Agencia Española de Medicamentos y Productos Sanitarios (Spanish Agency for Medicines and Medical Devices, AEMPS)

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Institution | EU Institution/Body/Agency | Not-for-profit | Regulatory Authority

Institution identification

Institution ID

3331474

Institution countries

Spain

Type of institution

EU Institution/Body/Agency

Not-for-profit

Regulatory Authority

Institution role

Other

Institution website

https://www.aemps.gob.es/

ENCePP partner

Yes

Institution description

The Spanish Agency for Medicine and Medical Devices (Agencia Española de Medicamentos y Productos Sanitarios or AEMPS) is the regulatory agency of the Spanish administration that oversees the quality, safety, efficacy and correct information of medicines and medical devices in Spain, as well as cosmetics, from their research to their use, in the interests of the protection and promotion of human health, animal health and the environment.
The AEMPS is committed to research, development and innovation; for that purpose, it sponsors and also participates in a number of national and international research programs and projects. Among them, BIFAP (Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público) is a nonprofit program administered and fully financed by the AEMPS that started in 2001 when primary care Electronic Medical Records (EMRs) were fully implemented throughout Spain (http://bifap.aemps.es).
The AEMPS also is the coordinating centre for the Spontaneous Reporting Scheme in Spain and also administer the database supporting this program (FEDRA).
The main use of BIFAP is to serve as a real-world data source for independent research projects to study adverse and beneficial effects and utilization patterns of medicines in the general population.
BIFAP and FEDRA are managed by the Pharmacoepidemiology and Pharmacovigilance Division in the Department of Medicines for human use of the AEMPS.

Institution details

Experience with collecting data directly from individual patients or respondents:

No

Interest in carrying out research that is funded by pharmaceutical companies:

No

Contact

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