Assessment of the effectiveness of additional Risk Minimisation Measures (aRMMs) among pharmacists for provision of desogestrel 75 microgram tablets in a community pharmacy setting

First published: 28/09/2021

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Study Finalised

Administrative details

EU PAS number

EUPAS43307

Study ID

47418

DARWIN EU® study

No

Study countries

United Kingdom (Northern Ireland)

Study description

Desogestrel 75 microgram tablets was reclassified to a pharmacy only (P) medicine in the UK separately by Maxwellia Ltd and HRA Pharma in July 2021. To support the safe supply of the products via pharmacy, both companies have independently developed a Pharmacy Training Guide and an optional Pharmacy Checklist as additional Risk Minimisation Measures (aRMMs). The training materials and consultation checklists together constitute important aRMMs for the non-prescription supply of the products, so that an appropriate decision is made by pharmacists to supply patients and correct advice is given. The content of the materials is aligned and has been agreed with the MHRA. The overall objective of this study is to evaluate the effectiveness of the aRMMs in mitigating the risks of incorrect supply of desogestrel 75 microgram tablets to patients in a community pharmacy.

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Marlene Perret

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 26/02/2021

Actual: 26/02/2021

Study start date
Planned: 10/01/2022

Actual: 20/01/2022

Date of final study report
Planned: 18/04/2022

Actual: 22/04/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

HRA Pharma, Maxwellia Ltd

Study protocol

Hana_Lovima_PAS protocol.pdf (656.77 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

CIG030921

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To evaluate the effectiveness of desogestrel 75 microgram tablets adiitional Risk Minimisation Measures

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Non-interventional web-based survey

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

DESOGESTREL

Anatomical Therapeutic Chemical (ATC) code

(G03AC09) desogestrel

desogestrel

Medical condition to be studied

Oral contraception

Population studied

Short description of the study population

Inclusion Criteria

All respondents invited to participate will be qualified pharmacists working in community pharmacies in the UK, will have read at least one of the aRMM materials and held at least one consultation with a female customer regarding the supply of desogestrel 75 microgram tablets in the previous six months. The sample will aim to be representative of community pharmacists by age, gender,

outlet size, and by region within the UK, including Northern Ireland.
Respondents will be invited to participate on the basis that they meet and confirm their acceptance of the inclusion criteria:
• Their information will only be used for research purposes and will not be passed to any other organisation without their permission;
• They have the right to refuse to answer questions or withdraw at any time. They consent to CIG Research collecting and using the information that they voluntarily provide for the purposes of research;
• They understand that if they become aware of any AEs during the course of the study, they will report these to CIG Research, who will pass their comments to the client about whose products they relate. They may choose to have these passed on anonymously or with their contact details, which will be collected at the end of the survey.

Exclusion Criteria
Pharmacists will not be included in the study if they:
• Have not received and read the aRMM materials supplied for the products in the UK, or do not recall having received or read them;
• Have participated in the user testing of the draft questions for the survey
• Are employed in full-time research, GP practices or hospitals (i.e. not community-based pharmacists);
• Work only as online pharmacists and do not provide consultations;
• Are in the employment of or are contracted to the MHRA, Maxwellia Ltd, Laboratoire HRA Pharma, Communications International Group or Consensio LLP.

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

200

Study design details

Outcomes

Demonstrate that the training is effective in enabling pharmacists to make appropriate decisions to supply based on contraindications and special warnings, Identify whether there are particular contraindications or warnings for which pharmacists consistently make wrong supply decisions, Establish ease of access to and ease of use of the aRMMs

Data analysis plan

Data collected from the survey will be reported as descriptive statistics. Frequency distributions with 95% confidence intervals (CIs) will be calculated for pharmacist’s responses to all questions that address the survey objectives.

Documents

Study results

PASS Report Desogestrel Maxwellia and Labratoire HRA 13.04v2.pdf (1.65 MB)

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

Cross-sectional web-based survey of pharmacists

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