Personalised medicine is a set of scientific fields comprising epigenetics (the study of how environmental factors cause diseases like cancer or Alzheimer’s) and pharmacogenomics (the study of the effect of an individual’s genetic variability in their response to certain drugs). Personalised medicine is the (genetically) individualised diagnosis and treatment of diseases. Potential applications include cancer treatments where a treatment based on the genetic condition and molecular characteristics of the tumour is designed, maximising the immune response against the pathology and minimising the need to take medication and therefore side effects.

**INTRODUCTION**

**ORIGIN OF THE INVESTMENT OPPORTUNITY**

**ECONOMIC/BUSINESS**

The application of pharmacogenomics in the health system could help reduce total costs in the medium term, mainly by reducing the costs associated with the administration of drugs, especially in oncological diseases.

The diseases with the larger business opportunity for development of early diagnosis and treatments in medicine are haematology (e.g. transplant immunology and malignancies of lymphoid tissues) and oncology (the most common among the population: breast, colon and lung).

Research in personalised medicine is the "priority" area of H2020 European funding programme "Health, demographic change and well-being" with a budget of 543.5 million euros earmarked for personalised and stratified medicine during 2015.

The technology is currently in the development phase of the national biotech sector. This gives rise to the SUMMA project which coordinates public procurement projects of innovative technology in the areas of oncology and haematology.

**DEMAND**

While there are certain drugs considered to be precision, the field of oncology technology is currently more a stratified, meaning that different types of cancer are classified based on critical targets for developing effective drugs in place of a personalised one. Therefore the opportunity of personalised medicine is placed in the research phase.

**REGULATIONS**

**TECHNOLOGY**

**LOCATION OF THE INVESTMENT OPPORTUNITY IN THE SECTOR VALUE CHAIN**

While there are certain drugs considered to be precision, the field of oncology technology is currently more a stratified, meaning that different types of cancer are classified based on critical targets for developing effective drugs in place of a personalised one. Therefore the opportunity of personalised medicine is placed in the research phase.

**DIFFERENTIATING FACTORS OF THE INVESTMENT OPPORTUNITY**

**CONSUMER/USER**

- Innovation
- Price
- Quality

- The more highly patient-specific treatment can be done faster and is less traumatic for patients recovery, which is expected to reduce the average hospital stay significantly.

- Personalised medicine involves management and drugs savings, ensuring the provision of a more efficient service for patients and more sustainable from the economic point of view.

**COMPANY/INNOVATION**

- Operations
- Supplies
- New business lines

- New personalised drugs are accompanied in most cases by biomarkers (predictive and diagnostic tests) to identify patients for whom treatment is most appropriate and to monitor progress.

- In addition to the biomarker throughout all stages of development, the research of new drugs drives: research, clinical trials, manufacturing and commercialisation.

**SOCIETY**

- Environment
- Well-being
- Safety

- The search for effective drugs and without side effects (pharmacogenetics) is essential to increase the effectiveness of treatment and reduce negative side effects, which in some cases can even be fatal.

- Clinical experience shows the low efficiency of some treatments in various diseases such as Alzheimer’s (between 30% and 60%); schizophrenia (between 25 and 75%) or hypertension (between 10 and 70%).

**INVESTMENT OPPORTUNITY LIFE CYCLE**

**DEVELOPMENT**

Cellular regulation (epigenetic) was first described 50 years ago and technologies are currently under in the development phase with the national biotech sector. However, there is already pharmacogenetic information regarding 25% of the medicines used and pharmacogenetics is already a reality in most of the major Spanish hospitals (7 welfare, 7 research and 3 are very interested in starting this type of tests) [1], although there are still major barriers to implementation and final extension into hospital pharmacy services, such as training of staff and low budgets having impeded their spread.

**INTRODUCTION**

CHARACTERISTICS OF THE SECTOR (2)

- Supply

**TOP 5 COMPETITORS IN SPAIN**

<table>
<thead>
<tr>
<th>#</th>
<th>Company</th>
<th>Net sales</th>
<th>Last available data</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Roche farma SA</td>
<td>€635.4 M</td>
<td>2014</td>
</tr>
<tr>
<td>2</td>
<td>Sistemas genómicos</td>
<td>€3.49 M</td>
<td>2013</td>
</tr>
<tr>
<td>3</td>
<td>Pangaea biotech</td>
<td>€3.09 M</td>
<td>2013</td>
</tr>
<tr>
<td>4</td>
<td>Progenika biopharma</td>
<td>€2.82 M</td>
<td>2013</td>
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<tr>
<td>5</td>
<td>Vivia biotech</td>
<td>€0.72 M</td>
<td>2013</td>
</tr>
</tbody>
</table>

**Demand**

- It is expected that the global market of personalised medicine will reach a volume of 2.453 billion by 2020.
- By activity, the fastest growing segments will be the proteomics (the study of proteins in epigenetic) and genomics, which emerged as a result of intense research of the prior segment.
- Between 2011 and 2014, the number of personalised medicine therapies grew 57% from 72 to 113 products (diagnostic tests and targeted therapies). In 2006 there were only 13 treatments globally.

**Success Stories**

In 2012, Progenika Biopharma presented Proscan, a genetic test for predicting the risk of relapse (recurrence of an illness shortly after the end of convalescence) in prostate cancer. Proscan will help urologists in choosing personalised treatments from a sample of blood or saliva from the patient, the test detects five genetic variants associated with the risk of the disease recurring following convalescence after surgery. Among other successfully developed and marketed products is the IBDchips, the first DNA chip that can predict the clinical course of inflammatory bowel disease which includes ulcerative colitis and Crohn’s disease.

Pangaea Biotech has a laboratory of 380 m2 with the latest technology dedicated to applied research studies in the area of personalized medicine. It was the first pharmacogenetic laboratory to be certified by ENAC (National Accreditation) in Spain and audited by FDA (United States Food and Drug Administration), with more than 10,000 genetic tests a year, demonstrating a high operational capacity. Among the successes of the company are the patent (European Union) of its own method for determining the degree of EGFR mutations in blood. In 2013, Pangaea Biotech signed an alliance with the Institut Quimic de Sarrià (IQS) to jointly investigate lung cancer and other solid tumours over a period of three years.

Roche has a presence in Spain and are leaders in the healthcare industry on the world stage. In recent years, Roche has developed the area of personalised medicine, combining expertise in the areas of diagnostics and pharmaceuticals. There is some progress in oncology, such as the K-RAS mutation test in cases of colon-rectal cancer, which identifies tumour-specific mutations to anticipate the prognosis of the disease before symptoms. The test helps doctors identify patients who could benefit from a specific cancer therapy, depending on the absence or presence of the mutation.

Positive Factors for Investing in Spain

Favourable factors for the development of the opportunity

High level of research activity

Spain has a large number of both public and private centres. In the private sector, it the pharmaceutical company Ferrer stands out, with an investment of 30 million euros over the last eight years in the field of personalised medicine. At the public level, the National Cancer Research Centre stands out, which receives 7 million euros of European funds for cancer research.

Push in the development of new technologies

Spain stands out in diagnosis, search for biomarkers, developing microarrays, gene silencing, and development of personalised therapies. Specifically, they include the National Bioinformatics Institute and the Carlos III Institute of Health, which spent over 26 million euros on the training of researchers.

Partnerships with the National Health System

The SUMMA project aims to identify early demand for technologies in the field of Personalised Medicine (advanced markers). To do this, it will assess the needs of hospitals in the field of biomarkers and technology to coordinate public procurement projects of innovative technology, mainly in the areas of oncology and haematology.

Social factors and habits

The forecasts of the Spanish population by age reveals a progressive and continued ageing of the population. According to the INE (Spanish Statistical Office), the percentage of population over 65 years old currently stands at 18.2% and will become 24.9% in 2029 and 38.7% in 2064. This projection places the Spanish population as a market with great potential in terms of healthcare. (3)

Favourable factors for the sector in Spain

Macroeconomic situation

For weight of the sector in GDP (sales of companies using biotechnology respect to national GDP), the ratio continues to grow another year and reached 9.07% of GDP at constant prices (compared with 7.61% in 2012 and the low 2.91% in 2008). 88% of companies carried out some international activity, mainly in Europe and North America. (4)

Labour market

The average productivity per employee in the chemicals sector is 91,400 euros per year. Their average individual remuneration is 51,300 euros per year. The Unit Labour Cost accounts for 56.1% of the ratio between the remuneration per employee and the individual productivity (productivity defined as value added per employee). (5)

Incentives

The Centre for the Development of Industrial Technology (CDTI) finances R+D projects in four categories: Individual R+D projects, National Cooperation R+D projects, International Technological Cooperation Projects and specific announced R+D projects. Furthermore, there are other cross-sectional programmes such as the línea Directa de Innovación, the línea de Innovación Global, Innvierte and FEDER (ERDF) Interconecta. Also, the ICEX-IIS Technology Fund funded by the ERDF and ICEX offers companies with foreign capital aid of up to 75% of the project to carry out new R+D+i in Spain.

I+D+i

The Spanish biotechnology companies involved in R+D+i are small: 84% of companies have fewer than 100 employees, 68% no more than 25 employees and 38% have less than 10 employees (micro), mostly spin-offs. (6)

Suppliers, Supplies, Raw materials

Personalised medicine is based on the use of new discoveries and molecular diagnostic trials. The Spanish government backs the Programa Oncológica, focused on the development of biomarkers to improve the prognosis and diagnosis of cancer to detect cancers and predict its development.

The project consists of seven biopharmaceutical and biotechnology companies led by PharmaMar.

Geographic location

Spain is within reach of three main regions: the European region, the Mediterranean region and the Atlantic region. Spain is considered to be the gateway between North Africa and Europe, and a key link to Latin America, not only because of its geographical location but also because of its strong historical and cultural ties with the region. In Spain the Canary Islands play a key role with regards to maritime traffic with West Africa.

Technological and research infrastructure

The Healthcare Reputation Monitor (MRS) establishes the best public and private hospitals based on indicators such as human and material resources, number of beds, availability of basic and high-tech equipment, total admissions and average time of stay, and satisfaction with the service.

The top five public hospitals are La Paz, Hospital Clinic i Provincial de Barcelona, the Gregorio Maranon, Vall d’Hebron Hospital and 12 de Octubre. The five best private centres are the Navarra University Hospital, the HM Montepinici, the HM Sanchinarro, the Quirón de Madrid and the Hospital Ruber Internacional. (7)

Transport infrastructure and logistics networks

There are 250 airlines operating in Spain in its 47 airports; its high-speed rail network is the 2nd best in the world and the best in Europe; it is ranked 1st in the EU for its motorway network; and it has excellent sea connections to its 46 ports distributed along the Atlantic and Mediterranean coasts. (8)