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Responsiveness of Higher Education Programs to Policy and Recommendations in the BioPharmaceutical Sector

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Title: Responsiveness of higher education programs to policy and recommendations in the Biopharmaceutical sector.

This essay will review the business and government policies relevant to the biopharmaceutical sector which influence higher education programs. The mechanisms which enable higher education to adapt to policy will be summarised and the pace of the response estimated.

Higher education (HE) programs need to respond in a timely manner to dynamic industries to maximise opportunities for graduates and support the Irish economy. The author manages internships and teaches on pharmaceutical science programs and aims to ensure the program is current to maximise student success. This review intends to identify the most relevant policy sources that can inform the Pharmaceutical Science program and identify policy enabling strategies to use on an ongoing basis and in future programmatic review. Relevant policy and strategy documents include those relating to Irelands investment strategies and target sectors, future skills needs, industry input into programs and TU Dublin academic framework publications. The mechanism by which programs adapt to changes in government and industry policy is through university programmatic review processes which are published in the university academic framework documents (TU Dublin, 2021). These TU Dublin academic framework will be reviewed to understand the mechanisms in place that enable incorporation of policies through program revisions and how to apply them appropriately in the future. The strategies in place that enable HE to address business and government policy will be explored to assess the agility and practicalities for Higher Education Institutions (HEIs) to react to changing needs. This study will identify the correct sources for future reference and familiarise me with the academic policies required for future tasks.

The Biopharmaceutical sector in Ireland has changed dramatically in the past 5 years and is now undergoing further specialisations which require HE programs to supply suitably qualified graduates to sustain the sector (DES, 2017; IBEC, 2022; IDA, 2021). The manufacturing processes, characterisation of medicinal therapies and associated regulations are transforming. This has implications for the knowledge and skills required in science graduate skills and competencies. Business and government organisations are quick to publish new policies relevant to Irelands investment strategies and skills needs in the pharmaceutical sector to support economic growth and innovation (DES, 2017; EGFSN, 2022). These policies include recommendations to higher education institutions (HEIs) (DES, 2017; EGFSN, 2022) on program outcomes. There are many policy documents published by business and government organisations which contain detail on economic investment strategies in the biopharmaceutical sector (DES, 2017; EGFSN, 2022; IBEC, 2018; IBEC, 2022; IDA, 2021). Publications selected for analysis are those which include detail on therapeutic product type which is key to understanding relevancy of pharmaceutical science program content.

IBEC is an organisation that represents Irish businesses and is a powerful lobbying group which influences education policy. The organisation has discipline specific experts that regularly publish detailed policy and guidance. These publications provide expert and accurate insight into business and government investment strategy in Ireland for business sectors such as biopharmaceuticals. Current IBEC publications which provide sector specific information are selected as the key policy documents for discussion. A strategy for the BioPharmaceutical sector in Ireland was published in 2022 that reports on the investment and advised target areas by government experts (IBEC, 2022). Expansion into the area of advanced therapeutics including gene therapy and personalised medicines in Ireland is used as an example of changing skills needs. This document proposes that HEIs are aligned and resourced to meet the needs of the biopharma sector, that industry is changing at a very quick pace and that science programs must adapt at the same pace. It does not specify graduate skills but highlights key thematic areas which should be incorporated into pharmaceutical science programmes.

This is useful to support rationale for module names and outcomes and allows an initial program comparison with policy to facilitate a gap analysis in the future. IBEC *Future Ready improving graduate employability skills* reflects the ideal ways for education, business and Government to respond to industry changes (IBEC, 2018). The fast pace of technological advances is acknowledged and HEIs are advised to review teaching programs to consider opportunities for employment in the curriculum, introduce discipline specific profiles and skills maps. IBEC proposes that government drive policy to support HEIs and that business be involved in curriculum design and delivery (IBEC, 2018). I have found that business express interest in program involvement but availability of discipline specific experts for regular consultation is very difficult to arrange. It is more realistic to consult policy recommendations for comparison of program content with policy than industry HE partnership consultation strategies. These sources will be useful as a reference to support future programmatic review approach and rationale for technical skills and program content.

The IDA target foreign direct investment (FDI) in core sectors including biopharmaceuticals and their policies reflect how to sustain this sector including graduate skills. The IDA published a strategy document in Jan 2021 referring to economic growth and investment in advanced manufacturing including biopharmaceuticals in Ireland (IDA 2021). The IDA specify target areas including advanced therapeutic medicines, gene therapy and personalised medicines (IDA 2021) which will provide further support to program revisions.

The need to adapt to changing skills is addressed in the OECD Skills Strategy project for Ireland (OECD, 2019) and in Irelands National Skills Strategy 2025 (DES, 2017). Sector specific skills to support future investment and emerging trends in the biopharmaceutical sector are summarised by the expert group on future skills group (DES, 2017). A Work Programme was approved by the National Skills Council in 2022 as a result of the significant changes in this industry (EGSFN, 2021). The objective is to research the emerging skills needs in the Biopharmaceutical sector since the previous policy publication on skills needs in 2016 (EGFSN, 2016). This project will identify priority skills, any modifications required and provide useful information to inform program outcomes. Emphasis of the rapidly changing trends in the biopharmaceutical industry by the EGFSN demonstrates programs require ongoing comparison to policy to remain current. Key thematic areas in the Statement of Activity publication in 2021 include cell and gene therapies, precision and personalised medicines, combination therapies and API manufacturing (EGSFN, 2021).

Target and thematic areas referred to in IBEC, IDA and EGSFN documents (Table 1) are currently part of the program but realignment is needed in the program. The Pharmaceutical Science Program needs to be more specific to highlight how these thematic areas are addressed and content needs to be refocussed. These sources will be useful as rationale during program reviews and can be used to identify gaps between the pharmaceutical science program and investment strategy and trends.

Table 1. Biopharmaceutical Investment sectors and skills needs identified in recent Business and Government policy documents.

Investment sector (BioPharma Sector))	Policy source
Cell, gene and vaccine therapy (Advanced therapy medicinal products)	IBEC, 2018;IBEC 2022; IDA, 2017; IPHA 2022;IDA, 2021 ;EGSFN, 2021; DES 2017
Personalised/precision medicines	EGSFN, 2021
Combination therapies	EGSFN, 2021
API manufacturing	EGSFN, 2021

The National Strategy for Higher Education to 2030 published in January 2011 proposes a longterm framework for HEIs. Engagement of HE with enterprise is noted as critical for Ireland economic competitiveness. This document recommends strategies to enable policy including using feedback gathered during internship meetings that allows ongoing employer input into curriculum design. This strategy is already in place as I visit students and supervisors in the workplace and receive employer feedback every year. This is an example of a feasible ongoing strategy already in place and its inclusion in HEA recommended strategy will be referenced to support using industry input gathered during internship meetings.

Several policy documents specify industry input as the means to influence programs and align with policy (Table 2). Previous experience attempting to schedule external panels for programmatic review purposes has demonstrated that business presence is difficult to schedule and it is not possible to get representatives from a diverse range of sectors at programmatic review panels. It may be more appropriate to consider external panel input as part of broader government and business policy recommendations. Additional strategies to allow industry input into programs (summarised in Table 2) are challenging due to business demands and availability of industry representatives.

Table 2: Strategies that enable business and government HE policy specific to program input.

Strategies	Policy source
Business collaboration in curriculum design	HEA, 2011;IBEC 2018; IPHA 2022; DETE, 2022
Career clinics	IBEC 2018
External industry panel	TU Dublin 2021; IBEC 2018
Internship meetings used	HEA 2011;
Discipline specific profiles and skills maps	IBEC 2018

HE program outcomes are revised through University academic processes. TU Dublin academic processes must adhere to QQI policy. Program revision require review and approval in accordance with approved program review processes (QQI, 2022). The academic framework to allow changes to TU Dublin programs are approved (TU Dublin Dec 2021). TU Dublin *Academic Quality Enhancement Framework* outlines the policies and procedures relating to validation of new academic programmes and existing programs (TU Dublin, Dec 2021). The scope includes the process to make changes to existing approved modules and programs that reflect new university, government or business policies (TU Dublin, Dec 2021). Programme changes resulting from feedback from employers and a changing industrial landscape is specified. Changes are categorised into three levels which require different approval processes. A breakdown of the TU Dublin review steps to revise programs and modules is summarised in Figure 1 (TU Dublin Dec 2021).

Figure 1. Making changes to Programmes & Module Process (TU Dublin Dec 2021). Level 1 change.
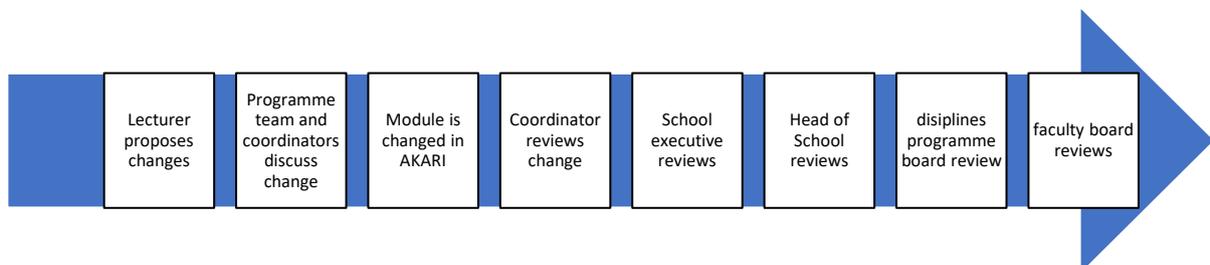
Note: Level 1 must be submitted and approved prior to teaching
Level 2 and 3 must be submitted and approved by the end of the academic year before next academic year

The likely duration from updated policy publications to program modification and implementation into the curriculum is difficult to assess but the breakdown suggests at least three months are required. Updates requires regular review of policy by an academic as it is not realistic to schedule ongoing frequent industry consultations. Changes which fall outside the scope of this process, as defined in the procedure, will require revalidation or programme review. Programmatic reviews are scheduled every four/five years and require academic review and approval stages and an external panel.

In summary, the biopharmaceutical manufacturing industry has changed rapidly in the past five years and requires HE programs to adapt to provide the required skills needs. Business and government organisations react quickly and provide ongoing accurate policy updates to guide HE. The academic framework does allow changes to programmes and modules between scheduled programmatic reviews, however, HEIs cannot respond at the same pace as business organisations. The academic framework in place that allows program revision requires attention by several levels in the organisation. Responsiveness of the HEIs is restricted by the necessary academic processes and practicalities of work demands during teaching semesters. Many recommended strategies to enable implementation of business and government policies to ensure program relevancy require industry input which can be challenging to schedule, so are not always practical. However, there are clear accurate policy publications available to HE which can be used instead of external industry input in between scheduled programmatic reviews. Ongoing policy review can give accurate direction to HE which may be the most practical and agile mechanism to ensure programs remain current rather than attempting to schedule enterprise involvement and consultation on a frequent basis. Published policy is also a broader more representative source of the entire Pharmaceutical business sector than reliance on experts from a small number of companies.

This review has identified the key policy sources and emerging trends most relevant to my discipline which will be consulted when reviewing program and module outcomes. Recent recommendations by a range of business and government sources are consistent with respect to thematic areas and skills which need to be considered in HE science programs. Disparity between skills and competencies in policy and program outcomes has become apparent which need to be addressed. This review has highlighted the need to initiate program updates in the short term and provided me with the appropriate sources to justify changes and familiarity with recommended strategies to enable policy updates into programs. The information gathered can provide rationale for program revisions. The recommended strategies provide useful guidance to enable policy updates into programs on an ongoing basis and during future programmatic review. The responsiveness at which higher education programs incorporate revised policies appears to be at a slower rate than industry requires indicating supplemental program revision may be required as part of an ongoing program improvement process. The academic processes are in place to allow this to happen.

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