

## BIFAP research database

### INFORMATION CLAUSE ON PERSONAL DATA PROCESSING

In accordance with REGULATION (EU) No 2016/679 of the EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and the free movement of such data, repealing Directive 95/46/EC (General Data Protection Regulation), you are INFORMED that the personal data collected will become part of the data treatment, the characteristics of which are as follows:

- **Treatment Name:** BIFAP research database
- **Treatment Description:** BIFAP is an electronic database of medical records of patients tended to in the Primary Care are of the National Health System, which aims to carry out pharmacoepidemiological studies aimed primarily at evaluating the use and safety of drugs.
- **Data Controller:** Medicines for Human Use Department (AEMPS)
- **Data Protection Officer:** delegado\_protecciondatos@aemps.es
- **Purpose of treatment:** Conduct population-based studies on the use, safety and effectiveness of drugs, as well as estimates of the prevalence/incidence of certain diseases and medical diagnoses. The results are representative of actual clinical practice.
- **Personal Data Categories:** Health data recorded in the primary care medical record, electronic medicinal products dispensations in pharmacy, and diagnostic records of hospital admissions. BIFAP does not contain patient personal identifiers.
- **Stakeholders Categories:** Patients cared for by family physicians and primary care paediatricians of the National Health System of the participating autonomous communities.
- **Deadlines for the erasing of the different categories of data:** They shall be retained for as long as necessary to fulfil the purpose for which they were collected and to determine possible responsibilities that might arise from that purpose and from the processing of the data. The provisions of the Archives and Documentation Regulations shall apply.
- **Legal basis:**
  - GDPR.- Article 6. 1. e) Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller
  - GDPR.- Article 89. Safeguards and derogations relating to processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes
- **Consignees:**
  - Researchers in Spain assigned to public bodies (health care, university, research) and primary care physicians of the National Health System collaborating with BIFAP. Researchers should register (Treatment Name: BIFAP services user management). In order to receive the data, project researchers must undergo training, submit a protocol that must be approved, and sign commitments.
  - No assignments or transfers of individual patient data records to third countries are foreseen.
- **Source from which the recorded data comes:** The data have been recorded by healthcare professionals who care for patients and incorporated into the health services information systems of the participating autonomous communities and are included in BIFAP already anonymized.
- **Right to information and transparency:** Detailed information on the purpose, the type of data it includes, information flows, access management, participants, data exploitation and information privacy protection procedures, in compliance with current regulations, is available at <http://bifap.aemps.es>.