Evaluating the effectiveness of the revised alli® pack information in helping pharmacy staff within the EU supply alli® appropriately (204675)

First published: 21/11/2016

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/28353

EU PAS number

EUPAS15840

Study ID

28353

DARWIN EU® study

No

Study countries

☐ Spain

☐ United Kingdom

Study description

Following the results of the two EU Risk Management Plan (RMP) surveys, several amendments to the information on the pack carton for alli® in the EU were recommended. The purpose of this survey, is to assess whether amendments to the pack text and format have been effective in ensuring appropriate recommendation of the product by pharmacy staff.Study Objectives are: 1. To evaluate whether revisions to the on-pack label changes for alli® are effective in enabling pharmacy staff make an appropriate decision to supply alli® to consumers based on the following criteria:• BMI (≥28 kg/m2)• Age (≥18 years old)• Contraindications to use of alli® (taking ciclosporin, chronic malabsorption syndrome, cholestasis, pregnancy or breast-feeding, taking warfarin or other oral anticoagulant)• Special warnings to use of alli® (kidney disease, taking levothyroxine, amiodarone, antidiabetics, antiretrovirals, antidepressants, antipsychotics, benzodiazepines or cholesterol lowering drugs): Consumer must have consulted their doctor prior to Use2. To identify whether there are specific criteria which pharmacy staff do not recognise as indications, contraindications or warnings for the use of alli®

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

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Institution

Multiple centres: 250 centres are involved in the study

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Study contact

Cdr_mailbox@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 22/12/2015

Actual: 22/12/2015

Study start date
Planned: 16/01/2017

Actual: 24/12/2016

Data analysis start date
Planned: 16/01/2017

Actual: 24/12/2016

Date of final study report
Planned: 19/03/2018

Actual: 19/03/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GSK Consumer Healthcare

Study protocol

Redacted Protocol.pdf(602.23 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)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

1. To evaluate whether revisions to the on-pack label for alli are effective in enabling pharmacy staff make an appropriate decision to supply alli to

consumers based on BMI, age and contraindications and special warnings to use alli.2. To identify whether there are specific criteria which pharmacy staff do not recognize as indications, contraindications or warnings.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Survey

Study drug and medical condition

Name of medicine

ALLI

Medical condition to be studied

Weight loss diet

Population studied

Short description of the study population

Male or female who was qualified and practising community pharmacist or pharmacy assistant in UK, Finland and Spain.

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

480

Study design details

Outcomes

The primary endpoint will be the proportion of correct answers bythe pharmacy staff to: a) Supply alli® when the virtual customer is suitable for theproductb) Not supply alli® when the virtual customer is not suitable for the product, a) The proportion of correct responses for each sub-score (indications, contraindications and warnings) analysedb) The proportion of false positives by the pharmacy staffc)The proportion of false negatives by the pharmacy staff

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Data analysis plan

80% correct answers will be considered to signify that the revised label is effective with respect to each sub-score (indication, contraindication and warning) in enabling pharmacy staff to supply alli®.The proportions of correct and incorrect pharmacy staff responses overall and by criteria, and their 95% confidence intervals will be calculated and presented.

Documents

Study results

204675-Clinical-Study-Result-Summary.pdf(181.16 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Information direct from pharmacy staff recruited in each of the 2 countries (UK and Spain).

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

Unknown