# Modified Prescription-Event Monitoring Study to Monitor the Introduction of Atrovent Inhaler CFC-Free® MDI in the United Kingdom (Atrovent CFC-free M-PEM)

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# Administrative details

### **PURI**

https://redirect.ema.europa.eu/resource/6353

### **EU PAS number**

EUPAS6352

# Study ID

6353

### **DARWIN EU® study**

No

### Study countries

United Kingdom

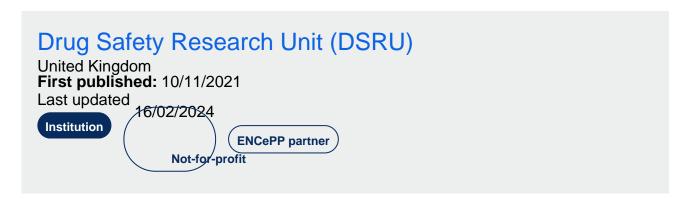
### Study description

This was a modified prescription event monitoring (M-PEM) study to monitor the safety of Atrovent® CFC-free MDI following a switch from CFC-containing propellants. M-PEM is a non-interventional prospective observational study methodology. The exposure data comprise information from prescriptions collected by the NHS Business Services Authority (NHSBSA) in England. The outcome data are event reports during three month pre- and post-exposure periods, obtained by sending questionnaires to the general practitioners (GPs) who issued prescriptions for Atrovent® CFC-free MDI.

Finalised

# Research institution and networks

# Institutions



# Contact details

Study institution contact

Saad Shakir

Study contact

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Primary lead investigator

Saad Shakir

Primary lead investigator

# Study timelines

Date when funding contract was signed

Actual:

05/05/2004

Study start date

Actual:

06/05/2004

Date of final study report

Actual:

06/07/2010

# Sources of funding

· Pharmaceutical company and other private sector

# More details on funding

Boehringer Ingelheim

# Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

# Methodological aspects

# Study type list

# Study topic:

Human medicinal product

### Study type:

Non-interventional study

### Scope of the study:

Safety study (incl. comparative)

### **Data collection methods:**

Primary data collection

### Main study objective:

To actively monitor the safety of the introduction of Atrovent® CFC-free MDI into general practice in England, for both adults and children.

# Study Design

### Non-interventional study design

Other

### Non-interventional study design, other

Prescription event monitoring

# Study drug and medical condition

### Name of medicine, other

Atrovent CFC-free MDI

# Population studied

### Short description of the study population

General practitioners (GPs) who issued prescriptions for Atrovent® CFC-free MDI.

### 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)

### **Estimated number of subjects**

13211

# Study design details

### Data analysis plan

Incidence densities for events occurring three months prior to and in the first three months of exposure to Atrovent® CFC-Free MDI were calculated, together with incidence density ratios to compare event rates before and during exposure. A matched analysis of specific events occurring in the three-month before and three-month after exposure period was performed to produce risk ratios.

# Data management

# Data sources

# **Data sources (types)**

Other

# Data sources (types), other

Prescription event monitoring

# 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