

1st BME Global Pharma Supply Chain Congress

INVESTINPORTUGAL

High Potential for health products and services



Frankfurt, Germany

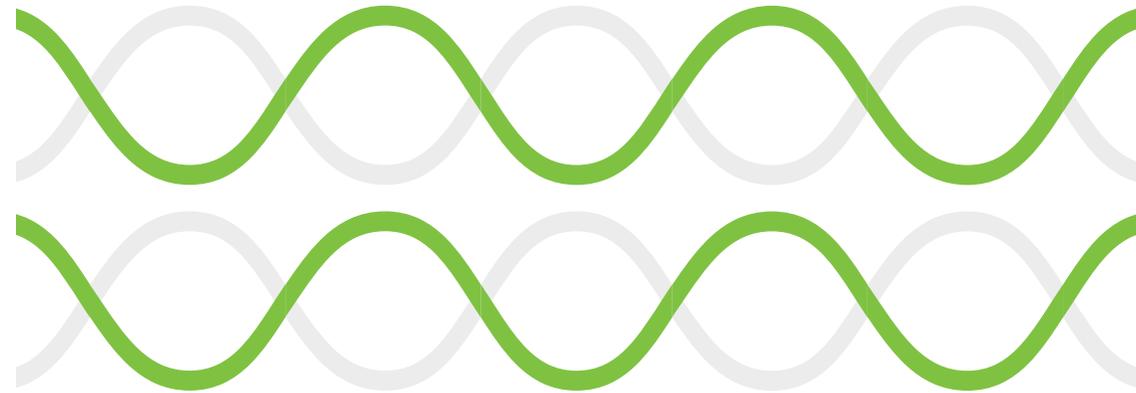
23 - 25.02.2016



aicep Portugal Global
Trade & Investment Agency

INVESTINPORTUGAL

High Potential for health products and services



R&D services

Clinical trials

Genetic tests

Generic drugs

ICT solutions for medicine

Medical devices

Active pharmaceutical ingredients

Biological therapies

Frankfurt, Germany

23 - 25.02.2016



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PORTUGAL

High potential for health products and services

Portugal has developed two new medicines: Zebinix for epilepsy and Opicapone for Parkinson's.

New drugs of Portuguese origin are about to improve your well-being.

But we go beyond drug development.

For your health, we develop sophisticated genetic tests that diagnose rare diseases and we create software that allows the treatment of patients more efficiently.

Portuguese researchers are awarded year after year for their findings in areas such as neurology, oncology, degenerative diseases or pathology, contributing to the cure of thousands of diseases.

In the delivery of health care, Portuguese clinics, hospitals and pharmaceuticals supply clients with turnkey solutions that allow providing the best medical care in every corner of the world.

We train top health professionals. Portuguese surgeons, doctors and nurses are scattered throughout the world and contribute on a daily basis towards the health of millions of people.

Meet some of the Portuguese companies that are changing the health sector.



Strong commitment to clinical research

Clinical trials are investigations in humans intended to discover or verify the effects of one or more investigational medicinal products. The regulatory environment of clinical trials aims to ensure that the rights, safety and well-being of trial subjects are protected and the results of clinical trials are credible.

Clinical trial data is included in clinical-study reports that form a large part of the application dossiers submitted by the Pharmaceutical Industry applying for marketing authorizations, enabling new treatments to reach patients. Academic driven research projects further advance the refinement of therapeutic strategies to change practice and establish the state-of-the-art treatments.

Promoting research and innovation at national level, including by making Portugal a more competitive destination for clinical trials is an enterprise pursuit by government, pharmaceutical industry, scientific community and health care intuitions in Portugal.

Portugal offers a well-defined clinical trials review and oversight system. The ethical review is provided by a national central Ethics Committee (CEIC) dedicated to clinical research and thus enabling for the directive's provision of one single opinion per clinical trial protocol. The regulatory services provided by national competent authority for human medicines and medical devices, INFARMED, I.P., include:

- Authorization and supervision of the conduct of clinical trials
- Regulatory support to facilitate clinical trials applications
- Scientific and regulatory advice to support the development of innovational products or technologies
- Coordination with other Member-states and with the national ethics committee, CEIC, in the assessment of clinical trials application under the EU voluntary harmonization procedure (VHP) that maximizes current harmonization and paves the way for the future EU legislation.

The clinical research activity in Portugal is mostly developed by pharmaceutical industry and dedicated to confirmative therapeutic, multi-center, multi-national studies, mainly targeting therapeutic areas with unmet needs, as oncology and rheumatology, where immuno therapeutic approaches are highly investigated. Infectious, cardiovascular, neurological and ophthalmological diseases, are also important areas of clinical

research in Portugal, with rare diseases and paediatric conditions also having a very significant expression.

The clinical trials above referred are generally conducted in a number of recognised high quality clinical research centers, integrated in the main health care institutions in Portugal, both from the public and private sectors. These sites generally display procedures centralized in clinical research units, integrate European networks and are associated with publications in peer-review scientific journals.

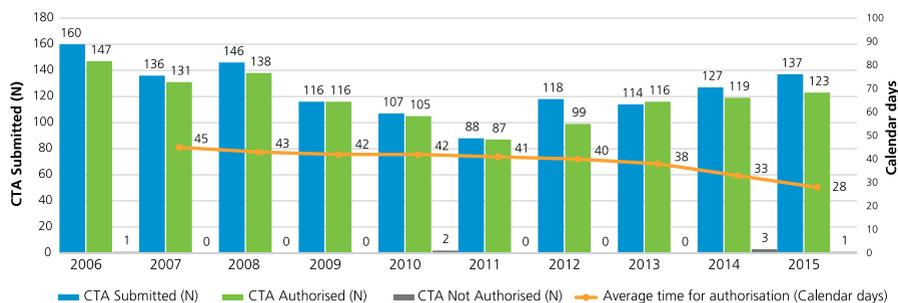
Early phase clinical research units, integrated or associated to the main Hospital institutions have also been increasingly active. Furthermore, there are a number of areas in biomedical research in Portugal with potential for translating to clinical research in the near future.

Increasing competitiveness of the clinical research in Portugal

The numbers of new clinical trials per year (submitted and authorized CTA) and the average time of review and decision by the Portuguese competent authority (INFARMED, I.P.) is presented in Figure 1 and shows:

- A steadily progressive rise in the clinical trials activation in the recent years and
- Competitive regulatory review timelines, consistently shorter than the legal deadlines and further reduced as a result of the enactment of the national legislation in clinical research in 2014.

Clinical Trial Applications (CTA) and Regulatory review timelines in Portugal



Currently, the commitment to foster innovative and competitive clinical research in Portugal has strengthened. Particular governance attention has been recently directed to this area driving the revision of the legal environment to expand the regulatory framework of the clinical trials with investigational medicinal products to all clinical research studies and to overcome operational constraints previously identified.

This favorable environment is launching new initiatives, both from public and private sectors, at several of the complex multidisciplinary levels involved in clinical research. In general, measures being taken to increase the efficiency of innovative and competitive research in Portugal are the following:

- Improving widespread awareness of the value of clinical research;
- Promoting information transparency and exchange capabilities;
- Developing conditions, as dedicated time and training, for physicians to advance clinical research;
- Strengthening existent or building new capabilities at clinical trial units, compliant with high quality GCP compliant research services, by:
 - Infrastructure support reorganization
 - Training and education programs focused in ICH GCP
- Expanding clinical sites capabilities with a focus to primary care units
- Diversification and reinforcement of funding opportunities in clinical research

It is expected, an already observed, that these measures and initiatives drive outcomes in the following areas:

- Early phase / exploratory clinical trials
- Recruitment rates
- Academic / investigator initiated clinical research projects
- Positioning of the Portuguese players in the international clinical research networks
- Internationalization potential.

In conclusion there is a strong commitment in Portugal to foster a research active culture considered critical for promoting research and innovation which are vital for the future of patient care.

Source: Infarmed

PUBLIC ENTITIES

aicep Portugal Global



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aicep Portugal Global is a Trade & Investment Agency created to increase the competitiveness of the Portuguese economy through the development and execution of structuring policies and the support to the internationalisation of the Portuguese companies, by:

- Promoting a competitive business environment to attract and assist structuring investment projects;
- Promoting Portuguese exports, by increasing the number of exporting companies and encouraging a larger incorporation of technology in their products;
- Promoting and spreading the Portuguese economic offer, namely in the area of goods and services;
- Supporting the internationalisation of Portuguese companies, mainly the small and medium-size ones;
- Promoting Portugal's image abroad as well as the Portuguese brands.

aicep Portugal Global – Trade & Investment Agency develops its activity supported by a large network of business offices, over the five continents. This network is a key factor to perform the strategy of the Agency as facilitator of business and commercial contacts.



Infarmed – National Authority of Medicines and Health Products, I.P.



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Role

Under the aegis of the Ministry of Health, INFARMED – National Authority of Medicines and Health Products, I.P., is the national regulatory authority that evaluates, authorises, regulates and controls human medicines as well as health products namely medical devices, and cosmetics. The Institute's main goal is to ensure the quality, safety and efficacy of medicines and the quality, safety and performance of health products in order to avoid the risks of their use while ensuring adequate standards of public health and interest. Infarmed performs at national and european levels its competences and responsibilities of National Competent Authority on medicines and health products and of Reference Laboratory on the Quality Control of Medicines within the scope of the Network of Official Medicines Control Laboratories (OMCL).

Areas of Activity

The Institute pursues its activity in several domains at national and european levels.

- Research, evaluation and authorisation of medicines;
- Quality, safety and efficacy control of medicines;
- Good Clinical Practices (GCP's) in clinical trials;
- Research, assessment, registration, monitoring and supervision of health products;
- Clinical research evaluation, assessment and registration of medical devices, notification of health care products and market supervision activities;
- Licensing and inspection of pharmaceutical activity;
- Licensing, auditing and inspecting manufacturers, wholesalers non-prescription drugs stores and pharmacies ensuring the respect for the rules applicable to each operator namely Good Manufacturing Practices (GMP's), Good Distribution Practices (GDP's) and Good Pharmacy Practices (GPP's). Medicines and health products quality control;
- Collecting medicines and health products samples along the whole circuit and ensuring their analytical control at Infarmed's laboratory.

COMPANIES



Azevedos Group



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Specialists in Pharmaceuticals

Azevedos Group is a specialist in pharmaceuticals, operating in Portugal, Angola, Brazil and Mozambique, exporting to more than 50 Countries in five continents. Through its companies it offers integrated marketing, production, R&D, logistics and international services.

Our companies are specialized and highly competitive in their respective areas. Their performance allows for the creation of a dynamic and efficient group that looks towards the future.

Quality

Total quality is the attitude for the Azevedos Group. We fully comply with pharmaceuticals standards. Our references – cGMP; ISO 9001; ISO 14001; OHSAS 18001 – are the core of our management.

Flexibility

Our goal is to present solutions for partners, markets and our own demands. We are able to answer on a larger scale to the requests we receive.

Figures

- More than two centuries of history
- More than 50 million units produced annually
- Export to more than 50 Countries
- 18 specialized companies, three continents
- More than 200 AIM's in Portugal and more than 1.000 AMMs worldwide

Bluepharma – Indústria Farmacêutica, S.A.



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Bluepharma is a Portuguese capital pharmaceutical group based in Coimbra, which currently comprises more than 10 innovative affiliates that cover all stages of the pharmaceutical industry value chain.

Bluepharma's mission is to market pharmaceutical products of the highest quality at competitive prices, contributing for the rationalization of expenses in the health sector and simultaneously to the improvement of the life quality of populations.

Based on a continued experience of over 40 years in manufacturing pharmaceutical products, on the know-how of its technical team and on the vision and dynamism of its management team, Bluepharma focuses on research, development, registration, production and marketing of pharmaceutical products.



Kent Pharma, S.A.



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Kent Pharma S.A. was born in 2011 from the need of getting more medicines to deal with for CEF's group. CEF company was dedicated to International Trade Business of medicines since 1985 and is pioneer in his activity.

Kent Pharma S.A. has as its main target the national and international trade of medicines business and other medical devices, negotiating directly or via partners brand medicines of all categories.

Kent Pharma's export markets are USA, Middle East, Europe and Africa. With the purchase of Port Farmaceutical we became owner of another warehouse, this way extending our action in the National Market. We are a group offering the needed medicines for acting in all targets of the market.



Laboratórios Basi – Indústria Farmacêutica, S.A.



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Laboratorios Basi is a leading Portuguese Pharmaceutical company with decades of experience dedicated to the development, manufacture and marketing of high quality medicinal products, being present over the 5 continents, with strong presence in Europe, Africa, Middle East & CIS countries.

Laboratórios Basi is committed to provide treatments at competitive cost with a guarantee of excellence based on our long existence and experience.

Our team is young, dynamic, highly qualified and permanently in training, allowing us to meet the specific needs and requirements, with high adaptability and capability to evolve and to make the difference to our customers and partners. Our top management has a solid know-how in the pharmaceutical sector, resulting from several years of experience.

Our state of art manufacturing site is dedicated to the Development and Manufacture of Liquid and Semi-solid dosage forms (oral and topical).

Laboratórios Basi offers a wide diversity of pharmaceutical products for out license as well as tailor made solutions for co-development and contract manufacturing. Presently we have more than 200 pharmaceutical products registered belonging to 50 different therapeutic areas.

Synergistically integrated in a relevant pharmaceutical group in Portugal, Laboratórios Basi can also offer in a simple way interesting solutions on Logistics & Regulatory affairs in the global market. The group is constantly looking for partners willing to participate and to be involved in its ambitious expansion project.

Laboratório Medinfar – Produtos Farmacêuticos, S.A.



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Medinfar is a fully integrated Pharmaceutical Company headquartered in Lisbon, Portugal.

Founded in 1970, Medinfar is focused in R&D, Production, Distribution, Marketing and Sales.

Medinfar is the N°1 Portuguese Company in Consumer Health Products and Dermatology. In Portugal besides our own brands we market licensed products in partnerships with top international pharmaceutical companies.

The company markets a wide range of products: Prescription medicines, Consumer Health, Dermocosmetics, Food Supplements and Veterinary products, in more than 50 countries.

Through our R&D – GMP center and our GMP manufacturing site Farmalabor, we offer our customers a focalized assistance based on personalized turnkey solutions being total customer satisfaction our priority and aspiring always to great long-term commercial relationships.

We offer:

- Licensing out
- Marketing & Distribution
- Contract Manufacturing
- Packaging Services
- EU Batch Release
- R&D Services
- Pharmaceutical and cosmetics product development
- Analytical services
- Pilot batches
- Stability studies

Medlog SGPS, S.A.



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The Coopprofar-Medlog Group has been developing logistic solutions in Healthcare for 40 years. Its vast expertise built in the supply chain of pharmaceuticals and health products makes the Group a reference logistics operator, with recognition in the industry as a strong and competitive player. Today, it holds a vast know-how and positions itself in the market as a global logistics partner.

The Group stands at the top of rankings, being among the 100 Biggest and Best national companies, and also being the largest company in the sector with national equity.

The know-how accumulated over three decades and its profile have resulted in differentiated and innovative services with customised solutions as part of logistics partner in Healthcare.

Management of the Coopprofar-Medlog Group is focused on mirroring Experience, Innovation and Proximity, values that are materialised in a team of 300 highly qualified employees.

The Coopprofar-Medlog brand is driven by a guiding force directed towards success.



Rangel Logistics Solutions



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In 2009 we started the development of integrated logistics services for the pharmaceutical industry in Portugal. Today we are the reference player and specialized market leader, operating with the highest quality standards. Our highly qualified team has all the technical, operational, administrative and technological skills, which enables us to provide tailor made solution for your pharma & healthcare supply chain, including warehousing services, domestic and international distribution and on-line information in real time for the Pharmaceutical industry. Our culture is based on commitment, dedication and professionalism. At Rangel, we work daily to provide you the service excellence that our customers are expecting and that characterizes our brand.



BUSINESS ASSOCIATIONS

Apogen – Portuguese Generic and Biosimilar Medicines Association

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Apogen – Portuguese Generic and Biosimilar Medicines Association is a national, non-profit, association which is governed by democratic criteria, independent of the State, public authorities and professional organizations. Founded on 26th of May 2003, Apogen consists of pharmaceutical companies present in the Portuguese market and dedicated to the production and marketing of generic and biosimilar medicines.

Apogen's mission is to promote the concepts of Generic and Biosimilar medicines, actively contributing to the development of this market in Portugal, making medicines more affordable, in a sustainable health system.

Apogen's main activity is to monitor, study and analyze all aspects, legal, scientific, economic and technical that have impact on the common activity of its members companies.

As an entity constituted of several member companies, Apogen seeks to inform its members of all actions aimed at increasing the quality of their products and/or processes. In this sense, develops before the competent official authorities, efforts to improve production, marketing, distribution and sales of Generic Medicines and Biosimilar Medicines, at the same time that represents the member companies before the public.

Health Cluster Portugal (HCP)



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The Health Cluster Portugal (HCP) is a private non-profit association that currently brings together about 160 members, including R&D institutions, universities, hospitals, organisations from civil society and companies in the areas of pharmaceuticals, biotechnology, medical devices, ICT and services.

Together, HCP and its members develop innovative projects in areas such as translational and clinical research, active and healthy ageing, health tourism and eHealth, with the purpose of turning knowledge into new solutions that contribute to the improvement of human health and wellbeing, and work to make Portugal the right place to invest and build partnerships in Health. More information about HCP and its members is available at www.healthportugal.com and www.healthportugal-directory.com.

PharmaPortugal

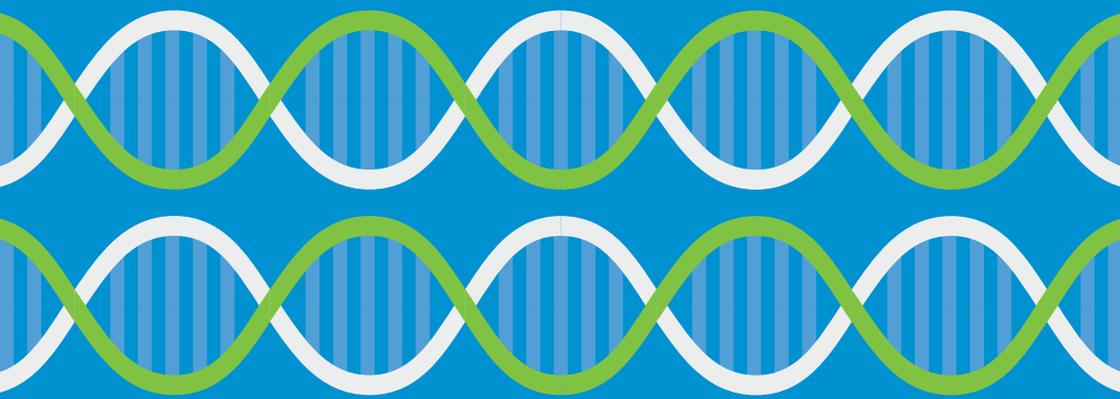


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PharmaPortugal is a partnership between the Portuguese Pharmaceutical Industry member companies of APIFARMA, which aims to promote the export and internationalization of Portuguese pharmaceutical companies that produce and export medicines and other health products from Portugal.

The project is established in partnership with INFARMED, I.P. (Regulatory Authority), who streamlines contacts and regulatory procedures in order to promote recognition between regulatory authorities.

PharmaPortugal's main goals are, among others, to promote an external image of the pharmaceutical sector based in Portugal, to increase cooperation between companies in Portugal and abroad, and to contribute to a greater value for the products and services in their respective value chain, through the incorporation of R&D, obtained by the cooperation between companies and universities and between companies with a technological base.



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