis (totals and percentages) for data extracted from identified articles.

Data management

Data sources

Data sources (types)
Other

Data sources (types), other
We will conduct bibliographic database searches in MEDLINE and EMBASE.

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