ICSTI
IRELAND

Irish Council for Science,
Technology and Innovation

ICSTI Statement

Embedding the PharmaChem Industry in Ireland

February 2003

Forfás

Established by the Government and Forfás to advise on Science, Technology and Innovation

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- To advise on science and technology policy-related issues in response to specific requests from the Government (through the Minister responsible for Science and Technology) or from the Board of Forfás.

- To advise the Minister responsible for Science and Technology, the Office of Science and Technology and the Board of Forfás, on the Council's own initiative, on policy for science and technology and related matters.

- To advise the Minister on the strategy for the preparation and implementation of national programmes in science and technology.

- To advise the Minister on the strategic direction for State investment in science, technology and innovation.

- To undertake from time to time such other functions as the Minister may decide. In this case the information sought is to be submitted to the Minister.

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Executive Summary

The pharmaceutical and chemical (PharmaChem) sector is the largest contributor of corporation tax to the Exchequer in Ireland (€700 million in 2001). It has been a mainstay of the Irish economy for over 30 years, characterised by ongoing expansion, investment and job creation. It encompasses companies of all sizes, both indigenous and multinational. The industry here in Ireland is mainly manufacturing based, dominated by the high technology end of the industry and strictly regulated. Most company research and development takes place outside of Ireland, although later stage development, closer to the market place, is undertaken by a few companies here. The industry employs over 20,000 people in more than 80 facilities and is responsible for significant indirect employment.

The pharmaceutical and chemical industry in Ireland must adapt to the new global environment if it is to continue to be a significant employer and taxpayer here. The Government has shown its ability to be very forward thinking in creating a tax regime to attract manufacturing industry and to stimulate industrial development. The enterprise environment has changed and a coherent package of measures needs to be put in place now to embed the pharmaceutical and chemical industry in Ireland into the future.

The global PharmaChem industry is undergoing significant change. Many major drugs, which have generated a strong revenue stream, are coming to the end of their patent protection and new and modified drugs are being sought, through research and development (R&D), to replace the revenue stream which will be lost. However, the high costs of development and manufacture are driving the trend to reduce the time to market through innovations in product and process development. Consolidation of company activities by locating process development R&D close to manufacturing helps companies to scale up processes quickly and efficiently, to troubleshoot and to optimise production.

Global competition for the location of new manufacturing and R&D facilities is fierce. The risk for the Irish economy lies in the high potential for new products to be manufactured in competitor countries, even in foreign sister plants of facilities located here. Without significant action, it is recognised by the industry here that this will lead to the gradual downsizing and potential demise of the industry, resulting in falling national employment and reduced tax revenues as new capital projects are located elsewhere, rather than in Ireland.

The advent of biotechnology is creating a separate sector within the pharmaceutical industry. Ireland is investing significant public funds in biotechnology research and development which can help to generate and support small indigenous companies in the biotech and the biopharmaceutical areas of the PharmaChem sector. The interests and needs of such companies must also be considered.

The Council, informed by its discussions with industry and other key stakeholders, has determined that a major opportunity for Ireland to strengthen its position in the global market lies in increasing its involvement in drug development through process development and optimisation by locating such operations close to the already significant cluster of manufacturing in Ireland. Process optimisation encompasses the applied research phase between drug discovery and production and has different stages which mirror the clinical studies. Process development is relatively low risk, compared with drug discovery, when it relates either to a tested drug close to the market or to a set of drug candidates, at least one of which has a high probability of being a market success.

In order to increase the amount of process development activity, it is essential that a package of complementary actions is implemented as a matter of urgency by Government and other stakeholders. In the past, taxation and skills have been the key magnets for manufacturing industry to locate in Ireland. These

remain key and, together with the necessary infrastructure (e.g. waste disposal, electricity) and regulation, can continue to sustain the industry here for the long term. Complementary actions, if successful, should also provide an environment conducive to the development of other higher added value functions (e.g. financial and other shared services).

In this Statement, the Council makes recommendations to embed the PharmaChem industry through initiatives both targeted at the sector as a whole and specific to process development.

Recommendation 1

The Government, its agencies and State institutions should create the fiscal, business and research conditions to support process development.

Actions proposed to achieve this include:

- Research and development, including process development, should be made attractive for all Irish based companies through a range of effective tax credits *and* internationally competitive grants. In conjunction with these, the long term commitment to a low corporate tax rate must be reinforced.
- Successful process development and R&D projects in the PharmaChem sector and advantages of the industrial and business environment in Ireland should be highlighted to technical executives and senior industry management through briefing documents produced and disseminated to industry by IDA[1] Ireland.

1 *Industrial Development Agency*

- Targeted initiatives at graduate and post-graduate levels in areas of research which underpin process development must be funded adequately through IRCSET[2], PRTLI[3] and SFI[4] .
- Actions by industry and the third level sector to improve the industry - third level interface in areas including industry related aspects of the third level curriculum, industry placements for students, industry internships and scholarships for postgraduates, an industry-third level process development centre and the provision of information accessed by industry on expertise, research and courses at third level.

Recommendation 2

The Government, with its Departments and agencies, should optimise the operating environment for the PharmaChem industry.

Actions proposed to achieve this include:

- Immediate implementation by Government of an effective national waste disposal strategy.
- Timely action by Government to address the issues raised through the EU[5] White Paper on the Chemicals Policy. The Council endorses the views presented by the IBEC[6] in its position paper.
- Continued adequate resourcing of the Irish Medicines Board to enable it to work efficiently and to maintain its high reputation as a regulatory body, both internationally and in the EU. It should continue to develop and maintain good relationships and international co-operation, particularly with the Food and Drug Administration (US).

2 *Irish Research Council for Science, Engineering and Technology*
3 *Programme for Research in Third Level Institutions*
4 *Science Foundation Ireland*
5 *European Union*
6 *Irish Business and Employers' Confederation*

- Immediate implementation by Government of the recommendations outlined in the report of the Task Force on the Physical Sciences, in order to foster a continuous supply of skilful scientists.

1. PharmaChem in Ireland – the Current Position

The pharmaceutical and chemical (PharmaChem) industry has been a stable and successful sector of the Irish economy for over 30 years, characterised by ongoing expansion, investment and job creation. The sector is the largest contributor of corporation tax to the Exchequer in Ireland (€700 million in 2001). Exports for the sector in 2002 totalled €39 billion (up from €2 billion in 1990) i.e. 37% of all exports from Ireland.

9 of the top 10 pharmaceutical companies in the world are located in Ireland. The pharmaceutical industry is mainly manufacturing based, high technology and strictly regulated. Most company research and development (R&D) work takes place outside of Ireland, usually at parent sites abroad, although later stage development work, closer to the market place, is undertaken at many manufacturing plants here. The sector can be divided into two main areas - manufacturing of active pharmaceutical ingredients (APIs) and drug product manufacturing. Within this group, approximately 40% of companies in Ireland are API manufacturers with about 60% engaged in finished product manufacture (a small proportion of these undertaking formulation development work). There is also a relatively small indigenous industry providing human and veterinary pharmaceutical products and specialist services.

The industry has benefited from low corporate tax rates in Ireland and from the availability of an educated workforce. In return, it has provided significant employment. The PharmaChem industry employs over 20,000 people in more than 80 facilities located across the country. It is also responsible for significant indirect employment e.g. in a range of ongoing support functions and in the construction industry during the current expansion phase. Direct employees comprise approximately 50% graduates, many with higher degrees: the percentage may be significantly higher in some companies. The pharmaceutical industry has shown significant employment growth while the non-pharmaceutical chemical sector has remained static.

Proximity to European markets and membership of the European Union are key attractions of Ireland as a location, particularly for US companies. There is no language barrier for the US and the US/Ireland time zone difference is small, allowing for direct interaction during the normal working day.

The global PharmaChem industry is undergoing change to which the industry in Ireland is seeking to respond. The high costs of development and manufacture, particularly for pharmaceutical products, are driving the trend to reduce the time to market through innovations in product and process development. It typically takes at least 8-10 years to complete the development, clinical trial and regulatory approval phases to bring a drug to the consumer. There are concerns that the already rigorous regulatory environment for drug and chemical production will be tightened excessively under European laws and agreements.

Many blockbuster drugs, which generated a high revenue stream and supported investments in Ireland to date, are coming to the end of their patent protection and new and modified drugs are being sought to replace the revenue which will be lost. Irish subsidiaries of the relevant multinational companies are working hard to compete with sister plants abroad (e.g. in Singapore or Puerto Rico) for the responsibility of supplying the new drugs and formulations.

The advent of biotechnology is creating a separate industry within the pharmaceutical sector, one able to generate a new range of therapeutic products. The work on the human genome is helping researchers to understand genetically based diseases and to develop treatments for previously untreatable conditions. The strong R&D investment in biotechnology, such as that made through Science Foundation Ireland and BioResearch Ireland[7], is

7 *BioResearch Ireland is funded through Enterprise Ireland.*

positive in this context. Indeed, small indigenous biotechnology firms are expected to emerge in this environment. This must be facilitated and encouraged.

Global competition for the location of new manufacturing and R&D facilities is fierce. Countries such as Singapore and Puerto Rico (see Appendix 1) are providing effective corporate tax rates of 0% in conjunction with R&D funding and facilities and training grants. Several countries use tax credits for R&D to enable companies to offset costs against their tax bill.

The industry in Ireland must adapt to the new global environment if it is to continue to be the significant employer and contributor to the Exchequer that has made it a mainstay of the economy for so long. The importance of the industry to Ireland had already led ICSTI to examine its needs as part of the Technology Foresight exercise in 1999. The recommendations in the ICSTI report[8] led to the establishment of Science Foundation Ireland which is providing significantly increased support for basic scientific and technological research. R&D has been further strengthened by increased funding for the Research, Technological Development and Innovation programme (RTDI) and the Programme for Research in Third Level Institutions (PRTLI)[9].

More can be done. There are opportunities for the development of the sector which, if they are acted upon now, can help to secure continued stability and growth in the industry. In this Statement, the Council identifies a major opportunity for the industry and makes recommendations for a suite of actions to support the further embedding of the PharmaChem industry in Ireland.

8 *Technology Foresight Ireland – ICSTI Overview, 1999*

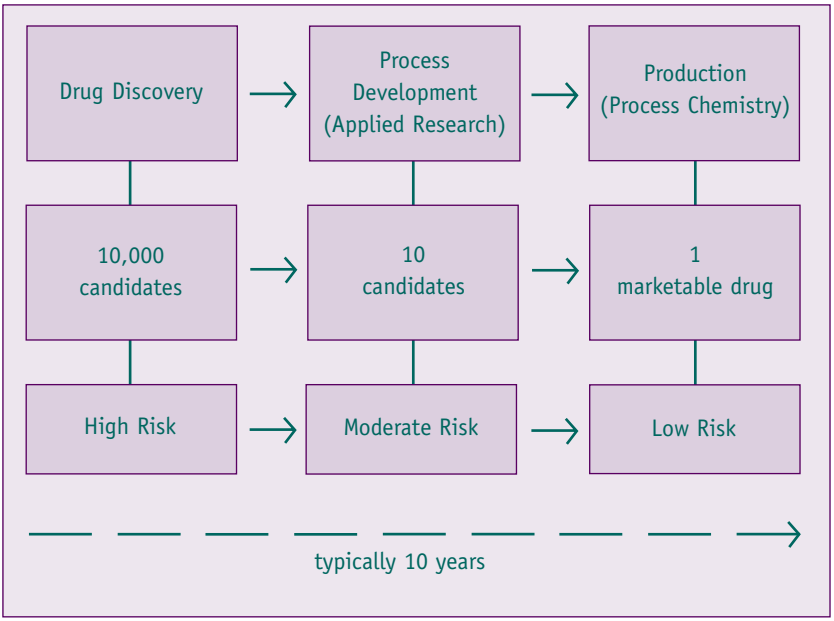
9 *While the PRTLI has in 2003 experienced a pause in provision of funding for the capital elements of new programmes, recurrent funding for new and ongoing projects is still being provided and the total budget for the duration of the National Development Plan is over €600 million.*

2. PharmaChem in Ireland – the Opportunity

The Council, informed by its discussions with industry, has determined that a major opportunity for Ireland to strengthen its position in the global market lies in increasing its involvement in drug development through process development and optimisation.

Diagram One is a schematic of the life cycle of a drug from discovery to production. Process optimisation encompasses the applied research phase between the basic research phase (drug discovery) and the process chemistry phase (production). Drug discovery is high risk with few potential products being identified out of many thousands of candidates. Production is very low risk as the drug has already been approved for the market at this stage.

Diagram One: The Life Cycle of a Drug



Process development[10] is relatively low risk where it relates either to a tested drug close to the market (commercial process development) or to a set of drug candidates, at least one of which has a high probability of being a market success (early stage process development). In addition to process development in relation to API or bulk drug manufacture, commercial process development also takes place in total drug product manufacturing and can involve, for example, drug delivery mechanisms and the development of dosage forms.

There are two distinct, but complementary, process development activities in the active pharmaceutical ingredient (API) sector - the development of efficient synthetic routes for new entities and the development of new routes for existing APIs. The latter has the advantage of being much lower risk as the product is already approved for the market[11]. Furthermore, involvement of Irish plants in the latter activity can be a stepping stone to becoming involved subsequently in the former, more speculative, process development. Most of the existing API facilities already undertake some process development within regulatory filing. Such an activity is clearly easier for a facility to undertake where additional regulatory approval is not required i.e. where the modification is relatively minor.

Drug discovery is generally undertaken by the parent company and is a centralised activity. It is labour intensive, involving highly skilled people, and requires significant infrastructure. The Council believes that Ireland will not secure the location of significant industrial drug discovery facilities (i.e. early stage research and development) within the multinational sector in the foreseeable future and should not base its future security on seeking to do so. There is scope for early stage R&D in clinical trial work and in small research companies, including biotechnology companies. The opportunity for indigenous start-ups to develop on the basis of

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10 See Appendix 2 for an explanation of the term process development and other terms used in this Statement.

11 Some may require additional regulatory approval (see Appendix 2).

existing pharmaceutical companies may also depend on the scale of research undertaken by such companies: the more research, the greater the probability of start-ups. Such start-up companies can be facilitated through appropriate financing and venture capital, access to market networks overseas and support facilities such as incubators.

The focus in Ireland is currently on manufacturing which, for most multinational PharmaChem companies, is not a centralised activity undertaken in the country where the headquarters is located, unlike R&D and marketing[12]. Manufacturing is global while R&D is not. Companies can relocate manufacturing plants and site new plants in countries where they do not already have a facility with relative ease compared with R&D. The task for industry here is to engage, alongside production facilities, in higher added value activities which are less mobile than pure manufacturing.

Locating process development R&D close to manufacturing helps companies to scale up processes quickly and efficiently and can reduce the time to market. Furthermore, process development batches produced at the manufacturing site can ultimately become part of the product inventory and do not have to be discarded which is important for high value drugs. Combining R&D with manufacturing can benefit companies in Ireland by reducing their royalty payments for using corporate intellectual property and by facilitating companies in developing intellectual property here, thereby producing a valuable revenue stream. Proximity of R&D and manufacturing also allows companies to offset some costs of R&D against manufacturing profits, although this is more beneficial in countries with a higher corporate tax rate.

The Council, through its discussions with industry, believes that backward integration through the maximisation of process development opportunities is the next stage in the evolution of the

12 *Biopharmaceutical manufacture is more often located close to R&D than PharmaChem manufacture. This reflects the different nature of the development and manufacturing processes in biopharma and PharmaChem.*

pharmaceutical industry in Ireland for its future stability and growth in the long term. This evolution will require a significant change in the culture of some companies but many are already moving in the direction of process development and engage in R&D as a supplementary activity. Such work takes place outside of the recognised and corporate approved manufacturing activities but produces welcome results in terms of cost reductions. Despite the lack of recognition, the number of process development R&D people has increased in the last 5 years from an estimated 200 to 400 people.

In order to increase the amount of process development activity, it is essential that a package of complimentary tax, skills and infrastructure actions is implemented as a matter of urgency by Government and other stakeholders.

3. PharmaChem in Ireland – Strengths of our Environment

The environment for the PharmaChem industry in Ireland has strengths in areas including taxation and patents, regulation and skills.

3.1 Taxation and Patents

The competitive tax regime which has been in place in Ireland for many years has been an important factor in the growth of the PharmaChem industry here. Ireland now has strong competition from countries including Singapore and Puerto Rico (see Appendix 1), but firm statements about continuing the 10% manufacturing tax rate until 2010 and thereafter introducing a rate of 12.5% have reinforced its position as a European base for many established multinational companies.

Companies are choosing to take advantage of attractive aspects of the tax regime in different ways depending on their corporate priorities. Some multinational companies hold intellectual property at headquarters and receive royalty income from their sites abroad as a means of repatriating earnings. Others are eager to use the protected profit stream here for reinvestment, which can be of direct advantage in Ireland.

Patent royalty income from intellectual property created and exploited here has tax free status, a positive feature of the system which it is essential to retain. The 12.5% trading income tax rate applies to know-how licensed out for use abroad in the context of an active business. Using modern communications technologies, there are enhanced opportunities to position development teams here, to work as part of an international group.

Patenting intellectual property in Ireland and in Europe is a cost effective process. Short term patents, which are available through the Irish Patent Office, facilitate speedy access to royalties. This can represent an opportunity for rapid returns on certain types of innovation.

R&D cost sharing agreements within corporate structures can minimise the tax payable in the parent country (where there is usually a higher tax rate) since imputed royalty payments are reduced on passing the benefit of intellectual property to an Irish entity. The more an Irish subsidiary can contribute to the knowledge base, the less the cost of royalties.

3.2 Regulation

The PharmaChem sector operates according to a broad range of standards and regulations. These range from environmental protection and health and safety, which apply to the entire PharmaChem sector, through to pharmaceutical regulations and good manufacturing practice (GMP) which apply only to the pharmaceutical part of the sector. Agencies (such as the Environmental Protection Agency (EPA), Health and Safety Authority (HSA) and the Irish Medicines Board (IMB) in Ireland, the European Medicines Evaluation Agency (EMEA) and the US Food and Drug Administration (FDA) abroad) are responsible for the implementation and enforcement of these regulations.

Regulatory approval is required by companies for drug products and for active pharmaceutical ingredients (APIs), i.e. the active compound used in the manufacture of drugs. For companies located in Ireland, regulatory approval for *new* pharmaceutical products is routinely dealt with by the parent company of the multinational. Even new products developed in Ireland are approved through the main regulatory office, which for many companies is in the USA.

It is internationally acknowledged that PharmaChem companies in Ireland operate to high regulatory standards. There is a strong regulatory ethos in the work force, which contributes to the attraction of inward investment from companies (PharmaChem and biopharma) considering locating in Ireland.

3.3 Skills

The availability of an educated workforce has been a key factor in attracting the overseas PharmaChem industry to Ireland. The growth of the industry has led to increased demand for skilled people over recent years, a welcome trend. The PharmaChem industry can sustain high levels of employment and growth in jobs in the future if action is taken now to embed it more fully in Ireland. To achieve this, the industry needs more people to become trained in the sciences, specifically as organic chemists, analytical chemists and chemical engineers.

PharmaChem production is highly technical in nature. In many companies, strong problem solving groups have been formed to support manufacturing. Such groups co-operate closely with the production and quality assurance teams in many successful multinational companies manufacturing in Ireland. Their core competences are in the areas of process optimisation and development. These support groups are a resource which can form the skills base for formal process development.

Recent government initiatives to improve the science and technology (S&T) infrastructure in Ireland (e.g. SFI, Enterprise Ireland programmes, IRCSET and PRTLI) aim to strengthen the science base[13]. They also have the potential to increase the quantity and quality of third level research collaborations with the PharmaChem industry. Investment in biotechnology research will be particularly important in the development of the biopharmaceutical sector, including the creation of new companies and ventures.

The Irish education system for science and engineering is of high calibre, albeit with the same concerns as are found internationally in terms of the difficulties of attracting students to S&T areas.

13 *It is noteworthy that in the first year of operation, IRCSET scholarships were very heavily over-subscribed and more places were taken by applicants from Engineering and Information Technology than for Chemistry. It is of concern to the Council that these well funded studentships, which replaced the Enterprise Ireland scholarship programme (which provided students with £2,000 per annum), have resulted in fewer PhD studentships for chemistry than was previously the case.*

These are being addressed through a variety of skills and awareness initiatives including the Expert Group on Future Skills Needs, the Science, Technology and Innovation Awareness Programme and the Skills Awareness Programme[14]. The industry is also taking action: the IPCMF[15] has a current skills initiative, including the appointment of an education officer, which is focused on attracting students into sciences relevant to the sector.

Despite the positive aspects of the environment in Ireland, there are many issues to be addressed if the PharmaChem industry is to embed itself here in the long-term. The next section highlights the key areas in which action needs to be taken and makes recommendations to Government and other stakeholders.

14 See www.forfas.ie for more information.

15 Irish Pharmaceutical and Chemical Manufacturers' Federation

4. PharmaChem in Ireland – Recommendations

The Council has 2 recommendations which can, through associated actions, help to embed the PharmaChem industry in Ireland:

1. **The Government, its agencies and State institutions should create the fiscal, business and research conditions to support process development and**

2. **The Government, with its Departments and agencies, should optimise the operating environment for the PharmaChem industry.**

4.1 Recommendation 1 – Supporting Process Development

The Government, its agencies and State institutions should create the fiscal, business and research conditions to support process development.

In order to achieve this, several actions need to be taken:

Action 1: Fiscal

Effective tax credits for R&D should be introduced immediately to encourage companies to engage more in these activities.

Process development and other forms of R&D should be made attractive for all Irish based companies through a range of internationally competitive grants.

Long term commitment to a low business tax rate should be reinforced.

Companies moving up the value chain by increasing their process development activity will have increased R&D related costs. These can be partially written off against profits, thereby reducing the amount of corporate tax paid to the Exchequer. In general, industry prefers to undertake R&D in high tax regimes (e.g. US, UK) as the reduction in tax paid is greater than in low tax countries (e.g. Ireland, Singapore). Some countries (e.g. the UK) are made more attractive as R&D locations for industry through R&D tax credits. Tax credits allow companies to increase the proportion of R&D expenditure which they can write off against corporate tax (or in some countries against payroll tax) and have been proposed for Ireland. It has also been proposed that tax credits could be set against PRSI[16] or PAYE[17] to give the greatest immediate cash flow benefit to those who undertake R&D.

IBEC has long been advocating the introduction of R&D tax credits, favouring volume based tax credits i.e. based on total annual R&D spend, regardless of whether or not the level of R&D spend is increasing. A joint agency[18] submission prior to the Budget 2003 recommended that a tax credit, at a rate of 20% of qualifying expenditure[19], should be introduced in 2003 for incremental R&D above a baseline of €50,000. ICTU[20] has expressed the view that the corporate tax rate should be set at 16% but that R&D tax credits should serve to reduce the tax burden to an effective level of 12.5% for some companies. The aim of the ICTU proposal is to encourage companies to embed themselves in Ireland through R&D, while excluding the non-trading sectors (e.g. banks, restaurants, hotels) from the lower tax regime. The ICTU proposal is not supported by industry[21] as it could severely impact on companies and reduce the attractiveness of Ireland as a location for foreign direct investment.

16 *Pay Related Social Insurance*

17 *Pay As You Earn taxation*

18 *Enterprise Ireland, Forfás and IDA Ireland*

19 *For example, with a tax rate of 10% and a rate of qualifying expenditure of 20%, this would result in a tax credit of 200% of qualifying expenditure.*

20 *Irish Congress of Trade Unions*

21 *IBEC and IPCMF have strongly expressed their opposition to the ICTU proposal.*

The priority for any R&D tax credit is that it should not be a token action but should bring significant savings to industry undertaking R&D, thereby making Ireland a more attractive R&D and process development base for companies, PharmaChem and otherwise. Details of the implementation of such a system should be examined by Government without delay.

The existing IDA Ireland and Enterprise Ireland R&D Capability Grants Scheme and Enterprise Ireland RTI[22] grants can assist companies to expand into process development. R&D project grants help to create the environment for the generation of intellectual property. Companies establishing process development groups in Ireland should be encouraged to do so through these grants. Efforts should be made to increase the accessibility of grants to industry, to optimise their administration and to highlight their availability more widely.

While the tax levels in Ireland are attractive to manufacturing industry, there is uncertainty about their duration. Long term commitment to a low business tax rate should be reinforced.

The Council previously made recommendations[23] to Government and other stakeholders to enhance the commercialisation of publicly funded research in Ireland in a Statement in February 2001. Specific recommendations were made on increasing resources for industrial liaison, encouraging commercialisation as one mission of the research sector and increasing early stage funding for research with commercial potential.

There has been significant progress in some areas since the publication of the ICSTI Statement. Funding for commercialisation is more commonly available within publicly funded research programmes and support for the early stages of development of

22 *Research, Technology & Innovation (RTI) Competitive Grants Scheme administered by Enterprise Ireland. The Scheme covers high quality, risk intensive R&D projects, which are essential for companies to establish or to maintain their overall competitiveness. Projects can relate to either product or process development.*

23 *ICSTI Statement "Commercialisation of Publicly Funded Research" (February 2001) (see appendix 3) and ICSTI Statement "Utilising Intellectual Property for Competitive Advantage" (in press).*

research with commercial potential has increased. Campus companies are being supported through a suite of positive measures. While some progress is being made, further actions must be taken to facilitate the professional management of intellectual property and to enhance technology transfer into industry of the outputs of publicly funded research. The recommendations on "Commercialisation of Publicly Funded Research" and those soon to be published in the ICSTI Statement "Utilising Intellectual Property for Competitive Advantage" should be fully implemented.

A package of complementary actions is needed to help to increase the amount of process development being undertaken by industry here. To date, taxation and skills have been the key magnets for manufacturing industry to locate in Ireland. These, together with the necessary infrastructure (e.g. waste disposal, electricity) and regulation, can continue to sustain the industry here for the long term. Complementary actions, if successful, should also provide an environment conducive to the development of other higher added value functions (e.g. financial and other shared services) and one which is supportive to indigenous and start-up companies (e.g. through finance, venture capital, supportive expertise and research incubators). As multinational companies become more involved in R&D, relevant opportunities will be opened up for the indigenous sector.

Action 2: Business

IDA Ireland should commission and disseminate concise and focused briefing documents explaining, in clear language, the process development and R&D opportunities in Ireland, highlighting the positive aspects of the skills, taxation, patenting and regulatory systems.

The arguments in favour of increased process development at the Irish subsidiaries of multinational companies need to be in the hands of Irish executives presenting the case for development in

Ireland to their multinational headquarters. IDA Ireland can further assist this by commissioning and disseminating targeted briefing documents highlighting, with industry examples, the following positive aspects of the Irish system:

Locating R&D close to manufacturing can reduce costs, increase efficiency and reduce time to market as R&D acts as a support for production. This has been successfully demonstrated by companies here which have gone on to further expand their R&D activity as a result. A first key step in creating this model is convincing the parent R&D establishment of the R&D capability of the Irish site. The more this model is shown to work well and the case made to support it at corporate level, the more widely accepted it will become. Some proven R&D successes, such as those of Schering-Plough and Bristol-Myers-Squibb, should be and are being highlighted by IDA Ireland. These have flourished despite the fact that the low corporate tax rate that makes manufacturing in Ireland attractive is a relative disincentive to locating expensive functions such as R&D here[24].

Some Irish subsidiaries of multinationals have demonstrated the regulatory advantages of performing Phase II and Phase III clinical trial material development in Ireland. These include the acquisition of on-site development expertise, the facilitation of scale up and validation on site and the reduced inventory volume maintained during regulatory filing period (e.g. 10% of the anticipated commercial scale) which can all lead to shorter times to market and associated cost savings. These successful projects can be models for other multinational companies in Ireland to develop the skills and infrastructure needed to support early development work and the production of Phase II and Phase III clinical quantities.

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24 Tax relief for R&D expenses is only offset against 10% or 12.5% tax in Ireland and against much higher tax rates in some other countries (e.g. UK, Germany).

Action 3: Research / skills

Targeted initiatives at graduate and post-graduate levels in areas of research which underpin process development must be adequately funded. Responsibility for this lies with existing structures such as IRCSET[25], PRTLI[26] and SFI[27].

Action 4: Research / skills

Postgraduate top up courses should be made available by the third level institutions in key areas of relevance to industry e.g. validation, bio-processing. Thus graduates will have a solid science base and retain the flexibility to modify and enhance their skills over time.

The Council acknowledges the recent increases in public funding for research. It believes that further action in this area is essential in order to support the industry and to secure long-term employment prospects for a large number of citizens.

The sector requires highly motivated Ph.D. graduates with specialised skills e.g. in synthetic organic chemistry, scale-up expertise and development of analytical methods. While recent initiatives have improved opportunities for the support of postgraduate students and for research projects in Irish third level institutions, much of the funding is identified with biotechnology rather than chemistry. The establishment of process development groups requires a supply of highly trained chemists (especially organic, analytical and pharmaceutical chemists, mainly at PhD level) and chemical engineers, usually at graduate level. Initiatives under SFI, IRCSET and PRTLI focused on postgraduates in these key areas of chemistry can help to ensure the necessary supply of skilled personnel. Such initiatives should be targeted at fundamental research, not process development, in these areas. Undertaking fundamental research in chemistry develops the skills necessary to carry out advanced process development work in

25 *Irish Research Council for Science, Engineering and Technology*
26 *Programme for Research in Third Level Institutions*
27 *Science Foundation Ireland*

companies upon graduation. Currently many postgraduates in chemistry receive relatively low levels of support (€6,000 per annum) as they are unable to access targeted funding such as that provided for biotechnology and information and communication technologies by SFI.

Development of research expertise in areas of strategic importance to the sector in third level institutions is needed. Key research areas[28], identified through discussions between industry, funders and the research community, could be supported through existing mechanisms, e.g. Science Foundation Ireland.

Process development activities require highly developed skills in synthetic organic chemistry different from those required to work in a production environment. Ph.D. programmes do not currently include structured elements to develop the necessary scientific skills of graduates. Validation is one area of critical importance to the sector but there are no educational opportunities through the third level system. Graduates and postgraduates usually require training on state-of-the-art equipment when they take up employment in industry as the equipment pool in the third level sector is dated. PRTLI initiatives focused on improving the research infrastructure in the relevant disciplines are essential in addressing this.

Action 5: Research / skills

Actions must be taken by industry and the third level sector to improve the industry - third level interface.

With the proposed growth in process development activity, there will be more attractive career opportunities for graduates who wish to stay as scientists and those seeking to return to Ireland from overseas. Salaries in Ireland are lower that in the US, making it attractive for companies to locate process development groups

28 Suggested areas include biocatalysis, polymorphism and physical properties of materials.

here. In the majority of cases, advancement within the production sector entails promotion out of the scientific and technical area into management. There is no acknowledged and rewarded technical career path to senior levels in most companies. Scientists who wish to progress their careers in industry often find themselves on the management track. In an environment in which significant, high level R&D skills are necessary for the success of process development, this pattern of scientists migrating to management will be effectively addressed.

Graduates frequently accept offers to undertake PhDs overseas (especially in the U.K.) well before they graduate from Irish universities and well before the outcomes of Irish research grant applications are known. These graduates, many in the area of chemistry, rarely return home or take up careers in the Irish PharmaChem sector. Also, a significant proportion of postgraduate research positions in Irish universities are taken by overseas students; these students tend not to remain in the country for any extended period afterwards. The welcome development of the third level research base is expected to increase the number of people taking up post-doctoral posts in colleges, further reducing the number of graduates potentially available to industry.

The challenge is to attract and retain a continued supply of highly talented and trained graduates in the key areas of chemistry. The emphasis should be on analytical and organic chemistry, and chemical engineering. The expansion in the area of biopharmaceuticals also requires graduates and postgraduates with skills in bio-processing. Due to the nature of biopharmaceutical manufacturing, involvement of a development group to support manufacturing is necessary. Industry is particularly supportive of the concepts of cross-functional education, interaction between scientists and engineers from different disciplines, diverse teams and industry placements for researchers as providing high quality process development personnel.

Competitor countries are taking action to address skills issues. In Singapore, the equivalent body to IDA Ireland (EDB) offers grants to support the training of people for industry e.g. they take final year students and fund their training expenses in Singapore and while they gain experience in the industry worldwide. This is just one of many initiatives being taken to support the PharmaChem industry in Singapore including tax exemptions (resulting in a zero tax regime for companies), entrepreneurship and innovation funding programmes and streamlining and minimization of the planning system.

Actions to improve the industry-third level interface would include:

- Establishment of a joint industry-higher education group, convened by CHIU[29] with the co-operation of IPCMF, to optimise industry-related aspects of the curriculum including course content, placements and industry-higher education research collaboration. For example, consideration should be given to the inclusion of biotechnology principles in chemical engineering courses to support the growing activity in biopharmaceuticals, courses in advanced synthesis within PhD programmes in organic chemistry to support process development and general topics of relevance to the industry such as intellectual property, commercialisation and business development. This joint industry-higher education group should also give consideration to the establishment of higher education-industry research centres[30].
- Placements at undergraduate level (minimum 6 months) and postgraduate level (minimum 3 months) should form part of all relevant courses. Placements at post-doctoral level are valuable to industry, as well as to students, e.g. in the early stages of establishing process development activity.

29 *Conference of Heads of Irish Universities*

30 *Concerns have been expressed in particular about the lack of specialised incubation facilities, wet lab space and scale-up facilities.*

- A web-based database should be established to assist companies in accessing information about courses and research areas in the third level institutions. Industry-university interaction tends to be on the basis of personal contacts leading to an *ad hoc* information exchange on courses and research at third level. The database should be a CHIU/IPCMF initiative, with specific, mutually agreed targets for progress, and should link with related work. One initiative in this area, on a North-South basis is the research portal project, ExpertiseIreland.com, led by InterTrade Ireland and involving CHIU and IBEC. This project aims to provide information on third level research and skills in a format useful to industry and is currently in the early stages of implementation. (See Appendix 4 for more information.)
- IPCMF should work with its members to establish industry scholarships and internships for postgraduates to enhance industry-university links and provide a cohort of industry-aware postgraduates. These scholarships should incorporate a work placement in the industry.

Action 6: Research / skills

A process development centre targeted at both the PharmaChem and biopharma sectors would be of benefit in supporting existing companies and in assisting companies at start up in process development.

It has been proposed to Government that a Biopharmaceutical Research Centre would be of benefit in supporting industry through both basic research and applied research of relevance to industry, through industry collaborative projects and in the provision of laboratory space to biopharmaceutical companies. The suggestion is that such a centre could benefit the PharmaChem industry by offering wet-lab and incubator space, particularly to small, indigenous companies. It could also be a source of advice,

expertise and potential employees and act as a shop window to assist in attracting foreign direct investment.

The Council believes that the establishment of a biopharmaceutical process development centre would be more valuable than a Biopharmaceutical Research Centre. A process development centre would offer scale-up facilities for industry, particularly for any indigenous start-up companies which could result from the recent SFI investment in biotechnology. The centre would play a very valuable role in training graduates in the techniques and generic processes (e.g. fermentation, isolation of biopharmaceutical entities) involved in the scale-up of bio-processing. It would also act as a valuable marketing tool in attracting future investment in the biopharmaceutical area.

While the proposed centre would service the needs of the smaller start-up biopharmaceutical companies, the situation for the larger multinational companies in the PharmaChem and biopharmaceutical sectors is quite different. The multinational biopharmaceutical companies are unlikely to contract out key projects (for example leading to clinical trial material) due to regulatory issues which would need to be addressed, when they have the capacity to conduct such work within the company. However, a biopharmaceutical process development centre would be attractive to them as a source of highly trained graduates and as a showcase to their parent companies to highlight the advantages of biopharmaceutical investment in Ireland.

In the case of the multinational PharmaChem sector focused on API production, the proposed biopharmaceutical process development centre would be of relevance in the following ways:

- A number of multinational pharmaceutical companies are currently considering investment in biopharmaceutical facilities. The existence of the biopharmaceutical process development

centre would act as an incentive to locate these large capital investments in Ireland.

- A process development centre should provide an environment in which collaborative projects of relevance to both the biopharma and PharmaChem sectors could be undertaken on generic processes and process technologies which are future priorities within these sectors (e.g. bioprocessing, physical characteristics of pharmaceutical materials, polymorphism, crystallisation and novel synthetic methods). Such a centre would offer an ideal environment for collaborative research between process development groups in industry and researchers in the third level sector, particularly if it were located on, or adjacent to, a third level campus (which should be decided through open competition). Issues of confidentiality and quality assurance would be much more readily addressed through a structure of this nature than in an individual research laboratory in a university.

The key issue is that any such centre should be provided only as part of a package of measures to support the PharmaChem industry, not as an isolated initiative.

4.2 Recommendation 2 – Optimising the Environment

The Government, with its Departments and agencies, should optimise the operating environment for the PharmaChem industry.

In order to achieve this, several actions need to be taken:

Action 7: Waste

The Government should immediately implement an effective national waste disposal strategy.

Waste disposal is a significant concern for companies considering Ireland as a location for inward investment. Hazardous and/or toxic waste generated by the PharmaChem industry in Ireland has to be shipped overseas (usually to the UK or Finland) for incineration. Cross-border shipments of such waste have an associated risk. If they were banned, it would create a severe problem for the industry in Ireland because there is no national or contract facility here for disposal.

Waste disposal constitutes a major strategic risk for companies manufacturing in Ireland. If, for some reason, the route for disposal is closed off, companies would be unable to continue to produce here. The continued absence of a national waste disposal infrastructure could also block future investment in the sector. Proposals have been made for a national strategy to address the issue of waste[31] but essential recommendations for hazardous waste disposal have not yet been acted upon.

Action 8: Regulation

The Council endorses the views presented by IBEC in its position paper on the proposed European Chemicals Policy and urges Government to act in a timely manner to address this issue.

The European Union White Paper (February 2001) on the "Strategy for a future Chemicals Policy"[32] could have serious implications for the regulatory environment of the PharmaChem Industry in Ireland. The main element of the White Paper is the **R**egistration, **E**valuation and **A**uthorisation of **Ch**emicals for new and existing chemical substances marketed in Europe (the REACH system). It is anticipated that the Chemicals Policy, if introduced, will increase the cost of regulation and cause delays in the time to market for chemicals and pharmaceuticals in this sector in the EU without significantly increasing the level or quality of protection for public

31 *Key Waste Management Issues in Ireland, Forfás 2001*

32 *Available at http://europa.eu.int/comm/environment/chemicals/whitepaper.htm.*

health or the environment. This could also have a major impact on the ability of EU countries, and specifically Ireland, to attract new products and plants in the current competitive global environment by putting it at a disadvantage relative to non-EU countries.

IBEC have prepared a report[33] on the potential impact of the White Paper on the European PharmaChem Industry stating that:

> "The proposed legislation, which may be adopted under the REACH programme, will have a severe negative impact on a wide range of Irish Industry, which manufactures imports or uses chemicals. IBEC recognizes the need to define a new chemicals policy concept for the protection of human health and the environment and welcomes the idea of setting this within a framework of sustainable development. However, it is the consensus of all sectors of our membership that the currently proposed REACH system is overly bureaucratic, burdensome and in short unworkable. Not only is it unclear how the new proposal would provide a coherent framework to detect and enhance the safety of man and the environment, many of the key political objectives set out in the white paper .... are inadequately addressed or not at all. .... any new regulations that put European, and especially Irish industry at a competitive disadvantage with respect to other trading zones could have potentially disastrous effects, and these issues must be addressed at the highest level."

While appropriate legislation is essential and welcomed by industry, the strong views voiced by IBEC indicate the level of industry concern that the proposed system is overly bureaucratic and unworkable. For example, the current proposal covers site limited intermediaries i.e. materials which never leave the manufacturing site and never enter the market. Given the already appropriately stringent regulatory environment in place, the need for additional

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33 The executive summary of the IBEC Position Paper on REACH is given in Appendix 5.

regulation of such materials is unclear. Draft legislation is under discussion at European levels. Measures should be taken to ensure that the final legislation is effective, workable and efficient. The Council urges Government to act in a timely manner to address this issue.

Action 9: Regulation

The Irish Medicines Board must continue to be adequately resourced to enable it to work efficiently and to maintain its high status as a regulatory body, both internationally and in the EU. It should continue to develop and maintain good relationships and international co-operation, particularly with the FDA.

The EU/USA Mutual Recognition Agreement (MRA) on Good Manufacturing Practices (GMP) in the Pharmaceutical Industry[34] is unlikely to be implemented in the foreseeable future. Efforts to reach agreement and to progress the introduction of the MRA should continue at Government and regulatory levels. In the meantime, good informal relationships between the Irish Medicines Board (IMB)[35] and Food and Drug Administration of the US (FDA) can help to maintain consistency of regulatory approaches without increasing bureaucracy. Other international co-operation can help to ensure appropriate regulation e.g. the International Conference on Harmonisation (ICH) guide for inspections for active pharmaceutical ingredients (APIs) (i.e. Q7A). Having a strong regulatory agency, such as the IMB, able to provide advice to industry, could assist in attracting inward investment from companies considering locating in Ireland for the first time.

The IMB must work efficiently and maintain its high status as a regulatory body, both internationally and in the EU. It must therefore retain sufficient trained personnel with appropriate

34 *The aim of the Mutual Recognition Agreement (MRA) is to facilitate trade between the signatories (the US and countries of the European Union) by allowing good manufacturing practice (GMP) pharmaceutical inspections conducted by US regulatory authorities (Food and Drug Administration (FDA)) to be recognised in Europe and vice versa. While the MRA has been signed it has not been implemented.*

35 *The IMB is an agency of the Department of Health and Children.*

experience (e.g. in API inspection), who can work with and provide advice to the PharmaChem industry, both individual companies and through industry workshops and discussion fora, while continuing to maintain high regulatory standards. Close interaction between the IMB and companies is an essential part of the good working relationship in Ireland, e.g. through IMB involvement at the earliest possible stages of planning for plant approval.

Action 10: Infrastructure

Infrastructural issues must be dealt with by Government in an efficient and effective manner. These include the provision of appropriate planning approval in a realistic timeframe. Measures are also required to ensure an adequate, competitively-priced electricity supply.

The good time frame for construction and the high engineering standards in Ireland lead to production facilities being completed efficiently and to a high international standard. However, it is generally acknowledged that the planning system for new plants and laboratories is unpredictable, especially when the appeals process, through An Bord Pleannala, is set in motion. In the legislation, the time allocated for completion of the appeals process is 18 weeks[36] but this is often not achieved. Both pharmaceutical and chemical companies have suffered in the past from problems derived from public concerns. Companies have also been adversely affected by a lack of awareness in some local authorities of European legislation[37] which requires that land around PharmaChem plants be appropriately zoned.

While strict regulation with a sound scientific basis is essential, manufacturing has experienced problems based on political rather than scientific decisions. For example, a plant may be approved on scientific grounds as no threat to people or the wider environment but it may be rejected because of local protests. Even when approval may be forthcoming, the delays resulting from the appeals

36 *The Planning and Development Act 2000 states that "It shall be the objective of the Board to ensure that every appeal or referral is determined within (i) a period of 18 weeks beginning on the date of receipt by the Board…".*

37 *EC Directive 96/82/EC (Seveso Directive II) and its implementing legislation.*

process can be excessive and risk industry withdrawal.
The Council acknowledges that the public right to object to planning applications on environmental, health or safety grounds has an important role to play. However, there is a due process for dealing with objections, which should be fully and transparently adhered to by An Bord Pleannala. Planning disputes must be resolved through the appeals process within a realistic timeframe.

The Planning and Development Act 2000 introduced the concept of Strategic Development Zones, to facilitate the accelerated development of large scale industrial facilities that are deemed to be in the national good in both economic and social terms. This essentially involves completing much of the planning and environmental assessment for a designated area, in advance of a specific project being identified. Planning approval can then be granted for the project within two months provided the project complies with the broad scheme for the site, with no right for third party appeal other than by judicial review.

These provisions may prove to be of benefit of the PharmaChem industry by allowing all the necessary planning procedures for the approval of the area to be completed in advance of extensive industry involvement. Thus a zone could be available to industry with prior planning approval. No action has been taken to date to test out the effectiveness of Strategic Development Zones.

Competitor countries are able to offer planning approval on a much shorter time scale than is currently the case in Ireland (e.g. a typical time on continental Europe would be 1 month and in key non-European competitor countries such as Singapore and Puerto Rico times are even shorter). The Department of the Environment and Local Government, in co-operation with the agencies and local authorities, should establish the effectiveness of strategic development zones. If the zones are effective and beneficial, a small number of zones should be designated for use by the PharmaChem industry and the necessary planning authorisation activities should be commenced.

The PharmaChem industry requires a significant and continuous supply of electricity. The Generation Adequacy Report 2003-2009 (ESB National Grid) highlighted the need for new generation capacity in 2005 to avoid electricity shortages, an issue which should be addressed by the Commission for Energy Regulation (CER). Any shortages, or predictions of shortages, are a significant disincentive for multinational companies considering Ireland as a location for inward investment. The situation in Ireland is further complicated by the separation of the generating and distribution companies. Government must take immediate action to ensure a sufficient, continuous and competitively priced supply of electricity to meet the needs of industry and the wider society.

Action 11: Skills

The Council urges Government to embark on the early implementation of the recommendations outlined in the report of the Task Force on the Physical Sciences.

The expansion of PharmaChem manufacturing in recent years has already led to increased demand for chemists and chemical engineers to support production[38]. The establishment of embryonic process development activities in a number of companies has further increased demand, especially for those with doctorates in organic and analytical chemistry. New projects, most notably the current development of large facilities based on biopharmaceutical production, are placing significant demands on the skills pool, and will continue to do so as manufacturing of biopharmaceuticals necessitates support from adjacent development facilities.

The challenge to meet the skills needs is set against a back drop of decreased interest in S&T among the general population of students. Public perception of the industry is a key factor in attracting people to careers in the PharmaChem sector. A number of recent reports have focused on measures to attract more

38 *Many of the employee skills and competencies relevant to the PharmaChem sector are of increasing importance to the medical devices sector and diagnostics companies, areas which are also expanding in Ireland.*

students to the sciences, most recently and comprehensively the report to the Minister for Education and Science by the Task Force on the Physical Sciences (2002). The Council endorses the recommendations of these previous reports as proposing measures to improve the general attractiveness and accessibility of the sciences for students.

Through these recommendations to create the conditions for process development and optimise the environment, the PharmaChem industry can become embedded in Ireland.

Appendix 1

Examples of Industry Support Measures in Singapore and Puerto Rico

Singapore

The effective corporate tax rate for many companies in Singapore is 0%.

The general corporate tax rate in Singapore is 22%. Companies can obtain tax exemptions or reductions under the Economic Expansions Incentives Act. A 90% tax exemption is available for export profits for 5 years.

Current expenditure on R&D is deductible in the year in which it is incurred. Enhanced deductions are available for current expenditure on qualifying R&D (e.g. double deductions for laboratory, testing and medical research services).

Capital allowances are available including accelerated depreciation on R&D, computer and other prescribed equipment (e.g. energy efficient, pollution control, etc.). The Technopreneurship Fund (of over €0.5bn) provides for industry related training and supports for those gaining international experience in key industries.

The Singapore biomedical initiative was launched in 2000 with a €600 million fund for investments in world class biomedical firms undertaking R&D in Singapore, programmes for biomedical sciences education, a genomics programme, a Biomedical Research Council to co-ordinate public sector activities and bio-ethics Advisory Committee to examine legal, ethical and social issues.

Support is being provided for the combined BioMedical Sciences (BMS) cluster of the pharmaceutical, medical technologies, biotechnologies and healthcare services industries which accounted for 5% of manufacturing output (i.e. €3.7bn) in 2001. The cluster employed about 6000 people in 2002. The aim is to increase manufacturing output in the sector to €6.7bn by 2005 through four strategies:

- developing world class capabilities across the value chain (from discovery and development of new drugs to clinical trials management to manufacturing to healthcare delivery);
- increasing the breadth and depth of manufacturing (for the pharmaceutical sector through new activities such as biologics manufacturing and by growing the base of formulation and finishing, pilot scale manufacturing and process R&D);
- expanding and diversifying the base of companies (to include all sizes of company of foreign and local ownership and with strong supporting and service industries); and
- generating, sustaining and attracting world-class talent in all areas including R&D, manufacturing, management, business development and venture capital investment.

Specialist facilities being funded by the Singapore government include the Biopolis science park which provides state of the art laboratory facilities for biomedical sciences companies near to research institutes and universities. These institutes include a bioprocessing technology centre, bioinformatics laboratory and genomics institute.

Measures have also been taken to prevent employees from moving from company to company in search of better pay and conditions.

Puerto Rico

For many companies, the effective corporate tax rate in Puerto Rico is 0%.

The general corporate tax rate is 39% but under the Tax Incentives Act of 1998, eligible companies qualify for tax credits, exemptions and special deductions. Eligible companies, including those in manufacturing and scientific R&D, have a maximum tax rate of 7% and can qualify for a lower rate (0-2%) if they are Core Pioneer Industries (those deemed to have a novel or innovative technology not used in Puerto Rico before January 2000). Also available under the scheme, there are accelerated capital allowances – 100% in the year in which the capital expenditure was incurred – and 90% relief from real property tax and personal property tax. Capital allowances are available on investments in office and factory buildings, manufacturing machinery and equipment.

There is a 200% deduction for R&D expenses and training costs. The term R&D is not well defined and is loosely interpreted.

Appendix 2

Explanation of Selected Terms used in this Statement[39]

Antibody

An infection-fighting protein molecule that tags, neutralises and helps destroy foreign micro-organisms or toxins. Also known as immunoglobins, antibodies are produced by immune system in response to antigens, which are often bacterial or viral particles or components.

Antigen

Any agent, often a large molecule, which stimulates production of an antibody that will react specifically with it.

Biopharmaceutical

A therapeutic product created through the genetic manipulation of living things including (but not limited to) proteins and monoclonal antibodies, peptides and other molecules that are not chemically synthesized along with gene therapies, cell therapies and engineered tissues.

Biotechnology

The use of biological processes for industrial and other purposes especially the genetic manipulation of micro-organisms for the production of hormones, antibiotics, etc.

Drug Delivery

The process by which a formulated drug is administered to the patient. Traditional routes have been orally or by intravenous perfusion. New methods that are being developed are through the skin by application of a transdermal patch or across the nasal membrane by administration of a specially formulated aerosol spray.

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39 Several definitions are taken from Pharmaceutical Engineering, May/June 2002.

Good Manufacturing Practice (GMP)

A part of quality assurance which ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use. GMP is concerned with both production and quality control.

Fermentation

A process of growing micro-organisms for the production of various chemical or pharmaceutical compounds. Microbes are normally incubated under specific conditions in the presence of nutrients in large tanks called fermentors.

Human Clinical Trial

Controlled clinical studies in human volunteers to test the safety and efficacy of pharmaceutical candidates.

Human Genome

The complete set of DNA in each human being. The Human Genome Project is a global, long-term research effort to identify and map the estimated 30,000 genes in human DNA (deoxyribonucleic acid).

Patent

A patent is a legal right granted by the Patent Office for a new and novel invention that has technical applications. It prevents others making or using the invention commercially for a specified period of time.

Peptides

Proteins consisting of fewer than 40 amino acids.

Phase I

A Phase I trial usually focuses on a small number of participants, sometimes healthy volunteers, and is designed primarily to evaluate the safety of an experimental drug treatment, given at a small dose.

Phase II

A Phase II trial tests the safety and therapeutic efficacy of a treatment, and usually involves an increase of the dose. The number of participants also increases and is limited to people who have the disease under study.

Phase III

Phase III trials are large-scale trials designed to establish the final word on therapeutic efficacy. Sometimes, a range of treatment doses is investigated to identify the optimal dosage. If the treatment proves beneficial, its developers will ask for permission to market it from the U.S. Food and Drug Administration (FDA).

Pilot Plant

A medium scale processing facility used as an intermediate in scaling up processes from the laboratory to commercial production.

Process Development

Process development includes the development of new processes for new compounds and the development of new processes for existing compounds. The second of these can be further divided into incremental improvements of an existing process (usually within the scope of the existing regulatory approval for manufacture of an API) and major process improvements requiring extensive plant trial work and regulatory approvals. Thus it includes:

- any involvement in the development of the process for the production of new compounds, including the development of

the route for filing information to obtain regulatory approval but not the filing itself nor minor adjustments undertaken within the filing process;

- the production of Phase I to Phase III clinical trial batches and production up until the commercial launch;
- exploration of novel routes to produce existing compounds including development through chemistry and through innovative use of technology;
- significant modification of existing processes requiring alteration of the filed route (e.g. solvent change, replacement of reagent) and
- scale-up to pilot plant and ultimately full scale production.

Process development associated with drugs close to market or a suite of drugs with a high probability of market success for at least one of them is relatively low risk compared with drug discovery. Process development also has a role in the early stages of development of a new drug candidate, e.g. in biopharma, and then has a higher associated risk.

Scale-up

Transition from small-scale production to production of commercial quantities.

Validation

Validation reinforces GMP and is concerned with regulating manufacturing and analytical equipment, and the cleaning of equipment. It ensures that products and processes meet the same high expectations every time.

Wet-lab / Incubator Space

A range of services and support (including lab and administration space) for emerging companies and researchers exploring the commercialisation route.

Appendix 3

Summary of ICSTI Statement on *Commercialisation of Publicly Funded Research* (February 2001) and Developments since its Publication

Summary of ICSTI Statement

The Issues

In modern industrialised economies, it has been shown that the output from science and technology has been doubling every seven to ten years. Total intangible investment exceeds physical investment in a number of them. These economies are commonly classified as knowledge-based, their reliance on knowledge being their key feature. Ireland is on track to becoming a knowledge-based economy due to national, European and multinational influences on its educational, technological and work environment.

In this context, the transfer of research and development results from universities, institutes of technology and Government research institutes to the commercial market place for public benefit - the commercialisation of research - is an activity of increasing importance. While the primary outputs of research are knowledge and education, which in turn both produce skilled researchers and make Ireland more attractive to industry, there are increasing opportunities to derive economic benefits from the enhanced commercialisation of research. However, to date, Government Departments and their agencies have under-invested in the commercialisation of non-commissioned research even relative to the historically low level of publicly funded research and development (R&D) carried out. As the opportunities for commercialisation increase, targeted action must be taken to avail of them.

Only a proportion of R&D projects can be expected to provide results suitable for progressing down the road to commercialisation. However, relative to the previous low level of investment, the massive boost in public funding of non-commissioned R&D currently in train will raise the level of research in Ireland substantially. This increase can be expected to give rise to a proportionate increase in the opportunities for

commercialisation. Institutions should continue to return the benefits of commercialisation of research, firstly to Ireland and secondly to Europe, where possible.

To exploit the opportunities effectively, the environment, the policies being implemented and the incentives under which the key actors -the researchers - operate also have to be favourable. Otherwise, entrepreneurs will not be able to bring research outcomes to the market place. Entrepreneurs, including those from academia, are key to continuing, and increasing the amount of, successful commercialisation of research.

Currently, the environment for the commercialisation of research, as determined by the policies of Government Departments (such as Agriculture, Food & Rural Development, Education & Science, Enterprise, Trade & Employment and Health & Children) and their agencies is not seen as favourable. The increase in public funding of research and development in Ireland warrants a corresponding increase in the actions of these stakeholders in support of commercialisation of research. The host institutions of researchers also have a significant role to play in providing positive incentives in the future.

The Recommendations

To develop a positive culture, a supportive framework and incentives are required. The following actions are recommended:

- In regard to the commercialisation of research, Government Departments should make a clear statement of intent and set specific objectives; should ensure that agencies under their aegis have adequate procedures in place and should commit sufficient resources to commercialisation of research. Measurement of progress against the objectives should be undertaken in addition to monitoring to ensure the effective use of resources.

- Funding agencies should encourage commercialisation of results of research they sponsor. They should drive forward the process of commercialisation, allocate funds for the initial stages of commercialisation of R&D and carry out an audit of projects already supported to review the possibilities for commercialisation. There is scope for Enterprise Ireland (EI), including the PATs (Programmes for Advanced Technology), to play a more pro-active role in supporting new businesses, ventures and products arising from research in third level institutions.

- Universities, institutes of technology and research institutes should see commercialisation of R&D as an essential mission. They should encourage it as an option for all researchers in third level institutions and research institutes. They should have clear policies, allocate senior management responsibility and designate both sufficient personnel and adequate resources. In the area of intellectual property and spin-off companies they should adopt a flexible approach.

  Universities, institutes of technology and research institutes should take all reasonable steps to obtain the maximum benefits for the economy and society and should support researchers in their commercialisation activities by offering incentives and by ensuring that no unnecessary barriers are in place. Financial returns should be proportionate to the services they provide. They should seek normal commercial royalties from patents and licences. The negotiation of equity holdings in spin-off companies should be consistent with achieving appropriate returns for all parties involved.

- In the Irish context, the resources available to the industrial liaison offices for commercialisation activities in third level institutions are totally inadequate. It is recommended that resources for the technology transfer/commercialisation function be increased substantially and that this be enabled by the relevant funding authorities. Interaction between researchers and industry clusters should continue to be facilitated by the

industrial liaison offices with an increase in activity in this area being recommended.

- ICSTI believes that research outcomes are not being commercialised in sufficient numbers due, in part, to the lack of financial resources to advance the projects to the proof of concept stage. This work can be carried out by third level institutions, by research institutes and by companies. It is recommended that proof of concept funding be provided through the relevant agencies and Government Departments to third level institutions, research institutes and small and medium-sized enterprises, on a competitive basis. In the case of the research institutes, this funding should extend to demonstration trials where appropriate. The Council sees a particular need for Enterprise Ireland to review and strengthen its role in this area.
- It is recommended that an adequate new source of first stage venture capital finance be provided. After the proof of concept stage, early or seed venture capital can still be difficult to obtain, particularly for projects with long lead times which may require significantly greater funding than shorter term projects. This fund would be targeted at bridging the finance gap which exists for projects in which capital is at risk for longer periods. Given the experience of Enterprise Ireland in this area, ICSTI would welcome its involvement in establishing this fund.
- It is recommended that the Higher Education Authority, in developing its policies for the allocation of public funding to the universities, should have regard to the need to encourage the institutions to pursue active policies for the commercialisation of research.
- Training in commercialisation activities should be provided as an option for all researchers and research programme managers, both in third level and in research institutes. ICSTI exhorts the HEA, for the colleges, and Government Departments and agencies, for other researchers, to support and encourage this activity.

Additional key recommendations are that:

- The development agencies should support and assist in providing suitable formal networking fora for enterprises throughout the country on a regular basis. These fora could, for example, facilitate interaction between entrepreneurs and/or contact between entrepreneurs and those offering finance.
- In addition to the incubation supports currently available, the establishment of a small number of incubation companies to support start-ups requiring specialist facilities, business advice, mentoring and support services through their formative years should be encouraged and financially assisted. This could take the form of a public private partnership with each incubation company providing specialist support for several start-up companies. The Council would welcome the involvement of Enterprise Ireland in such a partnership.
- Systematic monitoring of a selected range of commercialisation indicators should be undertaken as an ongoing priority.

Developments since the publication of the ICSTI Statement on *Commercialisation of Publicly Funded Research* (February 2001)

There has been significant progress in some areas since the publication of the ICSTI Statement on *Commercialisation of Publicly Funded Research* in February 2001.

Areas in which progress has been demonstrated include:

- Funding for commercialisation is available within some research programmes (e.g. Enterprise Ireland Research Innovation Fund established March 2001, Enterprise Ireland Commercialisation Fund launched 2003).

- Support for early stage development of research with commercial potential has increased (e.g. under the Enterprise Ireland Seed and Venture Capital Funds).
- Incubator units are being funded in many of the Institutes of Technology under two Enterprise Ireland schemes: Business Incubator Space in the Institutes of Technology and the Incubator Centre Initiative. A new initiative on wet laboratory space has been put in place to encourage spin-off companies from the life sciences.
- The Atlantic University Alliance Technology Transfer Initiative has been established between three Universities (UCG, UCC and UL) with Enterprise Ireland funding with part of the deliverables relating to the transfer of research results with commercial potential.
- Campus companies are being supported through a variety of Enterprise Ireland measures, for example, the Campus Enterprise Unit at EI, Campus Companies Programme, CORD and Mentor programmes.

It should be noted that many of these initiatives are applicable only to the third level sector and not to public research institutes. There are still areas to be addressed - most notably the support for industrial liaison.

Appendix 4

ExpertiseIreland.com – a web-based database of research capability

ExpertiseIreland.com is being developed as a North-South initiative backed by InterTradeIreland, a cross-border body established to exchange information and coordinate work on trade and business development. It will combine, in one searchable database, information about R&D expertise, up-to-date details of research work, patents, technology transfer and collaborative R&D opportunities. Being a web-based site, ExpertiseIreland.com will provide an opportunity to showcase the island's knowledge capabilities to the world.

The initiative had its origins in an agreement among the island's universities. In 1997 the universities agreed to develop a unified knowledge management system. Five of the island's universities have already installed the system and a further three will complete installation within the next couple of months.

ExpertiseIreland.com aims to position itself as the first point of contact for anyone seeking details about the R&D community on the island of Ireland. The goal is to encourage and facilitate linkages both between, and within, industry and academia. However, InterTradeIreland recognised that such a comprehensive database of the island's academic expertise would be of interest to a wider audience. Not only were there implications for linkages with business that could drive forward the commercialisation of intellectual property, but in addition it was realised that it could also serve as a shop window for commercial research interests.

Current Situation

In 2002, InterTradeIreland agreed to financially support the development of ExpertiseIreland.com. The Conference of Heads of Irish Universities (CHIU) will direct the project with the guidance of an advisory panel drawn from InterTradeIreland, Enterprise Ireland, Invest NI, IBEC and representatives from the universities. ExpertiseIreland.com went live in late spring 2003.

Appendix 5

IBEC Position Paper on REACH: EU Commission Proposal on Chemicals Policy Management - Executive Summary

1. Introduction

The proposed legislation, which may be adopted under the REACH programme, will have a severe negative impact on a wide range of Irish Industry, which manufactures imports or uses chemicals. IBEC recognizes the need to define a new chemicals policy concept for the protection of human health and the environment and welcomes the idea of setting this within a framework of sustainable development. However, it is the consensus of all sectors of our membership that the currently proposed REACH system is overly bureaucratic, burdensome and in short unworkable. Not only is it unclear how the new proposal would provide a coherent framework to detect and enhance the safety of man and the environment, many of the key political objectives set out in the white paper:

- Maintenance and enhancement of the competitiveness of the EU chemical industry
- Prevention of fragmentation of the internal market
- Full harmonization of future legislation
- Increased transparency to consumers
- Integration with international efforts
- Conformity with EU international obligations under the WTO
- Promotion of non-animal testing

are inadequately addressed or not at all. Noting the importance of the pharmaceutical/chemical sector in the Irish economy, the widespread and necessary use of chemical substances, and products, throughout manufacturing industry, it will be clear that any new regulations that put European, and especially Irish industry at a competitive disadvantage with respect to other trading zones could have potentially disastrous effects, and these issues must be addressed at the highest level.

2. Issues for Irish industry/Irish economy

- The scope of the new regulations is far too broad, the time scale for implementation is unrealistic and much more consideration needs to be given to working out the detailed operating mechanisms. It appears that the Commission has underestimated the volume of testing and the real costs associated with this and has not taken realistic account of the available resources or the actual time scale involved.
- As the proposed legislation would only apply in the European Union, not in other trading zones, the real costs of the various test packages and the time scales needed to produce the data will place European/Irish industry at a competitive disadvantage and would inevitably lead to a loss of business and a loss of jobs to other trading zones.
- In particular, with respect to the proposal for "site limited intermediates", the costs involved and the requirement to place confidential technical and commercial information in the public domain would place most companies in Ireland at a disadvantage with regard to their competition outside the EU, who would be entirely free to use this information without restriction, and would not be faced with the costs and administration burdens opposed within the EU. It follows, that multinational companies who have manufacturing facilities outside the EU, will remove productions sites preferentially to those countries, noting that they will still be free to import the finished product without restriction.
- The white paper takes no account of available resources, or of the need to target the finite resources available to industry, regulatory bodies and all other agencies, so as to secure maximum benefit for protection of mankind and the environment within a coherent and practical framework.
- The requirement, set out in fairly arbitrary fashion, for banning some substances, or substitution of some substances by others within a fixed time scale, takes little account of practical

reality or sound scientific evidence. It is hard to believe but European (Irish) industry could be faced with this kind of regulation, while the EU would be unable, under WTO regulations, to enforce this kind of regulation on importers from other trading zones, noting that any such attempt at restriction on foreign imports must be based on sound scientific argument, and there is a high level of burden of proof.

- In a climate where manufacturing industry is under attack by animal rights lobbyists for conforming with current legal obligations imposed on it by EU regulatory bodies, the European Commission now proposes what would be a greatly increased volume of animal testing, which takes little account of available test facilities, or of the climate of public opinion in the matter.

3. Suggested Improvement to Proposed System

- Instead of the current overly broad scope for proposed regulation, the REACH system should only apply to non-polymeric substances placed on the EU market in quantities greater than 1MT per year per manufacturer or importer.
- "Site-limited" intermediates that present a much lower order of magnitude of risk for the consumer should be excluded from the REACH system. The resulting more narrowly defined range of compounds would allow focus to be placed on those substances, which because of the volume of production or particular properties, might be expected to present a higher risk.
- Hazard data should be provided and generated following a risk based approach: if a risk-based, tiered and tailored approach to the provision of hazard data, based on the principles of reviewing substances produced in quantities greater than 10MT initially, carrying out only those tests that are essential for decisions and use control measures, and minimising animal tests, far greater progress could be made in much less time and

produce significant benefits for safety and environmental protection, without placing industry at an unrealistic competitive disadvantage.

- The deadlines/timescales to complete registration and testing of the various substances at particular levels must be based on a realistic assessment of the information required, suitability of various test regimes and the resources available. It is a plain fact that the timescales provided in the current white paper are simply not achievable for the testing regimes described.
- It would be far better to focus on a tiered approach as already suggested and, with a credible and achievable timetable, produce the desired benefits, and, of great importance, maintain credibility in the working of the program, and timely delivery of the objectives.
- It is important that the new European regulations are not produced in a vacuum, but should take account of systems elsewhere, as in the USA, Japan etc so that a new framework based on global harmonisation results. This would provide a much sounder basis for protection of man and the environment within a neutral competitive framework, respecting all the political objectives of the white paper, and taking into account obligations under WTO.
- Risk and risk assessment must be the basis for any regulatory action, and should be used to set priorities within the framework for the registration and testing of chemical substances as well as possible authorisation processes, and/or moves to substitute other substances within a particular time scale. Where authorisation is necessary, this should be confined to high volume substances of very high concern and the scope and procedures must be well defined and practical and take account of all scientific data, including the possible availability of substitutes.

Appendix 6

Participants in the PharmaChem Project and Task Force Membership

Organisation	Name	Responsibility
Bristol-Myers-Squibb	Mary Collins	Technical Operations Manager
	Brian Harrison	Senior Director for Europe
	Mary Moran	Chemical Development Manager
CIRCA	Jim Ryan	Associate Director
CSS Almac	Tony McKervey	Honorary Vice President
Dublin City University	Dermot Diamond	Associate Professor
EiRX Therapeutics	Ian Hayes	R&D Director
Élan	Frank Reddan	General Manager
Eli Lilly	William Barrett	Director of HR and Public Affairs
Enterprise Ireland	Garry Forde	Senior Development Advisor
	Dick Lenehan	Department Manager, Healthcare, Pharmaceuticals and Life Sciences
	Martin Lyes	Manager, Science, Technology and Innovation
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IBEC (IPCMF)	Matt Moran	Director
IDA Ireland	Pat MacGovern	Manager Pharmaceutical Division
Irish Medicines Board	Pat O'Mahoney	Chief Executive Officer

Organisation	Name	Responsibility
IPCMF	Conor O'Brien	Chairman
IPHA	Brian Murphy	Commercial Affairs Manager
Irish BioIndustries Association	Mike Comer	Former Chairman
Irish Medical Devices Association	Sharon Higgins	Director
IT Cork	John O' Shea	Head of Chemical Engineering Department
IT Tallaght	Tim Creedon	Head of Science School
IT Tralee	Sandra Hanley	Lecturer in Chemistry and Life Sciences
Janssen	John Farragher	Quality Assurance Manager
	James Dineen	Quality Assurance and Technical Support Manager
KPMG	Sharon Burke	Partner in Tax Division
Mallinckrodt	Elizabeth Collins	Process Improvement Team Leader
Merck Sharp & Dohme	Declan Buckley	General Manager
	John Condon	Human Resources and Public Relations Director
	James Kelly	Senior Director of Technical Operations in Europe
	Tom O'Ceallaigh	Principal Scientist (Associated Director) in Technical Operations
Nollaig Buckley Consulting	Nollaig O'Neill	Consultant
Novartis	Leonard Kelleher	Process Manager
	Ray Timmons	Head of Engineering
University College Cork	Jean Van Sinderen - Law	Development Office Director
	Michael Murphy	Dean of Medicine

Organisation	Name	Responsibility
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	Mark Hand	Director of Technical Services
	Peter Hetherington	Technical Services Manager
	Liam Tully	Chemical Services Manager
Roche	Dennis Smith	Director of Technical Services
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	Henry Doran	Senior Manager R&D
	Declan Farrell	Senior Director Regional Quality Europe and Canada
Science Foundation Ireland	Bill Harris	Director General
Sifa	Mary Shire	New Product Development Manager
University College Dublin	Frank Hegarty	Professor and Chair of Organic Chemistry
University of Limerick	Timothy Smyth	Senior Lecturer, Organic Chemistry
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	Stephen Fitzpatrick	Director Regulatory Affairs
	Frank Hallinan	Director Quality
	Brendan Hughes	Director Drug Development
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Appendix 7

List of Acronyms

API	Active Pharmaceutical Ingredient
CHIU	Conference of Heads of Irish Universities
EDB	Economic Development Board (Singapore)
EI	Enterprise Ireland
EMEA	European Medicines Evaluation Agency
EPA	Environmental Protection Agency
ESB	Electricity Supply Board
EU	European Union
FDA	US Food and Drug Administration
GMP	Good Manufacturing Practice
HSA	Health and Safety Authority
IBEC	Irish Business and Employers' Confederation
ICH	International Conference on Harmonisation
ICTU	Irish Congress of Trade Unions
IMB	Irish Medicines Board
IPCMF	Irish Pharmaceutical and Chemical Manufacturers' Federation
IRCSET	Irish Research Council for Science, Engineering and Technology
MRA	Mutual Recognition Agreement (between EU and US)
PAYE	Pay As You Earn Taxation
PRSI	Pay Related Social Insurance
PRTLI	Programme for Research in Third Level Institutions
REACH	Registration, Evaluation and Authorisation of CHemicals
RTDI	Research, Technological Development and Innovation
SFI	Science Foundation Ireland
UCC	University College Cork
UCD	University College Dublin
UCG	University College Galway
UL	University of Limerick
WTO	World Trade Organisation

ICSTI Membership

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ICSTI Statements to Date

Report	Date of Publication
State Expenditure Priorities for 1998	September 1997
£250 Million Scientific and Technological Education (Investment) Fund	January 1998
A Partnership Approach to Research Funding - The Need for a National Science and Engineering Research Fund	May 1998
Science in Primary Schools	May 1998
Mechanisms for Prioritisation of State Expenditures on Science and Technology	June 1998
Innovation in Enterprises in Ireland	July 1998
Science Technology and Innovation Culture	November 1998
State Expenditure Priorities for 1999	November 1998
Investing in Research, Technology and Innovation (RTI) in the Period 2000 to 2006	March 1999
Technology Foresight Report	April 1999
Public Sector Research and Technology Services for Innovation in Enterprises	September 1999
Science in Second Level Schools	November 1999
Benchmarking School Science, Technology and Mathematics Education in Ireland Against International Good Practice	February 2000
Commercialisation of Publicly Funded Research	February 2001
Biotechnology	February 2002
Measuring and Evaluating Research	August 2002
Design and Development	September 2002
Utilising Intellectual Property for Competitive Advantage	February 2003

ICSTI Secretariat

The Secretariat is provided by Forfás, the national policy and advisory board for enterprise, trade, science, technology and innovation.

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