Regulation of psychotropic fixed dose combination drugs in India: a retrospective longitudinal study (Regulation of psychotropic FDCs in India)

First published: 14/02/2022

Last updated: 12/04/2022

Study Ongoing

Administrative details

EU PAS number

EUPAS45738

Study ID

46707

DARWIN EU® study

No

Study countries

India

United Kingdom

Study description

Fixed dose combination (FDC) products contain two or more drugs. Few clinical studies have considered the use of FDCs in psychiatry. FDCs containing psychotropic drugs, including combinations not approved by the Indian central regulator, are widely available in India. The Indian government has been attempting to ban the sale of FDCs lacking central approval since 2007. This study aims to assess the impact of the efforts to regulate psychotropic FDC sales.

Study status

Ongoing

Research institutions and networks

Institutions

Newcastle University

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Institution | Educational Institution

Population Health Sciences Institute

Public Health Foundation of India Delhi, India, The William Harvey Research Institute, Queen Mary

University of London London, UK

Contact details

Study institution contact

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Primary lead investigator

Bogowicz Paul

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 11/02/2022

Actual: 11/02/2022

Study start date

Planned: 07/02/2022

Actual: 07/02/2022

Data analysis start date

Planned: 21/02/2022

Date of final study report

Planned: 31/08/2022

Sources of funding

- Other

More details on funding

No funding

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

The study aims to assess the impact of the efforts by the Indian government to regulate psychotropic fixed dose combination (FDC) drug sales.

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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

0

Study design details

Data analysis plan

Descriptive statistics will be obtained to characterize sales trends over time. Where possible, interrupted time series analysis will be used to assess for

changes in sales trends, for drugs banned by the Indian government.

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 source(s), other

PharmaTrac India

Data sources (types)

Other

Data sources (types), other

Commercial database

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