

THE BELGIAN PHARMACEUTICAL CLUSTER



INSTITUTE FOR STRATEGY
AND COMPETITIVENESS



HARVARD | BUSINESS | SCHOOL

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1.0 Executive Summary

Despite a lack of natural resources and a small domestic market, Belgium is one of the most prosperous and competitive countries in the world. Belgium is divided into three regional areas: Flanders, Brussels and Wallonia. Each region has its own executive and legislative power which encourages local specialization and better allocation of government resources. However, this leads to regional inefficiencies and inconsistencies, increasing the cost of doing business in Belgium.

Belgium's macroeconomic competitiveness is determined by EU integration and strong institutional infrastructure. Microeconomic competitiveness is shaped by a competitive business environment across the diamond, with excellent distribution infrastructure and access to EU markets. Belgium has four large, export-oriented clusters: chemicals, biopharmaceuticals, plastics and jewelry. Country risks include regional political instability and increasing government deficits. We recommend that the government implement a national cluster strategy and harmonize regional regulations.

Belgium is the world's second largest exporter of biopharmaceutical products. Strong factor conditions include a dense network of 167 hospitals and quality educational institutions (as measured by citations). This supports one of the highest pharmaceutical R&D re-investment rates in Europe. Belgium's favorable business context includes the fastest approval process in Europe for clinical trials. As a result, Belgium is the world's no. 1 location for clinical trials per capita. The cluster also benefits from strong supporting industries such as biotech, chemicals and logistics, which complement industry activities in R&D, manufacturing and distribution.

Cluster risks include a complex and lengthy reimbursement process for new drugs and scarce availability of skilled labor. We therefore recommend that the government establish a fast-track new drug approval process and amend its *Numerus Clausus* policy (which currently limits the number of medical students). Cluster participants can encourage further upgrading of the cluster by establishing an IFC to coordinate the sharing of research best practice for specific therapeutic areas.

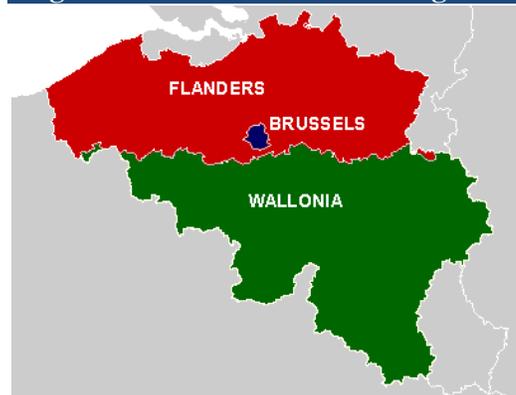
2.0 Overview of Belgium

Although Belgium is a small country with limited natural resources, it is still one of the most prosperous countries in the world. The country has a population of 10.7 million people and a GDP per capita of US PPP \$35,238.¹ Belgium ranks 16th in the Global Competitiveness Index and 18th in the world in terms of hourly labor productivity.² Belgium is located at the heart of Europe, on the North Sea, and is bordered by Germany, Netherlands, Luxembourg and France. The country has an open economy with very high levels of international trade, in part due to its excellent port and road infrastructure. Brussels serves as capital to both Belgium and the EU, and is the home of 1,200 international organizations.³

Belgium was historically organized as a collection of feudal duchies and states. It was part of the Hanseatic League which stimulated regional trade during the Middle Ages. The country was part of the United Kingdom of the Netherlands until its independence in 1831.⁴ Belgium's

federated structure continues to this day; the country is divided into three regional areas, each with its own executive and legislative power: Flanders in the north, Brussels in the center, and Wallonia in the south (see **Figure 1**).⁵

Figure 1: Federal Structure of Belgium

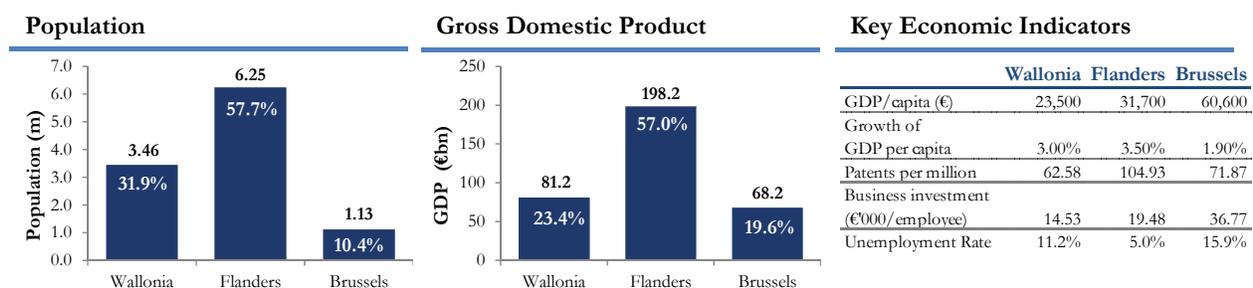


2.1 Regional Overview

Belgium is a federalist state, and hence we assess the country's competitiveness across each of the three regions. This is outlined below in **Figure 2**.⁶ There has been an increase in decentralization and regional decision-making since 1970. This federal approach allows government officials to pay closer attention to regionally oriented interests, resulting in better allocation of federal resources. Despite these benefits, the country's regional structure increases administrative costs, both in terms

of budgeting and coordination efforts, and hinders business operations by increasing business transaction costs.

Figure 2: Regional Economic Performance



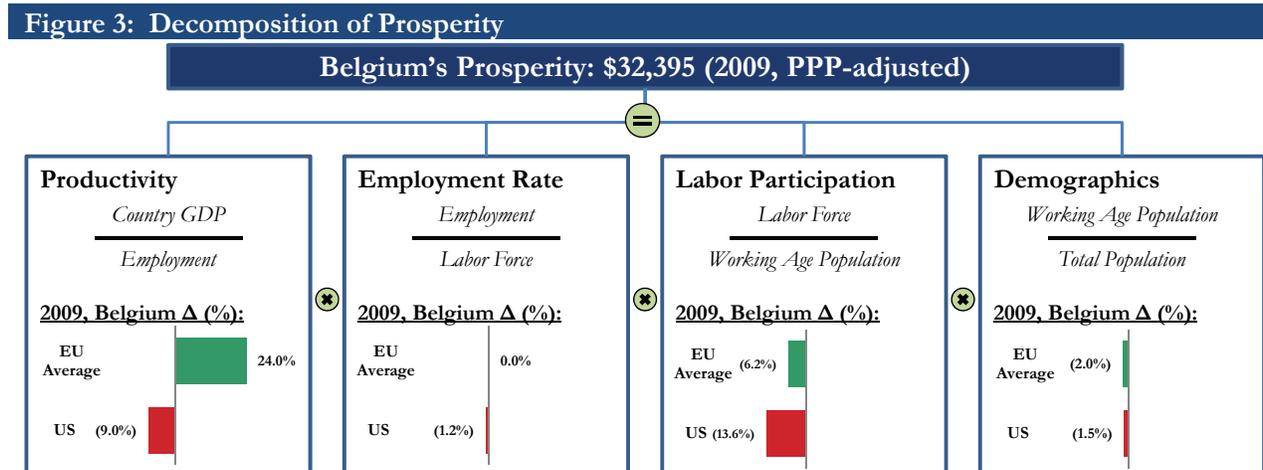
There has been an emergence of political and cultural tensions in recent years. In 2005 a group of 50 Flemish businessmen & academics authored the *Warrande Manifesto* which proposed partitioning Belgium into two states.⁷ The political system has since been in crisis: Belgium has not had a government since June 13, 2010.⁸ This political paralysis leads to uncertainty and inefficiency within the current federalist structure, increasing the probability of division.

2.2 Belgian Economic Performance

Belgium is one of the world's richest countries, and a member of both the EU and the OECD. Belgium is home to 3% of the EU population, and had a 2009 GDP of US PPP \$377 billion (~3.7% of the EU total).⁹ This corresponds to a national prosperity (as measured by GDP per capita) which is comparable to other developed countries such as the UK, France, and Germany.¹⁰

During the global financial crisis in 2008, Belgium's economy grew by 1.1%, well above the EU and OECD averages of 0.7% and 0.4%, respectively.¹¹ This robust recovery demonstrates the strong fundamentals and diversity of the Belgian economy. Services account for 75.3% of Belgium's GDP, industry and manufacturing account for 23.9%, and the remaining 0.8% corresponds to agriculture.¹²

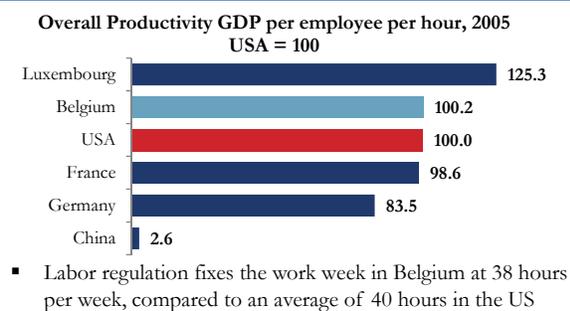
A decomposition of Belgium's headline prosperity figure allows us to identify the main differences between Belgium's GDP per capita and the US level. Belgium has lower productivity per worker (GDP per employee) and reduced labor force participation (see **Figure 3**).¹³



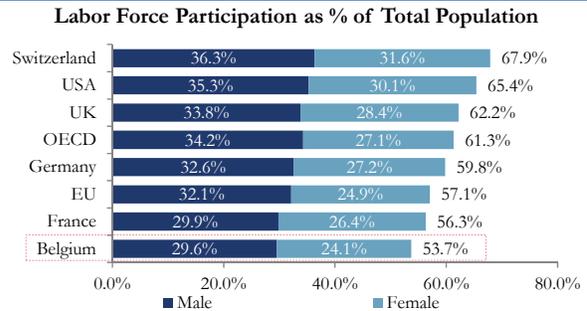
However, the productivity difference is a function of different working hours per week. When adjusted by hours worked per employee, Belgium's hourly productivity level remains comparable with the US and above that of Germany and France. Belgium's low labor force participation remains consistent across both men and women (see **Figure 4**).¹⁴

Figure 4: Labor Force Indicators

Hourly productivity is similar to the US...

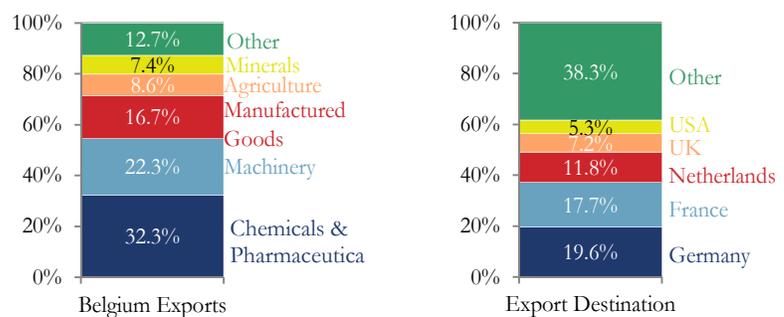


Less people are willing to work in Belgium...



Trade: Belgium’s economy is characterized by trade openness and a strong export orientation. Total trade (imports and exports) stands at 185% of GDP, well above Belgium’s regional peers and the EU average of 69%.¹⁵ Belgium’s largest trading partner is Germany, which accounts for 20% of total exports.¹⁶ Chemicals and pharmaceuticals have the largest share of Belgium’s export basket at 32.3%.¹⁷ Belgium has a highly diversified set of export industries and export partners. This diversification helped the country to swiftly recover from the current account deficit it incurred during the 2008 financial crisis. **Figure 5** outlines Belgium’s main exports by product category and destination.

Figure 5: Belgian Export Products and Destination



FDI: Belgium has substantial levels of FDI, most of which are concentrated in the Flanders

region.¹⁸ Before the financial crisis, inflows stood at €70.2 billion, or ~22% of GDP.¹⁹ There has been significant growth in FDI over the last decade, and this has increased competitiveness of the private sector (through both M&A and greenfield investments). The largest inward investor is the US, which accounted for 47% of FDI inflows in 2009.²⁰ The UK and France account for 14% and 13% of inflows respectively.²¹ Foreign entities own companies in a range of Belgian industries including utilities, steel, telecommunications, insurance, and pharmaceuticals.

2.3 Competitive Analysis

According to the New Global Competitiveness Index (New GCI) compiled by the Institute for Strategy and Competitiveness, Belgium was the 16th most competitive country in the world during 2010.²² Belgium’s overall country competitiveness ranking is a function of six determinants.

National Endowments: Belgium has few natural resources. However, it occupies a central location within Europe. This location, coupled with well-developed seaports, airports, roads, and highways, all support trade and transportation in the region.

Social Infrastructure and Political Institutions (SIPI): Belgium has a strong rule of law and a respected independent judicial system. The New GCI ranks Belgium 18th in the world according to its Social Infrastructure and Political Institutions. Belgium has an established parliamentary democracy and a popular monarchy (installed in 1831 following concerns that the country would become annexed to France).²³ Belgium has a strong public education and health system.

Macroeconomic Polices: Since Belgium is part of the European Union, its monetary policy is set by the European Central Bank. Belgium's macroeconomic indicators are sound; however, the country's budget deficit reached 4.8% of GDP in 2010. The government is focused on reducing Belgium's annual deficit below 3%.²⁴ These actions will have a significant impact on future fiscal policy, and as a result, the country will have to either raise taxes or cut public spending.

Quality of National Business Environment: Belgium's business environment ranks 18th in the world, despite having a corporate tax rate that is higher than the EU average.²⁵ The country has an investment climate which is aligned with EU policies and standards and which supports open trade and full capital mobility. Belgium's strong infrastructure and its educated and multi-lingual workforce support both domestic and foreign businesses in meeting local and global customer demand.

State of Cluster Development: Belgium has developed strong export-oriented clusters, such as: biopharmaceuticals; chemicals; plastics; and jewelry, collectibles and precious metals. From 1997-

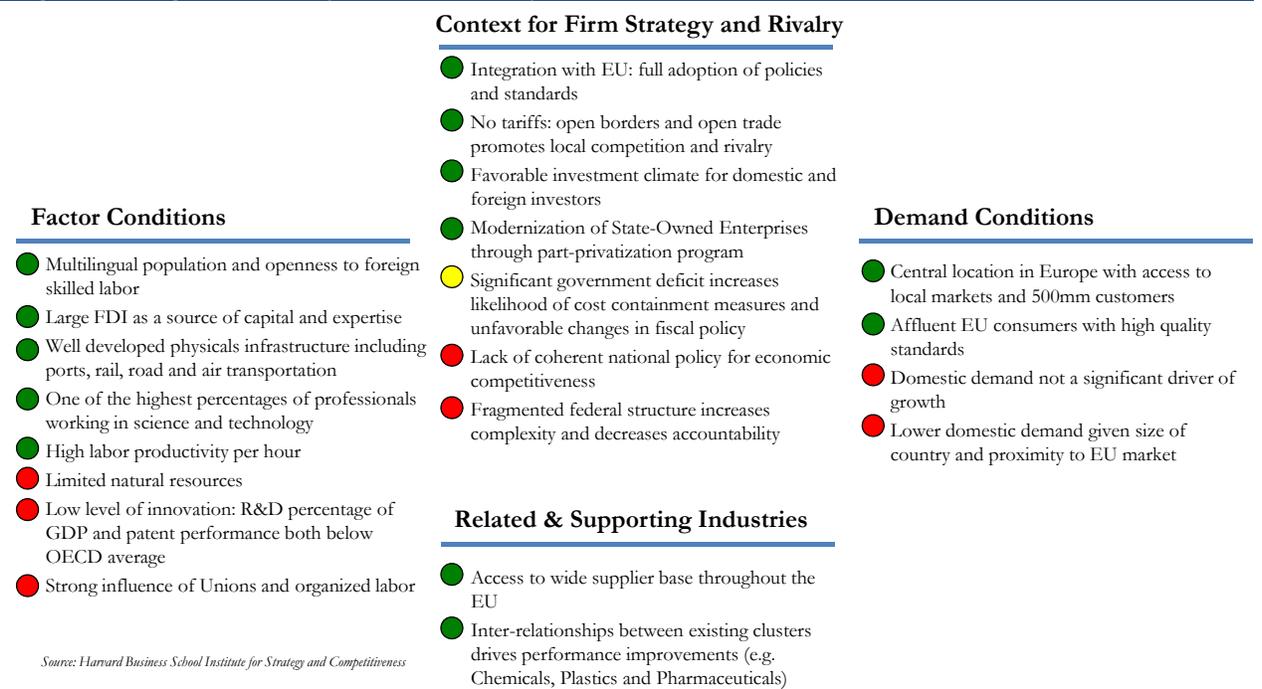
2007 the world share of Belgium’s biopharmaceutical and chemicals cluster grew rapidly, while the plastics cluster and the jewelry, collectibles and precious metals cluster both lagged behind.²⁶

Sophistication of Company Operations and Strategy: The New GCI ranks Belgium companies 15th in the world in terms of sophistication. 12 Belgian firms are listed on Forbes Global 2000 (two of them linked to chemicals and pharmaceuticals/biotech industries) and six Belgian firms are in the Global 500 Rank.²⁷

2.4 Diamond Analysis

Figure 6 below outlines the country’s strengths and weaknesses by applying the diamond framework.²⁸ We then explore each element of the diamond in greater detail. Note that Belgium’s location and EU membership drive a number of cross-linkages within the diamond, which we explore for each element of the diamond in turn.

Figure 6: Belgium Country Diamond Analysis



Context for Firm Strategy and Rivalry: Belgium is subject to EU competition policy which promotes free-market competition, private enterprise and FDI. The European Customs Union encourages free trade of goods, services, capital and labor within the EU, and common low import tariffs with the rest of the world. These policies advance the country’s trade openness and encourage strong competition in local markets.

Belgium’s investment climate matches EU standards, and supports national and foreign investors with full capital mobility.²⁹ This approach encourages expansion of local companies and increased levels of FDI (either in the form of acquisitions or new market entry). Belgium recognizes the importance of FDI in attracting new capital and skills; each region has its own foreign investment agency, allowing for greater specialization of the regions.

The Belgian government has also overseen modernization of a number of State-Owned Enterprises (SOE). A partial privatization program was pursued to increase the efficiency and infrastructure of the provision of a number of public goods and services such as utilities, telecommunications, transport and postal services. **Figure 7** summarizes a number of recent partially privatized SOEs in Belgium.³⁰

Belgium’s anti-trust legislation promotes and maintains market competition by regulating anti-competitive conduct. Belgium has two bodies to regulate anti-trust activities: the *Competition Council*, which works to break up naturally-formed monopolies, and *The Agency for Control and Mediation*,

Figure 7: Belgian State-Owned-Enterprises	
Government Promoted Privatizations	 <ul style="list-style-type: none"> 53.5% stake held by the government.
	 <ul style="list-style-type: none"> 25% ownership. No further privatization envisaged
	 <ul style="list-style-type: none"> 35.5% held by Belgium Government. No further sell-down anticipated.
	 <ul style="list-style-type: none"> Flemish government holds 27%.
	 <ul style="list-style-type: none"> 50% held by Belgian Government. Sold 50% to CVC Capital Partners and Post Danmark in 2006 to modernize the company

which investigates commercial malpractices.³¹ Sectors that are deemed to be monopolistic (e.g., water supply, waste handling, etc.) are subject to price controls. Prices in sectors related to social welfare, such as medicines, are also strictly regulated. We will address this later.

Despite these strengths in Belgium's context for firm strategy and rivalry, we observe the lack of a coherent national policy for economic competitiveness. This may be the result of internal divisions within the country and recent political instability. A national competitiveness policy would provide a framework for dialogue between firms, the public sector and other institutions. This can lead to improved coordination and quality of policy and government action.

Demand Conditions: Although the population of Belgium consists of sophisticated consumers, the domestic market is small in size. However, companies located in Belgium have access to the larger European market (almost 30 times the size of the local market).³² 60% of EU spending power lies within a 300-mile radius.³³ The country's North Sea coastline and its expansive port structure reduce transportation costs when shipping products to destinations outside of continental Europe (e.g. the US).³⁴ These destinations constitute an important part of Belgium's export market. The high quality standards demanded by Belgian and neighboring European consumers all serve to enhance product standards and quality, increasing the competitiveness of Belgian companies.

Factor Conditions: The government has capitalized on Belgium's location by investing in physical infrastructure. Seaports, airports, railroads and roads create an excellent distribution network. According to a series of biennial Cushman & Wakefield reports on European Distribution, Belgium ranks first in Europe.³⁵

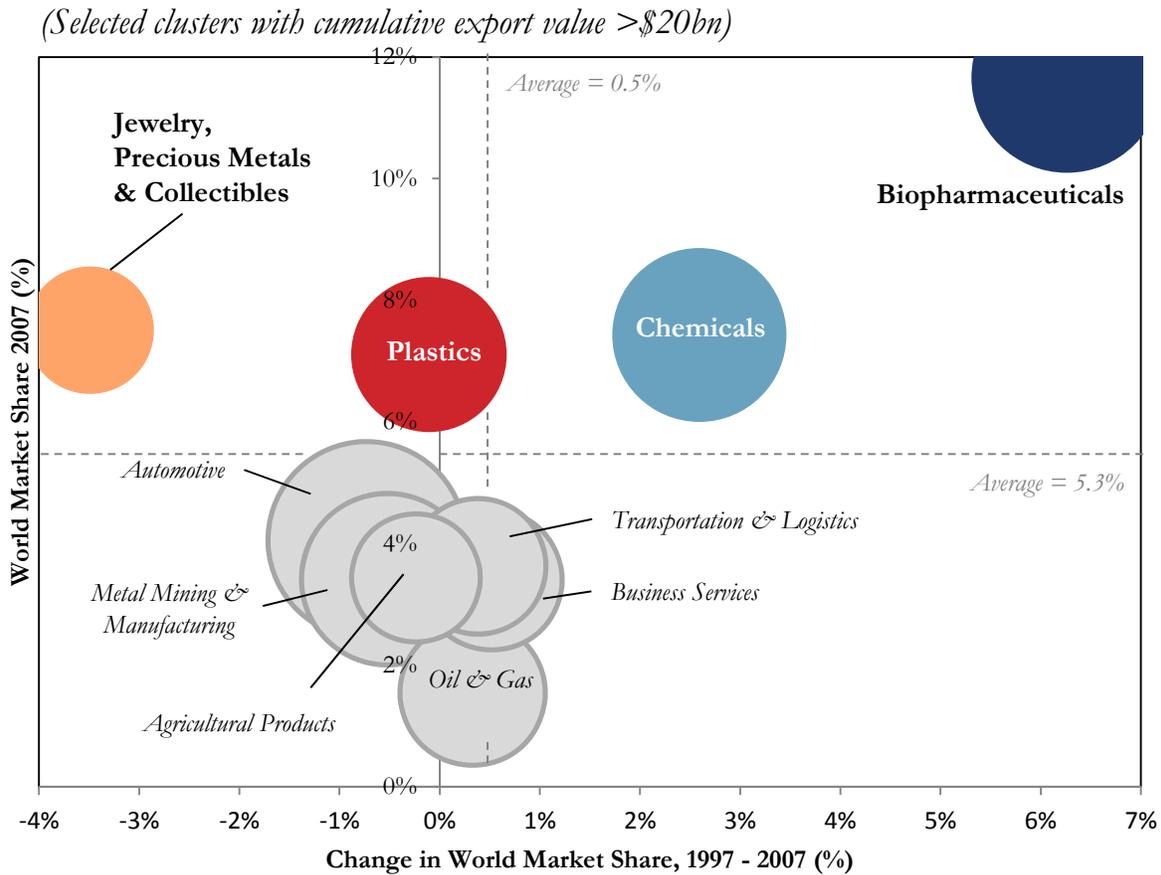
Belgium has invested in its human capital: Belgium's educational institutions and its management schools enjoy worldwide recognition.³⁶ Belgium's labor force has an average of 10.6 years of

schooling, which is above the UK and Switzerland.³⁷ Belgium's education system places strong emphasis on the study of science and mathematics and more than 30% of the workforce is employed by science and technology related industries.³⁸ In 2005, Belgium was ranked 13th in the world for employment in R&D per capita,³⁹ and *The Scientist* ranked Belgium as the second best place in the world to work for post-doctorates in the life sciences.⁴⁰ However, Belgium still lags behind its peers on several measures of innovation. Belgium has low levels of investment in R&D and low volumes of patent registration. Belgium's R&D expenditure is 1.9% of GDP, which is lower than Switzerland, Germany, France and the OECD average. Belgium also scores low in comparison to its peers on patent applications per 100,000 inhabitants.⁴¹

Some weaknesses associated with Belgium's factor conditions include: poor telecommunications infrastructure, a high regulatory burden and high taxes. In 2006, only 54% of Belgian households were connected to the Internet, compared to 70% in Luxembourg and 80% in the Netherlands.⁴² The country's federated structure contributes to regulatory inefficiencies and discrepancies. For example, it is hard to register property in Belgium. The country ranks 177th with respect to ease of registering property.⁴³ In 2008, Belgium came in third place in *Forbes'* tax misery index due to high corporate and personal tax as well as high employer social security payments.⁴⁴

Related and Supporting Industries: Figure 8 presents a snapshot of Belgium's clusters as a function of both their world market share and their growth between 1997-2007.⁴⁵ The biopharmaceuticals cluster is the largest and fastest growing cluster in the country. The plastics and chemicals clusters are tightly linked to the biopharmaceutical sector, requiring similar expertise in process management and manufacturing. This creates an important competitive advantage in terms of related and supporting industries given the availability of common skills for all industries.

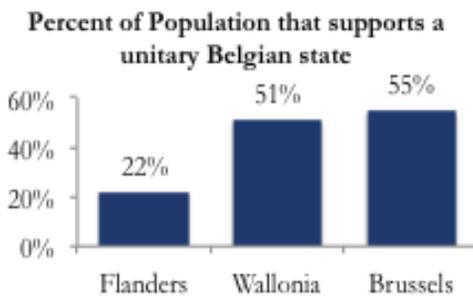
Figure 8: Belgian Clusters



2.5 Key Issues facing Belgian Competitiveness

Belgium has high political risk, due in part to the country's parliamentary system and its federalist structure.⁴⁶ Belgium holds the world record for number of days without a formed government.⁴⁷ This political instability and lack of government structure impacts the country's business

Figure 9: Unitary Belgium



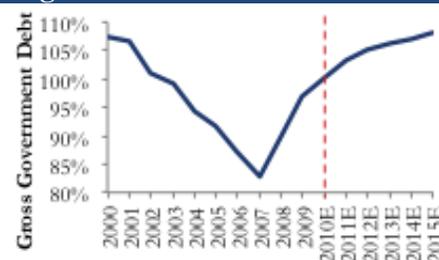
environment. There is wide disparity on whether Belgium should remain united or not. **Figure 9** shows results from a 2010 survey which highlights that most people in Flanders support a separate country rather than a unified Belgium.⁴⁸

As outlined in **Figure 10**, Belgium's increasing budget deficit and government debt is a source of macroeconomic risk. Belgium's government debt is projected to increase further in 2011-2015.⁴⁹

As the government pursues tightened fiscal policies to reduce the deficit, there is an increased risk of economic contraction and declining competitiveness (due to a higher tax burden).

Belgium's aging population also poses a challenge, as the older generation will serve as dependents to a much smaller, tax paying, labor force.

Figure 10: Government Debt



In terms of microeconomic risks, four areas require

improvement: first, Belgium has low transparency of government policy-making. Government policies and regulations are often inconsistent across the three regions. This is challenging for the private sector, especially when a firm seeks to expand geographically across the country.

Second, the regulatory framework is overly complex. The country's decentralized structure and a lack of regulatory harmonization across the regions increase the cost of doing business in Belgium.

Third, Belgium has low levels of R&D investment and innovation output. Improving innovation productivity would be an important enabler to upgrade the competitiveness of existing clusters.

Finally, Belgium has one of the highest tax rates in the world which may limit business investments and R&D. The regions have worked to mitigate the effect on research by offering tax subsidies for R&D investments in sectors such as life sciences. However, as the tax system relies heavily on labor

income, this can, according to the Laffer curve, create an incentive to work fewer hours as incremental income is taxed at a higher rate.⁵⁰

2.6 Recommendations to Improve Belgium's Competitiveness

Firstly, to address the political risk of fragmentation, Belgium should pursue policies to promote social cohesion and improve regional disparities. Government programs to support academic exchange and inter-regional business partnerships can improve social cohesion. Developing a long-term national strategy for competitiveness will also promote national unity. A national action plan to improve prosperity will allow the Belgian government to better coordinate activities between the regions and encourage efficiency-enhancing collaboration such as joint marketing initiatives and joint design and sponsorship of training.

Secondly, to address the government's fiscal deficit, Belgium will need to reduce government spending and raise taxes. A continued privatization program can reduce ongoing expenditure, improve efficiency and may increase extraordinary receipts. The government should also restructure its tax policy to shift the burden towards VAT. A consumption tax is a good substitute for receipts from income taxes and has less of a distortive effect on labor supply.

Thirdly, to address the challenges of different regional regulations, the federal government should centralize regulation to ensure that federal and regional legislative processes do not overlap.

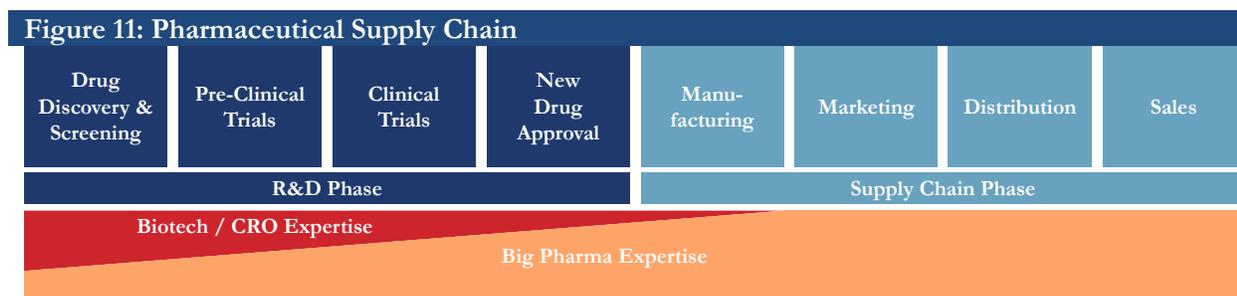
Fourthly, Belgium must improve its low levels of R&D investment and innovation output. This requires targeted effort across three stages with collaboration between government, universities and private sector participants. Belgium needs to increase its R&D expenditure to match the OECD average. Fiscal incentives can support this, for example through tax credits and a national investment fund which matches private sector contributions. Belgium also needs to improve the productivity of R&D to increase the number of patents developed. The government should

establish a working party to identify barriers to innovation (e.g., a lack of particular skills, the complexity of the regulatory system, intellectual property laws, etc). Ensuring wide participation from the academic and industrial sectors will ensure that a collaborative and integrated approach is taken. Belgium can improve the commercialization of R&D efforts by strengthening technology transfer offices.

Finally, Belgium needs to increase the country's low rate of labor force participation. Policies should discourage early retirement by increasing tax rates on early withdrawal of retirement or pension funds. Improving child-care services, adopting better policies for maternity leave, and introducing flexible at-home employment opportunities may help increase female labor participation.

3.0 Overview of the Pharmaceutical Sector

The Pharmaceutical Value Chain is divided into two specific phases: Research & Development and Supply Chain, with each phase consisting of four sub-activities. See **Figure 11**.⁵¹



According to Deutsche Bank, the global market for pharmaceutical products is ~\$800mm.⁵² The industry has recorded 10% of annual sales growth in the last 30 years, and underlying volume growth has remained strong (see **Figure 12**).⁵³



North America and Europe constitute more than 70% of global pharmaceutical sales, but significant growth in emerging markets, a rising middle class and more affordable and accessible health care services will increase the percentage of revenue from Asia, Africa and Latin America. **Figure 13**, based on Deutsche Bank forecasts, shows strong growth in all markets, with a 5-8% growth rate expected from 2009-2014.⁵⁴

Figure 13: 2009 Global Pharmaceutical Market Size and Growth

	Market Size (\$bn)	% Share	2009 - 14 CAGR
North America	322.1	40%	3 - 6 %
Europe	247.6	31%	3 - 6 %
Japan	90.3	11%	2 - 5 %
Asia/Africa/ Australia	102.6	13%	12 - 15 %
Latin America	45.8	6%	12 - 15 %
Global	808.4	100%	5 - 8 %

4.0 Overview of Belgian Biopharmaceutical Cluster

Belgium is the second largest exporter of biopharmaceutical products in the world with a market share of 13% in 2007, second only to Germany.⁵⁵ From 1997 to 2007 Belgium’s world export market share increased by 7%, while Germany’s market share increased by 1.2%.⁵⁶

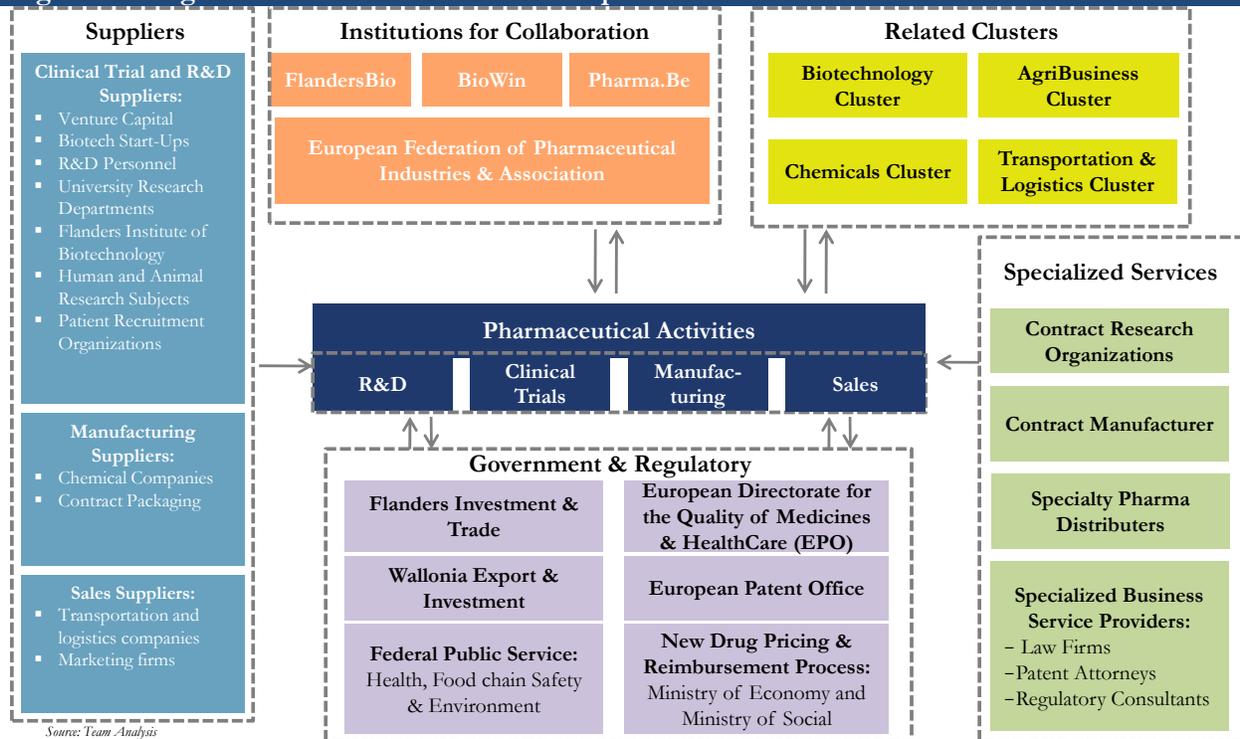
In terms of total export value, the cluster ranks second in the country with exports of \$50bn in 2007, just behind the automotive cluster whose exports amounted to \$52bn.⁵⁷ 60% of the cluster’s total production is exported to the rest of the world.⁵⁸ The cluster employs an estimated 27,300 workers, with 26,000 people working for pharmaceutical firms and 1,300 for biotech firms.⁵⁹ Roughly 5,000 of these jobs are in R&D.⁶⁰ Belgium pharmaceutical production has grown at a 7.1% CAGR between 1995 and 2010.⁶¹

Belgium’s pharmaceuticals cluster map is outlined in **Figure 14**.⁶² Core activities fall into four categories: R&D, clinical trials, manufacturing and marketing/sales.⁶³ The government plays a key role by creating legislation and enforcing certain regulations (e.g., drug approval; pricing and

reimbursement processes; and health and safety regulations). In addition, regional investment and trade bodies encourage inward investment; both from new and existing cluster participants.

Belgium also hosts several related clusters that complement the pharmaceutical cluster, including: biotech, chemicals, agribusiness and logistics. Each related industry supports a different pharmaceutical activity. For example, the biotech cluster complements R&D activities through commercialization of new research discoveries. The chemicals cluster complements manufacturing through supporting product and process expertise. The logistics cluster plays an important role in distributing pharmaceutical products to Belgium’s global customers.

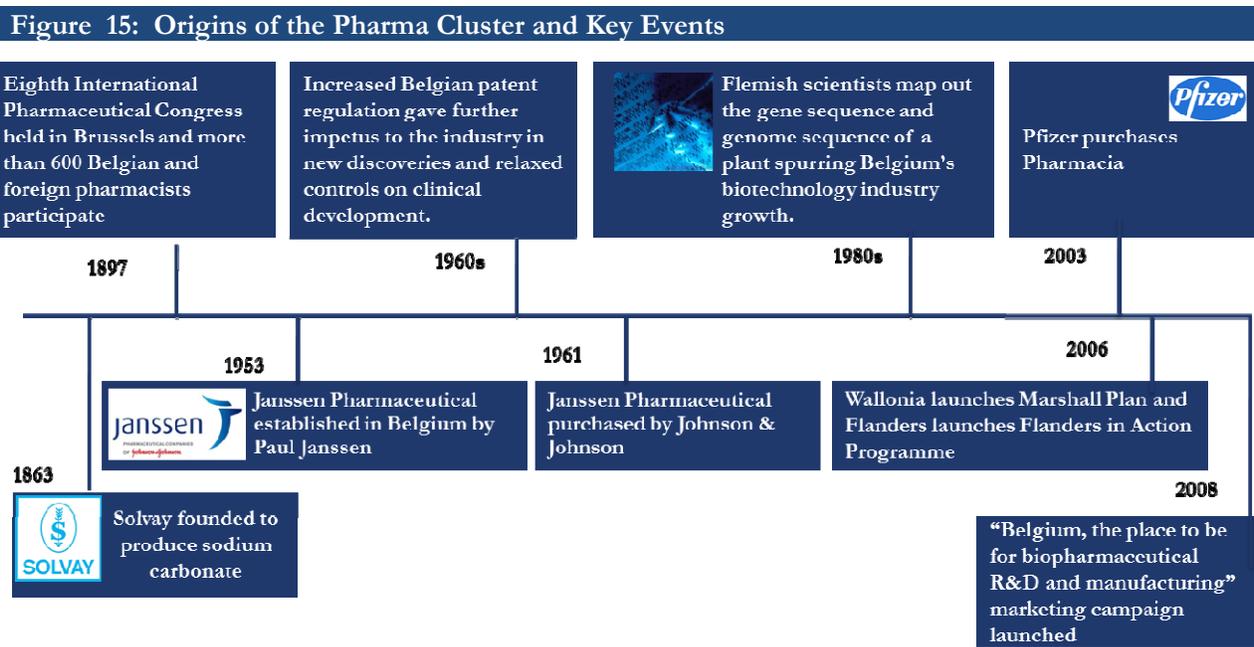
Figure 14: Belgium Pharmaceuticals Cluster Map



In recent years, pharmaceutical firms have begun to outsource R&D and clinical trials to reduce costs and focus on marketing and sales. This has led to the growth of contract research organizations (CRO) and biotech companies and increased the commercialization of university-led

research. It has also strengthened the relationships between start-ups and large pharmaceutical companies as biotech firms can have their innovations produced, marketed and distributed through a partnership with a pharmaceutical firm. Several Institutions for Collaborations (IFC) including FlandersBio and BioWin organize networking activities to facilitate these relationships.

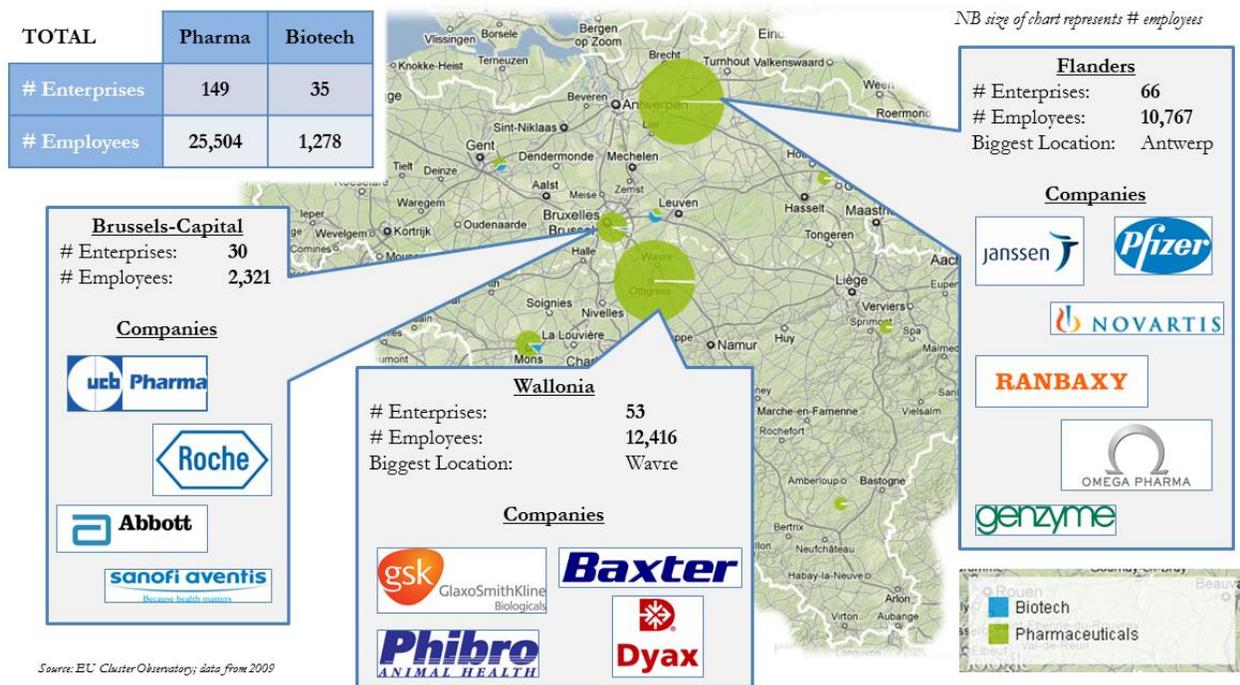
Milestones in the history of the cluster are summarized in **Figure 15**. The cluster emerged as a spin-off of the chemicals industry and hence the foundations can be traced back to 1867, when Solvay was established. Initially, activities existed as separate manufacturing lines within existing businesses, but the cluster was strengthened with the formation of specialty companies such as Janssen Pharmaceutica. These companies pursued more research activities and led to a number of therapeutic breakthroughs in the 1950s. Throughout the 1960s, Belgium strengthened its institutional infrastructure for drug regulation. This led to an increase in local and foreign direct investment. For example, J&J acquired Janssen Pharmaceutica in 1961. Belgium’s reputation as a competitive location for biopharmaceutical activities was enhanced as a result of Flemish scientists’ involvement in mapping out the gene sequence.⁶⁴



4.1 Private Sector Participants

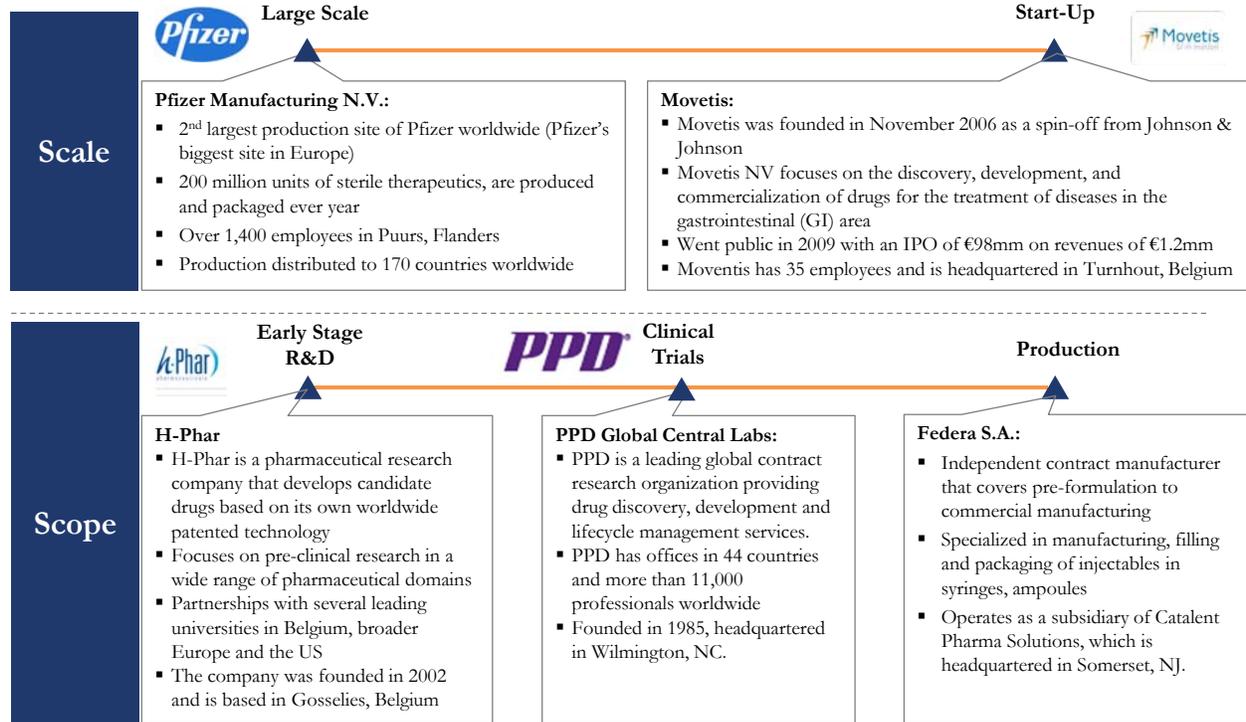
A number of global pharmaceutical companies (e.g. Roche, Sanofi-Aventis, Baxter etc.) have business activities in Belgium. 149 pharmaceutical and 35 biotech companies were registered in the country in 2009.⁶⁵ Most activities are concentrated in three key locations: Antwerp in the Flanders region, around the Wavre district in the Wallonia region, and in Brussels-Capital. **Figure 16** below outlines the geographic distribution of companies and employees.⁶⁶

Figure 16: Geographic Distribution of Companies and Employees



Belgium’s pharmaceutical companies differ both in absolute scale and in the type of business activities they conduct. There is variation in both scale and scope from small start-up firms to large scale manufacturing operations – see **Figure 17**.⁶⁷

Figure 17: Mix of Pharma Business Activities: Scale and Scope



Source: Capital IQ; "Flanders – Life Sciences" Publication by the Flanders Trade & Investment Office

As noted earlier, production activities that require economies of scale are predominately undertaken by subsidiaries of large global corporations, whereas pharmaceutical startups engage in clinical trials and R&D activities.

At a company level, the largest pharmaceutical companies in Belgium operate across the spectrum from early-stage R&D through to late-stage production. Most of the largest companies in the cluster are foreign-owned, evidence that Belgium's liberal regulatory approach has attracted both inward and continued FDI; see **Figure 18** for an overview of the largest pharmaceutical companies in Belgium.⁶⁸

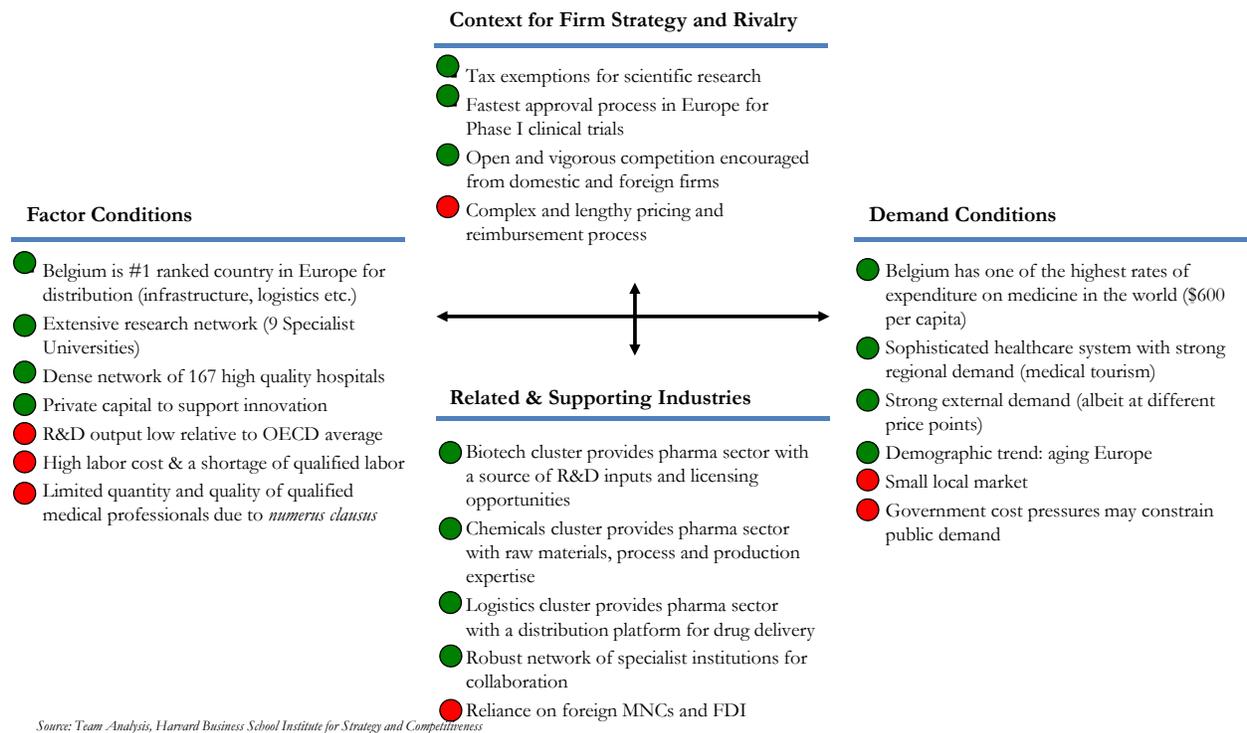
Figure 18: Overview of Top 10 Belgium Pharma Companies

	Revenue €mm	Employees	Region	Corporate Parent	Country of Parent	Business Description
Janssen Pharmaceutica NV	6,708	3,842	Flanders	Johnson & Johnson	US	▪ Janssen Pharmaceutica NV engages in producing and marketing pharmaceutical products in the US and internationally.
Glaxosmithkline Biologicals S.A.	5,797	1,000	Wallonia	GSK	UK	▪ Glaxosmithkline Biologicals S.A. engages in the research, development, manufacture, and supply of vaccines.
UCB SA (ENXTBR:UCB)	3,218	8,898	Brussels	N/A	Belgium	▪ UCB SA, a biopharmaceutical company, engages in the research, development, and commercialization of medicines with a focus on the fields of central nervous system and immunology disorders.
Corden Pharmachem P/A Controle B Nv	935	96	Flanders	Cambrex Corporation	US	▪ Pharmaceutical Preparations
Omega Pharma	856	1,945	Flanders	N/A	N/A	▪ Omega Pharma NV engages in the development, marketing, and sale of health and personal care products
AstraZeneca NV	759	500	Brussels	AstraZeneca	UK	▪ AstraZeneca NV operates as a pharmaceutical company.
Pharma Belgium Sa	650	200	Brussels	N/A	Belgium	▪ Pharmaceutical Preparations
Sanofi-Aventis Belgium S.A.	427	200	Flanders	Sanofi-Aventis	France	▪ Sanofi-Aventis Belgium S.A. also known as Aventis Pharma SA, engages in the development, manufacture, and sale of pharmaceutical products and vaccines in Belgium.
Eumedica SA	415	20	Brussels	N/A	Belgium	▪ Eumedica SA, a pharmaceutical company, produces, stores, and distributes medicinal products to treat serious and rare diseases in Europe.
Pfizer Manufacturing Belgium NV	391	1,000	Flanders	Pfizer	US	▪ Pfizer Manufacturing Belgium NV engages in developing and manufacturing innovative medicines for life of humans and animals.

4.2 Belgian Biopharmaceutical Cluster Analysis

The diamond framework provides supporting evidence for the success of the Belgian biopharmaceutical cluster.⁶⁹ Belgium’s expenditure on pharmaceutical R&D has grown from 2.3% of European pharma R&D in 1990 to 7.0% in 2009.⁷⁰ The cross-linkages between Context for Firm Strategy and Rivalry, Factor Conditions and Related and Supporting Industries are very strong. For example, Belgium has developed a strong research position because of investments in tertiary education, an attractive regulatory landscape and strong supporting industries. However, the cluster has weak demand conditions, a function of Belgium’s small population. **Figure 19** outlines the cluster’s competitiveness viewed through the lens of the diamond framework.

Figure 19: Diamond analysis of pharmaceutical cluster in Belgium



Context for Firm Strategy and Rivalry: Belgium has developed a strong business environment that encourages competition among cluster participants and supports continued investment. Belgium’s pharmaceutical sector has a high R&D reinvestment rate at 42% of sales, in contrast to the average European reinvestment rate of 17%.⁷¹ The cluster’s favorable context for firm strategy and rivalry has developed through three broad actions: supportive industry regulations, encouraging fiscal incentives and a government policy that actively promotes competition.

Belgium has the fastest drug approval process in Europe; approval for Phase I and II trials can be obtained in just 18 - 26 days.⁷² This is an encouraging setting for early-stage drug development, and has increased the total level of R&D activity and strengthened the cluster’s attractiveness. In 2006, there were approximately 1,800 clinical trials underway in Belgium.⁷³ Belgium is the world’s no. 1 location for clinical trials per capita.⁷⁴

“An approval for Phase I trials can be reached in a mere two weeks. This is a major advantage compared to other countries. The hospital testing infrastructure... is excellent and the trial publications are of high quality. **It is a top trial region for us in western Europe.**”

Robert Lins,

Business Manager Benelux, SGS Life Science Services



Belgium has a wide range of fiscal incentives to promote cluster investment in research. The government supports life science projects by providing regional grants of up to €38m each. Other fiscal measures include tax deductions. For example, income from new patents is eligible for 80% tax relief. Belgian companies can save up to 75% of payroll taxes on salaries for scientific researchers. All R&D initiatives are eligible for a 150% tax deduction and Belgium has one of the world's most favorable tax systems for patent income at just 6.8%.

Belgium aims to stimulate improvements in cluster productivity by encouraging open and vigorous competition. Although Belgium's competition policy is set by the EU, the country encourages local and foreign investments through M&A activity and greenfield developments. Foreign M&A brings both new capital and skills. For example, J&J's purchase of Janssen Pharmaceutica in 1961 led to a significant increase in company research activities. FDI supports both research and distribution. In 2009, Genzyme announced plans to build a US \$337 million manufacturing plant in Geel and, in 2007, Ranbaxy established a European distribution center in Antwerp.⁷⁵

Despite these attractive industry regulations, there remains room for improvement. Belgium's drug pricing and reimbursement process is both complex and lengthy. In 2007 the average delay for obtaining a reimbursement was 627 days, significantly longer than many other EU countries.⁷⁶ Furthermore, the government's aim to reduce healthcare costs has led to lower revenues from drug sales in Belgium. As such, the average price for the top 100 drugs on the Belgium market is 8%-32% below the average price in Belgium's neighboring countries.⁷⁷

Factor Conditions: Belgium has a number of strong factor conditions, including: strong universities and research institutions, a technically skilled workforce and easy access to European markets.

Belgium has many high-quality technical universities and research institutions, such as Ghent, Brussels, Liege, Leuven, and Antwerp. A recent academic study indicated that 4 of the top 10 universities in life science research (as measured by citations) are located in Belgium – the greatest concentration of any country outside the US.⁷⁸ Research institutions support the cluster in two ways: they train technical labor for the industry and they act as a source for new drug development. Cluster innovation comes from research and Belgium has a long history of biopharmaceutical advances. Past breakthroughs include: the first unraveling of the DNA sequence of a gene; the development of the first plant recombinant technology; the discovery of tPA (a major treatment for heart failure); the discovery of the HIV drug tenofivir; and the discovery of medicines for schizophrenia, pain-management, gastro-intestinal disorders and parasitic infections.⁷⁹

Capital plays an important role in commercializing research, and Belgium has a higher pool of available capital for the biopharmaceutical industry compared to other European countries.⁸⁰ This capital supports commercial spin-offs from university research departments, and serves to strengthen the cluster’s research pipeline. Examples of private biopharmaceutical ventures include: Galapagos, Ablynx, Movetis and Innogenetics.

Belgium has a dense medical network of 167 hospitals, which trains healthcare professionals and serves as a channel to conduct clinical trials.⁸¹ According to the IMD world competitiveness yearbook 2006, Belgium scored very highly on the strengths of its healthcare system.⁸² Although trained physicians and specialists support the cluster through their clinical research, there are signs of a labor shortage. Belgian universities have a policy of limiting medical student enrollment through

legislation titled *Numerus Clausus*.⁸³ As a consequence, there are fewer medical school graduates which impacts the availability of qualified research and medical personnel.

Related and Supporting Industries: Activities in the pharmaceutical cluster are supported by four related industries which strengthen overall competitiveness. Complementary industries include: biotech, chemicals, agribusiness and logistics.

Belgium has developed local clusters dedicated to biotechnology (genomics and agriculture) in both the Flanders and Wallonia regions. Close working relationships exist between biotech and pharmaceutical companies and Belgium has created a regulatory environment to support partnerships and licensing deals. In recent years, this has led to an increase in the number of licensing deals. Many start-ups have been raising public equity capital, an indication of successful research commercialization (e.g., Ablynx was a successful spin-off from the Flanders Institute of Biotechnology; the company IPO'd in 2007 and has completed partnership deals with Boehringer Ingelheim, Procter & Gamble and Merck).⁸⁴ The establishment of these successful small enterprises can help offset Belgium's heavy reliance on multinational companies.

Belgium remains a center for industrial manufacturing. Roughly 75% of the world's largest chemical firms have production sites in Belgium. A number of byproducts from chemical processes serve as feedstock for the manufacturing of active pharmaceutical ingredients and excipients (e.g., calcium carbonate is a common filler in drug capsules). Furthermore, the chemicals cluster provides process and production expertise to support the manufacturing of pharmaceutical products.⁸⁵

Since 60% of Belgian pharmaceutical production is exported, this requires strong transportation infrastructure and a network of capable distributors. The country's central location and the

existence of a number of specialty pharmaceutical distributors (e.g. Celesio, Aprophar) support the global reach of Belgium's pharmaceutical cluster.⁸⁶

Demand Conditions: Belgium has one of the highest pharmaceutical expenditures in the world (\$600 per capita); however, the country's small population of just 10 million people limits the absolute size of local demand for pharmaceutical products.⁸⁷

Belgium has a universal and comprehensive healthcare system. The mandatory government insurance covers 75% of total medical expenses and private insurance covers the remainder.⁸⁸

Hence both state and private health care providers spur demand and are important customers in the domestic drug market.

Furthermore, Belgium's aging population is expected to increase domestic demand for a range of pharmaceutical products in areas of chronic disease management (e.g. congestive heart failure, diabetes, chronic obstructive pulmonary disease etc).

The Belgian government is seeking to manage healthcare costs and it has instituted a policy to maintain drug price increases below the rate of inflation.⁸⁹ In addition, the government is encouraging increased use of generic drugs. These policies have the potential to reduce healthcare spending but at the cost of squeezing the cluster by reducing domestic sales and profit margins. This could threaten future drug development.

Despite these threats, we assert that Belgium's demand conditions play a limited role in influencing the cluster's competitiveness as pharmaceutical companies retain access to the open markets of nearby EU countries.

4.3 Competing Clusters

We identify competing pharmaceutical clusters in six different countries. The clusters are all located in developed markets, and they serve as a research hub and headquarter locations for the world's largest pharmaceutical companies. Although Belgium ranks strongly in terms of pharmaceutical exports, the other clusters have higher employment, a larger company density and greater innovation productivity. **Figure 20** provides a snapshot of the different clusters:⁹⁰

Figure 20: Competing Biopharmaceutical Clusters

Country	Cluster Location	Approx. # Employees	Companies	Pharma Exports, 2007 \$mm	Comments
	Antwerp, Wavre	27,000	174	\$46,869	<ul style="list-style-type: none"> Fastest approval process for clinical trials Central location for pharmaceutical distribution High per-capita spending rate on drug R&D
	Munich	40,000 - 50,000	150	\$54,039	<ul style="list-style-type: none"> Largest pharmaceutical market in Europe Strong export focus Companies identify connection with research institutions as key success factor
	Basel	40,000	60	\$36,104	<ul style="list-style-type: none"> World's most successful biotech cluster by hourly productivity 250 biotech patents per million inhabitants from Switzerland (vs 70 from US)
	New Jersey	150,000	320	\$31,992	<ul style="list-style-type: none"> Home to 17 of the world's 20 largest pharmaceutical, Medical Technology, and Diagnostics companies Lack of pricing constraints provide high margins NJ is home to the highest concentration of scientists in America (184,000)
	Cambridge	5,000	70	\$28,152	<ul style="list-style-type: none"> Scholarly collaboration supports a strong "ideas market" National Health Service acts as single consumer Significant pharma production in surrounding area
	Hauts-de-Seine	25,000 – 35,000	120	\$27,897	<ul style="list-style-type: none"> 23 research organizations Large # of independent pharmacists (source of industry) Europe's largest hospital network

The cluster in New Jersey is the largest cluster by scale: the region serves as home to 17 of the world's 20 largest pharmaceutical companies.⁹¹ Switzerland sets the benchmark for best-in-class innovation productivity: the Basel cluster produces 250 biotech patents per million inhabitants.⁹² One common theme across all the clusters is the role played by local research institutes and universities: from early-stage candidate development through to late-stage clinical trials. The vitality of local academic and clinical research has significant influence on the attractiveness of the cluster.

4.4 Cluster Initiatives

Belgium's regions have the autonomy to design and implement their own competitiveness strategies. Wallonia and Flanders have both developed policy plans to promote pharmaceutical activities at the regional level.

IWT, the Flemish institute for innovation in science and technology, is a one-stop-shop that provides research grants and tax subsidies to support R&D investment. Flanders has established an Inter-University Institute for Biotechnology (FIB) which serves as a life sciences incubator. FIB has successfully spun off 10 companies and produced 25 patent applications and over 70 R&D and licensing agreements with companies. Flanders also provides more than 500,000 sq ft of office space within research parks located close to 5 scientific centers of excellence.

Wallonia's pharmaceutical cluster is less established than in Flanders; however, the region accounts for 69% of Belgium's employees in biotech.⁹³ Wallonia has developed the *Marshall Plan: Walloon Poles Initiative* to encourage further growth in life sciences entrepreneurship. Specifically, Wallonia intends to finance 620 research positions to promote innovation and new drug development.⁹⁴ These efforts will be concentrated on three therapeutic areas: cancer, inflammation and brain diseases – supporting existing cluster strengths.⁹⁵

4.5 Institutions for Collaboration

Belgium's Institutions for Collaborations (IFCs) play an important role in encouraging dialogue and discussion between the government and cluster participants. We have analyzed Belgium's IFC at different levels of economic analysis, outlined in **Figure 21** below.⁹⁶

Interviews with cluster participants indicate a number of strengths amongst Belgium's IFCs.⁹⁷ For example, there is strong marketing of Belgium's capabilities in the pharmaceutical sector and a number of IFCs encourage coordination and networking across cluster participants (e.g. FlandersBio

organizes a range of seminars and workshops to encourage networking with scientists and expert speakers). However, the IFCs do a weak job gathering and collecting cluster intelligence at a local and national level. This limits the IFCs' ability to promote standards and regulations and organize factor improvements.

Figure 21: Institutions for Collaboration in Belgium

EU Neighborhood		European Federation of Pharmaceutical Industries and Associations (EFPIA) <ul style="list-style-type: none"> Represents the pharmaceutical industry operating in Europe Membership includes 31 national associations and 40 leading pharma companies
		Council of the European BioRegions (CEBR) <ul style="list-style-type: none"> Network of biotechnology professionals (not companies) Services include networking, incubation support, partnerships, and cluster promotion
Nation		Belgian Pharmaceutical Association <ul style="list-style-type: none"> Pharma.be is a Belgian non-profit organization which represents the Belgian pharmaceutical industry. Membership includes 140 companies covering both OTC and prescription drugs
		Belgian Society for Pharmaceutical Sciences <ul style="list-style-type: none"> The Society aims to support and promote research in Pharmaceutical Sciences both at the national and international level
		Belgian Association of Pharmaceutical Physicians (BeAPP) <ul style="list-style-type: none"> Supports and represents the interest of its members throughout their careers Creates, maintains and strengthens relationships with pharmaceutical companies
Regions and Cities		BioWin <ul style="list-style-type: none"> Aims to bring together all the Walloon stakeholders to promote innovation and training Seeks to stimulate the regional economy, increase Wallonia's international attractiveness, and stimulate job creation
		FlandersBio <ul style="list-style-type: none"> Represents the Flemish life sciences and biotechnology cluster. Members are organizations involved with life sciences R&D and/or production in Flanders or servicing the Flemish life sciences community.

4.6 Risks Facing the Belgian Pharmaceutical Cluster

Our analysis of the Belgian pharmaceutical cluster indicates that several issues pose risks to future competitiveness. These relate to factor conditions (the quantity of labor and research productivity) and also concern how demand can be impacted by government intervention (through price regulation, subsidies and administrative procedures).

The availability of skilled labor (research scientists, doctors etc) is crucial to supporting continued research and drug development. There are signs that the cluster is constrained by high labor costs and a shortage of healthcare professionals. With pharmaceutical companies increasing the number

of clinical trials that they conduct, the cluster must address the limited availability and quality of doctors in Belgium.

“The numerus clausus for medical students means that there are not enough young doctors today in hospitals and certainly not enough coming into the industry to work, for example, on clinical trials. There are a lot of very good companies specializing in clinical trials here, but the skills of locally trained MDs are not always up-to-date”

*Pascal Lizin,
Director of External Public Affairs, GSK Biologicals*



Industry regulation has the potential to promote or hinder cluster activities in research, and we see evidence of both impacts. Although Belgium’s federal and regional governments offer a broad and impressive array of incentives for research, the complex and lengthy reimbursement process undermines the progress Belgium has made in approving clinical trials and promoting research through fiscal incentives.

“You get a lot of encouragement from both the federal and the regional governments to invest and to do research but... when you launch a new product you have to wait a long time for reimbursement. The whole process is very complicated. You get a price from the Ministry of Economic Affairs and then you have to renegotiate the reimbursement with the Ministry of Social Affairs!”

*Didier Malherbe,
CEO of UCB Belgium and Vice-President of Public Affairs*



Research is vital for the success of the pharmaceutical cluster. Belgium has invested heavily in industry research: the country’s European market share of pharmaceutical R&D spending has doubled in the last 20 years.⁹⁸ However, Belgium’s ratio of pharmaceutical patent market share relative to GDP is below the US, Germany and far below Switzerland.⁹⁹ This suggests that Belgium has room to improve the productivity of pharmaceutical research commercialization.

4.7 Recommendations for the Belgian Pharmaceutical Cluster

To address the limited availability of skilled labor, the federal government should amend or rescind its controversial *Numerus Clausus* policy which limits the number of students who can study medicine. In addition, commercial cluster participants should develop an industrial placement and scholarship program. The program should target skilled young workers who have recently graduated as physicians and clinical scientists. By offering work on commercial research projects and tuition reimbursement, Belgium's pharmaceutical companies can attract more employees and diminish the effects of labor cost inflation.

Section 4.6 stressed that unclear government responsibilities for reimbursement have increased the time for new drug approval. Departmental cost pressures also reduce absolute pricing levels, potentially damaging the economics for new drug launches and perhaps undermining future R&D investments. To overcome these challenges, the federal government should clarify and streamline responsibilities between the Ministry of Economic Affairs and the Ministry of Social Affairs. This can be done by establishing a fast-track new drug approval process, reducing the use of generics and using drug prices in neighboring countries as benchmarks.

Finally, a key concern for the cluster is Belgium's moderate innovation output (as measured by patents) relative to its significant expenditure on R&D. We recognize that some of these innovation measures may be misleading, as new patents may be filed by an (often foreign) corporate parent. For example, J&J may file for all US patents that emanate from research conducted by Janssen Pharmaceutica. However, Switzerland illustrates that there is further potential to improve research productivity. Improvement activities could include: increased collaboration between research institutes and private companies; a restructuring and strengthening of university technology transfer offices; and the establishment of cluster IFCs to coordinate and encourage the sharing of research best practices across specific therapeutic areas (e.g. vaccinations, inflammations etc).

5.0 Required Disclosures

- (1) No member of the team is a Belgian national or long-term resident of the country.
- (2) No non-public information has been used in the preparation of this report.
- (3) No member of the team has traveled to Belgium during the project period.

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- ⁹² Swiss Biotech Report 2010 funded by SystemsX.ch
- ⁹³ Data presented in Biotech in Wallonia report 2005, biotech activities collected and compiled by CRGB center and PME
- ⁹⁴ Biotech in Wallonia, 2008
- ⁹⁵ Interview with Frederic Druck, Communication and International Relations Director, BioWin.
- ⁹⁶ Team Analysis, Individual Websites and Institution Filings
- ⁹⁷ Interview with Edith Mayeux, Trade Commissioner, Wallonia Trade & Investment, Consulate General of Belgium in New York, NY.
- ⁹⁸ Business Monitor International, Pharmaceutical Insight
- ⁹⁹ Switzerland has a ratio of pharma patent market share to GDP share of 2.69, vs a ratio of 1.43 for Belgium. Ratio analysis based on data from the OECD Science, Technology and Industry Scoreboard 2009