

# Impact of EU label changes for systemic diclofenac products: post-referral prescribing trends

**First published:** 30/05/2018

**Last updated:** 17/05/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS24089

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### Study ID

33662

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### DARWIN EU® study

No

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### Study countries

- ☐ Denmark
  - ☐ Netherlands
  - ☐ United Kingdom
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## Study description

To evaluate the impact of the risk minimisation measures implemented in 2013 to manage the cardiovascular risks of systemic diclofenac containing medicinal products authorised in the European Union (EU) in clinical practice

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## Study status

Finalised

# Research institutions and networks

## Institutions

### MEMO Research, University of Dundee

☐ United Kingdom (Northern Ireland)

**First published:** 12/05/2010

**Last updated:** 17/05/2024

Institution

Educational Institution

Not-for-profit

ENCePP partner

### UCL School of Pharmacy, University College London

☐ United Kingdom

**First published:** 11/03/2010

**Last updated:** 21/04/2015

Institution

Outdated

Educational Institution

ENCePP partner

# The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

☐ Netherlands

**First published:** 07/01/2022

**Last updated:** 19/12/2025

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## Contact details

### Study institution contact

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**Study contact**

[t.m.macdonald@dundee.ac.uk](mailto:t.m.macdonald@dundee.ac.uk)

### Primary lead investigator

Thomas MacDonald

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Planned: 06/09/2017

Actual: 06/09/2017

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**Study start date**

Planned: 01/07/2018

Actual: 01/07/2018

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**Date of final study report**

Planned: 06/01/2019

Actual: 06/01/2019

## Sources of funding

- EMA

## Study protocol

[final Study Protocol Diclofenac\\_130318 \(002\).pdf](#) (255.96 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

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Three main objectives as follows: To determine prescription patterns of diclofenac containing products. To determine prescribers compliance with cardiovascular contraindications and risk factors. To determine prescription patterns of alternative medicines prescribed in patient where diclofenac has previously been prescribed.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Population-based longitudinal study, Time series analysis

## Study drug and medical condition

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

DICLOFENAC POTASSIUM

DICLOFENAC SODIUM

## Population studied

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

All patients registered within each data source at any time during the study period who discontinued diclofenac-containing medical products covering the regulatory intervention in June 2013.

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### **Age groups**

- 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**

1000000

## Study design details

### **Data analysis plan**

In order to determine prescription patterns of diclofenac containing product, prescribers' compliance with cardiovascular contra-indications and risk factors and prescription patterns of alternative medicines prescribed in patients where diclofenac has previously been prescribed, the proposed primary analysis will use interrupted time series regression to fit time trends to each series of time period data (based on quarterly time periods) for each country. Using regression modelling we will evaluate: (i) the baseline slope before the regulatory intervention time point (ii) the change in slope from the baseline trend to the post-intervention trend, and (iii) the immediate change associated with the regulatory intervention time point. The choice of analytical technique will be decided based on visual inspection of the data. The analysis will be done by data source initially, and only pooled if the statistical models do not differ significantly between data sources.

## Documents

### Study results

[Impact\\_diclofenac\\_prescribing\\_abstracts.pdf](#) (190.34 KB)

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### Study, other information

[Diclofenac\\_Abstract\\_ISPE\\_submission\\_1\\_050319.pdf](#) (289.33 KB)

[Morales\\_et\\_al-2020-Pharmacoepidemiology\\_and\\_Drug\\_Safety \(2\) \(002\).pdf](#)  
(2.54 MB)

### Study publications

[Morales DR, Morant SV, MacDonald TM, Mackenzie IS, Doney ASF, Mitchell L, Benni...](#)

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## 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.

This study has been awarded the ENCePP seal

### **Conflicts of interest of investigators**

[Declaration of Interests.pdf](#) (779.42 KB)

[TMM\\_ENCePP Declaration of Interest\\_300518.pdf](#) (911.34 KB)

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### **Composition of steering group and observers**

[Steering Group\\_Diclofenac\\_May18v2.pdf](#) (9.98 KB)

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### **Signed code of conduct**

[2018-0050-Declaration of compliance\\_ENCePP CoC\\_EUPAS24089.pdf](#) (238.33 KB)

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### **Signed code of conduct checklist**

[2018-0050-Checklist ENCePP CoC\\_EUPAS24089.pdf](#) (1.71 MB)

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### **Signed checklist for study protocols**

[2018-0050-ENCePP checklist Study Protocols\\_EUPAS24089.pdf](#) (1.98 MB)

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## **Data sources**

### **Data source(s)**

Clinical Practice Research Datalink

Danish registries (access/analysis)

PHARMO Data Network

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**Data source(s), other**

eDRIS

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**Data sources (types)**

[Drug dispensing/prescription data](#)

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

## 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