Discontinuation of additional risk minimisation measure tools for centrally authorised medicinal products in the EU

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000762

Study ID

1000000762

DARWIN EU® study

No

Study countries

☐ European Union

Study description

This retrospective cohort study aims to describe post-authorisation discontinuation of additional risk minimisation measure (aRMM) tools for centrally authorised medicinal products (CAPs) authorised with aRMM tools in the EU between July 2012 and December 2021. This study will be a retrospective cohort study within a medicinal product cohort. This medicinal product cohort includes CAPs authorised in the EU between 1 July 2012 and 31 December 2021. From this medicinal product cohort, we will establishe a study cohort of CAPs with aRMMs at the time of initial MA. aRMM tool discontinuations until 31 December 2024 will be identified. Our study outcome will be the time to discontinuation of the aRMM tools for CAPs authorised in the EU between July 2012 and December 2021. Furthermore, we will assess the category of aRMM tool that was discontinued, corresponding safety concern(s) of the discontinued tools, the type of regulatory procedure(s) involved in the discontinuation of the aRMM, and the rationale for discontinuation of the aRMM tool.

Study status

Ongoing

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

European Medicines Agency (EMA)

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Institution

Contact details

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Study timelines

Date when funding contract was signed

Planned: 01/09/2025

Actual: 01/09/2025

Study start date
Planned: 01/09/2025

Actual: 01/09/2025

Data analysis start date
Planned: 01/11/2025

Date of final study report
Planned: 01/04/2026

Sources of funding

More details on funding

Medicines Evaluation Board

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

Other

Study type:

Non-interventional study

Scope of the study:

Other

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

Discontinuation of aRMM tools

Study design:

This study will be a retrospective cohort study.

Main study objective:

This retrospective cohort study aims to describe post-authorisation discontinuation of aRMM tools for centrally authorised medicinal products (CAPs) authorised with aRMM tools in the EU between July 2012 and December 2021.

Study Design

Non-interventional study design

Cohort

Population studied

Age groups

All

In utero

Paediatric Population (< 18 years)

Neonate

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)

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Study design details

Setting

This study will be a retrospective cohort study within a medicinal product cohort. This medicinal product cohort includes CAPs authorised in the EU between 1 July 2012 and 31 December 2021. From this medicinal product cohort, we established a study cohort of CAPs with aRMMs at the time of initial MA. We will identify aRMM tool discontinuations until 31 December 2024.

Comparators

None

Outcomes

- Time to discontinuation of the aRMM tools for CAPs authorised in the EU between July 2012 and December 2021;
- Category of aRMM tool that was discontinued, corresponding safety concern(s) of the discontinued tools;
- The type of regulatory procedure(s) involved in the discontinuation of the aRMM;
- The rationale for discontinuation of the aRMM tool.

Data analysis plan

We will use descriptive statistics to describe our study outcomes and the characteristics of the CAPs included in our study cohort.
To account for the time needed to accumulate sufficient data as justification for a discontinuation of aRMM tools, we will calculate the probability of discontinuation of aRMM tools using time-to-event analyses.
Regarding details on the rationale for aRMM tool discontinuation, we will perform thematic analysis.

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 source(s)

Other data source

Data sources (types)

Other

Data sources (types), other

Publicly available regulatory documents (EPARs, PIs, RMPs) and EMA internal assessment reports.

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

Not applicable