

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

**First published:** 03/10/2025

**Last updated:** 03/10/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000762

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### Study ID

1000000762

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### DARWIN EU® study

No

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### Study countries

 European Union

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### 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 establish 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.

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## 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:** 27/05/2026

Institution

Educational Institution

ENCePP partner

## European Medicines Agency (EMA)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

### Contact details

#### Study institution contact

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Primary lead investigator

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### Study timelines

#### Date when funding contract was signed

Planned: 01/09/2025

Actual: 01/09/2025

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### **Study start date**

Planned: 01/09/2025

Actual: 01/09/2025

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### **Data analysis start date**

Planned: 01/11/2025

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### **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

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### **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

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**Study type:**

Non-interventional study

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**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**

- **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.

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### Comparators

None

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## 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.
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## 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

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**Data sources (types)**

Other

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**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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

Not applicable