# Drug utilization study of cyproterone/ethinylestradiol (Diane®-35 and generics) in the Netherlands, UK and Italy

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## Administrative details

#### **PURI**

https://redirect.ema.europa.eu/resource/31117

#### **EU PAS number**

EUPAS8412

#### Study ID

31117

#### DARWIN EU® study

No

#### **Study countries**

Italy

Netherlands

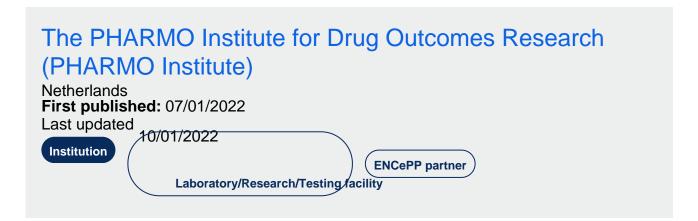
Spain

#### Study description

The study objectives are to characterize new users of Cyproterone Acetate / Ethinylestradiol (CPA/EE) in 2011/2012 and in 2014 according to demographics, treatment characteristics, previous diagnosis of acne, hirsutism or other hyperandrogenic conditions, previous acne treatment and (concomitant) use of hormonal contraceptives identified in Healthcare Databases in the UK (THIN), the Netherlands (PHARMO) and Italy (HSD).

## Research institution and networks

## Institutions





Italy HIS: The Health Search institute

## **Networks**

PHARMO: Database Network Netherlands

## Contact details

Study institution contact

CTP Team / Ref: "ENCePP"/ Bayer Pharma AG Bayer HealthCare AG

Study contact

clinical-trials-contact@bayerhealthcare.com

**Primary lead investigator** 

CTP Team / Ref: "ENCePP"/ Bayer Pharma AG Bayer HealthCare

AG

Primary lead investigator

## Study timelines

Date when funding contract was signed

Actual: 01/12/2014

#### Study start date

Planned: 01/02/2015 Actual: 01/05/2015

#### Date of final study report

Planned: 30/01/2016 Actual: 31/03/2016

## Sources of funding

Pharmaceutical company and other private sector

## More details on funding

Bayer

## Study protocol

17660\_Study Protocol DUS Diane\_2014-09-12.pdf(523.32 KB)

## Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

## Methodological aspects

## Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

#### Scope of the study:

Drug utilisation

#### Data collection methods:

Secondary data collection

#### Main study objective:

Characterization of new users of Cyproterone Acetate / Ethinylestradiol CPA/EE in 2011/2012 and in 2014 according to demographics, treatment characteristics, previous diagnosis of acne, hirsutism or other hyperandrogenic conditions, previous acne treatment and (concomitant) use of hormonal contraceptives identified in Healthcare Databases in the UK (THIN), the NL (PHARMO) and Italy (HSD).

## Study Design

## Study drug and medical condition

## Anatomical Therapeutic Chemical (ATC) code

(G03HB) Antiandrogens and estrogens

## Population studied

#### Short description of the study population

New Cyproterone Acetate / Ethinylestradiol (CPA/EE) users in 2011 and 2012.

#### Age groups

Adults (18 to < 46 years) Adults (46 to < 65 years)

#### **Estimated number of subjects**

10000

## Study design details

#### **Outcomes**

1. Proportion (%) of new users of Diane-35 (or generics) with a previous diagnosis of Acne2. Proportion (%) of new users of Diane-35 (or generics) with a previous diagnosis of Hirsutism3. Proportion (%) of new users of Diane-35 (or generics) with a previous diagnosis of other Hyperandrogenic Conditions (e.g. androgenic alopecia, seborrhea, polycystic ovary syndrome), 1. Determination of previous acne treatments (prescription drugs only) of Diane-35 (or generics) users with a previous diagnosis of acne.2. Proportion (%) of new Diane-35 (or generics) users, who have concomitant prescriptions of other combined oral contraceptives

### Data analysis plan

Patient, treatment and diagnosis characteristics will be reported descriptively. Categorical data will be presented as counts (n) and proportions (%). Continuous data will be presented as means with standard deviation (SD) and as medians with inter quartile range (IQR) when appropriate. Results will be presented for the 2011/2012 users together and stratified by year of diagnosis.

## **Documents**

#### Study results

17660\_EU-PAS\_Abstract.pdf(59.26 KB)
17660\_Study Report DUS Diane - final.pdf(727.15 KB)

#### Study report

17660\_04\_Report.pdf(2.12 MB)

17660\_04\_Report extension.pdf(4.03 MB)

17660\_04\_Report\_ 1\_interim.pdf(727.05 KB)

#### Study, other information

17660\_04\_Report.pdf(2.12 MB)

17660\_04\_Report\_ 1\_interim.pdf(727.05 KB)

## Data management

## Data sources

#### Data source(s)

THIN® (The Health Improvement Network®)

PHARMO Data Network

## Data source(s), other

**HSD** Italy

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

Administrative data (e.g. claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

## 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