

# Survey of pharmacists to evaluate the effectiveness of the Viagra Connect national additional Risk Minimisation Measure (aRMM) in the United Kingdom (UK) (NA)

**First published:** 28/12/2018

**Last updated:** 14/03/2024

Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/32208>

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### **EU PAS number**

EUPAS27346

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### **Study ID**

32208

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### **DARWIN EU® study**

No

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## Study countries

United Kingdom

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## Study description

This study will be conducted per request of the UK's MHRA (Medicines and Healthcare Products Regulatory Agency). The study will be a cross sectional, non interventional web based survey that will be conducted among pharmacists in the UK. The objective of the study is to evaluate the effectiveness of the Viagra Connect national aRMMs (i.e. the pharmacist training guide and the checklist) by assessing:

- The pharmacists' knowledge of the key risk messages contained in the Viagra Connect training materials,
- The pharmacists' participation in the Viagra Connect pharmacist training,
- The pharmacists' utilisation of the optional Viagra Connect Pharmacy Checklist at the point of dispensing.

Pharmacists must meet all of the following inclusion criteria to be eligible for inclusion in the study:

- Willing/consent to participate in this self administered survey,
- A practicing pharmacist in the UK,
- Received at least one patient face-to-face request to supply Viagra Connect in the past six months.

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## Study status

Finalised

## Research institutions and networks

### Institutions

**United BioSource Corporation (UBC)**

Switzerland

**First published:** 25/04/2013

**Last updated:** 06/03/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## Contact details

### Study institution contact

Joanna (Asia) Lem

**Study contact**

[Joannaasia.lem@pfizer.com](mailto:Joannaasia.lem@pfizer.com)

### Primary lead investigator

Joanna (Asia) Lem

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Planned: 27/09/2017

Actual: 27/09/2017

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### Study start date

Planned: 31/01/2019

Actual: 31/01/2019

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### Data analysis start date

Planned: 01/05/2019

Actual: 01/04/2019

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### **Date of final study report**

Planned: 31/07/2019

Actual: 23/07/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[Viagra Connect\\_A1481334\\_PASS\\_Pharmacist Survey\\_Protocol\\_Redacted for ENCeP registration.pdf](#)(1019.05 KB)

[A1481334\\_FINAL PROTOCOL AMENDMENT 2 \(V.1.2\)\\_13JUNE2018.doc.pdf](#)(2.15 MB)

## Regulatory

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

Yes

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

Not applicable

## Other study registration identification numbers and links

## Methodological aspects

### Study type

#### Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

To evaluate the effectiveness of the Viagra Connect national aRMM by assessing: • The pharmacists' knowledge of the key risk messages contained in the Viagra Connect training materials, • The pharmacists' participation in the Viagra Connect pharmacist training, • The pharmacists' utilisation of the optional Viagra Connect Pharmacy Checklist at the point of dispensing.

### Study Design

## **Non-interventional study design**

Cross-sectional

## Study drug and medical condition

### **Anatomical Therapeutic Chemical (ATC) code**

(G04BE03) sildenafil

sildenafil

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### **Medical condition to be studied**

Erectile dysfunction

## Population studied

### **Short description of the study population**

Pharmacists who have received at least one patient request to supply Viagra Connect within the six months preceding the survey administration.

Pharmacists must meet all of the following inclusion criteria:

1. Willing/consent to participate in this self-administered survey (Answered “Yes” to a survey question asking “Do you agree to proceed with this survey”);
  2. A practicing pharmacist in the UK;
  3. Received at least one patient face-to-face request to supply Viagra Connect in the past six months.
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### **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)

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### **Estimated number of subjects**

200

## Study design details

### **Data analysis plan**

Data collected from the survey will be reported as descriptive statistics. No statistical inferences will be made. Frequency distributions with 95% confidence intervals (CIs) will be calculated for pharmacist's responses to all questions that address the survey objectives. Survey data will be stratified by participating in the training and by other key pharmacist's characteristics if sample sizes are large enough (ie, no less than 25 in the minority group).

## Documents

### **Study results**

[a1481334-report-body.pdf](#)(4.81 MB)

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## Data management

## Data sources

### **Data sources (types)**

[Other](#)

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## **Data sources (types), other**

Cross-sectional survey of pharmacists

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No