

# The Impact of COVID-19 Pandemic on Drug Use: Implications for Regulatory Intervention Impact Studies

**First published:** 26/06/2023

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Study

Planned

## Administrative details

### EU PAS number

EUPAS105538

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### Study ID

105539

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### DARWIN EU® study

No

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### Study countries

☐ Lithuania

☐ Netherlands

☐ United Kingdom

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## Study description

In the European Union (EU), regulatory interventions known as risk minimisation measures (RMMs) are governed by the guidelines called Good pharmacovigilance practices (GVP). The current GVP guidelines also highlight the necessity to assess the impact of these regulatory interventions. However, in practice, implementing regulatory interventions depends on national and international authorities and might be affected by overlapping events, such as introducing a new competitor medicine. Medicine shortages can also cause perceived changes in medicine use. Therefore, it is challenging to discern whether the observed outcomes are directly caused by the intervention or are part of pre-existing secular trends. The COVID-19 pandemic introduced additional complexity to drug utilisation patterns disrupting the usual prescription and dispensation of medicines which caused changes in drug utilisation and health outcome patterns. In this study, we aim to explore whether the periods of strict pandemic restrictions (e.g. curfews and school closings) impacted drug utilisation patterns. Furthermore, we examine the implications of any disruptions for impact studies using data that includes the COVID pandemic period in the selected countries.

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## Study status

Planned

## 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**

## Contact details

### Study institution contact

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**Study contact**

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### Primary lead investigator

Helga Gardarsdottir

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Planned: 15/06/2023

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### Study start date

Planned: 15/06/2023

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### Data analysis start date

Planned: 01/12/2023

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## Date of final study report

Planned: 01/12/2024

## Sources of funding

- Other

## More details on funding

Utrecht University (PhD project)

## Study protocol

[COVID Study Protocol v1.0.pdf](#)(483.59 KB)

## 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 type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Main study objective:**

To assess whether the short- and/or long-term drug utilisation patterns were impacted by the COVID-19 pandemic.

## 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**

70000

## Study design details

## Outcomes

To describe the trends of prescribing the selected medicinal products from January 1, 2017, to December 31, 2023. To identify potential structural breaks in prescribing patterns of selected medicinal products over time. To assess if structural breaks in trends (if they are present) align with restrictions implemented due to the COVID-19 pandemic. To conduct sensitivity analyses to determine what assumptions reduce the probability of detecting structural breaks due to the COVID-19 pandemic in the secular trends of drug use (if they are present).

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## Data analysis plan

The study design will be a retrospective population-based dynamic cohort study. We will use interrupted time series analysis to identify the potential breaks in drug utilisation patterns before and during the COVID pandemic.

# Data management

## Data sources

### Data source(s)

PHARMO Data Network

Clinical Practice Research Datalink

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### Data source(s), other

Electronic prescriptions database Lithuania

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### Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

## 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**

No