PRIORITY AREA G
THERAPEUTICS: SYNTHESIS, FORMULATION, PROCESSING & DRUG DELIVERY ACTION PLAN
JULY 2013

Therapeutics: Synthesis, Formulation, Processing and Drug Delivery (Area G)

Context

This priority area is focused on developing competence and activity in research, technology and development areas relevant to industry needs in Ireland in therapeutics/pharmaceuticals manufacturing. Drug delivery/formulation is also an opportunity for further enterprise development based on innovative drug delivery systems.

Therapeutics are chemical and biological products used to treat diseases. Ireland is a major manufacturer of pharmaceuticals and biologics, with 25,000 employed within 81 foreign companies based in Ireland and exports of €38.2 billion (2008). There are also small but growing indigenous pharma and drug delivery sectors.

The main focus for Ireland within the field of therapeutics is to develop competence and activity in research, technology and development areas to support therapeutics manufacturing, for example, the manufacture and formulation of small molecules, biologics and associated process research.

This industry support should also include investment in research that generates appropriately skilled ‘industry-ready’ graduates that provide an employment pool for in-company development operations. Involvement in relevant RTD enhances the value of graduates to the industry and thereby Ireland’s appeal as a manufacturing location.

Development of innovative drug delivery systems was also identified as an area where Ireland already has significant enterprise and research capacity which can be leveraged and developed further. Drug Delivery technologies may also find utility across additional priority areas (e.g. Medical Technologies) as the underpinning technologies in many cases will be the same.

While the RPSG did not recommend discovery or development of new therapeutics as a priority area for Ireland, the Group recognised that Ireland has, as a result of significant State investment over recent years, built a credible international reputation in a range of research fields relevant to this area. The RPSG's view was that Ireland should retain activity in these areas, but in a highly selective, focussed manner; funding a smaller number of elite researchers doing high quality work.

The RPSG report asserts the importance of maintaining a vibrant research base to ensure Ireland remains competitive and well positioned to respond to short, medium and long term research needs in priority areas identified now, and in the future. It recommends that the majority of funding for both platform technologies, and the associated underpinning research capabilities should be focussed in areas that directly support the 14 identified priority areas.

It is important to acknowledge, however, that strong potential for therapeutics discovery exists as an output of basic biomedical research; regardless of the original priority area of focus. The RPSG report specifically recognises that "serendipitous discoveries in therapeutics will arise

from basic biomedical research and that the State should support compelling translational research opportunities to develop IP to a stage where it is ready to attract VC investment or license".

Therapeutics: Synthesis, Formulation, Processing and Drug Delivery (Area G)

Vision/opportunity: "To further embed, diversify and support the international competitiveness of (bio)-pharmaceutical manufacturing and process development (small molecules, biologic based therapeutics and vaccines) in Ireland by developing our public research capacity in drug synthesis, formulation and delivery."

This will give companies access to knowledge and expertise that will support increased productivity through the development of new or improved manufacturing processes while maintaining Ireland's reputation for excellence in quality and consistency through investment in cutting edge analytics technology. Our public research capacity will also support the on-going diversification of the manufacturing industry from predominantly small molecule drug substance to a mixture of small molecule and biologics drug substance and drug product.

Input from industry on novel therapeutic platforms (e.g. novel formulations/delivery systems/biomaterials, antibody-drug conjugates, next-gen vaccines, cells therapies, nucleic acids) close to clinical validation and market acceptance will guide public sector research strategies and provide the appropriate capabilities to support the future diversification of the Irish pharmaceutical sector into these advanced therapeutic platforms, underwriting the long-term health of the sector. In the case of novel therapeutic platforms, industry will benefit from academic insights into the underpinning science surrounding these new platforms and academia can support industry in addressing aspects of "design for manufacture", process engineering, and regulatory challenges associated with new therapeutic platform development and manufacturing activities.

Due to the focus on supporting and growing Ireland's (bio) -pharmaceutical manufacturing base, it is considered beyond the scope of this action plan to make recommendations pertaining to publically funded research in the areas of therapeutics discovery, biological pathways relevant to disease, or preclinical/clinical assessment of novel therapeutics.

Objective 1	To increase the number of internationally recognised excellent 'industry-relevant' researchers within the public research system who will develop partnerships with the manufacturing and process development leaders in the (bio)pharmaceutical industry, supporting process R&D in small molecule, biopharmaceutical, formulation and "next generation" therapeutics (drug device combinations, antibody-drug conjugates, biomaterials, nucleic acid-based therapies, cell therapy etc.).
Objective 2	To optimise collaboration, coordination and possible consolidation of publicly funded research groups and researchers to increase critical mass to meet the immediate and strategic needs of the Therapeutics Sector and improve the marketable value proposition of the Irish research base.
Objective 3	To leverage investment in academic research on therapeutics manufacturing to help ensure continuation of Ireland's reputation for a strong supportive responsive regulatory environment for the therapeutics development and manufacturing sector.
Objective 4	To optimise the transfer of knowledge between RPOs and enterprise through the increased mobility of researchers and the delivery of training in industrially relevant research.

No	Action	Deliverable	Benefit	Lead	Support	Timeline
Objective 1	To increase the number of internationally recognised excellent 'industry-relevant' researchers within the public research system who will develop partnerships with the manufacturing and process development leaders in the (bio)pharmaceutical industry, supporting process R&D in small molecule, biopharmaceutical, formulation and "next generation" therapeutics (drug device combinations, antibody-drug conjugates, biomaterials, nucleic acid-based therapies,cell therapy etc).					
G1.1	Update and maintain intelligence on research strengths, activity and investments that support this priority area across funding agencies building on the information generated during the	Current intelligence in the relevant funding agencies on research strengths relevant to this priority area.	Better understanding of what research strengths currently exist which will inform what gaps need to be filled; Better able to position the public	IDA	SFI, EI, HEA, Forfás.	Q3, 2013

No	Action	Deliverable	Benefit	Lead	Support	Timeline
	NRPE.		research system as a research partner to industry.			
G 1.2	Develop list of current and strategic research needs of the Therapeutics sector based on the following initiatives: ▪ the work done in creating the Pharmaceutical Technology Centre (predominantly focused on small molecule synthesis and formulation). ▪ summary of Pharma forum of key opinion leaders from industry organised by Graham Symcox (predominantly biologic focused) ▪ Continuously review trends in "next generation"	Supported by action 1.1 a gap analysis of industry (immediate and strategic) needs versus academic strengths. Assessment of need for targeted calls to address gaps or if existing bottom up approach is sufficient.	A regularly updated statement of research needs of the (bio)-pharmaceutical industry, combined with an analysis of existing research resources in the public sector will provide: ▪ A mechanism for alignment of the public research base with industry needs. ▪ A resource for research performers and funders.	EI, IDA	PCI, SFI	Q3, 2013

No	Action	Deliverable	Benefit	Lead	Support	Timeline
	therapeutics as they get closer to clinical approval (e.g. antibody drug conjugates, drug device combinations, biomaterials, gene therapy, RNAi etc) ▪ Validate findings with key industry executives (local and corporate) in a small number of selected companies to validate initial analysis and further define strategic research needs.					
G1.3	Based on the gap analysis, if found to be required, identify the most appropriate funding instruments and initiate calls to attract internationally recognised researchers (including	Increased number of internationally recognised researchers within the RPOs who can collaborate with enterprise.	Enhance Ireland's reputation as a location for world class research in this area and increase number of academic-industry	SFI	EI, IDA	Q1, 2014

No	Action	Deliverable	Benefit	Lead	Support	Timeline
	researchers from the (bio)-pharmaceutical industry) that will develop research capacity within the public research system and develop links with industry over the medium and longer term, either within existing or consolidated structures e.g. Principal Investigator Programme, Walton Call.		collaborations.			
G1.4	Consider/evaluate mechanisms, including bottom-up calls, to fund excellent research underpinning this priority area.	Strong research base in platform sciences and technology underpinning this priority area.	Ireland remains competitive and well positioned to respond to (short), medium and long term opportunities and research demands arising through disruptive technologies and new product direction.	SFI		Q1, 2013
Objective 2	To optimise collaboration, coordination and possible consolidation of publicly funded research groups and researchers to increase critical mass to meet the immediate and strategic needs of the Therapeutics Sector and improve the marketable value proposition of the Irish research base.					

No	Action	Deliverable	Benefit	Lead	Support	Timeline
G 2.1	Based on the deliverable of Action 1.1 and using the therapeutics manufacturing area as a pilot, develop a medium term vision with required actions for optimising collaboration between publicly funded research groups and centres in Ireland in order to better meet the immediate and long-term needs of the industry.	A vision of how research centres should interact and collaborate to ensure that the breadth of multi-disciplinary/cross disciplinary research that supports this area can be harnessed to meet both the short and long term needs of industry in a dynamic and sustainable way with a set of specific actions to support that vision.	Approach to promoting collaboration between research centres to support bilateral and multilateral research projects with industry.	DJEI through TI	IDA, SFI, EI	Q3, 2013
G2.2	Undertake pilot project in Therapeutics priority area to maximise synergies between research centres and develop a consolidated branding and marketing message around Ireland's research strengths in the therapeutics area.	A marketing tool to help industry understand what research capability is available in Ireland and how it can meet their needs An influencing tool to encourage existing and new research centres/individuals to collaborate and co-market their capability.	Create a sense of critical mass in research in this area through consolidation of brands without requirement for radical increase in spend or immediate consolidation of centres. Unified and coherent marketing message	DJEI through TI	IDA, SFI, EI	Q3, 2013

No	Action	Deliverable	Benefit	Lead	Support	Timeline
			around Ireland's research strengths in this area. Facilitate easier and faster access by industry to knowledge & expertise to meet specific research challenges.			
G2.3	Use the findings of this pilot project to develop a framework for how research centres in the other priority areas should interact and collaborate to ensure they meet industry needs in a sustainable way.	A framework around which funding agencies can design research funding programs to fill gaps, exploit synergies and avoid duplication in research relevant to the sector.	Increased numbers of collaborations between research centres to support bilateral and multilateral research projects with industry.	DJEI through TI	IDA, SFI, EI	Q4, 2013
G2.4	Complete roll-out of Pharmaceutics Technology Centre (PTC) and ensure that it can facilitate bilateral and multilateral research collaborations	The PTC will perform a number of functions: The PTC will fund and/or facilitate bilateral and multilateral research collaborations between	Increased number of collaborations between industry and RPOs.	IDA, EI	SFI	Q4, 2013

No	Action	Deliverable	Benefit	Lead	Support	Timeline
	among companies and all research centres that operate in the relevant research areas, and explore alignment with vision outlined in 2.1.	enterprise and research centres. Subject to action 2.1, the PTC may take lead responsibility for promoting Ireland's research capacity in this Priority Area to enterprise thereby presenting a comprehensive and coherent R&D landscape and making access for enterprise easier. The PTC will inform the RPO system of the immediate and strategic research needs of enterprise.				
G 2.5	Review the landscape of research centres in the EU in the therapeutics area and consider the provision of instruments to support Irish collaboration with EU centres to avoid unnecessary duplication.	Promote uptake of EU and International research funds, in particular leadership roles in Horizon 2020, Factory of the Future PPP and Key enabling Technology.	Leverage national investment to increase collaboration in complementary areas and draw down of EU funding.	IDA, SFI, EI		Q2, 2014

No	Action	Deliverable	Benefit	Lead	Support	Timeline
Objective 3	To leverage investment in academic research on therapeutics manufacturing to help ensure continuation of Ireland's reputation for strong supportive responsive regulatory environment for the therapeutics development and manufacturing sector.					
G3.1	Promote increased linkages between the academic research base and the IMB to assist the IMB in maintaining the knowledge and expertise to respond to next generation processes for Therapeutics manufacturing. Particular focus on linking regulators with academic opinion leaders with unbiased expertise in novel processes or analytical methods.	Continued strong, supportive and responsive regulatory environment for Therapeutics sector. Strong interaction between Regulators, the industry base and Irish research base.	Sustained attractiveness of Ireland as a location for development and deployment of novel processes for innovative and complex Therapeutics (e.g. drug-device combinations, biosimilars, biobetters and next generation therapies like stem cells/RNAi).	IMB	EI, IDA, PCI, SFI	Q4, 2012
Objective 4	To optimise the transfer of knowledge between RPOs and enterprise through the increased mobility of researchers and the delivery of training in industry-relevant research.					
G4.1	Launch the employment based postgraduate programme.	Critical mass of graduates with skills required by industry.	Skills to drive innovation and development and manufacture of next generation	Irish Research Council		Q2, 2013

No	Action	Deliverable	Benefit	Lead	Support	Timeline
			pharmaceuticals in Ireland.			
G4.2	Identify gaps in availability of industry relevant equipment for scale-up activity (both for research and training) and build a business case to bring to the funding agencies. As next generation therapeutics become more mainstream, continuous review of industry needs in terms of equipment will be required as the pilot production and manufacture of these therapeutics may require very novel and specialised equipment.	Needs analysis for capital investment in equipment for scale up in the RPOs.	Basis for addressing manufacturing industry training requirements.	IDA		Q4, 2013
G4.3	Based on the business case consider an approach to provision of funding for necessary equipment and infrastructure.	Availability of industry relevant equipment for research and training within RPOs.	Increased research and training aligned with industry need.	DJEI, via TI		Q2, 2014

No	Action	Deliverable	Benefit	Lead	Support	Timeline
G4.4	Map training programmes relevant to the therapeutics manufacturing sector for both new graduates and existing employees currently offered, identify gaps and work with training providers and incentivise research centres to address these gaps. Consider consolidation of marketing of industry relevant training programs along lines of marketing approach for national research capability.	Ensure an appropriate number of training programmes with contribution from internationally recognised researchers/research groups and relevant education providers in areas required by industry. Improve marketing of available training offerings to industry.	Transfer of knowledge between RPOs and enterprise in existing manufacturing sites (upskilling in existing facilities to ensure research outputs can be implemented effectively to increase productivity/maintain quality). Training programs and follow on skills/talent availability as a marketing tool to attract new manufacturing investment.	IDA	HEA, Solas, DJEI	Q4, 2012
G 4.5	Identify opportunities to leverage the consolidated academic base supporting therapeutics manufacturing to support	Continued and enhanced support for indigenous companies in the industrial and biotech space through exploitation of Ireland's	Transfer of knowledge from academic research base to indigenous Irish companies	EI	IDA, SFI	Q4, 2012

No	Action	Deliverable	Benefit	Lead	Support	Timeline
	the establishment and growth of indigenous Irish companies including: indigenous Pharma manufacturers; subsuppliers to the Pharma manufacturing sector; companies with high value platform technologies e.g. in areas of novel formulation and delivery technologies; and indigenous companies with novel therapeutics which can utilise strengthened academic-industry networks to explore options for pilot production in Ireland.	critical mass in therapeutics manufacturing (opportunities for company growth and B2B partnerships) and consolidation/strengthening of the academic research base in this area (opportunities for spin-outs/collaborations).	through collaboration Potential for greater rate of HPSU establishment and scaling Catalysing of increased B2B partnerships between MNC manufacturers and indigenous companies by using academic research centres as common “sandpits”.			

Forfás

An Roinn Post, Fiontar agus Nuálaíochta
Department of Jobs, Enterprise and Innovation