

Initial Regulatory Impact Assessment

Title: Future of Pharmacy Regulation in Northern Ireland	Regulatory Impact Assessment (RIA)
	Date: 22 March 2016
	Type of measure: Other
Lead department or agency: Department of Health, Social Services and Public Safety	Stage: Initial
	Source of intervention: UK
Other departments or agencies: N/A	Contact details: Workforce Projects
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Summary Intervention and Options

What is the problem under consideration? Why is government intervention necessary?

Pharmacy differs from other healthcare regulators in two key aspects: 1. Both the regulatory and professional leadership functions of the pharmacy profession in Northern Ireland are currently performed by the Pharmaceutical Society of Northern Ireland (the Society). This dual role is counter to modern thinking on regulation. 2. Pharmacy is the only healthcare profession which is not regulated on a UK-wide basis.

Pharmacy professionals are increasingly delivering patient focused care with a resultant emphasis on improving outcomes from the use of medicine through patient facing services, enhanced patient safety, collaborative working with other healthcare professionals and an increased focus on delivering care in the setting most suitable for patients and the public. Government intervention is necessary to achieve separation of these roles and to deliver modernised regulation of pharmacy which reflects the changing role of the profession.

What are the policy objectives and the intended effects?

The overarching objective is to deliver modernised and strengthened regulation of the pharmacy profession in Northern Ireland. Other objectives include: enhanced transparency and improved governance of regulation; enhanced public and professional confidence in the regulatory arrangements; modernised regulation aligned to changing pharmacy roles; and, more effective, efficient and proportionate regulation and enhanced public protection. Modernised regulation can also deliver future regulatory arrangements which better facilitate both the 'behaviour shaping' and 'overseeing' functions of a regulator.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)	
<p>i. Do nothing. The Society remains responsible for undertaking both the regulatory and professional leadership functions.</p> <p>ii. Separate the regulatory and professional leadership functions of the Society and establish a separate Northern Ireland-based arrangement for the regulation of the pharmacy profession.</p> <p>iii. Separate the regulatory and professional leadership functions of the Society and establish arrangements for the regulation of the pharmacy profession on a UK-wide basis.</p>	
Will the policy be reviewed? Within 3 years of final IA	If applicable, set review date: Not yet known

Cost of Options		
Total outlay cost for business £m	Total net cost to business per year £m	Annual cost for implementation by Regulator £m
To be fully established	To be fully established	To be fully established

Does Implementation go beyond minimum EU requirements?		NO X	YES <input type="checkbox"/>
Are any of these organisations in scope?	Micro Yes X No <input type="checkbox"/>	Small Yes X No <input type="checkbox"/>	Medium Yes X No <input type="checkbox"/>
			Large Yes X No <input type="checkbox"/>

Summary: Analysis and Evidence

Policy Option 1

Option 1 – Do nothing: The Society remains responsible for undertaking both the regulatory and professional leadership functions.

ECONOMIC ASSESSMENT

Costs

Costs associated with each option will be considered on an incremental basis (i.e. costs which might be incurred in addition to the current position).

Description and scale of key monetised costs by 'main affected groups'

The 'Do Nothing' represents the current cost and therefore it has a zero incremental cost. However, adoption of a status quo position will set in train a significant and ongoing legislative programme in support of modernisation which will ultimately require a commensurate level of investment.

Other key non-monetised costs by 'main affected groups'

The Society continues to perform dual regulatory and professional leadership functions. This dual role is counter to modern thinking on regulation. Significant potential exists for a lack of clarity amongst the public and other stakeholders regarding the regulator's core function which is protection of the public. Strong leadership, working independently but complementing the regulator, is the ideal outcome however with the 'Do nothing' option, the professional leadership function may become under-funded and underdeveloped.

Benefits

Description and scale of key monetised benefits by 'main affected groups'

No monetised benefits have been identified at this stage.

Other key non-monetised benefits by 'main affected groups'

Continuity of current regulatory service without disruption.

Continuing pharmacy regulatory arrangement which is focused on the local health care system.

Key Assumptions, Sensitivities, Risks:

This option fails to secure the aim of separation of regulatory and professional leadership functions. The Society's responsibility for professional leadership is potentially in conflict with its role as an independent regulator. There remains potential for a perception that professional self-interest may be prevalent and of a lack of independence between the regulatory and leadership functions.

Cross Border Issues

How does this option compare to other UK regions and to other EU Member States (particularly Republic of Ireland)

The Society remains the only one of the nine UK healthcare regulators which operates this dual, potentially conflicting, function. Pharmacy would remain the only healthcare profession not regulated on a UK-wide basis.

Summary: Analysis and Evidence

Policy Option 2

Option 2: Separate the regulatory and professional leadership functions of the Society and establish a separate Northern Ireland-based arrangement for the regulation of the pharmacy profession.

ECONOMIC ASSESSMENT

Costs
Description and scale of key monetised costs by ‘main affected groups’ Maximum 5 lines There would be transitional costs to separate the dual function; to establish and support a modern NI regulator and potential costs to establish a professional leadership function. The Society has projected that fees charged to pharmacy business owners (based on the planning assumption that the Society will undertake Inspections) will be the following: Registration Fee £590 (currently £113) and Retention fee £241 (currently £155). The projected retention fee for pharmacist registrants is £299. Projected costs will be developed further during and following consultation.
Other key non-monetised costs by ‘main affected groups’ Maximum 5 lines Close working between the regulatory function and the Department may at times make it difficult to retain sufficient and clear independence in working relations. A stand alone NI regulator must be adequately resourced in order to undertake its core responsibilities including inspection and legislation.
Description and scale of key monetised benefits by ‘main affected groups’ Maximum 5 lines No monetised benefits have been identified at this stage.
Benefits
Other key non-monetised benefits by ‘main affected groups’ Maximum 5 lines This option secures the Department’s fundamental policy aim that professional leadership and regulation should not be undertaken by the same body. It allows for a regulatory arrangement which is focused on the local health care system and one which can build upon existing networks. It provides an opportunity for strong and independent leadership voice to emerge.
Key Assumptions, Sensitivities, Risks Maximum 5 lines The relatively small size of a standalone regulator may give rise to concerns regarding sufficient capacity, resilience and sustainability.
Cross Border Issues
How does this option compare to other UK regions and to other EU Member States (particularly Republic of Ireland) Maximum 3 lines Pharmacy would remain the only healthcare profession not regulated on a UK-wide basis.

Summary: Analysis and Evidence

Policy Option 3

Option 3: Separate the regulatory and professional leadership functions of the Society and establish arrangements for the regulation of the pharmacy profession on a UK-wide basis.

ECONOMIC ASSESSMENT

Costs
Description and scale of key monetised costs by ‘main affected groups’ Maximum 5 lines Transitional costs to establish a UK-wide regulatory arrangement and to stand down the current regulatory arrangements. The projected retention fee for professional registrants is £250 with a UK-wide arrangement. Projected retention fee for premises is £241. All projected costs will be developed further during and following consultation. The Department and GPhC would consider relevant factors (including cost-effectiveness) associated with the possibility of holding fitness to practise hearings in Northern Ireland.
Other key non-monetised costs by ‘main affected groups’ Maximum 5 lines It is likely there will be some disruption in the transitional period whilst new arrangements are established.
Benefits
Description and scale of key monetised benefits by ‘main affected groups’ Maximum 5 lines Projected to be relatively cost neutral for pharmacy business owners. Projected retention for professional registrants is £250 within a UK-wide arrangement; projected at £299 for a NI arrangement. It is projected to be cost neutral for pharmacy technicians. All projected costs will be developed further during and following consultation. There may be some cost benefits as, arguably, a larger regulator could operate more efficiently in delivering the regulatory function.
Other key non-monetised benefits by ‘main affected groups’ Maximum 5 lines This option secures separation of functions. The public, registrants and business owners would be assured that pharmacy in NI is subject to UK-wide consistent standards. A UK-wide arrangement is more transparent and also likely to be more in line with public expectation, who may expect that pharmacists are subject to the same standards and regulatory processes across the UK.
Key Assumptions, Sensitivities, Risks Maximum 5 lines Any move to a UK-wide arrangement may give rise to concerns that Northern Ireland may lose some influence on shaping current and future regulatory policy.
Cross Border Issues
How does this option compare to other UK regions and to other EU Member States (particularly Republic of Ireland) Maximum 3 lines Pharmacy would become regulated on a UK-wide basis as is the case for all other healthcare professions.