

Circulation list

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Dear Colleague

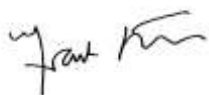
The Scottish Government is inviting responses to its consultation paper on the Control of Entry Arrangements relating to NHS Pharmaceutical Services. The consultation will begin on 22 March and end on 11 June 2010.

This consultation seeks views on various issues and proposals in relation to the current control of entry arrangements. The issues and proposals being considered have been raised in earlier discussions with key stakeholders.

If you would like further information about the consultation, please email: controlofentry@scotland.gsi.gov.uk or call 0131 244 2529.

We look forward to hearing from you.

Yours faithfully



FRANK STRANG
Deputy Director, Primary Care Division

Applications to provide NHS Pharmaceutical Services

Review of the Control of Entry Arrangements

Scottish Government, 2010

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CONSULTATION ON CONTROL OF ENTRY ARRANGEMENTS FOR INCLUSION ON THE PHARMACEUTICAL LIST

The Scottish Government is inviting responses to its consultation paper on *Control of Entry Arrangements for Inclusion on the Pharmaceutical List*. The consultation will start on 22 March and run until 11 June 2010.

Responding to this consultation paper

See **Annex A** for questionnaire/ response form.

We are inviting written responses to this consultation paper by 11 June 2010. Please send your response **with the completed Respondent Information Form** (see "Handling your Response" below) to:

ControlofEntry@scotland.gsi.gov.uk

or

Review of Control of Entry Arrangements
Scottish Government Health Directorate
Primary Care Division
1 East Rear
St Andrew's House
Regent Road
Edinburgh
EH1 3DG

If you have any queries please email as above or call 0131 244 2529.

We would be grateful if you would use the consultation questionnaire provided or could clearly indicate in your response which questions or parts of the consultation paper you are responding to as this will aid our analysis of the responses received.

The Scottish Government's Consultation Process

Further information is provided at **Annex C**

A list of bodies to which this consultation has been sent is provided at **Annex D**

This consultation, and all other Scottish Government consultation exercises, can be viewed online on the consultation web pages of the Scottish Government website at <http://www.scotland.gov.uk/consultations>.

The Scottish Government now has an email alert system for consultations (**SEconsult**: <http://www.scotland.gov.uk/consultations/seconsult.aspx>). This system allows stakeholder individuals and organisations to register and receive a weekly email containing details of all new consultations (including web links). SEconsult complements, but in no way replaces SG distribution lists, and is designed to allow stakeholders to keep up to date with all SG consultation activity, and therefore be

alerted at the earliest opportunity to those of most interest. We would encourage you to register.

Handling your response

We need to know how you wish your response to be handled and, in particular, whether you are happy for your response to be made public. Please complete and return the **Respondent Information Form** (see Annex B), included with this consultation paper, as this will ensure that we treat your response appropriately. If you ask for your response not to be published we will regard it as confidential, and we will treat it accordingly.

All respondents should be aware that the Scottish Government are subject to the provisions of the Freedom of Information (Scotland) Act 2002 and would therefore have to consider any request made to it under the Act for information relating to responses made to this consultation exercise.

Next steps in the process

Where respondents have given permission for their response to be made public and after we have checked that they contain no potentially defamatory material, responses will be made available to the public in the Scottish Government Library by 1 July 2010 and on the [Scottish Government consultation](#) web pages by 6 July 2010. You can make arrangements to view responses by contacting the SG Library on 0131 244 4552. Responses can be copied and sent to you, but a charge may be made for this service.

What happens next?

Following the closing date, all responses will be analysed and considered along with any other available evidence to help us reach decisions on what changes are required. We aim to issue a report on this consultation process by the autumn and make changes to Regulations as soon as is practicable.

Comments and complaints

If you have any comments about how this consultation exercise has been conducted, please send them in the first instance to the address details overleaf for the attention of Shelagh Scott

Respondent Information Form

Please complete the Respondent Information Form, which is provided alongside the questionnaire. **It must be returned with all responses.**

Introduction

1. The Scottish Government announced in 2009 that there would be a review of the Control of Entry arrangements. These are the arrangements that NHS Boards must follow when applications are made by people/ corporate bodies to offer NHS Pharmaceutical Services. There had been plans to review the arrangements for some time and comments from a number of NHS Boards as well as the comments and concerns relating to some specific applications were an additional driver for starting the review process.
2. The review began over the summer of 2009 with meetings between the Scottish Government Health Directorates 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. This paper builds on that activity and sets out proposals for a number of the issues raised. In some areas, further comments and contributions are sought.

Background

3. There are currently over 1,200 community pharmacies across Scotland providing NHS pharmaceutical services. They are based in the heart of communities, from rural areas to deprived inner-city areas. These pharmacies are often an essential part of life in those areas employing people locally.
4. Pharmacies are often patients' first point of contact, and for some their only contact, with healthcare professionals. With this in mind, Scottish Government policy remains that wherever possible, people across Scotland should have access to NHS pharmaceutical services via a community pharmacy. The community pharmacy arrangements are designed to meet the needs of the people of Scotland.

The Right Medicine¹

5. The Right Medicine, published in 2003, set out our strategy for modernising pharmacy services. Its main aim was to work in partnership both with other healthcare professionals and with patients, to ensure they make the best and safest use of medicines.
6. Pharmacists can and do make a unique contribution to improving patient care because of their in depth knowledge of medicines. They have a key role to play in ensuring health gain wherever medicines are used and provide care not just to patients but to the wider general public. The Scottish Government is committed to making the best use of pharmacists within the NHS to continue to introduce new pharmaceutical services to contribute to the quality and patient safety agenda.

¹ <http://www.scotland.gov.uk/Publications/2002/02/10633>

7. The Scottish Government believes that collaborative working wherever possible between GPs and pharmacists provide the best care for patients making the full use of their differing clinical skills and expertise.

Provision of pharmaceutical services

8. Any registered pharmacist or corporate body can open and run a pharmacy anywhere in the country provided it is registered with the Royal Pharmaceutical Society of Great Britain. This does not require permission from a Health Board. If the registered pharmacy wishes to provide NHS pharmaceutical services, it must seek entry onto the pharmaceutical list of that Health Board.
9. The 1978 Act² sets out the persons with whom a NHS Board may arrange the provision of NHS pharmaceutical services. Generally, arrangements may only be made with a registered pharmacist, or a person/ corporate body lawfully conducting a retail pharmacy business in accordance with the Medicines Act 1968³, who undertakes that medicines will be dispensed by, or under the direct supervision of, a registered pharmacist.

Current arrangements for considering applications

10. The arrangements made by Boards with community pharmacists must comply with Regulations made under the 1978 Act. Those Regulations (the National Health Service (Pharmaceutical Services)(Scotland) Regulations 2009⁴ - “the 2009 Regulations”) set out the ways by which persons can apply to provide NHS pharmaceutical services and set out the terms and conditions under which those services will be provided.
11. It is the role of the Board, in whose area the pharmacy is located, to administer the arrangements set up by the 1978 Act and related Regulations. This includes a requirement that Boards must prepare lists of the persons with whom they have made arrangements for the provision of NHS pharmaceutical services and the premises from which they will provide those services. The list that Boards prepare is known as their “pharmaceutical list”. An application for inclusion in the pharmaceutical list is essentially an application to provide NHS pharmaceutical services in the relevant Board’s area. The procedure for consideration of applications is set out in the 2009 Regulations and is explained in more detail below. These Regulations apply only to registered pharmacies that wish to provide NHS pharmaceutical services.
12. An application may only be granted if the Board’s Pharmacy Practices Committee (PPC) is satisfied that it is “necessary or desirable”⁵ to approve the application in order to secure the adequate provision of NHS pharmaceutical services in the neighbourhood in which the premises are located. Cases of ‘minor relocation’, or

² Section 28 of the 1978 Act

³ Section 69 of the Medicines Act 1968 (c.67)

⁴ SSI 2009/183

⁵ See section 27(3)(c) of the 1978 Act and regulation 5(10) of the 2009 Regulations

where a new provider applies to take over existing arrangements for the provision of services, are excepted from the control of entry rules.

13. It is important to note that whilst NHS pharmaceutical services are provided from commercial premises, the commercial aspects are not a consideration of the arrangements when NHS Boards are determining whether an application should be granted. Similarly, the effect on neighbouring pharmacies income is not a consideration. The arrangements focus on the adequacy of NHS pharmaceutical services that are provided to patients in the area and whether an application must be approved to ensure adequate provision is available.
14. On receipt of an application to which the control of entry rules apply, the Board must first notify a number of parties about the application. These parties include relevant local committees and persons already included in a pharmaceutical list whose interests might be affected if the application were granted. Certain of those persons are entitled to make representations to the Board and thereafter must be given notice of the Board's decision. Such persons and the applicant are entitled to appeal against the decision and those appeals are determined by an independent body - the 'National Appeal Panel'.
15. Under the current Regulations, there is no requirement for an NHS Board to notify a dispensing GP that there has been an application to open a pharmacy in the area. Whilst there is a requirement to inform the Area Medical Committee who represent all GPs in an area (and to whom any GP may offer representations), there has been some concern that this channel of communication doesn't always operate timeously.
16. The key aspect of the process is a legal test which has been a feature of the arrangements for over twenty years. The Board PPC must consider applications in line with this 'test'. In short, this requires the PPC to:
 - Identify the boundaries of the 'neighbourhood' in which the premises named in the application are located (this will vary greatly e.g. in a city this may only be a street or two whilst in a more rural setting, it could be a whole village(s));
 - Consider and agree whether the current provision of NHS pharmaceutical services in that neighbourhood is adequate and;
 - If the current provision is not adequate, consider and agree whether it is necessary or desirable to approve the application to ensure the adequate provision of NHS pharmaceutical services in the neighbourhood.

Volume of applications

17. As part of the pre-consultation activity last year, the Scottish Government requested information from Health Boards in relation to the number of applications they had received in recent years. Whilst a small number of the smaller Boards didn't respond, this activity suggests that there were just under 70 applications between the start of June 2008 and end May 2009, just over 70 for each of the previous two years and just over 50 between those months in 2005/06. The number of appeals submitted in each of the last four years has been around 40.

The Role of Pharmaceutical Care Services Plans

18. NHS Boards now prepare a Pharmaceutical Care Services Plan (PCSP) for their areas. These are intended to fulfil two main functions:

- To provide a comprehensive picture of the range, nature and quality of pharmaceutical care provided within the NHS Board area; and
- To identify needs and gaps in the provision of pharmaceutical care within the NHS Board area.

19. In time, we want to deliver an approach to considering pharmacy applications in Scotland which is based on local needs, perhaps relying on a Board PCSP. We will continue to consider further-reaching options for achieving this. In the meantime, we propose a number of changes to the current Regulations and arrangements to improve the procedures that are followed.

Provision of Dispensing GP Practices

20. Under the terms of National Health Service (Scotland) Act 1978 (“the 1978 Act”), NHS Boards (“Boards”) are required to make and administer arrangements for the provision of NHS pharmaceutical services as well as primary medical services to people in their area. They must assess the needs of patients based on their individual circumstances. It is for the Board to determine whether any patients will have serious difficulty in obtaining their medicines and to take steps to ensure they can receive that medication. Where a patient would have serious difficulty in having their prescribed medicines dispensed, Boards can instruct general medical practitioners (GPs) to dispense medication to patients.

21. There are currently around 130 dispensing GP practices in Scotland. Most are located in the Highlands and Islands, whilst the majority of the rest are located in Dumfries & Galloway, Grampian and the Borders. They account for around 12% of GP practices and around 3% of patients. Scottish Government supports the need for and recognises the importance of dispensing GPs in many rural communities. The need for the vast majority of such dispensing practices will remain unchanged.

22. Scottish Government remains clear that everybody should have access to the full range of NHS pharmaceutical services. We will continue to explore ways in which such services can be provided to patients alongside dispensing GP practices in areas where an NHS community pharmacy is never likely to be viable.

23. Scottish Government also believes that the skills and knowledge of the GP and of the pharmacist complement each other and together produce the best advice and care for patients.

24. Under the 2009 Regulations, when an application to open a new pharmacy is made, the Board’s PPC will consider the adequacy of the NHS pharmaceutical services provided in the area by pharmacy contractors on the pharmaceutical list,

any representations received by the Board and also any other information available which is considered relevant.

25. An application should be granted only if the PPC is satisfied that the provision of NHS pharmaceutical services at the premises named in the application is necessary or desirable in order to secure adequate provision. In terms of the 1978 Act, the fact that there is a dispensing GP in the area is not a factor which the PPC can consider.
26. Where a pharmacy application is approved in an area served by a dispensing GP, the Board would need to consider the issue again. They would need to decide whether any patients will still have serious difficulties in collecting their medication. Where they decide that a patient will still face serious difficulty, they may choose to instruct the GP to dispense to those specific patients.

Consultation Issues

Stakeholder views – pre-consultation activity

27. The Scottish Government wrote to stakeholders last year seeking comments on specific issues. Further comments are sought in this consultation process. In some cases, specific proposals are suggested whilst in others, further information is sought from stakeholders to help shape future proposals.

Summary

28. A number of general observations can be made in relation to the issues discussed as part of the activity undertaken. A number of proposals are being made to address these issues. They include:

- Stakeholders are concerned about repeated applications when a previous application, and possibly appeal, has been rejected and there is no material change in circumstances.
- Generally, the PPC process is considered to be robust when procedures are followed. However, processes and guidance should be reviewed to ensure they are implemented consistently across the country.
- There have been some comments seeking a review of the membership of both PPCs and the NAP.
- There are concerns that there is no requirement to ensure that Community Health Partnerships and dispensing GPs are notified as a matter of course when an application is made in a relevant area.

29. In other areas, Scottish Government does not intend to propose specific changes at this time. They include:

- Comments were offered in relation to potentially assessing the financial effect on dispensing GP Practices where an application is made to open a pharmacy in an area served by such a GP Practice. There was both support and concern in relation to making this part of the application process. Alongside such concerns however, such a change would require significant and substantial amendments across both primary and secondary legislation. The Scottish Government does not intend to take such a proposal forward.
- Consideration of multiple applications. A variety of concerns were raised in relation to this issue and whilst this proposal will not be taken forward at this time, this issue will be considered further in the future as part of longer-term activity on the provision of NHS pharmaceutical services more generally.
- A number of stakeholders suggested the potential introduction of fees for applications. There are currently no powers in Primary Legislation which would enable the Scottish Government to introduce such fees.

Consultation Proposals

Volume of applications/ repeat applications

30. A number of the comments received from stakeholders raised the volume of applications and repeat applications as an issue of concern and one which had associated costs both in terms of resources and time.

31. An increasing number of applications are referring to previous applications and some appear to apply simply because someone had previously thought there was a potential for success and a previous application had been made. A rejected application isn't seen as the end of the matter as applicants are happy to take the chance that another might be successful. Perceived inconsistencies in decisions give hope that a subsequent application or appeal may succeed. Some examples of the views offered include:

- *“Pointless to rehear [re-applications] when no obvious change”*
- *[The Board should] “only hear if there is substantial new evidence supporting the re-application.”*
- *“In the past 10 years, [we have had] 19 applications for the same premises although they have been rejected by the PPC and NAP every time”*
- *“Little point in reconsidering applications when nothing has changed.”*

Potential 'first stage' consideration of applications

32. A number of comments have been offered suggesting that there is a potential waste of public resources where applications must be heard in areas where a previous/ recent application has been considered and rejected and where there has been little or no changes to the area/ neighbourhood concerned. At the moment, even where an application is made in the same area and there has been no significant change, a Board must establish a full PPC to hear every application. In effect, if there has been no change to the neighbourhood, an applicant is simply hoping that the PPC - or subsequent NAP hearing - may approve an application where a previous one did not.

33. To aid with this and the process more generally, Scottish Government is considering the introduction of a first stage consideration of applications. As part of this, we have explored a number of options for giving Boards the ability to take into account a number of issues when considering 'adequate provision'. For example, we could give NHS Boards the ability to consider the time since a previous application was rejected and whether there have been any significant changes in the neighbourhood (as defined by the Board during the previous application) since then. The applicant could be asked to outline what significant changes had occurred in the time since a previous application was rejected on the grounds that there was already adequate provision.

34. Where there have been no such changes, this might suggest that there was still adequate provision and as such would be a relevant factor to be considered by the Board in determining whether that is the case.
35. Similarly, NHS Boards could be enabled to have regard to their Pharmaceutical Care Services Plan (PCSP) when considering the issue of adequate provision.
36. If a first stage in the process was introduced, this should remove the necessity for the establishment of a full PPC for every application, particularly those where application(s) have been made in the past. However, this process would be subject to appeal and any 'first stage' would have to make a reasoned, robust and defensible decision akin to that of a full PPC.
- 37. Views are invited on these issues/ proposals. Do you believe that an NHS Board should be able to consider applications at a first stage and decide whether or not a full PPC is required or whether they can decide that current provision is adequate?**
- 38. Whether or not a first stage is introduced, Scottish Government proposes to introduce an amendment which would allow NHS Boards to consider applications and/ or appeals which have already been rejected in a specified time period as a relevant factor when considering the question of adequate provision. Do you agree with this proposal?**
- 39. Do you agree that 12 months is an acceptable length of time (since a previous application was rejected/ failed at appeal) prior to which an applicant would be asked to establish that a significant change in the area/ neighbourhood had occurred?**
- 40. Scottish Government proposes an amendment to require Boards to consider their Pharmaceutical Care Services Plans as part of their consideration as to the adequacy of current NHS pharmaceutical services in an area. Do you agree with this proposal?**

Relocations

41. There is currently an exception in the arrangements whereby an application does not need to go through the full PPC process if the applicant states that it is a "minor relocation" and the Board judges that there would be "no appreciable effect" if it were approved.
42. Whilst around half of the comments we have received on this think the current arrangements are adequate, others offered clear concerns. Most of these concerns related to the fact that moves can only be considered as minor relocations where there is "no appreciable effect". A number of responses suggest that "appreciable" should be amended to read "significant" so as to allow some freedom to Boards to approve such relocations without the need for a full PPC. A number of stakeholders suggest that this will help to encourage improvements to service provision.

43. The Scottish Government proposes to alter the Regulations such that they refer to “no significant effect” and thus allow room for Health Boards to consider this freedom in more circumstances. Do you agree with this proposal?

44. Likewise, there was some unease that there is no current requirement that an existing pharmacy must close if relocation is approved. Addressing this would ensure that applications for relocations could be considered on the basis that the existing pharmacy would no longer exist; otherwise there are difficulties considering the adequacy of current services.

45. Scottish Government proposes to alter the Regulations such that where a minor relocation is approved, the existing entry on the pharmaceutical list will be amended, rather than result in a new entry. Do you agree with this proposal?

Notification of a pharmacy application

46. A number of comments received suggest some changes to this aspect of the arrangements. Some suggested that Community Health Partnerships (CHPs) should be notified whilst most that mentioned dispensing GPs suggested that those in the area where an application was made should be notified for their information. At the moment, the Area Medical Committee must be informed and they represent all GPs, including dispensing GPs.

47. The Scottish Government proposes to alter the Regulations to:-

a) ensure that dispensing GPs are informed of an application in the locality where they operate, and

b) ensure that CHPs are informed of applications.

Do you agree with these proposals?

48. There have also been comments in relation to the requirement of Boards to consult with the public. These comments include suggestions that the Scottish Government clarifies the timescales that should be offered by Boards when carrying out such consultation. Recent guidance has issued to NHS Boards from the Scottish Government to assist them in their engagement with the public (“Informing, Engaging and Consulting People in Developing Health and Community Care Services”). We would expect NHS Boards to consider and follow this guidance when consulting with the public in relation to applications to provide NHS pharmaceutical services.

49. The Scottish Government will continue to consider this and whether any other changes are necessary in the future. **Your comments are welcomed on the issue of public consultation.**

Membership of Pharmacy Practices Committees (PPCs)

50. The current membership of Pharmacy Practices Committee consists of seven members:

- One (the chair appointed by the Board) who must be a member of the Board but cannot be an officer of the Board and cannot be or have been a doctor, dentist, ophthalmic optician or pharmacist or the employee of a person who is a doctor, dentist, ophthalmic optician or pharmacist.
- Three will be pharmacists. One of whom cannot be on a pharmaceutical list and is not the employee of anyone on a pharmaceutical list and should be appointed by the Board from a list of people nominated by the Royal Pharmaceutical Society of Great Britain. The other two pharmacists must be included on a pharmaceutical list or be employed by someone on a pharmaceutical list and must be appointed by the Board from a list of people nominated by the Area Pharmaceutical Committee.
- Three shall be lay persons appointed by the Board. None can be members of the Board and none can be (or have previously been) a doctor, dentist, ophthalmic optician or a pharmacist, or an employee of a person who is a doctor, dentist, ophthalmic optician or pharmacist.

51. There have been mixed views in relation to the current membership of PPCs. There were some concerns from NHS Boards that although the PPC is a committee of the Board, there is not enough actual Board influence in the decision making process given that the Board member on the PPC can only vote where a decision is tied.

52. There have also been some questions raised as to whether specified professional/ contractor groups should be asked to offer nominations. A possible alternative that we are content to explore is to seek nominations from Boards to form a pool of PPC members.

53. The Scottish Government therefore intends to remove the need for PPC nominations to be sought from specified bodies/ contractor groups. Rather, we intend to alter the Regulations such that a pool of PPC nominations is populated by Boards. Do you agree with this proposal?

54. Likewise, a question was raised as to the necessity of the specific provision which requires that lay members must not be (or have been) health professionals. Indeed, it has been suggested that representation of another health profession could offer a helpful and complementary view of the decision being made. **Comments are sought on this issue.**

The statutory test – ‘necessary or desirable’ and related PPC processes

55. There was support for the issuing of updated guidance for use by Health Boards and their PPCs as well as for the possible introduction of forms/ proformas for use during meetings and to note decisions. Likewise, the need for regular

training and information sharing for those involved in PPCs was raised a number of times.

56. The Scottish Government will consider what guidance can be provided in light of responses to this consultation. We will also continue to explore those other related issues including training needs for PPC members and discuss this with Boards in due course. Comments are welcome on this.

Appeals Process – the National Appeal Panel (NAP)

57. A variety of concerns have been raised in relation to the NAP and the appeals process. Of note is the increased number of appeals being lodged and heard in recent years compared with previously. Whilst the most recent information available suggests that the numbers may be falling, it is too early to be certain. Whilst such an increase in itself would not be concerning as a right of appeal must exist, there is a perception that the balance in the process between PPCs and the NAP appears to have eroded. Appeals are by no means the exception which suggests there may be issues with the decisions and process being undertaken by PPCs. There is a perception that not all are being consistent in their approach and this can lead to procedural issues which in turn results in appeals.

58. A number of stakeholders have raised such concerns and most suggest that some applicants regard the NAP as the key mechanism through which to gain approval to open a pharmacy, rather than a PPC. Some add that in a number of cases a PPC hearing is used as a ‘test-bed’ to seek weaknesses in the applications and to better prepare for the appeal.

59. The Scottish Government proposes to strengthen the appeal process such that it can divert more applications back to the Board and, for example, request that they remedy any procedural issues. Do you agree with this proposal?

60. Furthermore, there have been questions about who should have the right of appeal. At the moment, the Regulations provide that the applicant and any ‘interested party’ (as determined in the Regulations and who previously offered written representations to the PPC in respect of the application) can appeal a decision. Whilst no respondents suggest that an applicant should lose their right of appeal, there is a question as to whether there should be a third party right of appeal as at present.

61. Indeed, given the fact that a Health Board PPC has considered it necessary or desirable to approve an application to ensure adequate NHS pharmaceutical services can be provided in a neighbourhood (where without it therefore, the implication is that the services offered were not adequate), it is not immediately clear to all stakeholders why a third-party should have the right to appeal that decision.

62. The Scottish Government proposes a change to the Regulations which would result in only the applicant themselves having a right to appeal the

decision of the Health Board/ PPC in relation to their own application. Do you agree with this proposal?

63. Initial feedback has also suggested that a structured means should be established so that regular feedback is made available by the NAP to Health Boards in respect of the reasons why an appeal was heard and the result of the appeal. Likewise, there were related suggestions about training for people involved in PPCs and NAPs. **These are items that Scottish Government will consider and which do not require Regulation amendments.**

64. Although the NAP considers the views and findings of the PPC via the minutes of those meetings, a number of stakeholders have suggested that a representative of the involved Health Board/ PPC could be asked to provide evidence in any subsequent NAP hearing. They could provide input in relation to how the PPC came to their decisions.

65. The Scottish Government proposes an amendment requiring the NAP to hear representation from affected Boards at NAP hearings. Do you agree with this proposal?

Membership of the National Appeal Panel (NAP)

66. The current membership of the National Appeal Panel consists of nine members:

- One is the chair and is appointed by Scottish Ministers
- One is the vice-chair who is also appointed by Scottish Ministers
- Four must be pharmacists. Two must be people whose names are, or who are employees of people whose names are, included on a pharmaceutical list. One of the four must be nominated by the Royal Pharmaceutical Society of Great Britain and the other three by an organisation which is recognised by the Scottish Ministers as being representative of the general body of pharmacy contractors (currently Community Pharmacy Scotland)
- Three shall be lay persons appointed by the Board. None can be members of the Board and none can be (or have previously been) a doctor, dentist, ophthalmic optician or a pharmacist, or an employee of a person who is a doctor, dentist, ophthalmic optician or pharmacist.

67. There have been varied comments in respect of the membership of NAP. For example, there have been suggestions that the membership of NAP is too large and this is a view with which we have some sympathy. Many other appeals/tribunal bodies are far smaller in number and such a large number (9 members with a quorum of 5) adds to the costs of the process and also make it more difficult to schedule hearings. Questions have also been raised as to the requirement that nominations are sought from professional or contractor organisations as is currently the case and the specific provision which precludes any other health professional (past or present) from being involved in the process.

- 68. The Scottish Government proposes to alter the composition of the NAP. We are minded to do this with a view to reducing the number of members and with a view to removing the need to seek nominations from individual organisations. Likewise, we are keen to explore the potential of the membership including wider representation, although the consideration will need to remain in relation to NHS pharmaceutical services. We would be keen to hear views on these proposals.**
69. There will always remain a need to involve pharmacists in the decision making process given their expertise. However, rather than seeking such nominations from individual organisations, an alternative might be to identify a pool of pharmacists using Health Board nominations. Clearly there will be a need to ensure that appropriate safe-guards are in place to avoid a situation where a pharmacist from a Board is asked to take part in an appeal in relation to their own or neighbouring board.

Consultation Response Form

Volume of applications/ repeat applications (paras 32-40)

37. Views are invited on these issues/ proposals. Do you believe that an NHS Board should be able to consider applications at a first stage and decide whether or not a full PPC is required or whether they can decide that current provision is adequate?

38. Whether or not a first stage is introduced, Scottish Government proposes to introduce an amendment which would allow NHS Boards to consider applications and/ or appeals which have already been rejected in a specified time period as a relevant factor when considering the question of adequate provision. Do you agree with this proposal?

39. Do you agree that 12 months is an acceptable length of time (since a previous application was rejected/ failed at appeal) prior to which an applicant would be asked to establish that a significant change in the area/ neighbourhood had occurred?

40. Scottish Government proposes an amendment to require Boards to consider their Pharmaceutical Care Services Plans as part of their consideration as to the adequacy of current NHS pharmaceutical services in an area. Do you agree with this proposal?

Relocations (paras 41-45)

43. The Scottish Government proposes to alter the Regulations such that they refer to “no significant affect” and thus allowing room for Health Boards to consider this freedom in more circumstances. Do you agree with this proposal?

45. Scottish Government proposes to alter the Regulations such that where a minor relocation is approved, the existing entry on the pharmaceutical list will be amended, rather than result in a new entry. Do you agree with this proposal?

Notice of a pharmacy application (paras 46-49)

47. The Scottish Government proposes to alter the Regulations to:-

- a) ensure that dispensing GPs are informed of an application in the locality where they operate, and**
- b) ensure that CHPs are informed of applications.**

Do you agree with these proposals?

49. The Scottish Government will continue to consider [public consultation arrangements] and whether any other changes are necessary in the future. Your comments are welcomed on the issue of public consultation. (Para 48 refers)

Membership of PPCs (paras 50-54)

53. The Scottish Government therefore intends to remove the need for PPC nominations to be sought from specified bodies/ contractor groups. Rather, we intend to alter the Regulations such that a pool of PPC nominations is populated by Boards. Do you agree with this proposal?

54. Likewise, a question was raised as to the necessity of the specific provision which requires that lay members must not be (or have been) health professionals. Indeed, it has been suggested that representation of another health profession could offer a helpful and complementary view of the decision being made. Comments are sought on this issue.

The statutory test – ‘necessary or desirable’ and related PPC processes (paras 55-56)

56. The Scottish Government will consider what guidance can be provided in light of responses to this consultation. We will also continue to explore those other related issues including training needs for PPC members and discuss this with Boards in due course. Comments are welcome.

Appeals Process – the National Appeals Panel (NAP) (paras 57-65)

59. The Scottish Government proposes to strengthen the appeal process such that it can divert more applications back to the Board and, for example, request that they remedy any procedural issues. Do you agree with this proposal?

62. The Scottish Government proposes a change to the Regulations which would result in only the applicant themselves having a right to appeal the decision of the Health Board/ PPC in relation to their own application. Do you agree with this proposal?

65. The Scottish Government proposes an amendment requiring the NAP to hear representation from affected Boards at NAP hearings. Do you agree with this proposal?

Membership of the National Appeal Panel (NAP) (paras 66-69)

68. The Scottish Government proposes to alter the composition of the NAP. We are minded to do this with a view to reducing the number of members and with a view to removing the need to seek nominations from individual organisations. Likewise, we are keen to explore the potential of the membership including wider representation, although the consideration will need to remain in relation to NHS pharmaceutical services. We would be keen to hear views on these proposals.



RESPONDENT INFORMATION FORM

Please **Note** That This Form **Must** Be Returned With Your Response To Ensure That We Handle Your Response Appropriately

1. Name/Organisation

Organisation Name

Title Mr Ms Mrs Miss Dr Please tick as appropriate

Surname

Forename

2. Postal Address

Postcode

Phone

Email

3. Permissions

I am responding as...

Individual

/ Group/Organisation

Please tick as appropriate

- (a) Do you agree to your response being made available to the public (in Scottish Government library and/or on the Scottish Government web site)?

Please tick as appropriate Yes No

- (b) Where confidentiality is not requested, we will make your responses available to the public on the following basis

Please tick **ONE** of the following boxes

Yes, make my response, name and address all available

or

Yes, make my response available, but not my name and address

or

Yes, make my response and name available, but not my address

- (c) The name and address of your organisation **will** be made available to the public (in the Scottish Government library and/or on the Scottish Government web site).

Are you content for your *response* to be made available?

Please tick as appropriate Yes No

- (d) We will share your response internally with other Scottish Government policy teams who may be addressing the issues you discuss. They may wish to contact you again in the future, but we require your permission to do so. Are you content for Scottish Government to contact you again in relation to this consultation exercise?

Please tick as appropriate Yes No

THE SCOTTISH GOVERNMENT CONSULTATION PROCESS

Consultation is an essential and important aspect of Scottish Government working methods. Given the wide-ranging areas of work of the Scottish Government, there are many varied types of consultation. However, in general, Scottish Government consultation exercises aim to provide opportunities for all those who wish to express their opinions on a proposed area of work to do so in ways which will inform and enhance that work.

The Scottish Government encourages consultation that is thorough, effective and appropriate to the issue under consideration and the nature of the target audience. Consultation exercises take account of a wide range of factors, and no two exercises are likely to be the same.

Typically Scottish Government consultations involve a written paper inviting answers to specific questions or more general views about the material presented. Written papers are distributed to organisations and individuals with an interest in the issue, and they are also placed on the Scottish Government web site enabling a wider audience to access the paper and submit their responses⁶. Consultation exercises may also involve seeking views in a number of different ways, such as through public meetings, focus groups or questionnaire exercises. Copies of all the written responses received to a consultation exercise (except those where the individual or organisation requested confidentiality) are placed in the Scottish Government library at Saughton House, Edinburgh (K Spur, Saughton House, Broomhouse Drive, Edinburgh, EH11 3XD, telephone 0131 244 4565).

All Scottish Government consultation papers and related publications (e.g., analysis of response reports) can be accessed at: <http://www.scotland.gov.uk/consultations>

The views and suggestions detailed in consultation responses are analysed and used as part of the decision making process, along with a range of other available information and evidence. Depending on the nature of the consultation exercise the responses received may:

- indicate the need for policy development or review
- inform the development of a particular policy
- help decisions to be made between alternative policy proposals
- be used to finalise legislation before it is implemented

Final decisions on the issues under consideration will also take account of a range of other factors, including other available information and research evidence.

While details of particular circumstances described in a response to a consultation exercise may usefully inform the policy process, consultation exercises cannot address individual concerns and comments, which should be directed to the relevant public body.

⁶ <http://www.scotland.gov.uk/consultations>

CONSULTATION DISTRIBUTION LIST

Clerk of the Health and Sport Committee
All Scottish MEPs
All Scottish MPs
SG Library
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Chief Executives NHS Boards
Chief Executives Special Health Boards
Chairs NHS Boards
Directors of Finance NHS Boards
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NHS Boards Chief Pharmacists /Directors of Pharmacy
Pharmacy Practice Committee Chairs
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All Scottish Local Authorities
All Scottish Pharmacy Contractors
Scottish General Practitioners Committee
Community Pharmacy Scotland
Royal Pharmaceutical Society Great Britain
General Medical Council
BMA Scotland
Dispensing Doctors Association
Health Service Commissioner for Scotland
National Appeal Panel Chair/Vice Chair
Scottish Healthcare Service Centre
NHS Education for Scotland
Administrative Justice and Tribunals Council
Scottish Health Council
Area Medical Committees
Area Pharmaceutical Committees
Commission for Equality and Human Rights

Members of Public who have expressed earlier interest