Implementation of controlled access to and distribution of medicinal products in European Union (CONTROL-EU)

First published: 18/09/2024

Last updated: 14/04/2025

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000313

EU PAS number

EUPAS1000000313

Study ID

1000000313

DARWIN EU® study

No

Study countries

☐ Austria

- [ ] Greece
- [ ] Latvia
- [ ] Netherlands
- [ ] Portugal
- [ ] Slovenia
- [ ] Spain
- [ ] Sweden

Study description

This project aims to describe national implementation processes of controlled access programmes (CAP) as well as controlled distribution systems (CDS) on a given sample of eight centrally authorised medicinal products in eight different European health care systems (Austria, Greece, Latvia, Netherlands, Portugal, Slovenia, Spain and Sweden). Of special interest is to learn about national barriers and enablers as reported by key stakeholders.

A mixed-method approach is foreseen for this study, including desk research followed by a cross-sectional survey and qualitative semi-structured interviews with key national stakeholders including national competent authorities (NCAs), Marketing Authorisation Holders (MAHs), health care professionals, and patients.

The knowledge generated in this project will provide evidence that may be used for recommendations for regulators to engage with healthcare professional bodies and other responsible parties to investigate whether CAP/CDS are feasible and needed.

Study status

Planned

Research institutions and networks

Institutions

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

Netherlands

First published: 01/03/2010

Last updated: 23/05/2024

Institution | Educational Institution | ENCePP partner

Centre for Health Protection (RIVM-GZB), National Institute for Public Health & Environment

Netherlands

First published: 06/11/2022

Last updated: 27/03/2024

Institution | EU Institution/Body/Agency | Laboratory/Research/Testing facility | ENCePP partner

University Medical Center Utrecht (UMCU)

Netherlands

First published: 24/11/2021

Last updated: 22/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Department of Social Pharmacy, Faculty of pharmacy, University of Ljubljana

Slovenia

First published: 15/12/2021

Last updated: 20/08/2024

Institution | Educational Institution

Department of Medicine/Laboratory of Hygiene and Environmental Protection, Democritus University of Thrace

Greece

First published: 30/11/2022

Last updated: 05/12/2022

Institution | Educational Institution | ENCePP partner

University of Porto

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

Uppsala University

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Teamit Institute

Spain

First published: 12/03/2024

Last updated: 12/03/2024

Institution | Other | ENCePP partner

Gesundheit Österreich Forschungs und Planungs GmbH, a subsidiary of Gesundheit Österreich GmbH (GOEG); Public University of Navarre (Spain); Riga Stradins University (Latvia)

Networks

EU Pharmacoepidemiology and Pharmacovigilance (PE&PV) Research Network

Netherlands

First published: 01/02/2024

Last updated: 26/11/2024

Network

Contact details

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Primary lead investigator

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 23/07/2024

Actual: 23/07/2024

Study start date
Planned: 12/09/2024

Date of final study report
Planned: 31/03/2026

Sources of funding

- EMA

Study protocol

Study protocol_version 2.0_without Appendices.pdf(1.3 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Study design:

A mixed-methods approach is foreseen including document analysis, a quantitative analysis of cross-sectional survey data as well as a qualitative analysis of stakeholders’ perceptions.

Main study objective:

The study aims to describe processes in and national experiences of eight European countries (Austria (AT), Greece (GR), Latvia (LV), Netherlands (NL), Portugal (PT), Slovenia (SI), Spain (ES), and Sweden (SE)) of implementing the EU pharmacovigilance legislation on risk minimisation measures (RMM) with an emphasis on controlled access programmes (CAP) and controlled distribution systems (CDS) using eight centrally authorised medicinal products as examples.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Qualitative study including document analysis, survey and qualitative interviews

Study drug and medical condition

Name of medicine

ASPAVELI 1080 MG - SOLUTION FOR INFUSION

FINTEPLA

REVLIMID

SOLIRIS

SPRAVATO

STRIMVELIS

UPTRAVI

YESCARTA

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

AUTOLOGOUS CD34+ ENRICHED CELL FRACTION THAT CONTAINS CD34+ CELLS TRANSDUCED WITH RETROVIRAL VECTOR THAT ENCODES FOR THE HUMAN ADA CDNA SEQUENCE

AXICABTAGENE CILOLEUCEL

ECULIZUMAB

ESKETAMINE HYDROCHLORIDE

FENFLURAMINE HYDROCHLORIDE

LENALIDOMIDE

PEGCETACOPLAN

SELEXIPAG

Anatomical Therapeutic Chemical (ATC) code

(A08AA02) fenfluramine

fenfluramine

(B01AC27) selexipag

selexipag

(L01XL03) axicabtagene ciloleucel

axicabtagene ciloleucel

(L03) IMMUNOSTIMULANTS

IMMUNOSTIMULANTS

(L04AJ01) eculizumab

eculizumab

(L04AJ03) pegcetacoplan

pegcetacoplan

(L04AX04) lenalidomide

lenalidomide

(N01AX14) esketamine

esketamine

(N03AX26) fenfluramine

fenfluramine

(N06AX27) esketamine

esketamine

(S01XA31) pegcetacoplan

pegcetacoplan

Population studied

Short description of the study population

It is anticipated that the list will include all of the following stakeholders:

- National competent authorities / drug regulatory agency / health inspectorates
- Marketing authorisation holder / distributors of each of the eight medicinal products

- Professional organisations relevant for prescribing/dispensing the eight medicinal products (including physicians and pharmacists)
- Patient / care giver organisations relevant for the eight medicinal products

Estimated number of subjects

109000000

Study design details

Setting

Eight European countries (Austria (AT), Greece (GR), Latvia (LV), Netherlands (NL), Portugal (PT), Slovenia (SI), Spain (ES), and Sweden (SE))

Data analysis plan

Quantitative analyses will entail descriptive statistics, univariate and bivariate analyses will be conducted according to stratifying variables. The analysis of the semi-structured interviews involves a content analysis based on a close line-by-line reading of the responses and developing a conceptual coding scheme based on the major themes in the interview guide.

Data management

Data sources

Data source(s)

Other data source

Data source(s), other

Three methods are foreseen to collect data from eight European countries including text materials from (online) documents, survey data and interview data.

Data sources (types)

Other

Patient surveys

Data sources (types), other

- Online documents;
- Survey data (including NCAs, MAHs, health care professionals);
- Interview data with NCAs, MAHs, health care professionals, patients.

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