

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

**First published:** 08/01/2024

**Last updated:** 10/03/2026

Study

Finalised

## Administrative details

### EU PAS number

EUPAS107932

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### Study ID

199005

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### DARWIN EU® study

Yes

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### Study countries

 Belgium

 Germany

 Spain

 United Kingdom

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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). 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 ongoing efforts of the Agency to better monitor and coordinate its response to shortages of critical medicines. This study aims at generating monthly prescription rates 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**

[IQVIA NL, Real-World-Evidence](#)

 Netherlands

**First published:** 25/11/2022

**Last updated:** 21/03/2025

**Institution**

Other

ENCePP partner

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

 Spain

**First published:** 05/10/2012

**Last updated:** 23/05/2025

**Institution**

Educational Institution

Laboratory/Research/Testing facility


Not-for-profit

ENCePP partner















University of Oxford, PSMAR

## 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

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

**Last updated:** 30/04/2025

**Network**

## Contact details

### Study institution contact

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

**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: 06/09/2023

Actual: 06/09/2023

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### **Study start date**

Planned: 01/01/2013

Actual: 01/01/2013

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

Planned: 31/01/2024

Actual: 11/06/2024

## Sources of funding

- EMA

## Study protocol

[DARWIN EU\\_Protocol\\_P2\\_C1\\_012\\_V4.1.pdf](#) (651.28 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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**Main study objective:**

To estimate monthly incidence rates of use prescription or dispensation of the 11 selected medicines during the last 10 years of available data, stratified by age and sex, in each of the databases.

## Study Design

## **Non-interventional study design**

Cohort

## Study drug and medical condition

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

AMOXICILLIN

AZITHROMYCIN

BENZYL PENICILLIN

CEFTRIAXONE

CLAVULANIC ACID

MEROPENEM TRIHYDRATE

PHENOXYMETHYL PENICILLIN POTASSIUM

TAZOBACTAM SODIUM

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

(J01CA04) amoxicillin

amoxicillin

(J01CE01) benzylpenicillin

benzylpenicillin

(J01CE02) phenoxymethylpenicillin

phenoxymethylpenicillin

(J01CR02) amoxicillin and beta-lactamase inhibitor

amoxicillin and beta-lactamase inhibitor

(J01CR05) piperacillin and beta-lactamase inhibitor

piperacillin and beta-lactamase inhibitor

(J01DC02) cefuroxime

cefuroxime

(J01DD01) cefotaxime

cefotaxime

(J01DD04) ceftriaxone

ceftriaxone

(J01DH02) meropenem

meropenem

(J01FA09) clarithromycin

clarithromycin

(J01FA10) azithromycin

azithromycin

## Population studied

### Age groups

- 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)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

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### Estimated number of subjects

59800000

## Study design details

## Data analysis plan

Analyses will be conducted separately for each database. Before study initiation, test runs of the analytics are performed on a subset of the data sources or on a simulated set of patients and quality control checks are performed. Once all the tests are passed the final package is released in the version controlled Study Repository for execution against all the participating data sources. The data partners locally execute the analytics against the OMOP CDM in R Studio and review and approve the by default aggregated results before returning them to the Coordination Centre. Sometimes multiple execution iterations are performed, and additional fine tuning of the code base is needed. A service desk will be available during the study execution for support. The study results of all data sources are checked after which they are made available to the team in the Digital Research Environment and the Dissemination Phase can start. All results are locked and timestamped for reproducibility and transparency.

## Documents

### Study report

[DARWIN EU\\_P2\\_C1\\_012 Study Report\\_Risc of shortatges\\_v3.1.pdf](#) (3.25 MB)

## 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)

The Information System for Research in Primary Care (SIDIAP)

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

Clinical Practice Research Datalink (CPRD) GOLD

IQVIA Disease Analyzer Germany

IQVIA Longitudinal Patient Data - Belgium

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### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

[Other](#)

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### Data sources (types), other

Secondary care Hospital

## 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**

No