# 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

**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®

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**Study status**

Finalised

# Research institutions and networks

## Institutions

### GlaxoSmithKline (GSK)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

Multiple centres: 250 centres are involved in the study

## Contact details

**Study institution contact**

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Cdr_mailbox@gsk.com

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

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**Data analysis start date**
Planned: 16/01/2017

Actual: 24/12/2016

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**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

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**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

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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:**

Primary data collection

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**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

**Medicinal product name**

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)

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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.

## 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