EXECUTIVE NOTE

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES) (SCOTLAND) AMENDMENT REGULATIONS 2011

SSI 2011/32

The above instrument was made in exercise of the powers conferred on Scottish Ministers by sections 2(5), 27, 105(7), 106(a) and 108(1) of the National Health Service (Scotland) Act 1978 and all other powers enabling them to do so. The instrument is subject to negative resolution procedure.

In accordance with the paragraph 24(1) and (3) of Schedule 7 to the Tribunals Courts and Enforcement Act 2007 the Administrative Justice and Tribunals Council and its Scottish Committee have been consulted.

Policy Objective

The National Health Service (Pharmaceutical Services) (Scotland) Amendment Regulations 2011 amend the provisions for the control of entry application process. The amendments follow the consultation *Review of the Control of Entry Arrangements* and the recommendations made in the subsequent summary report. The revised procedures will apply to applications for entry to the pharmaceutical list received on or after 1 April 2011

Regulation 3 amends Regulation 2 (Interpretation) of the Principal Regulations to add definitions for dispensing doctor and pharmaceutical care services plan.

Regulation 4 amends Regulation 5 (Pharmaceutical List) of the Principal Regulations to provide for an applicants consultation and assessment of the application, as detailed below .

Applicants Consultation

The amendments provide that an applicant, except where applying for a minor relocation or change of ownership, shall be required to seek views from the public within the area to which their application relates. This is for the purpose of assessing whether the neighbourhood has adequate provision of pharmaceutical services by persons on the pharmaceutical list of some or all of the pharmaceutical services that the applicant intends to provide. It should be completed within the 20 working days immediately prior to the making of the application. If the application is to open new premises, this should be advertised in a local newspaper circulating within the neighbourhood in which the applicant intends to provide services. If relocating, this should be advertised in the current premises. Advertising of the applicant's intentions should be for a continuous period of at least 20 days and in the case of a relocation, should make clear that the existing premises will close if the application is successful.

Applicant's Assessment

The amendments further provide for an 'applicants assessment.' The applicants assessment is for the purpose of ensuring the Board has sufficient information for making a decision on the application and will also help to show evidence of the commitment of the applicant .

Application Form A (for use by pharmacists/by persons other than pharmacists) and Form A(MR) have been replaced by Form A(1) and A(2). Form A(1) is to be used by anyone applying to either relocate (minor or other than minor) or to open new premises. From A(2) is to be used when applying to take over ownership of existing premises on the pharmaceutical list.

Application Form A(1) provides for the completion of the applicant's assessment whereby the applicant is asked specific questions to so as to provide sufficient detail information to inform the Board. Boards shall disregard already listed premises when an applicant is applying to relocate i.e. the premises to be relocated should not be considered as providing pharmaceutical services when considering adequacy, by those on the pharmaceutical list, in the area.

An application for change of ownership (Form A(2)) does not require an applicant's assessment.

The regulation also replaces the word 'appreciable' with 'significant' in relation to minor relocations which responds to some concerns that the previous wording stifled Boards' ability to grant minor relocations.

Regulation 5 amends Regulation 8 of the Principal Regulations amending wording relating to the revised Forms for the purpose of notifying Boards of information not previously given so that the applicant can be included on the pharmaceutical list and removed from the provisional list.

Regulation 6 amends Regulation 15 of the Principal Regulations so that Boards are obliged to publish Pharmaceutical Care Services Plans. Boards have to produce a new Pharmaceutical Care Services Plan annually to reflect changes in service provision or patient needs and inform potential interested parties of those.

Regulation 7 removes Schedule 2 of the Principal Regulations to be replaced with the Schedule set out in these Regulations, which contains the replacement forms.

Regulation 8 amends Schedule 3 in the Principal Regulations increasing the period in which the Board is required to give notice of the application to the Area Pharmaceutical Committee, the Area Medical Committee, any person whose name is on the pharmaceutical list, or provisional list, who may be significantly affected if granted, and any Board whose boundary is within 2 kilometres of the proposed premises. The period has been increased from 5 days to 10 days.

The amendment also requires that dispensing doctors in the neighbourhood where the application has been made are given written notification. This will ensure that they are aware from the outset that an application is to be considered by the Board and can discuss with the Area Medical Committee if they wish to do so.

Boards will now be required to publish decisions about applications on its website alongside the reasons for the decision. This will ensure the process is as open as possible and that potential applicants can consider whether previous applications have been made in a given area.

Grounds of appeal are clarified such that an appeal is available where the Board has erred in law in its application of the provision of the regulations or there has been; a procedural defect; a failure to properly narrate the facts or reasons upon which the determination of the application was based; or a failure by the Board to adequately explain the application of the provisions of the regulations to the facts stated. The Chair of the National Appeal Panel may dismiss an appeal if there are no reasonable grounds for appeal or the appeal is frivolous or vexatious. The role of the National Appeal Panel Chair is being strengthened such that they may remit the decision back to the Board for consideration if it is the opinion of the Chair that the appeal is process based, or remit the appeal onto the NAP if a point of law has been raised. This responds to concerns that the National Appeal Panel previously heard most appeals afresh and in so doing was becoming regarded as the main decision making body, rather than the Boards' Pharmacy Practice Committees.

Regulation 9 amends Schedule 4 of the Principal Regulations to amend the structure of the Pharmacy Practices Committee and the National Appeal Panel. These amendments are detailed below.

Pharmacy Practice Committees

The PPC shall continue to consist of 7 members unless the application is for premises in a neighbourhood or an adjacent neighbourhood to the location of a dispensing doctor, in which case an additional member will be appointed by the Board from persons nominated by the Area Medical Committee ensuring wider representation on the committee. The amendments also provide that only lay members are now entitled to vote reinforcing the independence of the decisions made. The non-contractor pharmacist shall no longer be nominated by the Royal Pharmaceutical Society but by the Area Pharmaceutical Committee ensuring consistency with appointments to the National Appeal Panel and reinforcing independence.

National Appeal Panel

Nominations for membership shall no longer be provided by the Royal Pharmaceutical Society Great Britain or by the general body of pharmacy contractors. Panel members will be selected from nominations put forward by the Board. The Scottish Ministers, following consultation with all Health Boards shall appoint a Chair. As appeals are to be more focussed on errors in law, the amendment regulations provide that the Chair shall be a an advocate, a solicitor or a solicitor-advocate but shall not be nor previously have been a health professional or an employee of a person on the pharmaceutical list. A substitute Chair will be appointed in the event that the Chair is unable to attend hearings.

The National Appeal Panel will now consist of 3 members, the Chair, a non-contractor pharmacist and a lay member, who is not nor has been a health professional. All members shall have the right to vote.

Financial Effects

It is expected that in time costs will reduce for NHS Boards as the revised application process is expected to reduce the number of speculative or frivolous applications and reduce the need for Boards to convene full Pharmacy Practices Committees.

Savings are also expected to be made by the Scottish Healthcare Service Centre (a division of National Services Scotland) who administer the National Appeal Panel.

Minor costs will be incurred by applicants for new pharmacies who will be required to advertise their intention to apply in a locally available newspaper to inform patients in a neighbourhood of their intention to apply and seeking their views. The cost associated with this will be minimal, likely to be in the region of £50-£100, dependent on the publication used.

SCOTTISH GOVERNMENT HEALTH DIRECTORATE
JANUARY 2011

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 – NHS (Pharmaceutical Services) (Scotland) Amendment Regulations 2011

Purpose and intended effect

Objective

The NHS (Pharmaceutical Services) (Scotland) Amendment Regulations 2011 amends the provisions for the Control of Entry application process and revises the membership of the Pharmacy Practice Committee (PPC) and National Appeal Panel (NAP) in the National Health Service (Pharmaceutical Services)(Scotland) Regulations 2009, the principal regulations. The objective of amending the regulations is to make the application process more robust, reducing frivolous and speculative applications whilst ensuring adequate provision of pharmaceutical services across Scotland. Cost to NHS Boards will be reduced if application numbers are reduced and there is expected to be cost savings for administering the NAP.

The key changes to the Regulations will:

- Strengthen the application process
- Reduce the number of apparently speculative and repeat applications
- Require applicants to complete an 'applicants assessment' as part of the application which will include them seeking views from patients in the area to which their application pertains
- Amend the structure of the Pharmacy Practices Committees (PPCs) and National Appeal Panel (NAP)

Background

The Scottish Government announced in 2009 that there would be a review of the Control of Entry arrangements. The review began over the summer of 2009 with meetings between Scottish Government Health Directorate officials and a number of NHS Boards as well as other key organisations, including Community Pharmacy Scotland (CPS), the Royal Pharmaceutical Society of Great Britain (RPSGB) and the Scottish General Practice Committee (SGPC) of the British Medical Association (BMA). The Scottish Government also subsequently wrote to all NHS Boards and a number of key organisations seeking initial views.

Rationale for Government intervention

The Regulations had remained relatively unchanged for many years. Given the length of time since the introduction of the Regulations there was a growing need to consider whether they were fit for purpose. This was further highlighted following a variety of comments from Boards regarding the increase in applications and the

number of repeat applications. Concerns were also highlighted over the initial PPC process being used as a 'test bed' to test the application for weaknesses prior to going to the NAP for consideration. The review of the process was introduced to ensure that the application process was fit for purpose ensuring that community pharmacies were situated in areas without current adequate access to pharmaceutical services, to improve the quality of healthcare experience received by the public.

Consultation

Within Government

Discussions took place with colleagues in the Health Directorate, NHS Boards and key stakeholders to inform the consultation process. Comments/concerns were raised about aspects of the current process and the subsequent costs to the NHS. Discussions were also held with the Administrative Justice & Tribunals Committee and colleagues in the Justice Directorate: Courts and Administrative Justice Team, regarding the appeals process

Public Consultation

A consultation ran from 22 March to 14 June 2010 with the purpose of seeking views from the public and a number of key stakeholders on a number of recommendations derived from the earlier discussions with stakeholders. The consultation and report can be found at www.scotland.gov.uk/Publications/Recent

Business

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

The responses to the consultation can be broken down into the following categories (A full list of respondents is contained at **Annex A**):-

Responses by group	**No.**
NHS Boards/ CHPs/ LAs	18
GPs/ AMCs/ GP interests	36
Individuals/ patients/ patient interests/ community councils	58
Pharmacy contractors/ pharmacists/ interests	24
Others	6
Total	**142**

Following the review of the consultation responses the Scottish Government is implementing regulatory changes relating to the application process, the requirement to consult with the public, the process by which applications are considered, the membership of the PPC which considers the application and the NAP which

considers any appeals following a PPC decision. A summary of the proposals can be found at **Annex B**.

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 is not consistent with the objective of reducing the number of speculative and repeat applications and in turn reducing costs to the NHS.

2) Amend regulations in line with the summary of responses. This ensures a number of improvements can be made including making the application process to be more robust. Amending the makeup of the PPC and NAP to ensure consistency of decision making. The regulation amendments will also ensure that the public are further involved in consultation by the applicant. This is consistent with the objectives of reducing repeat and speculative applications, reducing cost to the NHS as well as contributing to the Quality Strategy by ensuring patients have access to the best possible care and advice via access to a convenient community pharmacy.

Sectors and groups affected

There is no affect to local authorities, vulnerable and equalities groups or organisations in the Third sector. Anyone who wishes to apply to open a community pharmacy to provide NHS pharmaceutical services will have a minor cost implication in that they will now be required to seek views from the public locally through an advertisement in a local publication. However, this ensures the public are involved from the outset and ensures they will have the opportunity to make comment following the early notification of an impending application in the area. This will give them an early opportunity to offer their opinion about the provision of pharmaceutical services in their area. Dispensing GPs will also be advised of any applications made in the neighbourhood in which they operate.

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. In doing nothing the application process would continue as normal with a number of seemingly speculative applications being received requiring PPCs to convene and consider the application at considerable cost to NHS Boards.

Option 2: By amending the regulations as envisaged the application process will be more robust so that apparently speculative applications are minimised, reducing the requirement for the Boards to convene PPCs. This will reduce associated costs. The information provided in the application will better inform the PPC prior to making its decision. This better informed decision making process will in turn reduce the number of appeals considered by the NAP.

For the NAP to convene and consider an appeal can cost up to £6k. On average in the last 4 years, there have been 40 appeals at a cost of £240k per annum.

Following regulatory amendments, it is expected the number of appeals having a full appeal will reduce significantly.

Costs will be incurred by applicants who require to advertise in local publications informing the residents of the neighbourhood their intention to apply to open a pharmacy in the area. This cost however is minimal, in the region of £50 - £100 per notice, and ensures the public are made aware and included from the outset.

Scottish Firms Impact Test

The process which has resulted in the preparation of these amendment regulations started prior to the changes to the Business and Regulatory Impact Assessment process. However, the consultation on the potential amendments was widely distributed, including to every dispenser in Scotland. All those parties that had an interest were therefore given the opportunity to comment on the proposals. Responses to the consultation broadly supported the proposals made.

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 have been amended in discussion with contacts at NHS Boards who are involved in the application process as well as the Scottish Government's Principal Pharmaceutical Officer. Guidance will be provided prior to the coming into force of the Regulations to ensure applicants understand the requirements placed on them.

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

The intention to review the regulations was announced in 2009. Initial scoping exercises were undertaken with interested parties to gauge thoughts/ views to shape consultation. The public consultation published in March 2010 and closed in June.

NHS Boards PPCs and the SHSC: NAP has responsibility to ensure that revised regulations are implemented.

The overall aim is to reduce apparently speculative applications, make the application process more robust and reduce the number of applications sent to appeal. The regulation amendments are being drafted to be laid on 24th January to come into force from 1st April 2011. The implementation of these amendment regulations will help in our strategy for modernising pharmacy services; ensuring patients are able to make the best and safest use of medicines. The amendments further support the Quality Strategy and NHS Scotland's commitment to providing the best possible care and advice to patients and their families.

Post-implementation review

The regulations will be monitored over the next year by Health Directorate officials. In addition we are also considering a strategic review of the existing community pharmacy network which will be fully discussed with stakeholders prior to moving forward.

Summary

The Scottish Government considers that the introduction of the NHS (Pharmaceutical Services) (Scotland) Amendment Regulations 2011 has the support of key stakeholders and will improve the application process for entry to the pharmaceutical list. We are satisfied that the minimal cost implications are justified by the expected benefits and savings.

The Scottish Government is committed to ensuring access to all of the full range of pharmaceutical services.

Declaration

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair a reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the cost. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Signed…S Robison…...

Date……20 January 2011…

Shona Robison
Minister for Public Health and Sport

ANNEX A

LIST OF RESPONDENTS

16 anonymous respondents

AH Tod Ltd (Edinburgh)
Alan Beevers c/o Spynie Hospital, Patient Participation Forum (Elgin)
Alan Black
Alan Jones
Alan Kennedy
Ann McCarthy, Mrs
Anne Brown
Ayrshire and Arran Local Medical Committee (Kilmarnock)

Ballantrae Medical Practice (Ballantrae)
Balmullo Community Council (St Andrews)

Carol Finnie
Clan Chemists Ltd (Clydebank)
Colinton Pharmacy Ltd (Edinburgh)
Community Pharmacy Scotland (Edinburgh)
Cumbrae Medical Practice (Isle of Cumbrae)

Dalhart Pharmacy (Biggar)
David Baker
Dickies Pharmacy (Balmedie)
Dispensing Doctors' Association
Doreen Hopkins
Dounby Patients SOS Focus Group (Orkney)
Dounby Surgery (Orkney)
Dr RD Beveridge
Drymen Health Centre (Drymen)

Edinpharm Ltd (Edinburgh)
Eyemouth Medical Practice (Eyemouth)

Fife Area Pharmaceutical Committee
Fife Independent Disability Network (Kirkcaldy)
Fife Local Medical Committee ltd
Frances Daniels
Frank Maguire

Gareth Jones
George Taylor
Gerry McGarvey

Hector McKinnon
Hoy and Walls Health Centre (Orkney)

Ian Jarvie
Isle of Cumbrae Elderly Forum (Millport)

John and Jackie Paddison
John Woods

Katy Clark

L Kolatobwicz, Ms
Larbert Pharmacy (Larbert)
Leuchars Community Council (Leuchars)
Lothian Area Pharmaceutical Committee (Edinburgh)

Mark Sharp
Mary Ballantyne
Mary L Thomson
Michael Cook, Councillor, Scottish Borders Council
Milngavie Apothecary's Co Ltd (Linlithgow)
Morvern Medical Practice (Oban)

National Appeal Panel
National Appeal Panel (Vice Chair, Michael Graham)
National Pharmacy Association
Newcastleton Health Centre (Newcastleton)
NHS Ayrshire and Arran, Ailsa Hospital (Ayr)
NHS Borders (Melrose)
NHS Borders Public Partnership Forum
NHS Dumfries and Galloway, Chief Pharmacist (Dumfries)
NHS Fife (Kirkcaldy)
NHS Forth Valley, Carseview House (Stirling) Ian Mullen
NHS Forth Valley, Primary Care Contracts (Stirling) Evelyn Hadden
NHS Grampian PPC (Aberdeen)
NHS Greater Glasgow & Clyde (Glasgow)
NHS Highland (Inverness)
NHS Highland, Pharmacy Services (Inverness)
NHS Lanarkshire, Strathclyde Hospital (Motherwell)
NHS Lothian, Primary Care Contract Org (Edinburgh)
NHS Orkney, Balfour Hospital (Kirkwall)
NHS Tayside (Dundee)
NHS Western Isles, Griminish Surgery (Benbecula)

Pat Shields
Pharmacy Medicines Unit, Westholme Woodend Hospital (Aberdeen) Caroline Hind
Pharmacy Medicines Unit, Westholme Woodend Hospital (Aberdeen) Terry Mackie
Port Ellen Practice (Port Ellen)

Rhynie Medical Practice (Huntly)
Richard and Linda Lucas
Richard Fowles
Robert John Dronsfield

Royal College of GPs Rural Forum (UK)
Royal Pharmaceutical Society (Edinburgh)

Scottish Borders Council (Newtown St Boswells)
Scottish Borders Public Partnership Forum
Scottish Committee of the Administrative Justice and Tribunals Council (Edinburgh)
Scottish General Practitioners Council (Edinburgh)
Scottish Health Council (Glasgow)
Shebburn Surgery (Dumfries)
Shiskine Surgery (Isle of Arran)
South Aberdeenshire LCHP (Banchory)
South Lanarkshire Council (Hamilton)
Southend Medical Practice (Southend)
Stow and Lauder Health (Stow)
Strathard Community Council (Aberfoyle)

Tarves Community Council (Ellon)
Tesco(Pharmacy)
The Compant Chemists' Association (Falkirk)
The Medical Centre (Aberfoyle) Anne Lindsay
The Medical Centre (Aberfoyle) William Pollok
The Neidpath Practice, Haylodge Hospital/Health Centre (Peebles)
The Scottish Parliament, John Lamont
The Surgery (Arrochar)
The Surgery (Ecclefechan)
Thomas Gilchrist

Valerie Nailor

West Dunbartonshire Community Health Partnership (Dumbarton)
Western Isles Carers, Users and Supporters Network (Stornoway)
William McConnell

ANNEX B

SUMMARY OF PROPOSALS.

The Scottish Government intends to amend the process and Regulations in a number of areas:

The Application Process

- Revise the application forms requiring applicants to provide more robust information and evidence in support of their application.
- Introduce a requirement for applicants to complete an "*Applicant's Assessment"* of their application which will require that they provide information supporting the application.
- Require applicants to provide a statement of consent from the owner (or person legally in charge) of the named premises to make the application in the application form
- Require an applicant to state whether there has been an application which has been rejected in the previous 12 months, either by a Board Pharmacy Practice Committee (PPC) or by the National Appeal Panel (NAP). If so, require them to provide evidence in support of their application as to what has changed significantly since the previous application.

Notification of applications

- Require Health Boards to inform dispensing GPs and Community Health Partnerships (CHPs) in the relevant area/ neighbourhood.

Consultation re applications

- Production of clear information for the public to ensure they can make fully informed judgements about the process.
- Clarify the timescale which should be offered for public consultation.
- Clarify issues in relation to what regard the NAP should have to feedback from the public.

Consideration of applications

- Enable Boards to reject applications that fail to (a) provide the required information required by Regulations and (b) provide a sufficiently detailed or robust "Applicant's Assessment".
- Enable Boards to reject applications where they do not believe the evidence of "significant change" (since a previous application within 12 months) is sufficiently robust.
- Ensure Boards are aware that an oral PPC hearing may not be necessary in all cases.
- Make amendments to Regulations in relation to relocations including specifying that approval of a relocation will result in the alteration to the respective entry on the Board's pharmaceutical list.

Membership of Pharmacy Practice Committees (PPCs)

- Alter the nominations process.
- Include a nomination from the Area Medical Committee at PPC meetings where a dispensing GP practice may be affected as a result of the application.
- Issue refreshed guidance on a number of the issues including the training of PPC members, conflicts of interest and the potential use of standardised templates

National Appeal Panel (NAP)

- Reduce the size of the NAP and bring it into line with other tribunals
- Alter the nomination process for membership
- Ensure the NAP does not hear cases afresh but considers an appeal on the original case.
- Strengthen the ability of NAP to divert more cases back to the Board/ PPC
- Explore how NAP can provide further information back to Boards about appeals that are heard.
- Enable the NAP to seek information from Boards if felt necessary

Other issues

- Boards will be required to publish the outcome of PPC hearings as a matter of course.
- Require Boards to prepare Pharmaceutical Care Services Plan (PCSP) and enable the PPC to consider the PCSP where they are complete and published.