IRELAND
Strategy in Action

Pharmaceutical Ireland is a business sector within IBEC
www.pharmaceuticalireland.ie
Introduction

In March 2010 PharmaChemical Ireland launched its industry strategy, "Innovation and Excellence" at the Drugs, Chemicals and Allied Technologies (DCAT) meeting in New York City. This strategy represents the industry's response to the challenges currently facing the sector globally, including the patent cliff, rising drug development costs and falling approvals of new medicines. While data point to a decline in quality globally, standards in Ireland remain high. The industry, however, concluded that the existing model of manufacturing only, was unlikely to secure a long-term future for the sector in Ireland.

It is against this backdrop that the concept of development plus manufacturing or "D&M" was adopted by the sector. Such investment facilitates the enhancement of existing manufacturing operations from a quality and cost perspective as well as attracting the development and launch of new entities or products.

In June 2011 PharmaChemical Ireland launched, "Ireland, a location of choice for scientific investment", documenting the real progress which has been made by the industry as it has begun to move towards the more integrated model referred to above. The report also contains a series of compelling testimonies by global and local CEOs describing why Ireland remains a location in which they are prepared to invest.

The objective of this report, "Strategy in Action" is to review the key drivers identified by industry which will ensure the future sustainability of the sector and recognise the progress achieved to date. We would like to thank the companies for supplying their case studies.

Executive summary

Ireland is one of the premier global locations for pharmaceutical and chemical product manufacture. Eight of the top-ten global pharmaceutical companies have a facility in Ireland, benefiting from a highly-skilled workforce, a proven level of manufacturing and compliance, a competitive tax rate and easy access to the European market.

The pharma sector has contributed significantly to Ireland’s economic development. Central Statistics Office (CSO) figures show that the sector exported products worth €55.1 billion in 2011, representing over 50% of total national exports. The sector contributes more than €1 billion in corporation tax to the State annually and employs over 50,000 people directly and indirectly, 50% of whom hold a third-level qualification.

Through the inclusion of case studies of leading companies located in Ireland, this report highlights the key drivers and strengths of the sector here. It outlines how companies have developed their facilities over the decades into centres of manufacturing excellence, R&D and commercialisation. It also sets out the advantages offered by Ireland as a location for a pharmaceutical manufacturing cluster.
Foreword

Ireland’s pharmaceutical, biopharmaceutical and chemical supply sectors contribute significantly to the Irish economy, delivering about 60% of the total value of Ireland’s exports in 2011, equivalent to more than a third of Ireland’s annual GDP. Ireland hosts most of the significant global companies in these sectors, as well as having a strong cluster of dynamic and innovative Irish firms. Ireland is now the second largest Development and Manufacturing (D&M) location in the world for Biopharmaceuticals.

This success story is no accident. The Irish Government and its Agencies have developed and implemented a range of policies and supports to enable the continued growth of these sectors which are of strategic importance to the Irish economy in terms of driving growth and jobs. We are committed to continuing to work closely with industry to support and further develop these sectors.

However, we must remain alert to the challenges facing the industry. These challenges are well documented: the need to maintain competitiveness through quality and productivity improvements, while repositioning existing facilities to engage in higher value-added development activities. What is less well-documented are the ways in which companies can respond to these challenges. The case studies in this report reveal how companies in Ireland are responding successfully, led by talented local management teams working together with well-educated, motivated and flexible workforces.

The report also provides a valuable insight into how the industry here is working with Government and academia. These factors explain why so many firms in Ireland have been able to successfully transition their operations and position themselves for the future. It also reaffirms that Ireland is a global location of choice for manufacturing and development activities in these sectors. This will greatly contribute to the Irish Government’s mission to develop Ireland as the best small country in the world for business.

Enda Kenny T.D.
Taoiseach
VISION

With the support of industry, Ireland will enhance its reputation as a recognised centre of excellence for innovation and development in pharmaceutical, biopharmaceutical and chemical supply, thereby becoming the location of choice for the launch of new products.

MISSION

As the representative body for the industry, PharmaChemical Ireland will continue to assist the sector in realising its ambition 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 pharmaceutical products.
CONTENTS

Industry at a glance 4
Background 6
Site of the future 8

**Allergan Pharmaceuticals Ireland** Realising the D&M Model 10
**Bristol Myers Squibb** Delivering innovative medicines to patients 12
**Eli Lilly** “A Transformation Journey” 14
**GE Healthcare** Achieving success by investing in the right people 16
**Genzyme Waterford** Expanding the mandate while improving productivity 18
**Janssen** Reliable, viable, valued and cost effective 20
**GlaxoSmithKline** A centre for innovation 22
**Helsinn Birex Pharmaceuticals Dublin** Shaping alliances, building pharmaceuticals 24
**Henkel** Open innovation 26
**MSD** Creating a new synergy between R&D and manufacturing 28
**Pfizer** Efficient and Agile at Manufacturing 30
Ireland’s collaborative research environment 32
Recommendations and conclusion 34
**Pharmaceutical Ireland** 36

in Action
IRELAND

Strategy in Action

THE IRISH PHARMACEUTICAL AND CHEMICAL INDUSTRY AT A GLANCE

Value of PharmaChemical sector investment
- The sector exported products to the value of €55.1 billion in 2011, representing over 50% of total national total exports.
- Ireland is the largest net exporter of medicines in the world.
- Nine of the top 10 pharmaceutical companies in the world have substantial operations in Ireland.
- The replacement value of the sector is estimated at €40 billion.

Talent
- Employment in the sector has grown from 5,200 in 1988 to 24,000 in 2012.
- Over 24,500 people are employed providing services to the sector.
- Over 50% of the employees are third-level graduates.
- The development of the sector in Ireland has been characterised by strong local management focused on strategic target delivery and a flexible and adaptable workforce.

Taxation
- A 12.5% corporate tax rate and a 25% R&D tax credit.
- No stamp duty on intellectual property transfer in Ireland.
- An intellectual property (IP) regime which provides a tax write-off for broadly defined IP acquisitions.
Compliance

- An inherent ability to comply with tough and demanding national and international regulations.
- No warning letters have been issued to any Irish facility by regulatory agencies over the past 10 years.
- A proven track record of manufacturing excellence.

Collaboration

- An excellent record for collaboration between industry and academia.
- Though a formal agreement structure with the state, the industry facilitates a partnership approach to the provision of innovative medicines to patients in Ireland.
- Strong collaboration between industry stakeholders.
- Continued support from the IDA and the Government.

Global pharmaceutical challenges

- Impending expiry of patents.
- Global over-capacity.
- Significant R&D costs.
- Declining pipelines for new products.
- Downward pressure on healthcare costs.
- Cost optimisation.
- Product failure at late stage clinical trials.
The Irish pharmaceutical and chemical sector was established in 1960 as a result of government policy at the time. Through the Industrial Development Authority (IDA Ireland), multinational pharmaceutical and chemical companies were encouraged to invest here.

Initial investments were primarily in bulk pharmaceuticals, now known as active pharmaceutical ingredients (APIs). Over the course of the 1970s, investment began to gravitate towards drug product manufacture. The 1990s saw this trend continue, with many established sites reinvesting significantly and expanding into shared-service activities. The advent of the human genome project saw many Irish-based companies invest in biotech or biopharmaceutical operations. Currently, many players are investing in product and process development, thereby adopting the D&M model. In addition, a number of indigenous specialist pharmaceutical and chemical companies have been established, adding to the overall diversity of the sector.

Fig 1.1 here summarises the evolution of the pharma sector in Ireland over the last 30 years, and its projected future development.
The global industry has now entered the post-patent cliff environment. Major blockbuster drugs are currently coming off patent. Prevailing healthcare policies in Ireland, and indeed across the developed world, are continuing to apply downward pressure on prices. However, as supply continues to circumnavigate the globe as efforts to reduce costs continue, a worrying trend has emerged within the sector in relation to quality standards. Trends evident from Fig 2.2 point to a reduction in quality standards globally. This contrasts with experience in Ireland, where quality standards remain very high. PharmaChemical Ireland member companies have prioritised compliance as part of their strategy. This should help to enhance the attractiveness of the country as a location for the continued supply of pharmaceutical and chemical products.

Fig 2.2
PharmaChemical Ireland members were consulted on what they thought the key attributes of future facilities should be. The findings are outlined here.

- highly-efficient, cost-effective manufacturing with the full implementation of the principles of lean manufacturing and operational excellence;
- best practice in regulatory management, including principles of quality by design and process analytical technology;
- on-site process and product development capabilities fully integrated into manufacturing;
- the site of choice for transfer of all new entities to market;
- a flexible and adaptable production facility;
- on-site pilot plant facilities;
- an on-site unit aimed at training the workforce in the latest principles of Lean, Six Sigma, etc;
- fully-networked and research infrastructure;
- best practice in systems and information management;
- best practice in all aspects of environment and health and safety (EHS) management;
- a fully-integrated development network for overall corporate structure;
- capacity and capability for clinical trials manufacture;
- regional HQ status for supply chain components, where it makes economic sense to concentrate them at one location;
- a strong local management team;
- a flexible workforce that can embrace and facilitate change.
In summary, for a site to be fit for purpose it needs to achieve excellence as a manufacturing unit by employing best practices in operational excellence. It also needs to maintain a close to perfect record of compliance across the entire regulatory spectrum. Where possible, operations need to be environmentally and economically sustainable. For multinational companies, on-site process or product development capabilities are vital if the site is to position itself as a location of choice for new investment. Indigenous sites need to base their own business models on significant investment in innovation.

Strategy in action
Since the launch of our strategic plan in early 2010, member companies have been implementing many of its recommendations. The majority of Irish sites have undergone significant transformation since they first established here. This has helped Ireland to move away from its traditional status as a sourcing location, primarily for APIs. Many sites are now engaging in fully-integrated operations, offering a range of activities beyond pure manufacturing, including process and product development, manufacture for clinical trials, shared services, etc.

The following detailed company case studies demonstrate how sites have evolved since establishing in Ireland, providing ample evidence of industry strategy in action.
REALISING THE D&M MODEL

Allergan is a multi-specialty health care company established more than 60 years ago with a commitment to uncover the best of science and develop and deliver innovative and meaningful treatments to help people reach their life’s potential. Today, the company has over 10,000 highly-dedicated and talented employees with a presence in more than 100 countries and an evolving portfolio of pharmaceuticals, biologics, medical devices and over-the-counter consumer products.

Allergan’s aim is to help millions of patients see more clearly, move more freely and express themselves more fully. From the beginnings as an eye care company, to our focus today on several medical specialties, including ophthalmology, neurosciences, medical aesthetics, medical dermatology, breast aesthetics, obesity intervention and urologics, Allergan is proud to celebrate 60 years of medical advances. With annual revenue in excess of $5.3 billion, the company has five operations facilities, the one in Westport being the largest in the network with the highest concentration of employees in one location outside of the US headquarters.
The facilities strategy is based on delivering a comprehensive D&M model to accelerate new products to commercialization and better service customers needs.

There is a strong focus on development from a process, product and analytical perspective at the site.

**Westport campus strategy**

The Allergan Westport facility has been in operation for 35 years, employing over 800 people and exporting to 70 global destinations. Production at the facility accounts for a significant portion of Allergan's total revenue with a diverse range of site activities from aseptic processing in glass and plastic to solid dose biodegradable ocular implants. The strategic vision for the facility is to become more than just a manufacturing facility, with emphasis placed on increased development activity leading to accelerated speed to market of new products. The D&M model is currently being advanced by Allergan Westport in accordance with the strategic vision for the Irish operation.

The facility strategy aims to both protect and expand on the current “core” manufacturing technologies while enhancing other activities. Such activities include a global stability testing centre, the supply of clinical trial material, involvement with corporate R&D in biologics and pharma development projects from phase I through phase III in certain instances and a shared financial service centre.

**Technical Operations**

The evolution of the D&M model has led to the creation of a dedicated Technical Operations function at the Westport site, to focus on development from a process, product and analytical perspective. The group aims to bring development activities closer to the manufacturing site in order to benefit from site knowledge and expertise. This has become an integral part of the R&D process from development through the full life cycle of the product. Technical Operations aims to be regarded as the centre of excellence and location of choice for late-stage development within the Allergan Corporation, adding significant increased value to the organisation and end customer. The ultimate goal is speed to market for our products to better service our customers’ needs. The Westport facility continues to secure significant investment from the corporate office. The facility has seen an increased level of up-skilling of employees and academically-qualified recruitment with over 70% of the employee population now holding a third-level qualification.

The future for the Allergan campus in Westport is very bright – continued investment in its infrastructure and people and endorsements received from corporate headquarters will help to deliver our vision into the future. This, in addition to the support from government bodies such as the IDA and the availability of innovative government schemes will ensure that Allergan continues to grow and expand here in Ireland.
IRELAND
Strategy in Action

DELIVERING INNOVATIVE MEDICINES TO PATIENTS

Bristol-Myers Squibb

The focus of BMS operations in Ireland is the manufacture of active pharmaceutical ingredients (APIs) and drug substances. Manufacturing capabilities and capacity have expanded significantly over time.

From the early 1960s, the Swords manufacturing plant has been a critical API supplier. A modern, highly-automated facility was added when the Cruiserath site began commercial operations in 2004. Capital investment on these two API sites exceeded €1 billion over this period. The operation and management of these two facilities tells only part of the story as there has been a continuous evolution over time with the addition of high-containment oncology and small-scale manufacturing and expansion of capabilities such as varied isolation and drying equipment. This expansion has enhanced flexibility and ensured that the Irish facilities are in position to manufacture high-quality products.
Capital investment on two API sites exceeded €1 billion.

BMs operations will celebrate its 50th anniversary in Ireland in 2014. Over that time, BMS has delivered many critical medicines to patients.

The company has recently expanded the technical organisation to include managing our third party-partners and this organisation is now based in Ireland.

In 2007, BMS announced a significant rationalisation of its manufacturing network. Performance, cost and efficiency were key focus areas as part of the assessment to determine which facilities would remain in the network.

The unit costs of manufacturing the APIs were significantly reduced by driving process improvements. Tough decisions were implemented with an overall reduction in the size of the organisation of approximately 15%. Energy costs were significantly reduced by lowering consumption by 22%, driven by the culture of operational excellence that exists across both sites.

While BMS has rationalised its facilities from 27 to 13 worldwide, the results of the significant improvements in efficiency and competitiveness ensured that the two API plants in Ireland remain to be the sole internal suppliers of key actives for chemically-derived products within the company.

This efficiency drive has been accompanied by an increase in the number of products being launched and their associated support. The value of products being manufactured supports sales of about €5 billion and this figure is anticipated to increase into the future.

A key factor in the success of the Irish operations has been the continued focus on raising the bar on compliance. While being inspected on a regular basis, neither API facility has received an FDA 483 or major non compliance from the Irish Medicines Board or other agencies for over 20 years. This compliance focus spans environmental health and safety also with national awards being received for sustainability efforts through the responsible care organisation and for safety standards and personnel on the sites.

The successes outlined have been achieved as a result of our people and their skills to sustain, enhance and drive performance for BMS in Ireland. Strong local management combined with excellent technical skills availability (> 60% of employees with degree level qualifications or higher). Collaboration with local universities is also key to success as it helps to ensure that the right skillsets are available for the changing technical challenges and requirements needed to bring new medicines to patients.

Future opportunities for BMS
The local BMS management has developed a strategy endorsed at corporate level to ensure continued success:

- Enhanced OPEX skills including statistics to drive continuous improvement in manufacturing performance and cost competitiveness;
- This improvement will be driven by prioritisation through a focussed project management approach;
- Competitive commercial processes at launch;
- A value stream approach to enhance value across the product supply chain;
- An enhanced life cycle management approach aligned with corporate strategy.
A TRANSFORMATION JOURNEY

Eli Lilly and Company is a leading, innovation-driven corporation committed to developing a growing portfolio of pharmaceutical products that help people live longer, healthier and more active lives.

The facility utilises a range of advanced chemical and biological processes to produce active pharmaceutical ingredients across a number of therapeutic categories, including neuroscience, oncology, diabetes and musculoskeletal disorders. These products are formulated at various facilities to supply medicines to patients worldwide.

The Kinsale manufacturing facility has evolved and transformed its mission and business focus over its thirty years in Ireland. Today the site not only continues to be a worldwide manufacturer and supplier of the company’s newest Small Molecule medicines, but has expanded its role to become the company’s primary location for manufacture of the company’s biopharmaceuticals portfolio. In addition, it has now also become a strategic location for the commercialisation and scale up of Lilly’s small molecule and biopharmaceutical pipeline of medicines.
Lilly’s first manufacturing investment in Ireland began with the construction of a facility in Dunderrow, close to Kinsale, County Cork in 1978. Today the Kinsale site employs 410 personnel across both its Small molecule and Biopharmaceutical businesses. Eli Lilly and Company employs over 700 people in Cork, Sligo and Dublin across a range of activities including Human and Animal medicines manufacturing, Shared Financial Services for Europe and Sales and Marketing.

Lilly medicines treat depression, schizophrenia, attention-deficit hyperactivity disorder, diabetes, osteoporosis, cancer and many other illnesses.

Many of the existing Lilly medicines portfolio is developed or manufactured at the Kinsale site and a high proportion of Lilly’s new molecules portfolio undergoes late-stage development manufacturing there.

The continued growth and success of the facility and its ability to develop successfully over the years has been based upon a number of factors.

People and organisation
Most of Kinsale’s employees were hired locally and are a product of the Irish education system, and many have gone on to develop their careers with Lilly in significantly more senior leadership roles within the company. This has allowed the alignment of the site’s continuing development with the strategic direction of the company and requirements of the corporate organisation as a whole.

A history of delivering on commitments
The facility has established a long track record in compliance, productivity improvement and in meeting its commitments, which was certainly a factor in earning the company’s trust to invest in new technologies and activities at the site.

Partnership: community, academia and State agencies
Community
The support of the local community has always been important to Lilly in Kinsale. Discussions are held twice a year with the local community to update them on the site’s plans and progress and to discuss any items of mutual interest and benefit.

Academic links
From the early days, strong links were established with the local universities which enabled the Kinsale facility to secure very strong graduate talent.

The academic links remain very important to the company and significant academic collaboration with Irish Universities continues today. The reputation that the Irish academic system has established was a significant factor in the company’s decision to invest in biotechnology and commercialisation facilities in Kinsale around 2006.

State agency support
The company has always recognised the advantages offered by Ireland as a location for its operations. The company has benefitted from a stable, pro business environment in Ireland that has appropriate regulation but facilitates the development of business activity with a minimal amount of bureaucracy.

Basis for future success
Eli Lilly in Kinsale has successfully met the company’s needs in the highly complex and rapidly changing pharmaceutical industry.

The following attributes are regarded as essential to securing the long-term success of Lilly in Kinsale.

- Firstly, to focus on what we can control ourselves by ensuring we remain an attractive option and retain the capability to respond to any shift in the company’s strategy.
- Paying attention to the calibre and the quality of our future employees and ensuring that we develop their technical competence and experience.
- Establishing close relationships with corporate functions such as R&D and actively seeking opportunities to add greater value to both our local and corporate business.
- Continued co-operation with the local community, academia and Government agencies.
- A commitment to our core values of integrity, excellence and respect for people.
IRELAND

Strategy in Action

ACHIEVING SUCCESS BY INVESTING IN THE RIGHT PEOPLE

Nycomed, now GE Healthcare was first established in Ireland in 1993, and 450 people are now employed the Cork facility. Its products are exported to around 80 markets globally.

Since the facility’s inception, there has been a strong emphasis on investing in a talented management team. Recruiting the right people has provided the foundation upon which the success achieved over the last 20 years has been built.

After a successful production start-up in 1993, the site improved its reputation as an organisation that delivered on its responsibilities. Volumes grew and the first expansion, "Phase 2" was completed in 1996/97. In 1999, Nycomed merged with Amersham and became part of "Amersham Health" a FTSE 100 company based in the UK. This was a strategic move for the Cork facility, which gave it the opportunity to develop within an excellent management structure. Between 1999 and 2002 a project called Global Sourcing was established. This project was a major vote of confidence in the site which resulted in the closure of the site in Puerto Rico and the reallocation of volume to the Cork facility with other volumes assigned to Oslo. This increase in volume meant a major physical expansion valued at £30m, a change to a three-shift system and a large increase in employees.
450 people are now employed the Cork facility
Approximately 30 people working at the site hold international roles
Serving 80 markets directly from the Cork facility

From 2002 to 2004 the facility increased production and became one of Amersham Health’s flagship sites with employees taking on international roles at corporate level.

GE acquired Amersham Health in 2004, bringing a new management style with an emphasis on costs and efficiency. The Cork facility successfully adapted to the GE’s culture and remains a crucial and successful part of GE’s global supply chain.

Approximately 30 people working at the site hold international roles. Employees are given the opportunity and encouraged to work in international roles at corporate level. This approach has proved to be highly beneficial not only to the Cork facility, but to the company as a whole, and reflects our strong focus on the importance of the qualities and abilities of our employees.

Our commitment to best practice
- One-to-one management with a strong focus on the individual.
- A diverse range of skills at management and all levels.
- Strong project management skills. The ability to deliver large cross-supply chain projects within time and budget.
- A focus on business goals and ensuring delivery.
- Building a strong reputation.
- At GE Healthcare we have a very strong focus on compliance with all aspects of regulatory requirements.
- A commitment to giving employees the opportunity to expand their roles into international and corporate positions.
IRELAND

Strategy in Action

EXPANDING THE MANDATE WHILE IMPROVING PRODUCTIVITY

Genzyme

Genzyme is a Biotech company focussed on products for rare diseases. Genzyme was acquired by Sanofi in 2011 to complement its existing product portfolio and to improve on the product pipeline. Sanofi is one of the largest pharmaceutical companies in the world and has over 100 manufacturing sites.

Genzyme came to Waterford in 2001, commenced manufacturing operations in 2003 and has expanded the site manufacturing capabilities to include two fill finish lines, two tableting lines, an oral dose development facility and all associated functions including packaging. Capital invested to date exceeds €450M and there are 500 full-time employees. Waterford is the Genzyme drug product site for 90%+ of Genzyme products, supporting revenues of over $3billion.

The facility was built in 2003 for development of oral dose drug product formulations, manufacture of phase 3 clinical materials and scale up for commercial manufacturing. About 50% of the products developed have made it through to commercialisation.
Genzyme came to Waterford in 2001, commenced manufacturing operations in 2003. Waterford is the Genzyme drug product site for 90%+ of Genzyme products, supporting revenues of over $3B. About 50% of the products developed have made it through to commercialisation.

In 2008 cost began to emerge as a significant challenge for the facility with a robust cost structure key to securing long-term sustainability. The commitment of the site’s personnel was secured and lean was chosen as the vehicle to deliver the strategy.

About 50% of the products developed have made it through to commercialisation.

In 2008 cost began to emerge as a significant challenge for the facility with a robust cost structure key to securing long-term sustainability. The commitment of the site’s personnel was secured and lean was chosen as the vehicle to deliver the strategy.

Additional productivity from the facility and its personnel has had a significant impact on costs. The flexibility of the site personnel in adapting to changed and new roles has been key to the productivity improvements. See below.

As part of the wider Sanofi group, Waterford now has the opportunity to:

- Attract Sanofi products to optimise plant utilisation;
- Build on a lead position regarding isolator technology for aseptic processing;
- Establish fill finish development similar to oral dose;
- Enhance lead positions in MES and Lean.

As with all site developments, the journey continues ….
GlaxoSmithKline (GSK) is one of the world’s leading research-based pharmaceutical and healthcare companies with one simple mission: to improve the quality of human life by enabling people to do more, feel better and live longer. With a firm foundation in science, it discovers, develops, manufactures and distributes prescription medicines, vaccines and consumer healthcare products. These help people stay healthy, patients get better and, crucially in these tough economic times, provide value to governments and other healthcare providers.

GSK has a long heritage in Ireland. Employing over 1,600 people across five sites, over the years it has shown its commitment to Ireland by expanding and diversifying its investment in the pharmaceutical and consumer businesses based here. GSK contributed over €1.5 billion in exports, more than €100 million in salaries and wages, €30 million in R&D and €140 million in payments to Irish suppliers.
GSK employs over 1,600 people across five sites.

The GSK site in Dungarvan employs approximately 700 people and supplies products to 70 markets around the world.

In 2009 GSK contributed over €1.5 billion in exports, more than €100 million in salaries and wages, €30 million in R&D and €140 million in payments to Irish suppliers.

GSK has fundamentally transformed its global business model in anticipation of and response to the changing marketplace. As a result, it is strongly and strategically positioned, with a balanced portfolio and strong operating model. However, to succeed in this ever-changing marketplace, one thing it must do is remain competitive by being more agile and identifying ways to simplify the operating model.

Patients and consumers depend on GSK’s global manufacturing supply to deliver great products and to do so better, faster and at a lower cost than ever before, so more people can benefit and commercial colleagues can compete effectively. By delivering sustainable great performance day in and day out, GSK Dungarvan will play a key role in achieving GSK’s mission and strategic priorities across its seven production streams which include Panadol, Solpadeine, Beechams and Poligrip.

Innovation and Research

GSK contributes to increasing Ireland’s profile as a centre for innovation through partnering with higher education institutions here. For example, GSK is an active participant in the Molecular Therapeutics for Cancer, Ireland (MTCI) in Dublin City University, a Science Foundation Ireland-funded strategic research cluster which aims to discover and develop new anti-cancer drugs. It is also committed to innovation in its internal processes which focus on continuous improvement and shared learning.

GSK Dungarvan

The GSK site in Dungarvan employs approximately 700 people and supplies products to 70 markets around the world.

GSK has fundamentally transformed its global business model in anticipation of and response to the changing marketplace. As a result, it is strongly and strategically positioned, with a balanced portfolio and strong operating model. However, to succeed in this ever-changing marketplace, one thing it must do is remain competitive by being more agile and identifying ways to simplify the operating model.

Patients and consumers depend on GSK’s global manufacturing supply to deliver great products and to do so better, faster and at a lower cost than ever before, so more people can benefit and commercial colleagues can compete effectively. By delivering sustainable great performance day in and day out, GSK Dungarvan will play a key role in achieving GSK’s mission and strategic priorities across its seven production streams which include Panadol, Solpadeine, Beechams and Poligrip.

Operational Excellence at GSK Dungarvan

The facility took a unique approach to delivering these efficiencies. It introduced an operational excellence programme that delivered savings of 20% to certain key processes through a combination of Lean Six and Sigma principles – or Lean Sigma. To ensure its success, it provided training on the programme to over 400 staff or ‘advocates’. These advocates championed the programme internally. Many were provided with opportunities to train further as either Green Belt or Black Belt practitioners.

To date, this programme has delivered significant savings, increased on-line efficiencies, reduced inventories, reduced testing times in the laboratories, improved material flow through the facility and ultimately, helped to reduce the cost of producing the product. This means that not only is GSK Dungarvan now a cost-efficient site, and an attractive proposition for internal and external investment, but its workforce is also valued for their problem solving capabilities and commitment to success.
IRELAND

Strategy in Action

SHAPING ALLIANCES, BUILDING PHARMACEUTICALS

Headquartered in Lugano, Switzerland with subsidiaries in the U.S and Ireland, Helsinn is a dynamic group focused on pharmaceuticals, medical devices and nutritional supplement products in niche therapeutic areas with a primary focus on Cancer Supportive Care aimed at improving the patient’s quality of life during treatment.

The group in-licenses early to late stage new chemical entities from other pharma companies, completes their development through the performance of pre-clinical and clinical studies supported by chemistry, manufacturing and control development then files and attains their market approval worldwide. The active pharmaceutical ingredients and the finished products are manufactured according to the highest quality, safety and environmental standards, at Helsinn’s facilities in Switzerland and Ireland, and supplied worldwide to its customers.

Through its self financing approach and careful management of its commercial and development businesses, Helsinn has established a valuable international market position with a strong medium-term pipeline of development projects.
Since moving to its purpose-built facility in Dublin in 1997, Helsinn Birex Pharmaceuticals now employs over 150 people.

Since 2009, the Group has invested over €17 million at the Irish site.

Helsinn Group, exports to over 45 countries including the US, EU and Japan.

Helsinn Birex Pharmaceuticals Dublin

When the Helsinn Group acquired Birex Pharmaceuticals in 1990, the site in Dublin was a small multiproduct facility focused primarily on supply to the Irish Market and employed only 40 people. Since moving to its purpose-built facility in Dublin 15 in 1997, Helsinn Birex Pharmaceuticals now employs over 150 people and manages the commercialisation development of oral forms and supply of all launched products of the Helsinn Group, exporting to over 45 countries including the US, EU and Japan.

Today it is an integrated development and manufacturing organisation aligned with core group pipeline development strategies. It has evolved into a manufacturing and supply centre to support the growth of commercial product volumes. The Irish plant operates to global standards of quality (EU, FDA, PMDA) and HSE compliance and has achieved multiple industrial safety awards for its occupational safety management systems, as well as recognition under the internationally-recognised Responsible Care Program.

Expanding the site mandate

Over the years, the Dublin site mandate has expanded to enable it to become the launch and supply site for the Helsinn Groups new products with the addition of CMO external network management, stability services, clinical supply packaging and release activities. Since 2007, the site has become responsible for EU Regulatory and pharmacovigilance activities.

Investment in R&D centre

Since 2009, the Group has invested over €17 million at the Irish site and, with the support of the IDA, established a centre of excellence for development of oral solid dosage forms and expanded the analytical laboratory and the stability centre, focused on developing group products of the future. This centre enables Helsinn to better manage key CMC development activities, ensure adherence to new product development milestones, and to respond to new challenges and regulatory requirements. The Dublin plant is today conducting new product development of oral dose forms with several projects on-going in support of NDA filings planned in 2013-2015.

Collaborating with HEI’s

Engaging with Higher Education Institutes (HEI’s) as well as and scouting for business development opportunities in the medical food and nutrition sector in Ireland. In 2012 it announced the commencement of a project with St Vincent’s University Hospital under the University College Dublin Newman Fellowship program and further projects are planned with the UCD Conway institute.

Dimensions of Irish success to date:

- An educated workforce and strong academic links;
- The acquisition, retention and development of top talent;
- A track record of accomplishment;
- A strong GMP compliance record;
- The establishment of close team working relationships with corporate colleagues, focused on strategic target delivery;
- Continued support from the IDA and the Government.
Henkel operates worldwide with leading brands and technologies in three business areas: laundry and home care, Beauty Care and adhesive technologies. Henkel holds globally leading market positions both in the consumer and industrial businesses with well-known brands such as Persil, Schwarzkopf, Pritt, Loctite and Teroson. The company is present in 120 countries. It has nine major R&D facilities around the world and 180 production sites in 56 countries.

Excellence is our passion
“Our vision at Henkel is to be a global leader in brands and technologies. Our innovations are the basis for successfully turning this vision into reality. They assure our future viability and our capacity to adjust proactively in a world where change is constant.”

Henkel's Operations in Ireland
Established in 1966, Henkel Ireland spans two sites in Tallaght and Ballyfermot, employing approximately 375 people. Approximately 250 people are employed in manufacturing, sales and shared services across Tallaght and Ballyfermot and a further 125 work in the R&D facility in Tallaght. The company’s main activities in Ireland are research, product development and manufacturing of adhesives for consumer and industrial market applications. The R&D facility is also home to Henkel’s European Centre of Excellence in product safety and chemical regulations. Henkel is currently investing €12 million in its operations in Tallaght and Ballyfermot in support of operations in Ireland.
Established in 1966, Henkel Ireland spans two sites in Tallaght and Ballyfermot, employing approximately 375 people.

The Dublin R&D facility is home to Henkel’s European Technology Centre of Excellence.

The Dublin facility ships to over 80 countries worldwide.

Henkel’s 38,000 sq. metre production site in Tallaght is a bulk formulation plant for anaerobics and epoxies, as well as a bottling and packaging plant. The operation runs 24 hours per day from Monday to Friday and fills approximately 1,500 adhesive batches, ranging in size from 30l to 4000l a year. The adhesive is then filled into over 117 million tubes a year, which are packaged and shipped to over 80 countries worldwide.

Adhesives produced and developed in Ireland are used in automotive, electronics, medical devices, general industry and consumer applications. INDERMIL®, Henkel’s medical grade skin tissue adhesive product range, is also produced in Tallaght.

The cyanoacrylates formulation plant in Ballyfermot is fully automated and produces a variety of instant bonding adhesives for industrial and consumer applications.

The research facility in Tallaght covers 8,700 sq. metres and undertakes fundamental research and development in acrylates, epoxies, instant adhesives and advanced materials. It is supported by process development, analytical lab and technical support. Product packaging design, an important element of adhesive product development, is also undertaken at the Technology Centre. Almost half (46%) of the R&D employees are educated to PhD level.

Open innovation

Henkel’s global R&D has eight platforms, two of which are based in the Technology Centre in Tallaght, Dublin: a global platform for acrylates and one for advanced technology development. The purpose of these platforms is to create and push new technological developments and market making opportunities within adhesive technologies.

The R&D operation in Tallaght caters for both product development and fundamental research related to these platforms and employs over 120 scientific staff. The development of primary packaging for adhesive products is another global function performed at the Dublin sites and is supported by employing polymer graduates.

The R&D operation is based on two research models:

- **Technology platforms**: where our focus is on medium to long-term research, which enables technology and competition monitoring;
- **Product development**: where our focus is on short to medium-term research, which is customer driven and has a business segment focus.

The Tallaght site is also one of Henkel’s three global centres for analytical labs and is also the European Centre of Excellence for chemical regulation and product safety.

Henkel operates a unique product development process with different areas all working closely together. Each new technology product is treated as a new project.

Henkel Ireland and external research

Henkel promotes the concept of open innovation and operates an active external research program, working with academics in University College Dublin (UCD), Trinity College Dublin (TCD), Dublin City University (DCU) and University of Limerick (UL) as well as research institutes such as Tyndall (based in UCC) and CRANN (based in TCD). These projects cover topics from basic chemistry research all the way to the engineering application of adhesives. Many of these research projects are part funded by the Irish Government (e.g. IRCSET PhD students, SFI Post-Docs, etc). We also work closely with the UCD Centre of Adhesion and Adhesives to promote the use of adhesives, and in practice, Henkel adhesives, with the next generation of engineers.
IRELAND

Strategy in Action

RELIABLE, VIABLE, VALUED AND COST EFFECTIVE

Little Island Site
Janssen Pharmaceutical commenced activities as a manufacturer of active pharmaceutical ingredients (APIs) in Little Island, Cork, in 1981. In 2009 the site encountered many challenges as product volumes declined. This resulted in a reduction in the workforce. Management had to re-evaluate ways to increase productivity. This was achieved and enabled capacity for further production volumes. Proving to be a key site for Janssen supply of small molecule API products, its capability grew to take on commercial products. Improvements in processes transferred to the site drove cost effective yields. Production at the site has since grown and currently it manufactures 14 products.

Ringaskiddy Site
The 100-acre greenfield site was purchased in 2004 as Janssen needed additional capacity to manufacture monoclonal antibody products. The project, which was built on 30 acres, was executed very successfully on schedule and within budget. This was the largest capital investment by J&J at €500 million. Construction commenced in 2005 and the plant commenced operations in 2009. Originally built to manufacture two blockbuster products, this state of the art facility now accommodates multi-product and clinical manufacture. Cleanroom space was retrofitted to include two small scale manufacturing suites which enabled early clinical phase product manufacturing. To date, 14 products have been manufactured there.
Technology enhancements:
Management at the Ringaskiddy site took the opportunity to develop quality control analytical laboratories in order to broaden scope beyond commercial product testing. The R&D testing unit was developed for R&D biologics products, generating a significant capability for analytical development and analysis, supporting the global stability testing programs.

A fully integrated manufacturing execution system (MES) - paperless site was introduced for R&D batches. This contributed to reduced development time and helped to accelerate the development process. In addition, lean approaches and systems were deployed to give significant efficiencies and reduce cost and time of manufacture.

Janssen Supply Chain Ireland (JSCI)
In 2010 the two sites which had been separate entities were brought together under a single leadership team. This brought significant benefit from a management and operations perspective and provided an ideal opportunity to cross train staff between chemical and biotechnology API. Business has continued to grow while continuing to reliably deliver product of the highest quality.

Across the two sites there are about 30 people supporting global leadership roles, executive and divisional responsibilities, quality, finance, supply chain, product value stream leaders and development operations.

Compliance has become a key focus (Quality and Environmental, Health & Safety). Operational efficiencies are driven by up skilling the workforce on lean manufacturing capabilities and have been a key focus on product delivery over the last couple of years.

Janssen used IDA grant aid to offset start up costs and expansion at both facilities. Janssen also availed of R&D tax credits to support the development work associated with new products. This has brought important benefits to the company and has been instrumental in bringing development opportunities to Ireland.

Research collaboration
Janssen engages in on-going collaboration with Irish academic institutions for specific development projects supporting activity at the sites. Janssen is also working with Irish academic institutions through industry collaborations (SSPC and Enterprise Ireland), where specific research is being funded jointly by a number of companies on projects which will benefit all of those involved.
CREATING A NEW SYNERGY BETWEEN R&D AND MANUFACTURING

MSD is a research-based global healthcare leader ranking second in the world. Its vision commits to increasing access to healthcare through far-reaching policies, programmes and partnerships to help people around the world lead healthier lives.

In the past MSD relied on a single point of technology transfer between research and manufacturing, encompassing critical activities between divisions at the time of new product registration. The company has crafted a new organisational model for the space between phase III of the clinical development programme and the early stages of commercial supply.
MSD in Ballydine, Co. Tipperary

Originally the Ballydine site was established as an API manufacturing plant in 1976. This site currently supports worldwide revenues of approx. €8bn and employs 450 people. The site’s activities have recently been redirected toward new product R&D commercialisation. The secondary mandate for this site is supply, which currently supports 17% of total MSD revenue. The deliverables for this site have been to reduce capital spent on risk by 70%, to improve efficiency by 30% and to reduce the development lifecycle critical path by 12-15 months. MSD has invested over €2.2bn in Ireland over the past five decades.

The scope of R&D commercialisation at Ballydine has also recently been expanded from the drug substance to the drug product area. Currently, there is an unprecedented level of R&D activity at the facility, including products in all three phases of process development, clinical supply and process performance qualification (PPQ) for early product launch. This includes six new products in commercialisation for drug substance and three in commercialisation for drug products. Despite the benefits of adopting this new model, Ballydine has been faced with a number of challenges.

The R&D commercialisation model requires new skills, and as a result, new staff had to be hired. This was partly offset by staff reductions in the supply side of the business through operational excellence, six sigma methodologies and lean manufacturing principles. New skills have had to be developed in the areas of niche technologies, process development, chemistry, manufacturing and controls regulation, clinical supplies and analytical development. Also, expertise in project management has had to be developed as staff on this site lead many development programmes internationally.

Overall, the Ballydine site has become one of the most important strategic sites in the MSD network worldwide. Of approximately 20 candidate products in the late-stage pipeline for the company, nine are currently in development at the site, including three of the top five investigative products from the MSD research pipeline.

The success of R&D commercialisation at Ballydine has been enabled by the sponsorship and vision of MSD senior management, the site’s credibility and track record, its technology and infrastructure, support from the IDA and other Government agencies, collaboration with industry/ academia, and favourable fiscal regimes including Ireland’s R&D tax credit policy and low corporation tax.
In an increasingly competitive marketplace, pharmaceutical companies are looking at innovative ways to increase the agility and efficiency of their manufacturing. Initiatives such as process analytical technology (PAT), quality by design (QbD) and lean manufacturing can reduce lead time, increase process robustness and improve manufacturing flexibility.

These initiatives are slowly taking hold within the industry and starting to produce results by applying science, process data and intelligence to manufacturing to create competitive advantage. Pfizer has adopted intelligence-based manufacturing (IbM) concepts which focus on harnessing the complementary power of data, modelling, engineering and IT infrastructure by transforming data into knowledge and ultimately intelligence. The goal of this IbM initiative is to move to proactive manufacturing strategies that deliver predictable manufacturing performance. Pfizer’s sites in Ireland are embracing IbM concepts and have embarked on multiple projects that are helping to turn data into intelligence.
Ireland’s largest pharmaceutical investor with €7 billion invested in Ireland since 1969, recently announced €200m investment in Grange Castle.

Many of Pfizer’s leading medicines and vaccines are manufactured in Ireland for cancer, heart disease and arthritis.

4,000 people employed across four regions in Limerick, Cork, Kildare and Dublin.

Ireland is home to eight Centres of Excellence across manufacturing and finance functions.

---

**Best practice in systems and information management**

The Pfizer manufacturing plant in Newbridge, County Kildare has adopted a number of IBM initiatives. An example is the development of an Intelligent Process Condition Monitoring (IPCM) strategy for a complex tablet coating process. The coating process applies a thin coat to the outer surface of pharmaceutical tablets. This is carried out in a large rotating pan equipped with spray nozzles for the application of the coating solution. Temperature-controlled air continuously flows through the coater bed. The temperature of the product bed in the coating pan is a critical parameter for this process. This is traditionally monitored by an IR sensor. Variation in the coating process and coating equipment performance, and especially IR sensor failures, pose a major risk to process outcomes and reliability and product quality. The IPCM strategy included the development of ‘soft sensors’ to replace the unreliable IR sensors. These soft sensors utilise advanced mathematical modelling to predict bed temperature with a high degree of reliability based on multiple input parameters collected during the manufacturing operation.

The soft sensor technology and intelligent real-time batch monitoring system uses data from traditional sensors, such as airflow and inlet and outlet temperature and existing data management infrastructure, and therefore, no capital investment is required. This can be used for early detection and real-time mitigation of bed-temperature IR sensor malfunction and ultimately replace the IR sensor as the primary means of control of this critical parameter and significantly improve process reliability.

IBM delivers high impact predictive and adaptive technologies and solutions that capture and embed critical knowledge and intelligence into manufacturing, at process, plant and enterprise levels. Performance criteria such as quality/compliance, process robustness and reliability are optimised, and, therefore, product supply performance. By applying intelligence to process data and introducing science into the analysis of process information, pharmaceutical companies can inject more competitive advantage into their manufacturing processes.

---

![Newbridge site, Kildare](image)
IRELAND

Strategy in Action

IRELAND’S COLLABORATIVE RESEARCH ENVIRONMENT

A unique feature of the Irish business environment is the productive collaboration between industry, academia and government agencies. All stakeholders work together, building a national team to consolidate Ireland’s position as a knowledge-based economy and as a primary location for research and development. The key element of the Irish Government’s Strategy for Science, Technology and Innovation is to establish a number of pharmaceutical and biopharmaceutical-related research centres and clusters in Ireland, alongside the Programme for Research in Third Level (PRITL) and the various programmes of Science Foundation Ireland (SFI). Industry is forming alliances with these research centres to share costs and avail of the unique skills available in Irish research institutions.

● MSD Brinny and the National institute for Bioprocessing Research and Training (NIBRT)

In 2011 NIBRT formed a partnership with IT Sligo to provide an educational training programme for the workforce at MSD Brinny. The Continuing Education Programme at Brinny is part of MSD’s commitment to supporting science education and research in Ireland as it takes a central role in the country’s future as a knowledge-based economy. The courses available include a Higher Cert in Science, Bachelor of Science in Pharmaceutical Science, Bachelor of Science in Biopharmaceutical Science and a Masters in Biopharmaceutical Science. MSD was given an outstanding achievement award for this innovative partnership in April 2011.

● GE Healthcare Life Sciences and the National institute for Bioprocessing Research and Training (NIBRT)

The GE Healthcare collaboration with NIBRT combines its leading expertise in glycobiology and novel bio analytical techniques with GE Healthcare’s capabilities in protein-protein interaction analysis, particularly in the company’s Biacore SPR technology. The aim is to drive advances in technologies for the development and functional analysis of therapeutic antibodies, protein-based drugs that are increasingly used to treat diseases such as cancer, rheumatoid arthritis and MS. The aim of the collaboration is to develop new, robust and reproducible biochemical assays for the analysis of the biological activity of therapeutic monoclonal antibodies.
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 pharmaceutics. SSPC has engaged in multiple industry/academia research projects on topics such as:

- Continuous crystallisation – determining the best future practice in this area.
- Particle engineering – addressing throughput issues around isolation and drying of API’s.
- Primary secondary interface – identifying the attributes of the API/exipient that influence the formulation process.
- Access to Third Level Analytical Services (ATTLAS), is a web-based portal that provides information on all of the facilities, equipment and analytical services available to industry across the Irish Higher Education Institutions (HEIs).

Pharmaceutical Manufacturing Technology Centre (PMTC)

Enterprise Ireland and IDA has provided €5m funding for the establishment of a Pharmaceutical Manufacturing Technology Centre. It is an Industry led, industry driven research programme, which will be led by a project leader and governed by an industry-led board. The research themes chosen by the PMTC include:

- Advanced rapid micro-biological techniques
- Enabling and control of continuous processing
- Soft sensor modelling
- API real time release PAT
- Pharmaceutical packaging technologies

The vision of the centre is to support and develop the Irish pharmaceutical industry by improving manufacturing competitiveness and enhancing the research and development mandate and activity of Irish pharmaceutical manufacturing sites and companies. The centre will work closely with other Irish research centres and academic institutions to source additional funding for Pharmaceutical Manufacturing related research through company specific projects, IDA research funding and EU framework programmes. It will be a one stop shop to showcase advanced pharmaceutical manufacturing expertise and support academic-industry collaboration in relation to advanced pharmaceutical manufacturing technologies and know-how for manufacturing industry and related service providers.

Academic Partners
University of Limerick
University College Dublin
Trinity College Dublin
NUI Galway
University College Cork

Industrial Partners
Clarochem
Roche
Pfizer
Hovione
Eli Lilly
MSD
BMS
GSK
Janssen

The Solid State Pharmaceutical Cluster (SSPC) has engaged in multiple industry/academia research projects.
IRELAND

Strategy in Action

RECOMMENDATIONS

More than ever, it is vital that Ireland continues to take advantage of its excellent record of cooperation between industry, the Government and the research community to further establish the sector within the overall economy. All parties need to keep collaborating to ensure that the following recommendations are acted upon in a timely and on-going manner.

1. The Irish tax regime must remain attractive for future investment. This includes maintaining the 12.5% rate of corporation tax and ensuring that competitive incentives exist to encourage and support investment in R&D and Intellectual Property.

2. The State needs to invest continuously in the education system and the industry needs to invest in training programmes to ensure that its workforce is equipped with the most up-to-date skills as the industry develops, eg, in the area of QbD, PAT, QRM, lean manufacturing and six sigma.

3. Maintaining competitiveness is essential to the continued success of the pharmachem sector in Ireland. Energy and waste are two critical costs. The State needs to continue to invest in the development of a world class energy and waste infrastructure.

4. The sector is, by necessity, highly regulated, and prides itself on its ability to comply with, and in many cases exceed, current regulatory requirements. Nevertheless, it is important that the regulatory burden is balanced and sustainable, and does not place the sector at a relative competitive disadvantage.

5. It is important that the industry increases collaboration with the healthcare system to ensure the development and related manufacture of innovative healthcare products and services, including clinical trials and co-diagnostics.

6. Industry links and networks with academia should continue to be developed and enhanced. The indigenous sector’s development can be enhanced through links with the multinational sector by way of supply and collaboration.

7. It is important that the excellent levels of support for industrial development provided by Government Agencies - IDA Ireland and Enterprise Ireland – are sustained and nurtured.
Since the launch of Phase 1 of the strategy document, Innovation and Excellence, there has been much development within the sector. The preceding case studies clearly show how companies have developed since establishing within the country. Many sites have evolved from pure manufacturing through to fully-integrated operations with considerable investment in process and product-related expertise.

The co-location of development with manufacture ideally places many of these sites for the introduction of new products. Such activity has also generated opportunity for the development of a strong indigenous base.

Undoubtedly, new challenges are very close as the world struggles to provide new products that are sustainable and affordable. This constitutes an enormous opportunity for the Irish pharmaceutical, chemical and biopharmaceutical sectors to collaborate internally and externally to produce solutions to these challenges.

PharmaChemical Ireland’s industry strategy provides a roadmap and in our view, the industry is well on its way but has some distance yet to travel. We remain confident that we will stay firmly on track to making Ireland a world-class centre for the supply of these types of products.
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 providing an environment that is conducive to the continued success of the Irish pharmaceutical and chemical sectors. 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), the Irish Medicines Board (IMB), Science Foundation Ireland (SFI), and Enterprise Ireland (EI). We also represent industry to the European institutions through our affiliation to the Irish Business Bureau and the European Chemical Industry Council (CEFIC).
Confederation House
84-86 Lower Baggot Street
Dublin 2.
Tel: 01 6051584
Fax: 01 6381584
www.pharmaceuticalIreland.ie