# The burden of rhinitis in Australia

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# Administrative details

### PURI

https://redirect.ema.europa.eu/resource/27684

### **EU PAS number**

EUPAS8507

### **Study ID**

27684

### DARWIN EU® study

No

### **Study countries**

Australia

### **Study description**

A set of three studies that aim to evaluate the burden of rhinitis on healthcare in Australia by assessing the real life treatment of rhinitis using prescribing and over the counter information, and the effect of introducing Dymista to the Australian market

### **Study status**

Planned

## Research institutions and networks

## Institutions



# Contact details

Study institution contact David Price



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Primary lead investigator David Price Primary lead investigator

# Study timelines

**Date when funding contract was signed** Planned: 30/01/2015

Study start date Planned: 06/02/2015

Data analysis start date Planned: 14/02/2015 Actual: 18/03/2015

**Date of final study report** Planned: 31/05/2015

## Sources of funding

• Pharmaceutical company and other private sector

### More details on funding

MEDA Australia

Study protocol

R01414\_Study 1 Rhinitis treatment patterns\_Protocol\_2015\_V10.For\_EnCEPP\_02Feb15.pdf(491.59 KB)

R01414\_Study 1 Rhinitis treatment patterns\_Protocol\_2015\_V11.pdf(585.11 KB)

# Regulatory

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

Unknown

### Is the study required by a Risk Management Plan (RMP)?

Not applicable

# Methodological aspects

# Study type

# Study type list

### Study type:

Non-interventional study

### Scope of the study:

Other

### If 'other', further details on the scope of the study

Real life treatment of rhinitis

Main study objective:

To evaluate the burden of rhinitis on healthcare in Australia by assessing the real life treatment of rhinitis using prescribing and over the counter information, and the effect of introducing Dymista to the Australian market

## Study Design

Non-interventional study design Cohort

# Study drug and medical condition

### Medical condition to be studied

Rhinitis allergic

## Population studied

#### Age groups

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)

### Estimated number of subjects

50000

## Study design details

### Outcomes

1) To assess the number of therapies (single vs. multiple drugs) used to treat rhinitis in Australia2) To describe the combination of therapies used to treat rhinitis in Australia3) To investigate the influence of OTC medications on the count and combination of therapies used to treat rhinitis in Australia, 4) To investigate the seasonality of rhinitis treatment patterns5) To estimate the cost of rhinitis treatment in Australia6) To investigate the relationship between rhinitis treatment patterns and co-morbid asthma treatment

### Data analysis plan

• Count of therapies will be reported as means and standard deviation SD, and/or median and inter-quartile range (25th and 75th percentiles) along with minimum and maximum values. Moreover, count of therapies will be presented as single, multiple and total number of therapies. • Within the multiple therapy patients group, the combination of different drug will be reported as absolute numbers as well as proportions and percentages.• Prescribed and over-thecounter medications will be reported as absolute numbers as well as proportions and percentages. • Time series analysis will be used to explore seasonality of rhinitis treatment patterns over the study period • The cost of rhinitis treatment will be reported as mean and median purchase (in Austrian dollars) along with their inter-quartile range and minimum and maximum values of purchases.

## Data management

Data sources

Data source(s), other

NostraData Australia

### Data sources (types)

Drug dispensing/prescription data

## Use of a Common Data Model (CDM)

**CDM** mapping

No

## Data quality specifications

#### **Check conformance**

Unknown

#### **Check completeness**

Unknown

#### **Check stability**

Unknown

### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No