

# DARWIN EU® – Monitoring prescription of medicines for public health emergencies at risk of shortages

**First published:** 11/02/2025

**Last updated:** 05/01/2026

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000473

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### Study ID

1000000473

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### DARWIN EU® study

Yes

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### Study countries

- ☐ Belgium
- ☐ Finland
- ☐ France
- ☐ Germany

☐ Netherlands

☐ Spain

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### **Study description**

The extended mandate of EMA reinforcing the role of the Agency in crisis preparedness and management of medicinal products and medical devices became applicable on 1st March 2022 (Regulation on EMA's extended mandate becomes applicable | European Medicines Agency (europa.eu)).

EMA is now responsible for monitoring medicine shortages that might lead to a crisis situation, as well as reporting shortages of critical medicines during public health emergencies (PHE). Such shortages would make it difficult or impossible to meet the treatment needs of individual patients or populations. The Agency has also the mandate to coordinate responses of EU / EEA countries to shortages of critical medical devices and in-vitro diagnostics in crisis situations. Scientific and commercial data on monthly prescriptions of medicines that may be critical in PHE can help understanding trends and seasonal variations. In conjunction with time series and forecasting models, as well as data on medicines supply, such data will contribute to the on-going efforts of the Agency to better monitor and coordinate its response to shortages of critical medicines.

This study aims at generating monthly number of prescriptions of selected medicines over the last 10 years and to fit Autoregressive Integrated Moving Average (ARIMA) prediction models to such data.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

## Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

☐ Netherlands

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**Last updated:** 02/05/2024

**Institution**

**Educational Institution**

**ENCEPP partner**

## Networks

### Data Analysis and Real World Interrogation Network (DARWIN EU®)

- ☐ Belgium
- ☐ Croatia
- ☐ Denmark
- ☐ Estonia
- ☐ Finland
- ☐ France
- ☐ Germany
- ☐ Greece
- ☐ Hungary
- ☐ Italy
- ☐ Netherlands
- ☐ Norway
- ☐ Portugal

- ☐ Spain
- ☐ Sweden
- ☐ United Kingdom

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Network

## Contact details

### Study institution contact

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Study contact

[study@darwin-eu.org](mailto:study@darwin-eu.org)

### Primary lead investigator

Marta Pineda Moncusi

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 14/01/2025

Actual: 14/01/2025

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### Study start date

Planned: 29/01/2025

Actual: 29/01/2025

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### **Date of final study report**

Planned: 30/05/2025

Actual: 28/05/2025

## Sources of funding

- EMA

## Study protocol

[DARWIN EU\\_Protocol\\_P3-C2-004\\_RR Shortages\\_V4.pdf](#) (646.99 KB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Study design:**

Retrospective cohort studies will be conducted using routinely-collected health data from 7 databases.

**Main study objective:**

- (i) To estimate monthly incidence rates of use prescriptions or dispensations of the 11 selected medicines during a 10-year period from the most recent data available, stratified by age and sex, in each of the databases.
- (ii) To conduct time series modelling by fitting an ARIMA model to data generated in objective 1 for short-term (12-month) forecasting.

## Study drug and medical condition

**Medicinal product name**

CEFOTAXIME

CEFUROXIME

CLARITHROMYCIN

PENICILLIN VK

PIPERACILLIN/TAZOBACTAM TEVA

AMOXICILLIN CAPSULES

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### **Anatomical Therapeutic Chemical (ATC) code**

(J01CA04) amoxicillin

amoxicillin

(J01FA10) azithromycin

azithromycin

(J01DD01) cefotaxime

cefotaxime

(J01DD04) ceftriaxone

ceftriaxone

(J01DC02) cefuroxime

cefuroxime

(J01FA09) clarithromycin

clarithromycin

(J01DH02) meropenem

meropenem

(J01CE02) phenoxymethylpenicillin

phenoxymethylpenicillin

(J01CR05) piperacillin and beta-lactamase inhibitor

piperacillin and beta-lactamase inhibitor

## **Population studied**

### **Short description of the study population**

The study cohort will comprise all individuals present in the database during the study period (the last 10 years of available data counting backwards from the respective latest date of data lock of the respective databases).

## **Documents**

## Study report

[DARWIN EU\\_Report\\_P3-C2-004\\_RR Shortages\\_V3.0.pdf](#) (2.72 MB)

[Shiny App](#)

## 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)

IQVIA Disease Analyzer Germany

IQVIA Longitudinal Patient Data - Belgium

Integrated Primary Care Information (IPCI)

Institut Municipal d'Assistència Sanitària Information System / Hospital del Mar / PSMAR / (Hospital del Mar Information System)

Clinical Data Warehouse of the Bordeaux University Hospital

InGef Research Database

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### Data source(s), other

H12O

## Use of a Common Data Model (CDM)

**CDM mapping**

Yes

**CDM Mappings****CDM name**

OMOP

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**CDM website**

<https://www.ohdsi.org/Data-standardization/>

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## 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**

Unknown