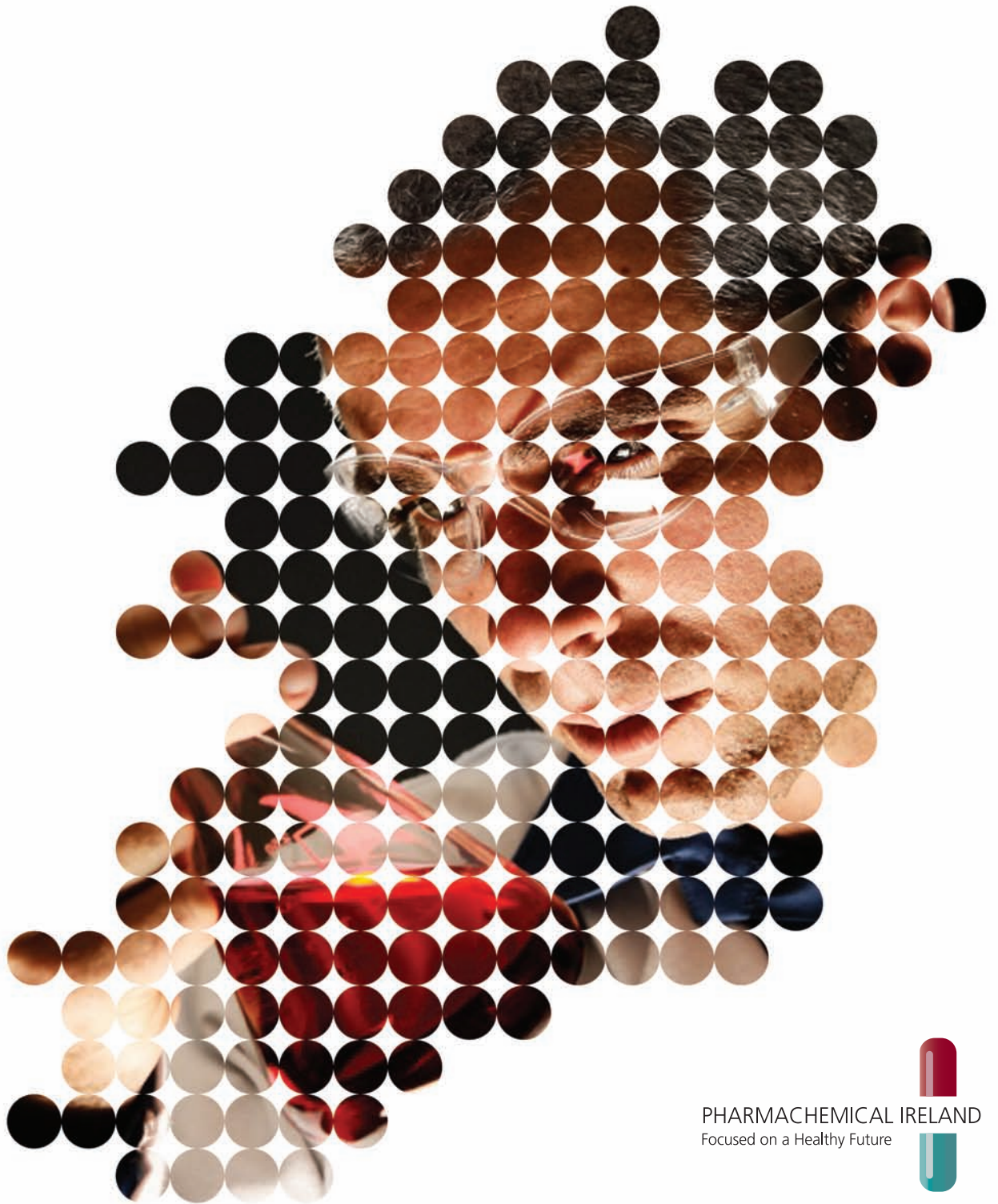


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PHARMACEUTICAL IRELAND
Focused on a Healthy Future



Pharmaceutical Ireland is a business sector within IBEC

www.pharmaceuticalireland.ie

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Introduction

Ireland has an international reputation as a location of choice for the pharmachem and biopharma industries. Eight of the top ten leading multinational companies in the world have a presence in Ireland, and benefit from a highly-skilled workforce, a proven level of manufacturing and compliance, a competitive tax rate and easy access to the European market.

The sector is a stable and strong contributor to the Irish economy with export figures of €50.8billion in 2010, accounting for over 50% of total Irish exports. The sector employs over 24,300 people, 50% of whom hold a third-level qualification. Since the 1990s, companies have reinvested in biopharma, process development, R&D and commercialisation, thereby reinforcing the sector's strong characteristics.

This publication documents many reasons why companies have established manufacturing here. It highlights the many advantages and attributes that Ireland has to offer and through which this country has consolidated its reputation as a global leader in this market.

We hope that you find the publication a useful and interesting reference source and hope that we have the opportunity to work with you in the future here in Ireland.



Gerry Collins

Global platform lead large molecule API
Janssen Supply Chain Ireland
Chairperson, PharmaChemical Ireland

Executive summary

Ireland has developed a globally significant pharmaceutical and biopharma sector comprising over 120 leading global and indigenous Irish companies, generating over 50% of the total Irish exports. Over the past decade the sector has experienced significant changes. Several blockbuster medicines have lost patent protection in recent years and more will do so in the future. At the same time, new high-profile replacement products are not emerging from research in the same numbers as those that are going off patent. Ireland needs to reposition itself to maintain its status as a leading global supplier of pharmaceutical, biopharmaceutical and chemical products.

Innovation and excellence are the key elements in the development of this vital sector. In 2010 PharmaChemical Ireland launched Innovation and Excellence which set out a strategy on how to combat the difficulties that the sector is facing. This strategy is a road map for industry, outlining the attributes which companies believe the sites of the future must have in order to make Ireland a centre of manufacturing excellence and development, and for the marketing of highly innovative products and services.

This publication shows how the industry has adopted this strategy and continues to add value to its activities. Companies have embraced the concepts of manufacturing and supply chain excellence, as well as those of on-site innovation. Irish sites have positioned themselves as innovation/R&D hubs.



Matt Moran

Director, PharmaChemical Ireland

Foreword

It has been well documented that Ireland is currently facing very significant economic challenges. However, my message is clear – Ireland is open for business. We have many unique strengths and our economy will return to growth this year.

Ireland is the second most globalised country in the world. Right now, we export 80% of what we produce. In 2010 our exports grew by 6%. By the end of 2011, we expect our exports to exceed our record, pre-recession level.

The pharmaceutical and biopharma industries play a vital role in our economy. The broad chemical sector accounted for over 58% of Irish exports in 2010, of which 27% were medical and pharmaceuticals. Eight of the top 10 pharmaceutical companies in the world have Irish facilities, and the country is one of the premier global locations for pharmaceutical and chemical product manufacture. Industry leaders including Pfizer, Eli Lilly, Genzyme, Merck, Elan and Allergan have all recently invested in Ireland.

We continue to attract significant levels of inward investment. We will maintain Ireland's 12.5% rate of corporation tax, which is a long-standing and core element of our enterprise strategy.

Research and development activity in Ireland trebled in the last decade and it is still increasing. We have a very high volume of business start ups and a strong entrepreneurial culture. The Irish are well-educated, resilient and we love to work.

We remain, according to independent international studies:

- fourth in the world for the availability of skilled labour;
- fourth for being open to new ideas;
- sixth for labour productivity;
- seventh for the availability of financial skills;
- seventh for the flexibility and adaptability of people.

We have made significant improvements in competitiveness. An estimated 14% improvement in unit labour costs relative to the euro area is expected by 2012. Our workforce is exceptionally flexible which is critical in a modern labour market.

These positive trends will further reinforce our status as an open, business-friendly economy.

If you are looking for a location for your business to prosper and grow, I urge you to consider Ireland seriously in that regard.

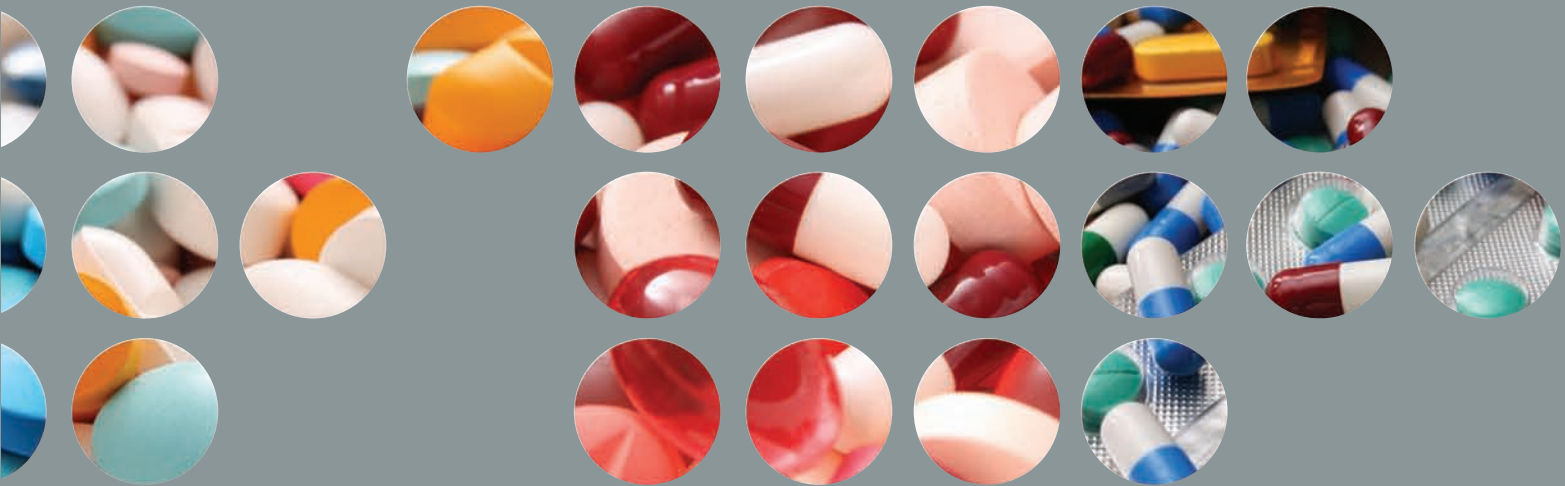


Enda Kenny T.D.
Taoiseach

Ireland-the location of choice

MISSION STATEMENT

PharmaChemical Ireland's mission is to facilitate the sector in achieving its vision. We will do this by bringing together all relevant stakeholders in the state, namely industry, the Government, the research community and the public at large to effectively communicate the unique attractiveness of this country as a leading location for the supply and development of such products.



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PHARMACHEMICAL IRELAND

PharmaChemical Ireland is the leading representative body for the pharmaceutical sector in Ireland. A major business association within the Irish Business and Employers Confederation (IBEC), PharmaChemical Ireland has access to IBEC's core support and research facilities and has a full-time executive staff. We represent manufacturers and distributors of pharmaceutical products and ingredients and general chemical materials. Our membership is composed of leading global corporations and indigenous Irish companies.

PharmaChemical Ireland is committed to maintaining an environment in which the pharmaceutical and chemical sectors can continue to flourish. We achieve this through representation to central government, local authorities and relevant state agencies. We liaise regularly with the Environmental Protection Agency (EPA), the Health and Safety Authority (HSA), the Industrial Development Agency (IDA), FÁS (the National Training Authority), the Irish Medicines Board (IMB), Science Foundation Ireland (SFI) and Enterprise Ireland (EI). We also represent industry at a European level through our affiliation to the Irish Europe and the European Chemical Industry Council (CEFIC).



Dave Shanahan, IDA
global head of life
sciences



Ireland's exports are growing strongly and we are driving ever better competitiveness and convergence between our globally leading clusters in pharmaceuticals, medical devices and information and communication technology. Only Ireland offers such depth from a single accessible global location. As the global pharmaceutical industry addresses innovation and market access, Ireland continues to benefit from increasing multinational investment through a period of consolidation and industry change. ”

Through the IDA, Ireland continues to provide attractive incentives and a supportive environment for the life sciences industry in all its complexity. Ireland is now recognised as a high-quality, reliable location for advanced manufacturing, and through investment of over exceeding €1billion in Science Foundation Ireland, has created academic research teams addressing critical components of pharmaceutical production as well as improving basic understanding of medical science. We are delivering better development and manufacturing earlier in the manufacturing process.

Ireland boasts the solid state pharmaceutical cluster, the Irish drug delivery network, the Biomedical Devices Institute, nanotechnology, materials science and micro-electronics centres, all of which are working with industry. Our science is now world leading with significant recognition for our genetics, immunology, materials science and nanotechnology capabilities. In addition, we are developing the devices of the future for biopharmaceutical administration.

IDA companies invested over €500 million in 2010 in business-related R&D, much of this in life science companies. Our clients can now access leading-edge support in small molecule chemistry, lean manufacturing, formulation and biopharmaceutical production. Our collaborative academic medical networks are developing to offer new clinical research facilities, supporting clinical trials in novel biomarkers and new chemical entities.

The IDA is delighted to welcome Amgen to Dublin to join eight of the top 10 global pharma companies manufacturing here. The IDA is supporting biopharma developments in Pfizer, Merck, Janssen Bio, Eli Lilly, Allergan and Elanco. IDA's National Institute for Bioprocessing Research and Training (NIBRT) is working on advanced training and collaborative programmes with leading biopharma manufacturers. Ireland's expertise spans global production of monoclonal antibodies, peptides and vaccines with specific expertise in glycosylation and process analytical technology (PAT).

Talent, a proven track record and a highly supportive tax structure behind operations and R&D make Ireland a destination of choice for people serious about developing, manufacturing and delivering tomorrow's medicines today.

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Takashi Mukuta PhD,
president, Astellas
Ireland Co., Ltd.

“

The raison d'être of Astellas is to contribute towards improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. In doing this we aim to generate sustainable growth in enterprise value. Important factors which allow us to achieve this in Ireland are high-quality labour, low corporate tax and the support of the Irish Government. I am therefore, convinced that Ireland will continue to be a location of choice in the future. ”

Astellas Ireland Co. Ltd. (AICL), a subsidiary of Astellas Pharma Inc, the second-largest pharmaceutical company in Japan, has two manufacturing operations. The plant in Killorglin, Co Kerry manufactures finished pharmaceuticals and in the plant in Mulhuddart, Co Dublin, manufactures a range of active pharmaceutical ingredients.

Working in an extremely high-tech industry, we have benefited immensely from having access to a very skilled Irish workforce. Irish graduates are second to none in terms of their technical knowledge and their commitment to attaining and exceeding the top international standards for our sector. From a financial perspective, we have benefited enormously from operating in a country with one of the lowest corporate tax rates in the world. As a member of the European Union, Ireland offers us an efficient distribution gateway into Europe. A further benefit is the stable political climate which the country enjoys and government policy, which promotes the development and expansion of multinationals within the country.

1. Economic contribution

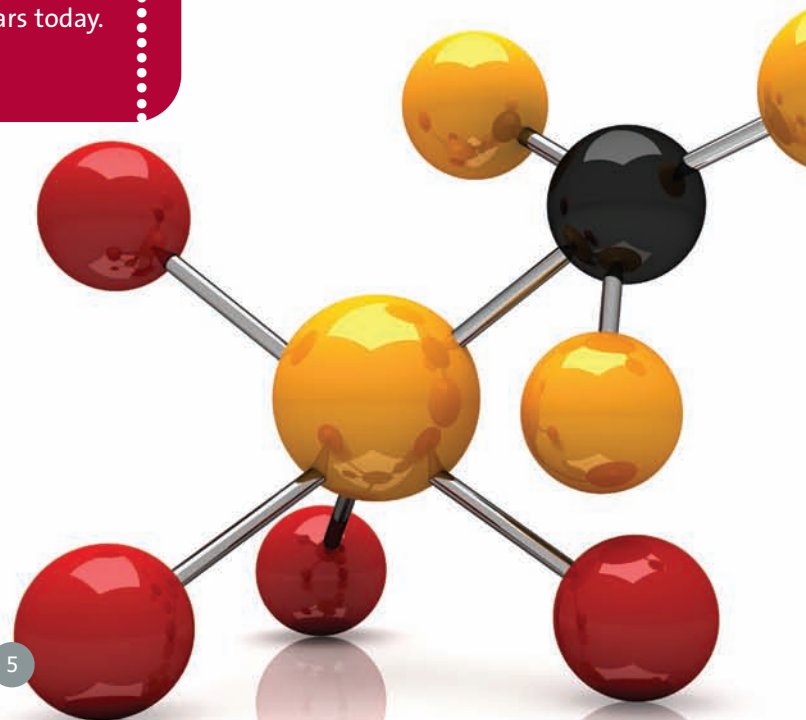
The pharmaceutical and biopharma industry is undoubtedly Ireland's most valuable and stable sector, attracting some of the world's leading pharmaceutical companies. Eight of the top 10 global pharmaceutical companies are located in Ireland, with seven of the top 10 selling medicines produced here. Ireland has become the world's largest net exporter of pharmaceuticals worldwide. The dynamics of the industry are changing. Ireland is emerging as a leading location for biopharmaceutical companies due to the mix of start-ups, SMEs and large multinational companies located here. Industry leaders present in Ireland, including Pfizer, Eli Lilly, Genzyme, Merck, Elan and Allergan, have all made additional investments recently. This investment has facilitated the rapid growth and development of the biopharma industry.

In 2010 the sector exported products to the value of €50.8 billion, a 7.3% increase from €47.2 billion in 2009. Pharmaceutical and chemical products account for over 50% of Irish exports, contributing more than €1 billion in corporation tax annually. The sector employs over 24,300 people directly and as many again indirectly.

In addition to the Irish economy, the pharmaceutical sector also contributes to the nation's health and well being by improving quality of life and combating illness. The industry has helped to improve life expectancy in Ireland by over a third in the last seventy years from 57 years in 1925 to 79 years today.

- Ireland's pharmaceutical exports are the seventh largest in the world;
- Ireland is the largest net exporter of pharmaceuticals in the world;
- the easiest country in Europe in which to pay corporation tax;
- a strategic location with easy access to the EU;
- Ireland ranks ninth in the world for the level of high-tech exports as a percentage of manufacturing exports;
- Ireland is ranked eighth for ease of doing business;

Source: IMD *World Competitiveness Yearbook 2010*, The World Economic Forum *Global Competitiveness Report 2009-2010*, OECD



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Torben Berlin Jensen,
managing director,
BASF business centre
Europe North

“

BASF has been a supplier to the pharmaceutical industry in Ireland for many decades. While we do not manufacture pharmaceutical ingredients in Ireland, we are committed to our customers and strive to deliver not only quality products, but also first-class support and technical advice. The appointment in BASF Ireland of a business development manager focusing on the industry, reflects our belief in the strength of the industry in Ireland. ”

BASF Ireland Ltd has been operating since the late 1950s, and over the years, has developed successful business with the chemical and pharmaceutical industry, delivering quality products, technical advice and service. BASF views Ireland as an important market for its products and gives total support and commitment to all of its customers, many of whom are also BASF's customers globally. BASF develops new technologies and uses them to meet the challenges of the future and open up additional market opportunities. It combines economic success with environmental protection and social responsibility, thus contributing to a better future.

2. Knowledge-based economy

Ireland has one of the best educated labour forces in the world. The percentage of the population aged 25-34 with a third level qualification is above the OECD average. The Government is committed to further developing and improving the Irish education system. Over the past five years publication rates have doubled from Irish universities. Ireland is ranked eighth in the world for university education attainment and first out of 10 European countries in a 2010 International Institute for Management Development (IMD) ranking.

The biopharma and pharmachem industry sector employs 24,300 people, over half of who have a level 6 qualification and above. This compares with a national average of 24 per cent. The sector has benefited from the increased output of PhD researchers, accounting for approximately 25% of all PhD researchers currently employed in Irish industry.

- Irish universities are now in the top one per cent of research organisations in the world for 17 fields of science, from immunology to engineering.



Table 1. Percentage With tertiary education (age 25-34)

Ireland	44%
Germany	22%
France	41%
Poland	30%
UK	38%
USA	40%
OECD average	35%

Source: OECD and IMD *World Competitiveness Yearbook 2010*

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Julie O'Neill,
vice president,
operations

Gilead Sciences' international region, supported by its operations facilities in Ireland, contributes around half of worldwide products sales. Gilead's employees and operations in Cork and Dublin are central to the provision of key medicines to the patients we serve across Europe, in Asia, and beyond. ”

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics. Its mission is to advance the care of patients suffering from life-threatening diseases worldwide. It is headquartered in Foster City, California, with international manufacturing, packaging and distribution operations located in Cork and Dublin.

Gilead's employees in Ireland ensure that its life-saving medicines reach its customers across the European Union, and in parts of Asia and Africa. In this way, they play an important role in the delivery of effective healthcare for people living with life-threatening diseases such as HIV/AIDS, hepatitis B, cystic fibrosis and systemic fungal infections. Their commitment to excellence is matched by a commitment to the company's responsibilities. The Gilead Access Program provides access to its key HIV antiretroviral medicines where resources are limited, and includes no-profit pricing in low-income countries including the whole of Africa.

3. Flexible workforce

Ireland has a very creative and flexible workforce with an excellent ability to innovate and lead. It has one of the youngest populations in Europe with over 33% under the age of 25 years. This young workforce is recognised for its ability to adapt to fresh ideas, and this capability has allowed the local workforce to readily embrace the new paradigm of development and manufacturing that now operates in the sector. Ireland has been ranked fourth in the world for its availability of skilled labour and willingness to innovate.

- Ireland's labour market flexibility is ranked 9th in the world.

Table 2. Future availability of workforce

Country	% Population under 25 2010 to 2015	
USA	34.4	33.4
Ireland	33.9	32.9
France	30.6	29.9
United Kingdom	30.6	29.8
Netherlands	29.8	29.0
Europe	28.1	26.6
Hungary	27.1	26.0
Portugal	26.1	25.2
Czech Republic	26.7	25.4
Germany	24.6	22.8
Spain	25.3	25.2
Japan	23.5	21.9

Source: The IMD World Competitiveness Yearbook 2010



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Pierre Brondeau,
president, CEO,
FMC corporation



Our Cork operation has supported the evolving needs of FMC Biopolymer's global pharmaceutical and food customers since it started in 1977. Supportive business environments and a high-quality and flexible workforce makes Ireland a good base from which to conduct international business. Over the years we have invested in the Cork operation, increasing capability and capacity with the most recent expansion coming on line in March of 2011. In a changing environment FMC Biopolymer in Cork is focused on adapting to today's and the future needs of our customers. ”

In 1977 FMC Corporation built the FMC international manufacturing plant in Little Island to manufacture Avicel PH Microcrystalline Cellulose, NF, Ph. Eur., JP for the European and Asian markets. The introduction of Avicel PH was a catalyst for the pharmaceutical industry's conversion to direct compression tablet technology, creating new levels of manufacturing efficiency. Its establishment in Ireland preceded the arrival of the pharmaceutical tableting industry. While the bulk of our output is still exported, a significant percentage now supplies the Irish market.

In 1990 further investment resulted in greater capacity, additional jobs, and a broader product range. Colloidal products were added to supply both the food ingredient and pharmaceutical markets.

In recent years the customer service and logistics team broadened its remit and now supports other biopolymer products such as carrageenan and alginate supplied to Europe and Asia. In March 2011 the most recent expansion was commissioned. This added 25% capacity to the combined output of the American and Cork plants while also creating additional employment.

FMC is committed to responsible care, and the Cork site is proud of its environmental and safety achievements, with more than a million hours worked without time lost due to injury.

Today's Avicel PH continues to set new standards, with enhanced grades designed to boost productivity for our customers and meet any formulation challenge.

The Irish Government’s commitment to research and innovation is reflected in its strategy for science technology and innovation 2006-2013 which has committed to over €6billion in investment from 2006-2013.

Science Foundation Ireland (SFI) was established in 2000, and plays a key role in facilitating collaboration between industry and academia in R&D. SFI collaborates with over 350 industry partners and is engaged in almost 2,000 academic collaborations across 56 countries. This is best exemplified through the centres for science, engineering and technology (CSETs), part funded by SFI in partnership with industry and academia.

The Higher Education Authority (HEA) supports this strategy through on-going public/private partnerships, and has developed a suite of research centres via the program for research in third-level institutes, the PRTLII.

Case Study The Solid State Pharmaceutical Cluster (SSPC)

The Solid State Pharmaceutical Cluster (SSPC) was established in 2008 to offer complementary research activities to industry in areas such as chemical engineering, organic chemistry, physical property science, polymorphism, analytics and pharmaceuticals. The objective of the SSPC initiative is to design solid-state pharmaceutical materials in the required physical and chemical forms to meet the demands of advanced formulation and drug delivery systems. Since 2008, SSPC research has led to significant improvements in knowledge progression, innovation and commercial output for industrial partners.

The SSPC is intended to provide the necessary skill set to comprehensively investigate pharmaceutical solids by bringing together complementary academic and industrial groupings from the disciplines of chemistry, pharmaceuticals, pharmaceutical technology, chemical and mechanical engineering. These groups have expertise in process modelling and design, scale-up, computational fluid dynamics, on-site solution and solid-phase monitoring, crystallography and powder characterisation.

The SSPC conducts industry-informed research, addressing three key areas for industrial partners:

- continuous crystallisation – determining the best future practice in this area;
- particle engineering – addressing throughput issues around isolation and drying of active pharmaceutical ingredients (API);
- primary secondary interface – identifying the attributes of the API/excipient that influence the formulation process.

Table 3.

Industrial Partners	Academic Partners
Clarochem	University of Limerick
Roche	University College Cork
Pfizer	University College Dublin
Hovione	Trinity College Dublin
MSD	NUI Galway
GSK	
Eli Lilly	
BMS	
Janssen	

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Dominic Carolan
senior vice president,
manufacturing



Waterford has established itself as one of Genzyme's state-of-the art manufacturing sites and supplies most of Genzyme's major products to global markets. To have grown so rapidly in less than 10 years is a tribute to the skilled and flexible site team and also to the ease of doing business in Ireland. ”

One of the world's leading biotechnology companies, Genzyme is dedicated to making a major positive impact on the lives of people with serious diseases. Since its foundation in 1981, the company has introduced breakthrough treatments across several areas of medicine that have provided new hope for patients. Today, approximately 10,000 Genzyme employees serve patients in nearly 100 countries.

Genzyme's products are focused on rare inherited disorders, kidney disease, orthopaedics, cancer, transplant, and immune disease. The company's commitment to innovation continues today with a substantial development programme focused on these fields, as well as cardiovascular disease, neurodegenerative diseases, and other areas of unmet medical need. Genzyme is a Sanofi company.

In Ireland, there are 500 people on the Genzyme team at the biotechnology campus in Waterford, where the company established its Irish operations in 2001. Seven key products in the Genzyme portfolio are produced at and supplied from Waterford to patients in more than 70 countries worldwide.

5. Corporation tax

A business-friendly tax regime and 12.5% corporation tax rate have been instrumental in attracting FDI to this country. Ireland has one of the lowest corporation tax rates in the world and is ranked by the World Bank as one of the 10 easiest places in the world to do business. Irish intellectual property law supports companies that invest in innovation. Ireland also has a tax credit regime that enables companies to claim a credit of 25% for investment in R&D.

- The Irish Government is fully committed to maintaining its competitive 12.5% corporation tax rate and continues to enhance the tax offerings for FDI through expanding tax treaty networks and supports for intellectual property and R&D. The corporation tax is simple and transparent and income taxes remain competitive.

Table 4. 2011 Corporate Tax rate for selected countries

Country	Corporate tax rate (%)
Ireland	12.5%
United Kingdom	27%
Belgium	33.99%
France	34.43%
Netherlands	25%
Spain	30%
Austria	25%
Germany	30%
Czech Republic	19%
Poland	19%
Singapore	17%
Bulgaria	10%
Lithuania	20%
Hungary	19%
Luxembourg	28.59%
Portugal	26.5%
Sweden	26.30%
Denmark	25%
USA	39.5%
Japan	41%

Source: Deloitte & Touche January 2011 & IMD June 2010



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Dr Michael Kamarck,
president, Merck
BioVentures and
senior vice president,
vaccines and biologics
manufacturing,
Merck & Co. Inc.

“ Since 2007 MSD has invested €360million in both new and existing facilities in Ireland, creating approximately 450 new jobs. The Irish Government's emphasis on research and development complements the mission of MSD. We are proud to employ 2,300 people here and to have invested in new facilities in Carlow (a biologics and vaccines plant) and Dublin (a regional shared business services centre). Our success here underpins our continued commitment to Ireland, where, despite challenging times globally, enterprise clearly is very much alive. ”

Over the last four decades, MSD has invested an estimated €2.2billion in Ireland, building facilities and employing people to support the research, discovery, manufacturing and launch of pharmaceutical, vaccine, biologic and consumer healthcare products.

In 2013, operations at MSD's new vaccines manufacturing facility in Carlow will begin. This plant specialises in the formulation and filling of vaccines and biologic treatments which help prevent and treat a variety of conditions. MSD invested more than €220million in the site and created 170 new jobs. More recently, MSD chose Dublin as the location for a European shared business services centre (SBS centre). Locating the regional hub in Dublin in May 2010 created 150 jobs for skilled professionals.

In collaboration with the IDA, MSD has also invested €40million in expanding its existing operations at the Brinny plant in Cork to include a bioassay centre of excellence and a vaccine conjugation facility. In addition, a €100million investment at the Ballydine plant in Tipperary will see a new formulation R&D manufacturing facility become fully operational in 2011.

MSD appreciates the continued support of employees, neighbours, local public representatives and the business community over the years. They all have contributed significantly to MSD's success in Ireland.

MSD continues to regard Ireland as an outstanding location for business, providing as it does, both a highly-skilled workforce and a collaborative working environment that encourages co-operation between MSD, state agencies, key business organisations and academic institutions.

6. Formulation R&D and manufacturing facility

Ireland has a record of excellence in process development, launch and supply, which has created the capacity and capability for world-class clinical trials manufacture across the country. Investment in R&D pilot plants and new product introduction facilities in Ireland have been accompanied by the upgrading of existing sites to meet the advancements in clinical trial manufacture requirements.

- **Eight of the top 10 global companies are based in Ireland. It is a very stable sector comprising many global leaders in quality and regulatory compliance.**

Case Study MSD, Ballydine

In September 2007 construction started on a new formulation R&D manufacturing facility located on MSD's existing Ballydine site. This €100million investment, backed by the IDA, supports MSD's commercialisation initiative to bring new medicines to market more quickly and flexibly, and will significantly increase the overall level of R&D conducted at the site. This worldwide centre for formulation R&D will develop innovative platforms for the formulation of solid dosage pharmaceutical products used in late stage clinical trials. The facility will also enable the plant to produce tablets for a number of new products in late-stage clinical trials and manufacture launch quantities of newly approved products.

Since 2007 a total of 50 new high-calibre roles have already been filled as part of this development, which will become fully operational in 2011.

The facility recently received its manufacturer's license and its IMP (Investigational Medicinal Products) license from the Irish Medicines Board, and is currently executing formulation development in support of two new candidate products in phase III clinical trials.



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Anthony J. Maddaluna,
president, Pfizer global
supply



From our manufacturing sites across Ireland, Pfizer supplies medicines to patients across the globe. We have built a competitive advantage in the country by offering fast, flexible and innovative supply solutions valued by our diverse customers. The favourable business climate, strategic location and highly-skilled and educated workforce have nurtured our success in Ireland, where we have established centres of excellence in the manufacture of biologics and vaccines, active pharmaceutical ingredients, solid oral doses and nutritional products that are critical to Pfizer's manufacturing operations. ”

Pfizer is the world's leading biopharmaceutical company with a diversified global health care portfolio that includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Pfizer is one of Ireland's leading employers and the largest pharmaceutical sector investor and employer.

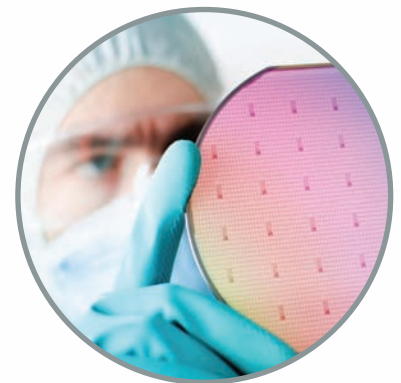
Pfizer began its manufacturing operations in Ireland in 1969 when it opened its first plant in Ringaskiddy and since then has had a long record of innovation and expansion over a forty-year period. The business has over 4,000 employees in locations including Cork, Dublin, Kildare and Limerick. Pfizer's business interests in Ireland are diverse and include manufacturing of a wide range of products, a global financial services centre and a global treasury operation. The Irish operations manufacture some of Pfizer's best selling and newest medicines. Total capital investment by the company in Ireland exceeds \$7billion. Additional capital investment in the biopharmaceutical plant in Dublin is under way.

7. Best practices/seamless transitions

Ireland has an exemplary record of getting projects finished on time and within budget. This reputation for reliability has recently been rewarded with investments from key players in the industry. Irish plants have put in place modern management practices such as lean and six sigma as well as multi-skilled and process-oriented organisational structures. Such initiatives are yielding excellent economic dividends on the investment through reduced levels of waste and improvements in productivity.

Case Study Pfizer Ringaskiddy API Plant, Cork

The global process development centre (PDC) was founded in 2001 to focus on developing innovative science and technology solutions to achieve operational and technical excellence in API synthesis. The PDC employs a wide range of skills across chemistry (synthesis/analytical), engineering and biocatalysis, which facilitate the development of new technology for Pfizer's priority products to meet pre-defined environmental, cost and productivity targets. The PDC supports each step of the API process engineering project from proof of concept through regulatory submission to commercial implementation. In addition, Pfizer recognised the need to have a flexible, state-of-the-art modular kilo facility capable of supporting API process development. Hence, the kilo technology laboratory (KTL) facility was launched in late 2008 to support the development of continuous processing technology in addition to providing pilot scale batch processing capability. This additional capability has been a key factor in allowing the PDC to continue to deliver significant cost, productivity and environmental benefits to Pfizer through the application of innovative science and technology.



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Dr William Heath,
senior vice president,
research and
development



The provision of these facilities in Ireland is a major milestone and demonstrates the ability of the Irish manufacturing component to understand and play a key role in the commercialisation of the future portfolio needs of our company.

It is a significant achievement that Kinsale, with the support of the corporate development group and the assistance of government and Irish academic institutions, made this transformation in developing both the infrastructure and people to play a key role in Lilly's future. ”

Eli Lilly and Company performs a range of activities throughout Ireland involving four different businesses employing over 700 people.

While biopharmaceutical medicines for human health are manufactured at Kinsale, animal vaccines are manufactured in ELANCO Sligo. In addition, Lilly's Irish sales and marketing organisation is located in Dublin and the establishment of a European financial shared services centre in Cork was announced in 2010. The manufacturing plant is located close to the historic town of Kinsale at Dunderrow, Co Cork. Production began at the facility in 1981 and today we employ over 400 people in the development and manufacture of a range of medicines.

In recent years, the company has, in addition to its manufacturing and development facilities, established a new biopharmaceutical manufacturing facility at Cork, allowing for the diversification of the site into a new technology platform (monoclonal antibodies mAb). The site is now responsible for the development and manufacture of a new generation of products for the corporation's global market.

Over the past 25 years the Kinsale facility has built a strong reputation within the Eli Lilly organisation for its ability to safely manufacture and supply a range of newer class medicines to patients worldwide.

One of the most significant factors behind Lilly's success in Ireland has been its employees. Many of the company's employees are people who grew up in the locality and have worked with the company for the last 25 years. In that time they have developed a high level of technical expertise in manufacturing medicines that is recognised throughout the organisation.

8. Process development and commercialisation

In response to the changing environment in which the industry finds itself, it is turning to newer technologies, including the manufacture of drugs through biotechnology and expansion into the development of new and more efficient drug delivery systems. These new developments will be important for the pharma manufacturing sector in Ireland, and several companies have made major investments in recent years both in primary biotech as well as in fill and finish operations. Such development requires the highest level of good manufacturing practice, as defined by regulatory agencies, as well as the availability of scientists and engineers with cutting-edge education and skills. In both of these key areas, Ireland has a superb track record that continues to underpin the attraction of future FDI to this sector of the economy.

- Ireland's robust legal system and sophisticated infrastructure makes it an ideal location for the exploitation and protection of intellectual property
- Ireland ranks first for FDI and knowledge transfer; (IMD2010)



Case Study Eli Lilly Kinsale, Co. Cork

In addition to recent investment in state-of-the-art biopharmaceutical facilities over the last three years, the Kinsale site has been transformed into a key commercialisation partner for the Lilly Product Research and Development group. The site is now the first choice location for pre-validation scale-up activities for the emerging portfolio. This has been enabled by the provision of a suite of manufacturing facilities at 5-, 50-, 250- (in construction) and 2000-gallon capacity, as well as parallel technology and capability in areas such as process analytical technology (PAT), crystallisation, continuous processing, data-rich experimentation and advanced analytical diagnostics. Substantial collaboration with third-level institutions has been a significant factor in the progress of this initiative. Five projects have been completed to date with several more currently in progress.

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John Alexander,
managing director,
Novartis Ringaskiddy
Ltd.

“

Novartis chose Ireland as a place to invest for a number of reasons, such as the support of the IDA, availability of suitable land for industrial development purposes, labour availability and the level of education within the Irish workforce, as well as opportunities to develop links with local universities and colleges. Thanks to the focus of our workforce to develop truly reliable and robust processes and to drive improved ways of working through process orientation, we believe we will continue to bring value to the Novartis global organisation for the foreseeable years to come. ”

Novartis Ringaskiddy Ltd is one of five manufacturing sites within Novartis Chemical Operations worldwide. A production site since 1994, the Ringaskiddy facility employs over 500 people and has been designated a launch site for some of the most promising drug substances coming off the Novartis drug development pipeline. The Ringaskiddy campus is also home to Novartis International Pharmaceutical Branch Ireland (NIPBI) which, in addition to housing a complex of analytical laboratories, is also responsible for the co-ordination, planning and supply of production materials for all chemical operations sites worldwide. Novartis produces a variety of drug substances used for the production of medicines in many therapeutic areas such as oncology and haematology, respiratory and dermatology, infectious diseases, transplantation and immunology (IDTI) and ophthalmics.

9. Innovative indigenous companies

Ireland is creating a smart economy with research, innovation and commercialisation at its core. Close links between industry, academia and clinicians means that innovative indigenous companies are expanding and are connecting with the large, well-established multinationals. Irish companies are becoming increasingly sophisticated and competitive, pricing Ireland back into international markets.

Case Study Luxcel Biosciences

Luxcel Biosciences is commercialising cutting-edge oxygen-sensing probes and sensors. Applications are targeted at the Pharmaceutical, Food Safety and Packaging industries.

Luxcel products provide direct benefits for customers: increased speed and accuracy, reduced R&D costs for manufacturers and safer products for consumers. Luxcel's customers include the major global pharmaceutical and biotechnology companies, universities and other research institutes. For example, Pfizer, the world's largest pharmaceutical company, is a key collaborator in the field of drug safety and mitochondrial toxicity screening.



IRELAND

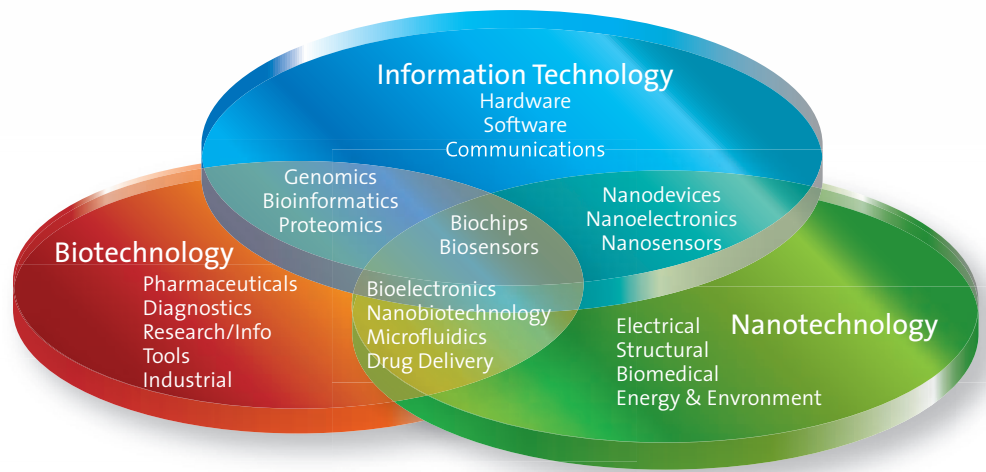
.....
The location of choice for scientific investment



“
Dr Giorgio Calderari,
group general
manager,
Helsinn, Lugano,
Switzerland

The employment of highly-qualified and technically-skilled employees available in Ireland has allowed Helsinn Birex Pharmaceuticals Ltd to develop a high-quality, customer-focused organisation with a ‘can do’ approach and the ability to deliver results. In addition, the competence of the staff permits the company to take on technically challenging new product development projects in support of the group strategy of in-licensing and clinical development. The Government commitment to building a knowledge-based economy and the availability of excellent training facilities through the universities and institutes of technology has been a significant contributor to enabling Helsinn deliver on this mission in Ireland.”

Since commencing its operations in Ireland in 1990, Helsinn Birex Pharmaceuticals has continuously adapted and changed in response to new business challenges and opportunities. This approach has contributed greatly to the success of our integrated pharmaceutical business ventures globally. Helsinn’s business model needs effective multi-project teams of professionals achieving results and we have found that the mix of Swiss, Irish and more recently, US cultures, gives the performance required to be a leader in late-stage product development and commercialisation of our chosen niche therapeutics. The addition in 2010 of the centre of excellence in drug product development in Dublin is making a particularly significant strategic contribution to our medium-term objectives.



Source: Forfas: Health lifescience in Ireland: An Enterprise outlook

10. Significant life science cluster

Ireland has long been established as a global hub for pharmaceutical manufacturing. Eight of the world's top 10 global companies have manufacturing operations here. As the industry changes and technologies converge, Ireland will have the unique advantage of a strong presence in the medical devices and ICT sectors. Despite its small size, Ireland is home to 15 out of the top 25 medical devices companies in the world and nine out of the top 10 global ICT companies. This cluster of high-tech industries, along with world-class researchers has already resulted in the creation of many convergent products, such as drug eluting stents, transdermal patches that transport drugs locally and systematically through the skin and implantable, programmable pumps coated with a growth protein that promote bone regeneration.



IRELAND



The location of choice for scientific investment



Peter Quane,
managing director,
Temmler Ireland Ltd



Ireland has a very well-educated, hardworking, flexible workforce with a can-do attitude and a pride that often results in the Irish operation excelling in a corporate environment. The labour force, together with low taxation, financial incentives and grants, and access to profitable key markets, make it the number-one choice for doing business. ”

Part of the Temmler Group, one of the largest pharmaceutical contract manufacturers in Europe, Temmler is based in Killorglin, Co Kerry.

The Killorglin plant was established in 1972 to synthesise active pharmaceutical ingredients (APIs). The API plant was decommissioned in 2007 and the site now specialises in large-scale contract manufacturing of multiple unit dosage forms, and modified release pellets in particular. The plant also has decades of expertise in the extraction and spraydrying of natural plant extract. Investment in the site to date has been in excess of €100M.

While the plant's location on the river Laune in Killorglin was often considered as too peripheral by some commentators, the company was always able to recruit the requisite skilled personnel and manage logistical issues with ease. It is Temmler's strategy to position itself as a dependable, competitive, key manufacturer of quality multi-unit dosage forms for the Temmler Group.

11.

Political stability

Political stability and pro-enterprise policies from successive governments have greatly enhanced Ireland's international reputation. The Industrial Development Agency (IDA), Enterprise Ireland (EI) and Forfás are state agencies with responsibility for attracting business to and supporting business in Ireland. The IDA has responsibility for securing new investment in manufacturing and internationally-traded services. EI assists in the development of Irish-based enterprise with the potential to trade internationally and offers grants to fund industry and academic collaborative research. Forfás provides overall policy advice and co-ordination for enterprise development and science, technology and innovation.



12.

Strong local management

A major benefit of the Irish market is the availability of home-grown managerial talent. In fact, most of the multinational companies located here are run by Irish management teams. Companies that have invested in the country have developed a trust in the judgment of their Irish management. In examining the strength of the industry, it is plain to see why. As Ireland is a small open economy which relies heavily on the export market, Irish managers have developed an acknowledged capacity for building strong business and trade relationships with their counterparts in other countries and can therefore work well on global project teams. They have also developed the flexibility which is necessary to respond to the changing market conditions which characterise today's global business environment.



IRELAND

The location of choice for scientific investment

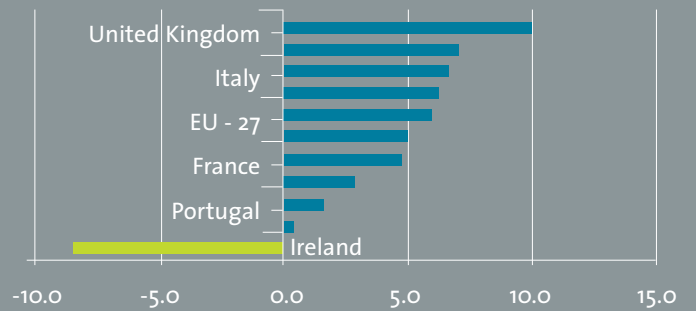
13. Cost effectiveness

During the 2000s, Ireland's cost base increased relative to competitors, but much of this has been mitigated over the past two years. Unit labour costs fell by 5% in 2010 and the European Commission projects a decline of over 8% during 2008-2015. Relative to the euro area average, this represents an improvement of 14%. This has been achieved through a combination of productivity improvements delivered by innovative workplace change and some reductions in wage costs. Other business costs have also come down, including the cost of renting or purchasing industrial space, which has fallen by around 50%. The cost of energy, another important non-labour input, has fallen from well above the EU-27 average in 2007 to around 8% below the average in 2010.

- Ireland ranks 6th in the world for labour productivity per person employed per hour, (US\$).

Unit labour cost forecast

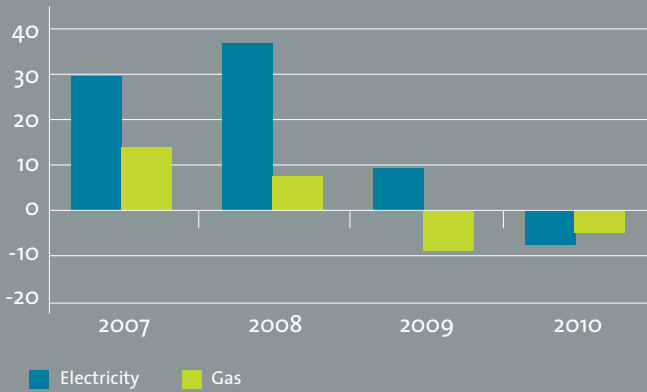
% Change 2008 - 2011



Source: European Commission

Non-pay business costs are coming down

Energy Price Differential (%) relative to EU-27 Average



Source: European Commission



Case Study

Roche Ireland Ltd

The operational excellence (OE) program started at Roche in 2005 with the implementation of the EDO methodology (effective development of organisations), which focused on behavioural aspects of achieving sustainable process improvements. In 2008, Roche additionally implemented lean six sigma (LSS) – this provides a powerful combination of the lean manufacturing (waste elimination) and six sigma (reducing variability) approaches. The initiative has led to the creation of a community of skilled continuous improvement specialists. Their use of these OE tools has resulted in significant process improvements at Roche Ireland. Some examples of these improvements include: reducing the release time for finished goods by 40%, reducing the lead time for a technology transfer by 50% and reducing cycle time in a manufacturing process by 38%. Initially, the programme focused on improving the site's API manufacturing processes by reducing waste, increasing yields and reducing process variation, resulting in improved quality and reliability of supply to patients. Recently, the OE programme has been expanded to focus on improving key business processes and supply chain activities by implementing business process management (BPM), in an effort to reduce overall costs, lead times and interfaces between functions and increase the overall reliability of its business processes. In the case of both OE and BPM, Roche Ireland has played a significant leadership role in the development and deployment of these innovative business improvement methodologies within the group. The continued pursuit of operational excellence at Roche Ireland is important in ensuring it remains a key member of Roche by consistently delivering a reliable, agile and competitive performance for the benefit of all its patients.

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The location of choice for scientific investment

14. Full compliance

Ireland's pharmaceutical sector has an extraordinarily good track record in terms of compliance with statutory and quality regulations. The US Food and Drug Administration (FDA), Irish Medicines Board (IMB) and consumer audits consistently rate Irish manufacturers' good manufacturing practice (GMP) compliance as world class. Companies' competence in this area gives them a key competitive advantage over industries in other regions around the world. Typically, inspections by the FDA rate Irish facilities extremely highly. No warning letters have been issued to any Irish facility by regulatory agencies over the past 10 years. This is an exceptional record.

The sector is a world leader in all aspects of environment and health and safety management, and is fully committed to minimising the impact of its activities. Over the past decade, the trend of the performance indicators for environment and safety continue downwards with significant decreases in both air and water emissions.

Table 5. Responsible Care programme for 2010

Performance indicators

Parameter	% Decrease from 2007-2009
VOC emissions	32%
Sulphur Dioxide	16%
Pollutant potential to waters	14%
Nitrogen discharge to waters	8%
Phosphate discharge to waters	20%
Hazardous waste	22%
Non-hazardous waste	14%
Lost time injury rate	24%

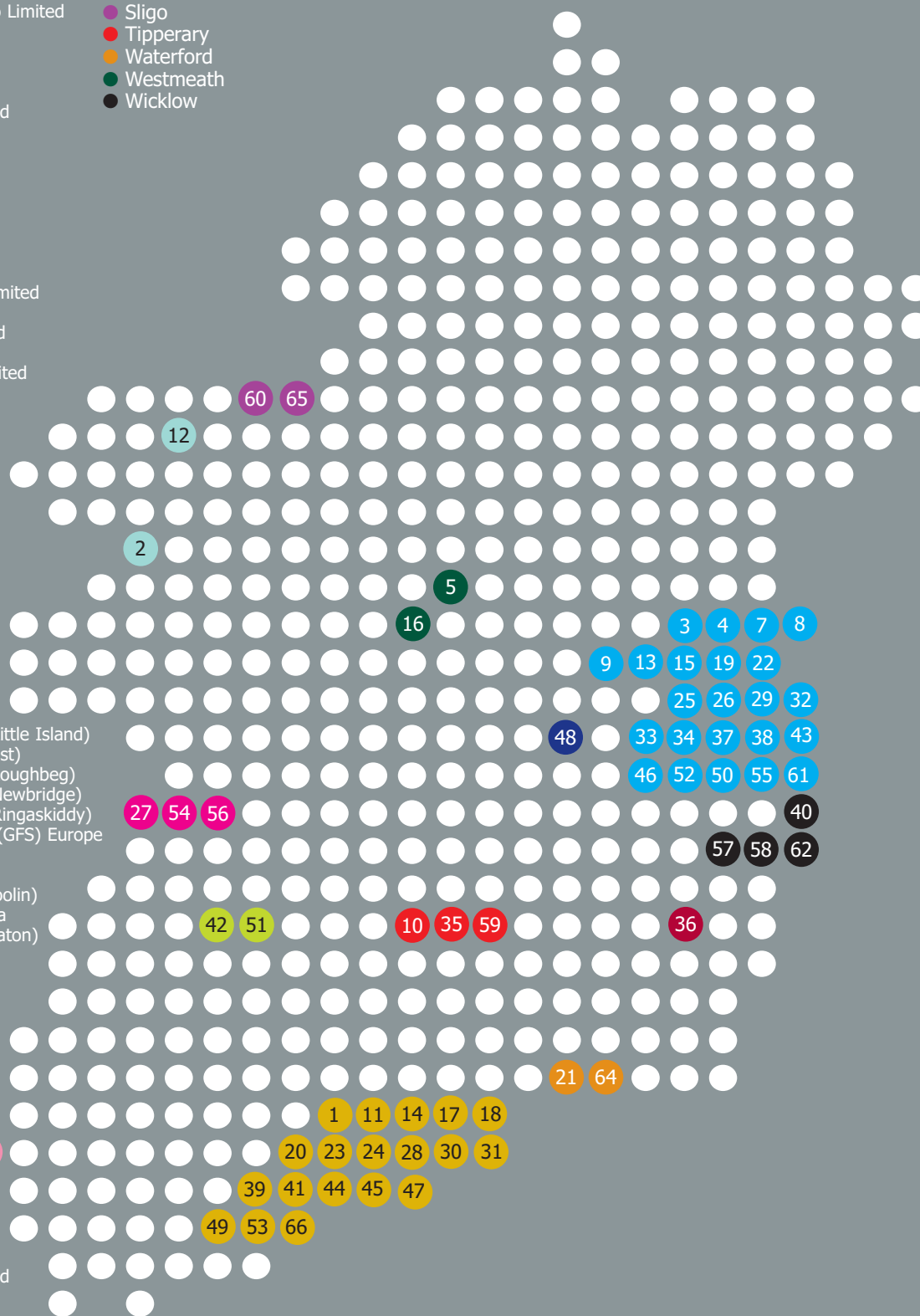
Source: Pharamchemical Ireland, Responsible Care Report 2010

IRELAND

The location of choice for scientific investment

1. Abbott
2. Allergan Pharmaceutical Ireland
3. Amgen
4. Arch Chemicals BV
5. Arran Chemical Company Limited
6. Astellas Ireland Co Limited
7. Astellas Ireland Co Limited
8. BASF Ireland Limited
9. Bristol Myers Squibb
10. Camida
11. Cara Partners & Wallingstown Co Limited
12. Chlarles River Laboratories
13. Clarochem Ireland Limited
14. Cognis Ireland Limited
15. Covidien
16. Elan Pharma International Limited
17. Eli Lilly SA
18. FMC International
19. Forest Laboratories
20. GE Healthcare Bio Sciences
21. Genzyme Ireland
22. Gerard Laboratories
23. Gilead Sciences Limited
24. GlaxoSmithKline Cork
25. Helsinn Birex Pharmaceuticals Limited
26. Henkel Locite
27. Heraeus Metal Processing Limited
28. Hovione Ltd
29. Ipsen Manufacturing Ireland Limited
30. Janssen Pharmaceutical
31. Janssen Biologics (Ireland)
32. Labopharm Europe Limited
33. LEO Pharma
34. Merrion Pharmaceutical
35. MSD (Ballydine)
36. MSD (Carlow)
37. MSD (Human Health)
38. MSD (Swords)
39. MSD (Brinny)
40. MSD (Rathdrum)
41. Novartis Ringaskiddy Limited
42. Olympus Biotech
43. Pfizer Ireland Pharmaceuticals (Grange Castle)
44. Pfizer Ireland Pharmaceuticals (Shanbally)
45. Pfizer Ireland Pharmaceuticals (Little Island)
46. Pfizer Healthcare Ireland (Citywest)
47. Pfizer Ireland Pharmaceuticals (Loughbeg)
48. Pfizer Ireland Pharmaceuticals (Newbridge)
49. Pfizer Ireland Pharmaceuticals (Ringaskiddy)
50. Pfizer Global Financial Solutions (GFS) Europe and Dublin Treasury Services (Ringsend, Dublin)
51. Pfizer Healthcare Ireland (Ballycoolin)
52. Pfizer Ireland Pharmaceuticals t/a Wyeth Nutritionals Ireland (Askeaton)
53. Recordati Ireland Limited
54. Roche Ireland Limited
55. Rottapharm Limited
56. Schwarz pharma Limited
57. Servier Irl Industries Limited
58. Sigma Aldrich Ireland Limited
59. Stada Production Ireland Limited
60. Stiefel Laboratories Ireland Limited
61. Swords Laboratories (BMS)
62. Takeda Ireland Limited
63. Temmler Ireland Limited
64. TEVA Pharmaceuticals
65. TopChem Pharmaceuticals Limited
66. Wexport (Leo)

- Dublin
- Carlow
- Clare
- Cork
- Kerry
- Kildare
- Limerick
- Mayo
- Meath
- Sligo
- Tipperary
- Waterford
- Westmeath
- Wicklow





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