Business Regulatory Impact Assessment

Title of Proposal

Review of the control of entry process for applications for inclusion on the pharmaceutical list to provide pharmaceutical services – The National Health Service (Pharmaceutical Services) (Scotland) (Miscellaneous Amendments) Regulations 2014

Purpose and intended effect

Background

In September 2013, the Cabinet Secretary for Health & Wellbeing announced an immediate review of the regulatory framework governing the pharmacy application process (also known as "Control of Entry") and the powers that allow NHS Boards to authorise or require GP Practices to dispense medicines and appliances to patients on their practice lists.

The intention of the review was to bring forward amended regulations that would best meet the needs of communities across Scotland – and in particular remote, rural and island communities. These amended regulations are set out in the National Health Service (Pharmaceutical Services) (Scotland) (Amendment) Regulations 2014 scheduled to come into force on 27 June 2014.

In summary, these amend the provisions for the "Control of Entry" application process by:

1) introducing "controlled localities" and a "prejudice test" for the purposes of considering pharmacy applications in remote, rural and island areas;
2) improving the arrangements for public consultation, community engagement and participation in the wider pharmacy application process;
3) improving engagement between the applicant and the Health Board at the outset of the process; and
4) introducing statutory timeframes for reaching decisions for both NHS Board Pharmacy Practice Committees (PPCs) and the National Appeal Panel (NAP).

Objective

The objective of further amending the NHS (Pharmaceutical Services) (Scotland) Regulations 2009 (the principal regulations) is to make the pharmacy application process more transparent and robust, and support stability and sustainability of local primary medical and pharmaceutical services whilst securing adequate provision of pharmaceutical services across Scotland.

We do not anticipate any significant increase in costs to Health Boards or applicants.

The key changes to the Principal Regulations will:

- Further strengthen the application process by making it more robust and transparent from the perspective of affected communities and "interested parties".
- Improve, and increase the emphasis on, public consultation, community engagement and participation by introducing new requirements for greater transparency in the public consultation processes by both the applicant and NHS Boards, as well as new requirements for community representation at key points of the pharmacy application process.
- Streamline the consultation process into one rather than the separate arrangements that currently exist for the Health Board and applicant.
- Promote the stability of NHS primary medical and pharmaceutical services in remote, rural and island areas through the introduction of "controlled localities" and a new additional legal test (the "prejudice test") that should be applied to pharmacy applications in these geographical areas.
- Improve the pharmaceutical care in GP practices that provide a dispensing service to patients on their practice lists.
- Allow health board Pharmacy Practices Committees (PPCs) to draw on independent technical advice and support from an appropriately trained legal assessor (ie an appropriately qualified person with relevant legal experience) during deliberations to help ensure that process and legal tests are properly adhered to and therefore to support the quality of decision-making, and
- Introduce statutory timeframes for reaching decisions for both NHS Board Pharmacy Practice Committees and the National Appeal Panel to improve the overall experience of the pharmacy application process.

Rationale for Government intervention

Since the Principal Regulations, the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009, were amended in April 2011 (SSI 2011/32) the "Control of Entry" framework has continued to be subject to criticism and scrutiny. This has been particularly so in relation to proposals to open community pharmacies in remote and rural areas served by GP practices who have historically been authorised, or required by the Health Board to provide dispensing services to patients on their practice lists.

In recent years the application, or approval, to open a pharmacy where there is an existing dispensing GP practice, has attracted high profile campaigning and lobbying to protect the dispensing GP practice concerned. It is strongly contended by dispensing GP practices and their patients that the income generated from dispensing medicines subsidises staff costs and other services offered by the practice, and the impact of opening a pharmacy would destabilise the viability of the practice and the healthcare hub they provide for their communities. The additional funding for providing a dispensing service within these practices is intended to remunerate for delivery of that service only.

Whilst the income GP practices receive for dispensing is not intended to subsidise the delivery of primary medical services, the Scottish Government considers that in

the circumstances it is reasonable that a degree of stability be provided for GP dispensing practices whilst the 10-year national work programme underpinning the delivery of *Prescription for Excellence* (http://www.scotland.gov.uk/Resource/0043/00434053.pdf) is developed and implemented.

There were also calls from MSPs and MPs from across rural Scotland to impose a moratorium on the pharmacy applications process due to the adverse impact that pharmacy applications were having on primary care services in these communities. This was not possible due to the constraints of primary legislation (the NHS (Scotland) Act 1978).

In addition to these concerns, the "Control of Entry" framework has also been criticised for a lack of transparency in process, as well as deficiencies in public consultation, community engagement and participation.

It is for these reasons that the Cabinet Secretary for Health & Wellbeing announced an immediate review of the regulatory framework in September 2013.

Consultation

Within Government

Discussions took place with colleagues in the Health Directorates to inform the consultation process. Discussions were also held with Health Board Directors of Pharmacy and Health Board Pharmacy Administration Leads.

Public Consultation

A full and open public consultation ran from 12 December 2013 to 20 February 2014, the purpose of which was to seek views from the public and a wide range of key stakeholders on a range of proposals, and to bring forward amendments to the Principal and 2011 Amended Regulations.

The principal purpose of the consultation was to ensure that the regulatory framework for pharmacy applications and related processes, and the powers which allow NHS Boards to put in place arrangements with GP practices to dispense medicines to their patients, remain fit for purpose.

The consultation responses were subsequently independently analysed and published on 30th May 2014 (http://www.scotland.gov.uk/Publications/2014/05/7116). The amendments build on the proposals tested during the consultation exercise.

Business

As above, a full and open consultation was held and this was sent to all pharmacy contractors and GP dispensers across Scotland.

The table below shows the distribution of consultation responses by category of respondent (a full list of respondents is contained at **Annex A**):

Category	**No.**	**%**
Individuals	34	40
NHS Board committees	13	15
NHS Boards	10	12
Representative or professional bodies	8	9
Pharmacy contractors	7	8
GP practices	3	4
MSP/MP	3	4
Community Council	2	2
NHS support organisations	2	2
Other	3	4
Total	**85**	**100**

Options

Following the consultation, two main options were considered.

1) **Do nothing – no change to current arrangements.** However this would retain the status quo and would not address the increasing criticism and scrutiny of the existing arrangements which are considered to be flawed.

2) **Amend regulations in line with the proposals tested during the public consultation exercise and the responses to those proposals.** This ensures a number of improvements can be made to make the "Control of Entry" framework more transparent and robust, and to support stability and sustainability of local primary medical and pharmaceutical services whilst securing adequate provision of pharmaceutical services across Scotland. It also ensures a greater emphasis and focus on public consultation, community engagement and participation. Overall, the consultation analysis report demonstrated broad support for the 11 proposals tested.

Sectors and groups affected

There is no effect on local authorities, vulnerable and equalities groups or organisations in the Third Sector. The amendments relate to improving and strengthening existing process rather than altering service provision.

Health Boards already prepare Pharmaceutical Care Services Plans (PCSPs). These new arrangements place greater emphasis on the effective use and maintenance of PCSPs and will facilitate early engagement between the Health Board and the applicant regarding the likely long term sustainability of the pharmaceutical services which the pharmacy contractor proposes to provide.

In addition, the Health Board and applicant are already required to carry out separate public consultation activity incurring separate costs and resource. The amended Regulations streamlines this consultation activity into a single joint exercise to be

conducted over a 90 day period. As a result, the outcome will be more transparent and robust.

The new arrangements also provide safeguards around the existing provision of NHS primary medical and pharmaceutical services in remote and rural areas to help support stability of these local NHS services in these geographical areas. Recent examples of pharmacy applications approved in these areas have resulted in the adverse impact on the security and sustainability of local primary medical services or increased costs to the health board concerned.

Benefits/ Costs

Option 1: Doing nothing would prevent us from fulfilling our objective of ensuring the application process is robust and fit for purpose, ensuring pharmaceutical services are adequately provided and sustainable across all communities in Scotland.

In doing nothing the application process would continue as normal with continuing criticism and risk of destabilising the disposition of service provision in remote and rural areas of Scotland where there are examples that this has led to increased costs and difficulties in recruitment and retention.

Option 2: Amending the Regulations as made improves the reputational status of the "Control of Entry" framework as transparent, balanced and with the NHS service needs of the community at the centre.

As indicated above, the Health Board and applicant are already required to carry out separate public consultation activity incurring separate costs and resource. The amended Regulations streamlines this consultation activity into a single joint exercise. Although ostensibly a joint exercise, consultation will be Health Board-led with the applicant contributing a proportion of the cost which will be agreed with the Health Board.

Scottish Firms Impact Test

The consultation on the potential amendments was widely distributed, including all pharmacy contractors and GP dispensing practices across Scotland and their representative bodies. All those parties that had an interest were therefore given the opportunity to comment on the proposals.

While responses to the consultation broadly supported the proposals made, consultation responses highlighted concerns expressed by the pharmacy contractors' representative body and the pharmacists' professional body. The main focus of concern was that the additional requirements for considering pharmacy applications in these areas could preclude a legitimate business opportunity or prevent patients from accessing the full range of NHS pharmaceutical services.

On balance, the Scottish Government considers that stability of NHS services and the needs of communities are paramount, rather than the potential business opportunities of pharmacy contractors. The priority is to have a "Control of Entry"

framework that provides a more balanced solution to address these competing interests.

Competition Assessment

There should be no competitive advantage to any particular individual or group as a consequence of the introduction of these amendment Regulations.

Test run of business forms

Forms will involve only minor consequential revisions as a result of the amended Regulations.

Legal Aid Impact Test

The Regulations do not introduce any new or additional right of appeal. However, people may still decide to seek advice on the operation of the amended processes, which they might already do in relation to the current process. Therefore, there will be no significant impact on the Legal Aid Fund.

Enforcement, sanctions and monitoring

NHS Boards have a responsibility to ensure that regulations are applied correctly and complied with. Application numbers will be monitored to consider the impact of the amendments following the implementation of the revised Regulations. Failure to comply with the amendment Regulations by applicants could result in failed applications whilst failure of the Board to comply could result in appeals or judicial reviews. Non compliance is not in the interests of applicants, Boards or the public.

Implementation and delivery plan

Health Board Pharmacy Practices Committees and the National Appeal Panel have a responsibility to ensure that revised regulations are implemented.

The Regulation amendments are being laid on 30th May 2014 to come into force on 27th June 2014. The implementation of these amendment Regulations will complement the Scottish Government's 10-year Vision and Action for pharmaceutical care in Scotland (*Prescription for Excellence* (http://www.scotland.gov.uk/Resource/0043/00434053.pdf), ensuring patients are able to make the best and safest use of medicines.

The amendments further support the ambitions of the Quality Strategy of person-centred, safe and effective care, and the 20:20 Vision of providing the best possible care and advice to patients and their families as close to home as possible.

The amended Regulations provide for transitional arrangements to allow for the new regulatory framework to become fully operational. This would allow for: the testing of national guidance; Health Boards to undertake preparatory work including the identification and determination of "controlled localities"; and for national and local training of the new arrangements.

Post-implementation review

The Regulations will be closely and regularly monitored by SG Health Directorates officials, and guidance modified to assist boards with the application and operation of the revised framework

Summary

The Scottish Government considers that the introduction of the National Health Service (Pharmaceutical Services) (Scotland) (Amendment) Regulations 2014 has the support of the majority of key stakeholders and will strengthen and improve the application process for entry to the pharmaceutical list.

We are satisfied that, once fully implemented, the new framework will be overall cost neutral as they set to reinforce and strengthen what is already expected of Health Boards and applicants. Any initial cost implications are justified by the expected benefits of improving the "Control of Entry" framework.

The Scottish Government is committed to ensuring the stability and sustainability of local primary care services, whilst securing the adequate provision of NHS pharmaceutical services across all communities of Scotland.

Declaration

I have read the Business and Regulatory Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Signed… …...

Date……28th May 2014 …

Alex Neil, MSP
Cabinet Secretary for Health and Wellbeing

ANNEX A

LIST OF RESPONDENTS

NHS Board committees

Aberdeen Community Health Partnership
NHS Ayrshire and Arran Local Medical Committee
NHS Fife Area Pharmaceutical Committee
NHS Fife Pharmacy Practices Committee
NHS Forth Valley Area Pharmaceutical Committee
NHS Forth Valley Local Medical Committee
NHS Greater Glasgow and Clyde Community Pharmacy Development Team and Pharmacy Practices Committee
NHS Greater Glasgow and Clyde Community Pharmacy Sub-Committee
NHS Highland Local Medical Committee
NHS Highland Pharmaceutical Committee
NHS Lothian Area Pharmaceutical Committee
NHS Scotland Directors of Pharmacy Group
NHS Scotland Pharmacy Administration Leads Group

NHS Boards

NHS Ayrshire and Arran
NHS Borders
NHS Dumfries and Galloway
NHS Forth Valley
NHS Grampian
NHS Highland
NHS Lanarkshire
NHS Orkney/NHS Shetland
NHS Tayside
NHS Western Isles

Representative or professional bodies

Boots Pharmacists' Association
British Medical Association
Community Pharmacy Scotland
Dispensing Doctors' Association
National Pharmacy Association Limited
Royal College of General Practitioners
Royal Pharmaceutical Society in Scotland
The Company Chemist Association

Pharmacy contractors

ASDA
Boots UK Limited
Celesio UK
Davidsons Chemist
Deans Pharmacy
Rowlands Pharmacy
The Co-operative Pharmacy
GP practices
Benbecula Medical Practice
Eyemouth Medical Practice
Glencairn Medical Practice

MSP/MP

Alison McInnes MSP & Rt Hon Sir Malcolm Bruce MP
Bruce Crawford MSP
Angus MacNeil MP

Community Councils

Newtonhill, Muchalls & Cammachmore Community Council
Tarves Community Council
NHS Support organisations
NHS National Services Scotland
Scottish Health Council
Other
B999 Health Trust
General Pharmaceutical Council
National Appeal Panel

Individuals

34 individual respondents