



Generic drugs are products that are synthesised using chemicals and that have a proven bioequivalence with a previously approved drug, also called brand-name drug products. Furthermore, biosimilars refer to biologically synthesised products, which are not identical to the drug but are equal in quality, safety and efficacy to the original, as generics are when compared to the brand-name equivalents. This opportunity is to attract companies that manufacture these drugs to supply the market and provide cheap and sustainable treatment for illnesses that affect citizens.

ORIGIN OF THE INVESTMENT OPPORTUNITY



Between 2015 and 2019, twelve patents of the best-selling biological drugs in the world will expire. These biopharmaceuticals treat key diseases such as cancer, diabetes, multiple sclerosis and rheumatoid arthritis and are among the most important in terms of cost for health systems as they are among the ten most expensive drugs in the world, and mainly in Europe. In fact this market, of the twelve main products lose their patents in the coming years, is worth about 1.3 million euros in Spain. This "patent cliff", as it known in the industry, along with the appeal of the Spanish market, favour the entry of a new generation of biosimilars.

Regarding the regulatory framework, the Spanish government favours the promotion and protection of the generics market to ensure access to drugs for the treatment of ailments and diseases for its citizens, and to confront the challenges of increasing life expectancy, the ageing population and the increase in chronic diseases. With respect to the biosimilars market, a legal regime that regulates its movement in the market and that ensures the replacement and traceability of these drugs with corresponding biological or innovative ones is necessary.

LOCATION OF THE INVESTMENT OPPORTUNITY IN THE SECTOR VALUE CHAIN



This opportunity is focused on the commercialisation of biological drugs and in the conduct of clinical trials to demonstrate the bioequivalence of them with the brand name drugs. There is also the possibility to enhance and develop the generics market to be an economical alternative to cover the demand of citizens.

DIFFERENTIATING FACTORS OF THE INVESTMENT OPPORTUNITY

CONSUMER/USER	COMPANY/INNOVATION	SOCIETY
<ul style="list-style-type: none"> Innovation (3 red circles) Price (3 red circles) Quality (3 red circles) 	<ul style="list-style-type: none"> Operations (2 red, 1 white circle) Supplies (2 red, 1 white circle) New business lines (3 red circles) 	<ul style="list-style-type: none"> Environment (2 red, 1 white circle) Well-being (3 red circles) Safety (3 red circles)
<ul style="list-style-type: none"> Biosimilars are a cheaper alternative to biological medicines, this difference allows a lesser restricted access to key therapies for diseases such as cancer, multiple sclerosis or rheumatoid arthritis. Improving the quality of life of patients with neurological, rheumatological, endocrine illnesses or those with tumours, among others. 	<ul style="list-style-type: none"> Collaboration with research centres and Public Administration in the development of research systems and the financing of these drugs. Opening of new business lines that favour attracting health tourists for conducting clinical trials. Improving the prestige and image of the company, which is concerned about citizens and the sustainability of the healthcare system. 	<ul style="list-style-type: none"> It fosters the financial sustainability of the National Health System by being cheaper than biological drugs. It favours the access of citizens to biological treatments against serious illnesses such as cancer, diabetes or rheumatoid arthritis. It encourages pharmaceutical innovation and optimises therapeutic protocols.

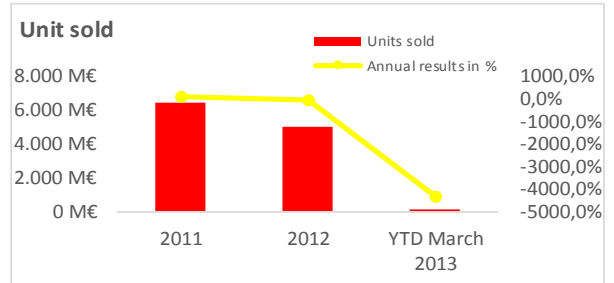
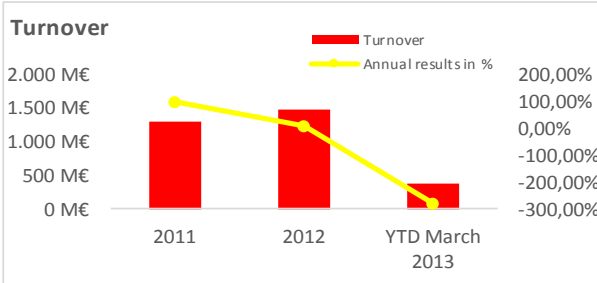
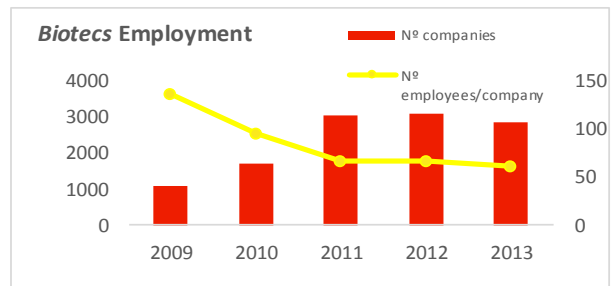
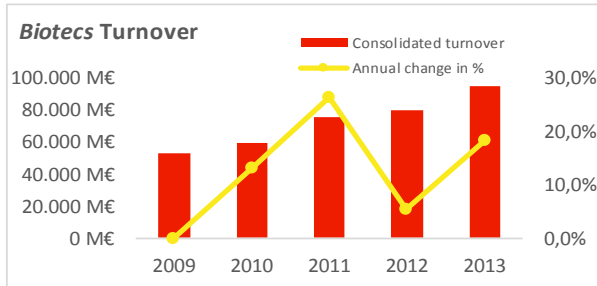
INVESTMENT OPPORTUNITY LIFE CYCLE



The biosimilars market will experience strong growth with the expiration of the patents of the most expensive biopharmaceuticals. This means that it predicts that biosimilars will fulfil the same role for Public Health as generics did, and continue to do. In fact, these drugs have allowed savings for the National Health System of 1 billion euros per year for the past 13 years, reaching 38.7% of market share in Spain, in terms of units sold. This percentage represents an increase of over 100% compared to 2010. The exponential growth of this market has been favoured by the policies of reducing pharmaceutical expenditure which have since been implemented in the country. (1)



CHARACTERISTICS OF THE SECTOR (2)



SUPPLY

TOP 5 COMPETITORS IN SPAIN

#	Company	Net sales	Last available data
1	Laboratorios Cinfa	€343.56 M	2013
2	Laboratorio Stada	€194.44 M	2013
3	Laboratorios Normon	€191.46 M	2013
4	Kern Pharma	€163.16 M	2013
5	Teva*	N. avai.	-

* Data not available in the queried database, SABI.

DEMAND

GROWTH

- The market for biosimilars in Spain has a turnover of around **40 million euros**, which could be multiplied exponentially over the next five years.⁽³⁾
- A new generation of biosimilars and the opening of a potential **1.3 billion euros** market, according to recent studies, a saving of 1.5 billion euros up to 2020. It is expected that in 2018, biosimilars will represent **50% of drugs spending**.

SUCCESS STORIES



Teva is a global company specialising in the development, production and commercialisation of generics and innovative drugs. Based in Israel, it operates in 60 countries and has 46,000 employees worldwide. It is n the **Top 10 Pharmaceutical Companies in the World** and is a global leader in generics. In 2004, Teva came to Spain, installing a **manufacturing plant in Zaragoza** and providing jobs for 950 people. 1.3 billion capsules, 1.1 billion tablets and 31 molecules are made in the plant, 40% for the domestic market and 60% for the international market. Teva has the leading share of the generics market in Spain.



The multinational pharmaceutical company Ratiopharm was founded in 1973 in Germany and has its headquarters in Ulm. It specialises in the development, production and commercialisation of **speciality generic pharmaceuticals**. In 2010, Ratiopharm joined the world leading group in the production and marketing of generic drugs, Teva. It currently has a presence in 60 countries, selling over 550 million units per year, turning over about 20 billion euros and has a portfolio of 750 drugs. Ratiopharm became the **first authorised generics in Spain** in 1997. Recently, it has included a picture of dosage on any packaging.



Barcelona Clinical Trials Platform (BCTP) is an initiative created in the last quarter of 2014 by the Department of Health of the Generalitat of Catalonia and Biocat (an organisation that promotes biotechnology) in order to position Catalonia among the top five European territories for **conducting clinical trials**, providing a gateway into seven prestigious teaching hospitals and a national primary care network of more than **5 million** patients. The research institutes bringing together the platform currently have the participation of 2,740 centres in ongoing clinical trials in different areas such as oncology, infectious diseases, neurology, cardiovascular disease, etc.



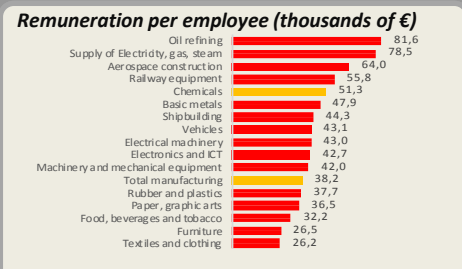
POSITIVE FACTORS FOR INVESTING IN SPAIN

Favourable factors in Spain for the development of the opportunity

Experience in clinical trials	The pharmaceutical industry has promoted the development of a platform of excellence in clinical research of drugs in Spain, collaborating with 43 laboratories, 57 centres, 14 autonomous regions and 4 independent research groups. The country's prestige in this field is recognised worldwide, with eight centres as part of Pfizer's "INSPIRE" programme .
Health tourism	The wide network of hospitals, of which there are 787 in total, along with the quality of the Spanish health system are a major attraction for health tourists. In 2014, 25,000 tourists came to be in private Spanish hospitals and this market is expected to turnover 500 million euros during 2015. The Spanish healthcare sector stands out for offering key medical specialities, among which are: assisted reproduction, cosmetic and plastic surgery, cardiology, oncology, urology, orthopaedics, ophthalmology, dentistry and wellness centres like Incosol Medical & SPA in Marbella, SHA Wellness Clinic. ^{(4) (5)}
Innovative potential	Four of the top ten companies having manufacturing plants in Spain: Cinfa, Normon and Kern Pharma are Spanish generics companies, and the Israeli company Teva has a plant in Zaragoza. Spain is ranked as the 4th country in the European Union for the authorisation of new drugs and the second busiest in terms of pharmacovigilance. ⁽⁶⁾
Social factors and habits	The forecasts of the Spanish population by age reveals a progressive and continued ageing of the population. 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, according to the INE (Spanish Statistical Office). This projection places the Spanish population as a market with great potential in terms of healthcare .

Favourable factors for the sector in Spain

Macroeconomic situation	With regards to the weight of the sector in terms of GDP (turnover of the business using biotechnology with respect to GDP), the ratio has continued rising for a further year, reaching 9.07% of GDP at constant prices (compared to 7.61% in 2012 and just 2.91% in 2008). 88% of companies carry out some international activity, mainly in Europe and North America. ⁽⁷⁾
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). ⁽⁸⁾



Graph created using data from Sectoral Presentation: construction and services 2015, April 2015 (Ministry of Industry, Energy and Tourism)

Incentives	The Ministry of Economy and Finance provides tax incentives for R+D+i for companies that are resident in Spain. A general deduction of 30% of expenditure on R+ D and 10% of investment in fixed and intangible assets. There is also an additional deduction of 20% of the amount of staffing costs . Also, companies that invest more than 10% of their turnover in R+D could increase the amount of their deduction for R+D by up to 5 million euros per year . In the case of technological innovation, the deduction will increase to 12% of expenses incurred. In addition, the Icex-IIS Technology Fund provides funding of up to 75% of investment in R+D+i.
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. In 2014, 58 biotech companies started their activity in the sector. ⁽⁹⁾
Bioclusters and bioregions	Spain has opted for cooperation to generate synergies between all stakeholders in the industry, an example of that are 8 bioregions in Spain: BioBasque in the Basque Country , Andalucia's BioRegion , Biocat in Catalonia , the Community of Madrid's Madrid Biocluster , the Valencian Community's Bioval , the Canary Islands' BioRegion , BioMed in Aragon and the Balearic Islands' BIOIB .
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 (<i>MRS</i>) 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 Clínic i Provincial de Barcelona, the Gregorio Marañon, Vall d'Hebron Hospital and 12 de Octubre. The five best private centres are the Navarra University Hospital, the HM Montepríncipe, the HM Sanchinarro, the Quirón de Madrid and the Hospital Ruber Internacional. ⁽¹⁰⁾
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. ⁽¹¹⁾

Location of the top 10 public and private hospitals in Spain in 2014



Graph created using the results of the Health Reputation Monitor - **Reputación (R)** (2014) World Ranking (7) FENIN "Annual Report" (2014). (8) MINETUR, "Sectoral Presentation: Chemical industry" (2015) (9) MINETUR "Report - profile of Spanish biotechnology companies involved in R+D+i" (2014) (10) MERCOR, "Healthcare provision indicators" (2014) (11) Brand Spain, "Foreign investment in Spain and its socio-economic contribution" (2014)

Sources: (4) Ministry of Health, Social Services and Equality (MSSSI); (5) Report - medical tourism, a potential economic engine for Spain - **Reputación (R)** (2014) World Ranking (7) FENIN "Annual Report" (2014). (8) MINETUR, "Sectoral Presentation: Chemical industry" (2015) (9) MINETUR "Report - profile of Spanish biotechnology companies involved in R+D+i" (2014) (10) MERCOR, "Healthcare provision indicators" (2014) (11) Brand Spain, "Foreign investment in Spain and its socio-economic contribution" (2014)