FarmaLabel23

Consulting Services

for Firms in the Health Industry

www.farmalabel23.com

Consulting firm for companies in the Health and Pharma Industry, offering services in Regulatory Affairs, Prices and Pharmacovigilance. These services include: Marketing authorizations, maintenance of licenses, advisory services, Price & Reimbursement, and Pharmacovigilance of medicines.

FarmaLabel23 provides technical and scientific support to its clients in the health sector, complying with national and international legal framework.

Our company has the technical support of a broad group of experts specialized in regulatory matters, pharmacovigilance, pharmacoeconomics and related areas.

cantabria labs · Biogen · Biofrontera · AOP ORPHAN (Focus on rare diseases) · ADAMED

Seqirus (A CSL Company) · SHIONOGI · tecnimede · 3M España · Actavis

Pharmis · mundipharma · MERCK · iREElit (Radiopharma) · EBEXCO (Ebert Executive Consulting Inc.)

CLINIGEN Group plc · Genesis Pharmaceuticals · CAMURUS · INDIVIOR

WHO WE ARE

FarmaLabel23 is a consulting company that offers a comprehensive service to national and international pharmaceutical companies for the marketing of their products in Spain, complying with national and international legislation.

FarmaLabel23 began operations in 2009 as a response to increased demand for highly skilled personnel in regulatory issues and business development within the pharmaceutical industry.

Our company has the technical and scientific support of a broad group of experts with proven expertise in Regulatory Affairs, Price & Reimbursement, Pharmacovigilance, and other related areas.

FarmaLabel23 is collaborating with a broad portfolio of clients:

- Multinational Laboratories
- Generic Companies
- Start-Up Companies
- Manufacturers of Raw Materials

PURPOSE & VALUES

FarmaLabel23 was born in order to offer the Pharmaceutical Industry, within and outside of Spain, the possibility of outsourcing all procedures that Health Authorities require to be able to market their products in our country.

Among the values that defines us we can highlight:

Our commitment to **High Quality Service**, ensuring **Confidentiality** of information at all times and pursuing **Continuous Improvements** to better adapt to client needs.

- Our search for **Talent**, relying on highly skilled professionals in their field.
- Our **Collaborative Spirit**, always looking for more efficient ways to serve our clients.
- Our goal for maximum **Technical-Scientific Rigor** in adapting the information to current legislation.
- Our **perseverance** to achieve **Excellence** in everything we do, being personal contribution essential to our success.

WHY FARMALABEL23?

Farmalabel23 offers its clients the following advantages:

- We offer a **Comprehensive Service**, that allows us to support our clients in all phases of the marketing of the drug, without having to contract the different services to different companies (better planning of time and resources).

- We count with **Qualified Professionals** in their field, with proven experience in the pharma industry.

- We have an extensive **Experience** with Regulatory Agents and Health Authorities involved.

- We provide **Highly Specialized** Language Service, searching the terms suggested and accepted by Regulatory Agencies.

- Clients will benefit from a **Reduction** of local infrastructure costs (office rentals, personnel, supplies).

Our experience and knowledge of the Spanish and international pharmaceutical market allows us to discern the best regulatory strategy to achieve a fast and efficient commercialization.

PHARMACEUTICAL INDUSTRY IN SPAIN

The pharmaceutical industry in Spain is characterized by:

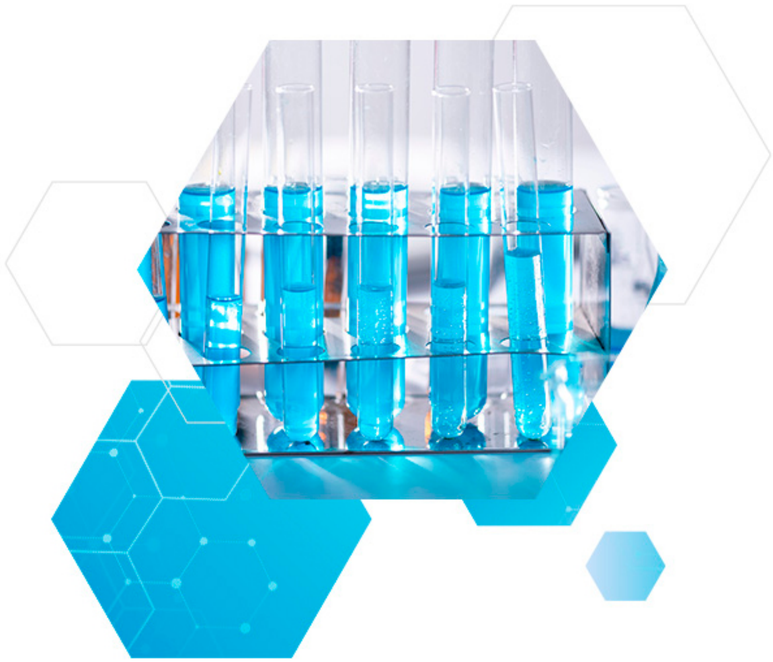
01 A highly regulated market (harmonized regulation with the EU).

02 Having high skilled professionals with diverse specialisations.

03 The prices of medicines are intervened for greater control of public health spending.

04 The market is very competitive and is fragmented in regions (CCAA).

ADVANTAGES OF INVESTING IN SPAIN



Fourth Most Populated country in the EU (47 million people) with a life expectancy at birth above 83 years.

Fourth Largest Economy in the EU (GDP of € 1.2 trillion).

Broad Hospital Network, spread throughout its territory (800 hospitals).

Fourth Health System in the EU with the highest allocation of resources to pharmaceutical spending, both in medicines and medical devices (€ 23,616 million / year).

Country with Highly Qualified Healthcare Professionals in their respective specialties (world leader in organ transplants with 117 transplants per million people and other therapeutic areas).

SERVICES

Farmalabel23 offers a comprehensive service to the pharmaceutical industry, starting from the initial phases before the marketing authorization, in the authorization, continuing with the decision on price & reimbursement, and its subsequent incorporation into the market.

Once the product is marketed, a license maintenance service is offered (variations, renewals ...), advice on price reviews that may occur due to changes in indications or indicated by the Health Authorities, and other services required by regulatory agencies.

With regard to Pharmacovigilance, **Farmalabel23** offers this service to companies that market drugs in Spain, either as a local responsible person or as a EU QPPV.

Pharmacovigilance

1. Advisory
2. Early Access Compassionate
3. Marketing Authorization
4. Price and Reimbursement
5. Market Access
6. Variations New Indications Safety Alerts
7. Off Label Use
8. Re-evaluation Efficacy Safety Price Use

REGULATORY AFFAIRS

- Registration in the **AEMPS platforms** to send documentation and maintenance of licenses
- **Centralized procedure**: translation of national texts (SPC and PL), blue box national information for requesting a National Code, fractioning of texts for CIMA
- **Decentralized Procedure and Mutual Recognition:** translation of national texts, national phase with the AEMPS, approval of packaging materials, fractioning of texts for CIMA
- **Variations** to Marketing Authorizations: Quality, Safety and Efficacy
- **Renewal** of Marketing Licenses
- **Processing** and follow up with Health Authorities
- **Readability test** and adaptation of texts to current legislation
- Scientific advice and **communication of advertising** to the CCAA authorities
- Review of **Promotional Material**

PHARMACOVIGILANCE

- **Contact person** for Pharmacovigilance / EU QPPV
- Registration in the **EMA platforms** for Pharmacovigilance management
- Pharmacovigilance System Master File **(PSMF)**
- **Reporting** of adverse reactions (Eudravigilance)
- Review of local and international **literature**
- Periodic safety reports **(PSUR)**
- Risk Management Plans **(RMP)**
- Pharmacovigilance **training**
- Pharmacovigilance **audits**
- Pharmacovigilance **SOPs**

PRICE & REIMBURSEMENT, MARKET ACCESS

- Service to apply for the NHS **Price and Reimbursement process**:
  - **Preparation and submission** of required documentation for the NHS P&R process.
  - **Strategic planning and price negotiation** with the Ministry of Health during the NHS P&R process.
  - **Advisory service** during the different stages of the NHS P&R process.
- Obtention of **digital certificate** and **registration** on GESFARMA platform.
- Preparation of **value dossiers**
- **Economic evaluation** reports for National Health Authorities:
  - Cost – effectiveness, cost – utility and cost – benefit analysis reports
  - Budget impact analysis report
  - Study on cost and burden of the disease
- Market Access

MEDICAL AFFAIRS

01 Specialized translations

02 Communications of investigational products to CCAA and AEMPS:

- Adverse reactions
- Annual Safety report (DSUR)

03 Labelling materials for clinical trials

04 Compassionate use

05 Off-label use

CLIENTS

3M España S.A.

Actavis S.A.

Adamed Laboratorios S.L.U.

AOP Orphan Pharmaceuticals

Biofrontera Pharma GmbH

Biogen IDEC Iberia

Clinigen Healthcare España

Genesis Pharmaceuticals LTD.

indivior PLC

Merck Sharp and Dohme S.A.

Mundipharma Pharmaceuticals S.L.

Pharmis Biopharmacéutica LDA.

Shionogi S.L.U.

Tecnimede España IND. FCA. S.A.

Cantabria labs

Seqirus Netherlands B.V.

Ire Elit S.A.

Camurus AB

Ebexco

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