Dissemination of additional risk minimisation measures for patients and healthcare professionals in EU/EEA countries

First published: 09/06/2025

Last updated: 29/07/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000524

Study ID

1000000524

DARWIN EU® study

No

Study countries

Finland

Hungary

Italy

Lithuania

Netherlands

Romania

Study status

Ongoing

Research institutions and networks

Institutions

University of Naples Federico II

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Pharmacy and Pharmacology center, Faculty of Medicine, Vilnius University (PharmCenter VU)

Lithuania

First published: 08/01/2024

Last updated: 08/01/2024

Institution | Educational Institution | ENCePP partner

Netherlands Institute for Health Services Research (Nivel)

Netherlands

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Not-for-profit

Pharmaceutical Policy - research group, University of Eastern Finland

Finland

First published: 30/10/2025

Last updated: 30/10/2025

Institution | Educational Institution | ENCePP partner

Syreon Research Institute, Universitatea Babes-Bolyai, DESAN Research Solutions

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Liset Van Dijk

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 28/02/2025

Study start date
Actual: 28/02/2025

Date of interim report, if expected
Planned: 28/04/2026

Date of final study report
Planned: 29/06/2026

Sources of funding

- EMA

Study protocol

ROC30_Annex V_Response template_Nivel_16012025_DEF.pdf (868.54 KB)

D2. Protocol_DEF_29082025.pdf (3.06 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:

Focus groups, interviews, and surveys among the different populations, desk research

Main study objective:

1. To describe and analyse aRMM dissemination: Process & frequency ; key stakeholders involved; roles & responsibilities by type of aRMM, by dissemination method, by medicinal product and by country
2. To describe and analyse how access is ensured by type of aRMM, by medicinal product, by key stakeholder involved, and by country
3. To identify key challenges of disseminating healthcare professional- and patient-targeted aRMMs by type of aRMM, by dissemination method, by key stakeholder involved and by country
4. To identify and describe preferences for aRMM tools by type of aRMM, by dissemination method, by key stakeholder involved and by country
5. To provide recommendations by identifying feasible and concrete steps at each step of implementation pathway

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

XELJANZ

AUBAGIO

LEMTRADA

EYLEA

Medicinal product name, other

Valproate containing medicinal products

Retinoids containing medicinal products

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

TOFACITINIB CITRATE

TERIFLUNOMIDE

ALEMTUZUMAB

AFLIBERCEPT

EDOXABAN

ACITRETIN

ADAPALENE

ALITRETINOIN

BEXAROTENE

ISOTRETINOIN

TRETINOIN

TAZAROTENE

Population studied

Short description of the study population

Patients using these drugs, HCPs prescribing these drugs, Competent Authorities, pharmacists, Marketing AuthorizationHolders (MAH)

Study design details

Outcomes

Relevant outcomes were: 1) process including the frequency of how aRMM materials are disseminated and the roles and responsibilities of key stakeholders (prescriber, pharmacist, MAH, NCA) in the dissemination process; 2) access to aRMM materials for patients and HCPs; 3) key challenges of disseminating aRMM; 4) preferences for aRMM tools for patients and HCPs and 5) usefulness of the materials. Data sources were scientific and grey literature, interviews with MAHs, focus groups with NCAs, focus groups/interviews with patients and HCPs, online questionnaires for patient organisations, patients and HCPs and a webinar for all stakeholders.

Documents

Abstract of study report

Abstract DIS-aRMM study voor HMA Catalogue.pdf (330.07 KB)

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)

Non-interventional study

Other

Patient surveys

Published literature

Data sources (types), other

Focus groups and surveys among healthcare professionals

Focus group and interviews with National Competent Authorities and Market Authorisation Holders

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