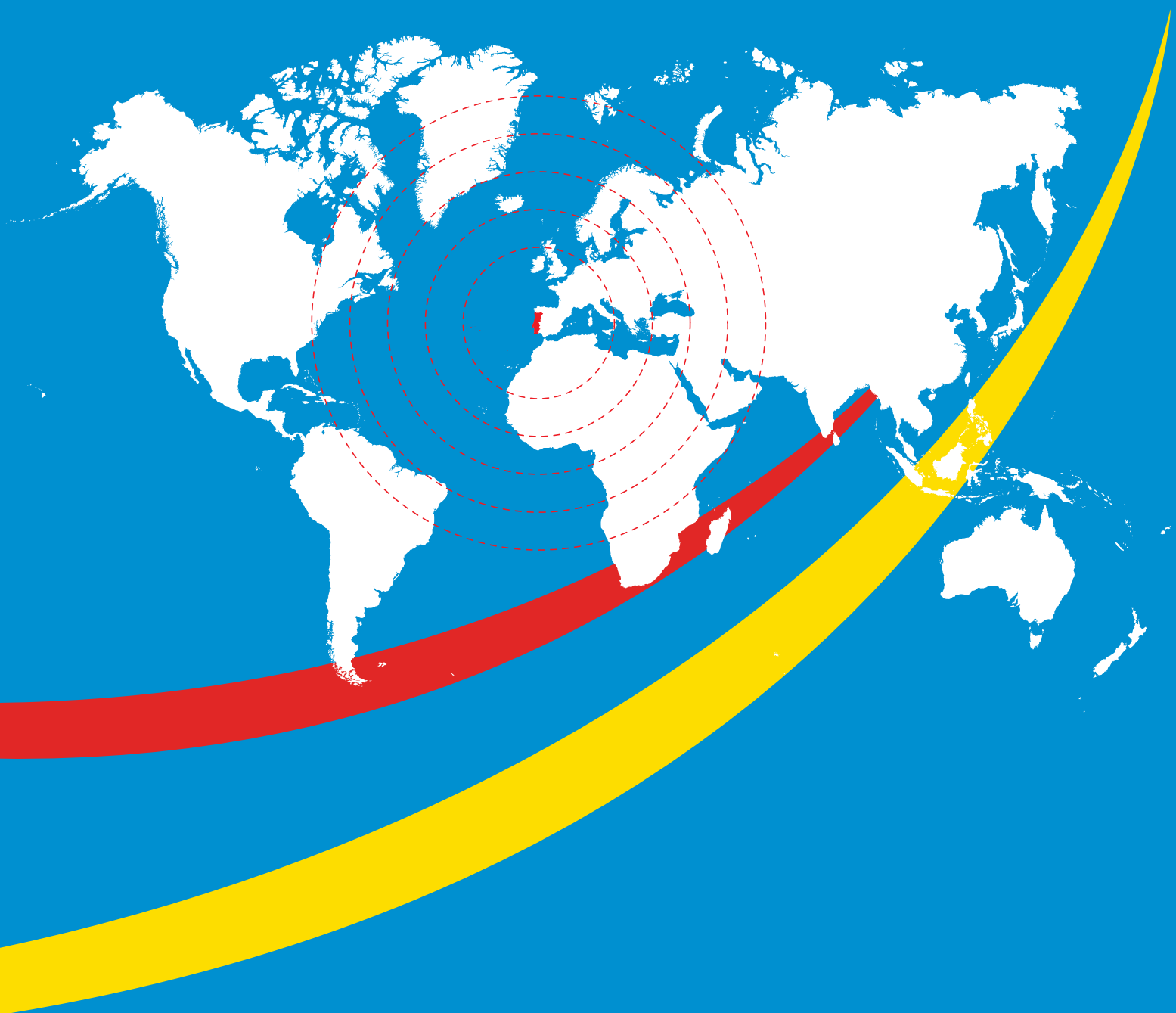


# PHARMACEUTICALS IN PORTUGAL

YOUR PARTNER IN EUROPE



PharmaPortugal



**Portugal** is the most westerly country in Europe, member of the European Union since 1986 and a founding member of the EURO currency. Portugal is an open door to the European market (500 million people) and Portuguese speaking countries (260 million people).

From Renewable Energies to Information and Communication Technologies the country is leading in a diversified range of sectors inspiring Global companies to invest in Portugal, and buy innovative products or solutions from leading Portuguese Brands.

With a highly educated talented people, Portugal has the second highest rate of engineering graduates in Europe, the fourth place in most spoken foreign languages with high proficiency in English, French, Spanish and German.

As to the **healthcare system**, Portugal has excellent professionals, has modern equipment and top rate indicators. This quality is regularly assessed by an independent national regulatory organization and there is a growing number of hospitals achieving international accreditation.

Portugal is a competitive partner for contract R&D services and clinical trials, given the quality of its infrastructures and its investment-friendly environment.

Portuguese companies are internationally recognized as high-quality suppliers of healthcare products and services, such as pharmaceuticals, medical devices and other medical technologies, having high standards of quality and being capable of developing, manufacturing and supplying a wide range of products and services with high flexibility. A consistent offer also exists in the country in terms of contract development and manufacturing organizations and producers of active pharmaceutical ingredients.

**aicep Portugal Global - Trade & Investment Agency** is a government business entity focused in encouraging the best foreign companies to invest in Portugal and contribute to the success of Portuguese companies abroad.

## ONE-STOP SHOP AGENCY

### INFORMATION

#### LOCATION

To help you finding the site that suits your project, AICEP will introduce you multiple location alternatives and will bridge you with utility suppliers

### CONTACTS

#### HUMAN RESOURCES

To support in the search of human resources and professional training, bridging contacts with Portugal's employment authorities and schools

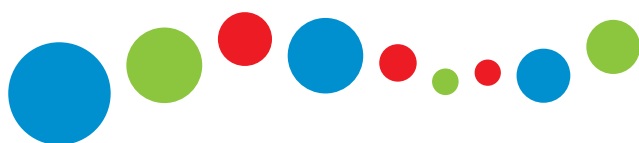
#### BUSINESS PARTNERS

AICEP will promote contacts with local suppliers and business partners that add value to your project.

### INCENTIVES & GRANTS

#### INCENTIVES

AICEP will analyse your eligibility to innovation, R&D, production and employment incentives



Created in 1993, **INFARMED – National Authority of Medicines and Health Products, I.P.**, the Portuguese Medicines Agency, is one of the authorities that has collaborated in the creation of the current European regulatory system since the establishment of the European Medicines Agency (EMA) in 1995. INFARMED follows and supports the growth of EMA and is actively engaged in the European Medicines System.

EMA relies on the network of national agencies to issue scientific opinions, which form the basis of the European Commission's marketing authorisation. EMA and the Member States cooperate and share expertise in the assessment of new medicines and of new safety information. They also rely on each other for exchange of information in the regulation of medicines, for example regarding the reporting of side effects of medicines, the oversight of clinical trials and the conduct of inspections of pharmaceutical manufacturers and compliance with good clinical practice (GCP), good manufacturing practice (GMP), good distribution practice (GDP), and good pharmacovigilance practice (GVP).

To ensure an adequate market supervision, Member State's regulatory authorities are responsible for granting licenses for manufacturers, importers and wholesalers of medicines intended for the EU market. INFARMED's inspectorate performs these activities at a national level and at international level, either by request from the EMA, in the scope of the centralized, mutual recognized and decentralized procedures, or in the context of national marketing authorisations. Equivalence between Member States' inspectorates is ensured by a variety of ways, including common legislation, common GMP and common procedures.

As one of the 10 founding members of the Pharmaceutical Inspection Convention, Portugal acceded to the PIC Scheme in 1999 (operating together, they are jointly referred to PIC/S). Representing Portugal, INFARMED participates actively in its development, producing guidelines for GMP and GDP and performing, with other countries, joint inspections to assess new applications to this organization.

As Member State, Portugal is also part of a number mutual recognition agreements with third country authorities relating to the conformity assessment of regulated products, covering mutual recognition of GMP compliance. Portugal is firmly committed and engaged in the EU project and the dissemination of its values and is well placed to contribute to the global regulatory environment.

## THE EUROPEAN UNION - KEY FACTS

Population: >500m



Medicines regulatory authorities: 50+

GDP: € 12.9tn



Official languages: 24

The EU has developed a single market through a standardised system of laws that apply to all its Member States. The same rules and harmonised procedures apply to all the 28 Member States regarding the authorisation of medicines and the supervision of the safety medicines.

### EU MEMBER STATES: 28



The European Economic Area (EEA) is formed of the 28 EU Member States plus:



Iceland Liechtenstein Norway

### Mutual Recognition Agreements



Australia Canada Israel Japan New Zealand Switzerland USA

**The Portuguese Association of the Pharmaceutical Industry – APIFARMA** - was established in 1975 in order to contribute to solving the problems of the sector and for the improvement of health in Portugal and patient access to new therapies. Currently, APIFARMA represents more than 100 companies responsible for the Production and Marketing of Medicinal Products for Human Use, Vaccines, and In Vitro Diagnostics.

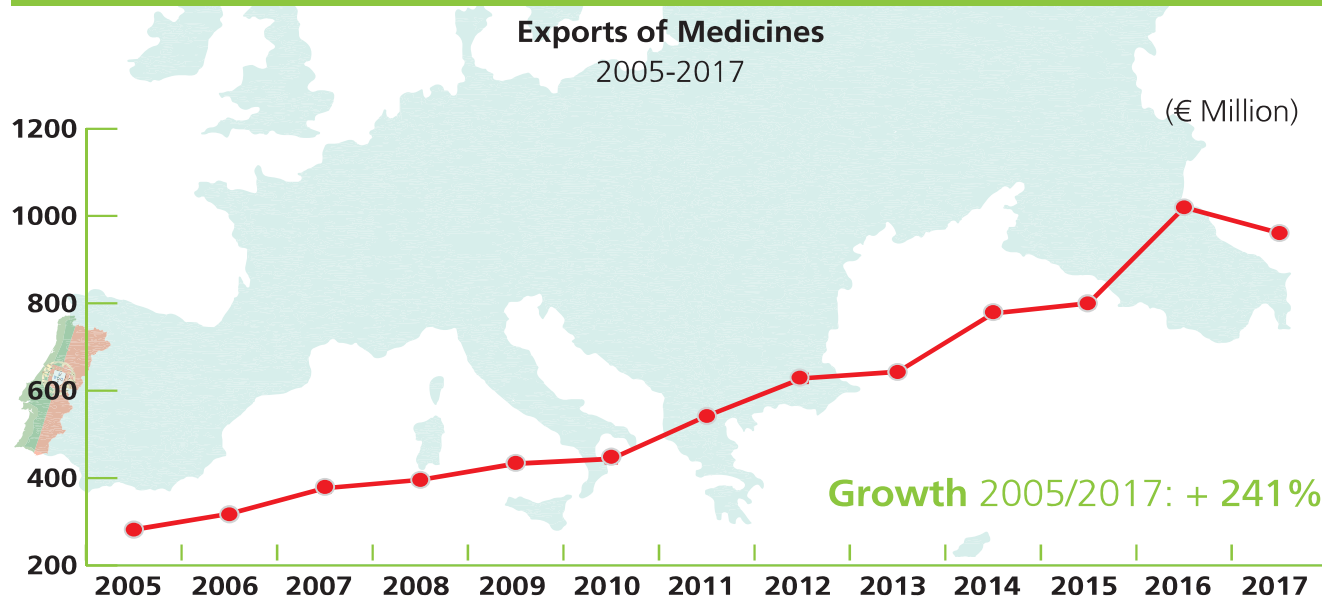
#### Pharmaceutical industry as a strategic sector:

- Portugal integrates the European medicines regulation system.
- Portuguese companies with European marketing authorizations of medicines, granted by INFARMED.
- Portuguese factories are inspected and approved according with the regulatory European system.

#### The Portuguese pharmaceutical industry is highly competitive:

- Portugal is an excellent gateway to Europe
  - Efficient R&D and a large offer of products and services
  - Flexibility and a unique ability to adapt to the needs of "worldwide partners"
- > 1.000 Medicines with marketing authorization EU/Portugal  
Export to 148 Countries  
Growth of exports over > 200% in the last 10 years  
High competitiveness: quality, productivity and qualified human resources  
Protection of industrial property rights

### PORTUGUESE PHARMACEUTICAL INDUSTRY



**Source:** National Statistical Institute of Portugal

1 – Exports are based on the EU's combined nomenclature:

- Code 30 – Pharmaceutical Products covering only Codes of Medicines: Code 300 and Code 3004

2 – Definitive data: until 2015; Provisional data: 2016; Preliminary data: 2017.

In 2017 **PORTUGAL** was among the **30<sup>th</sup>** largest world exporter of pharmaceutical products. Portugal exported around **1 billion of euros** to **148 countries**.



**PharmaPortugal** is the brand name that identifies national based exporting pharmaceutical companies and their products and communicates an image of European quality to the world.

The PharmaPortugal project, the Strategic Project for the Export and Internationalisation of the Portuguese Pharmaceuticals Industry, is a partnership between APIFARMA (the Portuguese Pharmaceutical Industry Association), aicep Portugal Global - Trade & Investment Agency and INFARMED – National Authority of Medicines and Health Products, I.P. and 12 Portuguese based pharmaceutical groups and companies.

The project's main objectives are: To increase exports as well as to internationalise the Portuguese pharmaceutical industry; To contribute to increasing the value of products and services in the value chain and the greater use of R&D; To build and promote an image of modernity and quality that meet the highest international standards.

Innovation, competitiveness, accessibility, efficiency, sustainability, quality, dedication, highly qualified human resources are some of the characteristics that the Portuguese pharmaceutical industry has to offer you.

All this makes PharmaPortugal companies excellent **partners for your business**.



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**APIFARMA - Portuguese Pharmaceutical Industry Association**

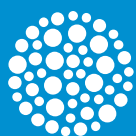
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Trade & Investment Agency



**Infarmed**  
Autoridade Nacional do Medicamento  
e Produtos de Saúde, I.P.



**apifarma**  
ASSOCIAÇÃO PORTUGUESA DA  
INDÚSTRIA FARMACÉUTICA