Behavior and knowledge survey to assess the effectiveness of educational materials among healthcare professionals who prescribe AUBAGIO® (teriflunomide) (cross-sectional survey)

First published: 30/05/2020

Last updated: 14/03/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS31013

Study ID

35676

DARWIN EU® study

No

Study countries

Belgium

France

Germany
Greece
Italy
Netherlands
Spain
United Kingdom

Study description

The overall objective of the survey is to assess descriptively the knowledge level and behavior of Healthcare Professional (HCPs) with regard to educational messages and thus the effectiveness of the educational materials to support the safe use of AUBAGIO.Research questions:1. What is the HCPs' knowledge about the HCP Education/Discussion Guide?2. What are the reasons for not using this guide, and are there suggestions for change of the guide? Wave 2 only3. What is the knowledge of HCPs about the key points of content:a. Hepatic effectsb. Pregnancy and lactationc. Hematologic effectsd. Infections4. What is the behavior of HCPs with regard to liver enzyme monitoring and discussion of risks with patients (including delivery of Patient Cards to patients)?

Study status

Finalised

Research institutions and networks

Institutions

Sanofi

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Institution

Contact details

Study institution contact

Trial Transparency Team Trial Transparency Team contact-us@sanofi.com

Study contact

contact-us@sanofi.com

Primary lead investigator

Trial Transparency Team Trial Transparency Team

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/01/2016

Study start date

Actual: 01/10/2017

Date of final study report

Actual: 31/03/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Study protocol

TERIFC09616_Wave 1 - protocol hcp - Aubagio.pdf (158.31 KB)

TERIFC09616_Wave 2 - protocol hcp - Aubagio.pdf (336.41 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

TERIFC09616

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Familiarity with Lemtrada educational materials among HCPs

Data collection methods:

Primary data collection

Main study objective:

The objective of the study is to assess descriptively knowledge and behavior of HCPs who prescribe Aubagio about the items of the educational materials and thus the effectiveness of these materials to promote the safe and adequate use of Aubagio.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

AUBAGIO

Population studied

Short description of the study population

HCPs involved in the treatment of MS using Aubagio.

Inclusion criteria

1. HCP is a neurologist/MS specialist

2. HCP has already prescribed Aubagio at study entry

3. HCP supplies informed consent by ticking a box on the survey website.

Exclusion criteria

1. HCP has not prescribed Aubagio

2. For Wave 2 only: participation in the questionnaire in Wave 1.

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

0

Study design details

Outcomes

Primary outcomes include the presentation of aggregate HCP responses. Subgroups are defined based on country, specialist role, and type of practice, as well as time since last initiation of Aubagio treatment and number of patients treated with Aubagio seen each month.

Data analysis plan

The study uses descriptive statistics, with a tabulation of the number and frequency of HCP responses.

Documents

Study results

Aubagio HCP Wave 1 and 2 combined report-Final.pdf (467.5 KB)

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 sources (types)

Other

Data sources (types), other

The questionnaire collected data concerning HCP characteristics.

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