

## CONSULTATION RESPONSE FORM

### Consultation Proposals - Part 1

#### Control of Entry (Pharmacy Applications) and Dispensing GP Practices

#### The stability of NHS services in remote and rural areas

##### Proposal 1:

The Scottish Government proposes amending legislation that will introduce the designation of '*controlled remote, rural and island localities*' for the purposes of considering pharmacy applications in these areas of Scotland and introducing a 'Prejudice Test' in addition to the test of 'necessary or desirable' (the adequacy test).

Do you agree with this proposal?

Yes

No

Please tell us the reason for your answer in the box below

The proposals contained in this consultation and the background information accompanying them appear to have been written in such a manner as to suggest that dispensing practices need to be commercially protected from pharmacies. Given that both GP Practices and Community Pharmacies are both independent contractors to the NHS in Scotland we believe that this means that the regulations proposed would be anti-competitive, in breach of competition law and would prove, ultimately, to be illegal.

Furthermore, paragraph 1.21 states that commercial considerations are not part of the decision-making process for pharmacy applications. By apparently seeking to protect dispensing GPs from pharmacy applications commercial considerations are being introduced to the regulations. As indicated above, GPs are also independent contractors and therefore the statement that "NHS pharmaceutical Services are normally offered from commercial premises" should be clarified so that it is clear that this also includes dispensing doctor services.

In addition, paragraph 2.2 states that the money to provide the dispensing service is not meant to subsidise other services within the practice. If this is the case, the removal of dispensing rights when a pharmacy opens should not affect the medical operation of the GP practice at all. It is therefore curious why the Scottish Government is seeking to introduce further regulations to prevent pharmacies from opening and why GPs are so vociferous when a pharmacy application is made.

Nevertheless, we agree that it is sensible for a prejudice test to be introduced. However, without a clear definition of what the regulations will say it is difficult to be fully supportive of the proposal. Any prejudice test must only be in relation to GMS services offered and not the dispensing element of the practice.

We also believe that it would have been more beneficial to define what is meant by 'controlled remote, rural and island' in the consultation as the definition will affect our overall view of the proposal.

### **Proposal 2:**

**The Scottish Government proposes that the designation of an area as a ‘controlled remote, rural and island locality’ should be reviewed periodically by NHS Boards so that NHS provided or contracted services are responsive to population changes, and changing healthcare needs and priorities both locally and nationally. It is proposed that the review should be carried out at a minimum of every three years.**

**Do you agree with this proposal?** Yes  No

**Please tell us the reason for your answer in the box below**

This timescale fits with the PCSP requirement to be re-written every three years and is therefore compatible.  
We believe that a further requirement should be placed on Health Boards to annually check that all those on GP dispensing lists are eligible to be there – i.e. there are no patients within the 1.6km distance from a pharmacy on the list and receiving dispensing from the practice.

### **Proposal 3:**

**The Scottish Government is of the view that people living in remote, rural and island areas should have access to NHS pharmaceutical services and NHS primary medical services that are no less adequate than would be the case in other parts of Scotland.**

**Where the dispensing by a GP practice is necessary, it should be supplemented with pharmaceutical care provided by a qualified clinical pharmacist sourced by the NHS Board to ensure the person-centred, safe and effective use of the medicines. NHS Boards would be required to develop local plans sensitive to local circumstances to achieve this.**

**Do you agree with this proposal?** Yes  No

**Please tell us the reason for your answer in the box below**

We agree that all patients should receive pharmaceutical care.  
However, there are some significant problems with this suggestion as proposed:

1. If adopted, this proposal will place a pharmacist, in effect, in the dispensing practice. It could be argued that this will mean that the GP dispensary becomes a de-facto pharmacy and should therefore be registered with the GPhC. This proposal therefore creates a ‘back-door’ route to opening a pharmacy which we do not believe was the intention. Furthermore, it is unclear what indemnity arrangements would need to be in place or what the costs of it may be.
2. We do not believe a feasibility study has been conducted into this proposal, particularly one which includes a full cost-benefit analysis. For example;
  - a. How will the pharmacist gain access to patient records?
  - b. How much contact time will the pharmacist have with patients (particularly if they are peripatetic rather than practice based)?

- c. What are the travel costs associated with this position?
- d. Who will be the employer/what will the performance management structure be?

There are clearly a significant number of costs associated with this proposal and we believe that a full costing needs to be carried out.

## **Consultation Proposals - Part 2**

### **Wider Pharmacy Application Processes**

The proposals discussed in Part 2 apply to all applications to open a community pharmacy whether in a remote, rural or island area, or in other parts of Scotland.

#### **Public consultation and the community voice**

##### **Proposal 4:**

The Scottish Government proposes that the regulatory framework going forward will look to include a community representative among those who should be notified, as an ‘interested party or persons’, of any application to open a community pharmacy in the locality. The community would therefore in statute be considered as a body or party whose interests may be significantly affected by the pharmacy application.

This would be a nominated representative from, for example, the local Community Council or the local Residents Association or another appropriate local community representative body recognised by the NHS Board.

As an ‘interested party’ the community representative would be entitled to make written representations about the application to the Board to which the application is made within 30 days of receipt of the Board’s notification of the application.

In addition, where the NHS Board PPC decides to hear oral representations, the community representative will be entitled to take part, together with the applicant and the other interested parties, and would be given reasonable notice of the meeting where those oral representations are to be heard. Once each interested party, including the community representative, has presented their evidence in turn they would then leave the hearing leaving the PPC to consider all the evidence presented.

As an ‘interested party’ the community representative will also have a right of appeal against the decision of the NHS Board PPC to represent the views of the local community.

Do you agree with this proposal? Yes  No   
Please tell us the reason for your answer in the box below

Currently, patients have a number of routes to have their voices heard. These include responding to the newspaper advertisements placed by applicants, where councils are notified of an application via their elected representatives and, on the PPC itself, through the presence of lay members. We therefore question whether further patient representation is needed and, if it is, what the role of the lay members of the panel is.

If a decision is taken to increase patient representation by having a community interested party representative then a number of issues must be considered:

1. The representative will need to have been briefed on the pharmaceutical regulations and the processes and procedures that are part of them. Pharmaceutical applications processes are complex and if the community representative is unaware of the procedures then there may be significant disruption at hearings.
2. Consideration needs to be given regarding how the community representative is chosen. The community representative should be someone who is not politicised, who can see a fair and balanced view of the application and is suitably independent of any applicants or other interested parties (including dispensing GPs). Equally, they need to be able to gather the views of their neighbours and be able to deliver them in a coherent and articulate manner.
3. Many patient representatives will always say that they would like to see a pharmacy in a particular area without understanding the costs associated with that desire. Efforts therefore need to be made to describe the costs to the NHS in Scotland to any community representative so that they are properly informed of the implications a new pharmacy may have on the NHS.

We do not believe that it is appropriate to give the community representative rights of appeal. In virtually all cases, the right of appeal is restricted to errors in legal process. It is highly unlikely that the community representative will challenge the legality of a decision and therefore it is unnecessary for them to have appeal rights.

### **Proposal 5:**

**The Scottish Government is of the view that in the future PPC hearings should be handled in such a way so that no one person or organisation is able to dominate the entire hearing. This might include options such as limiting the time allocated to give oral representations or the issuing of guidance to PPCs. The Scottish Government thinks that all PPC meetings in future should follow a standard process in the management of PPC Hearings.**

**Do you agree with this proposal?**

**Yes**

**No**

**Please tell us the reason for your answer in the box below**

There is already a clear procedure which describes how PPC meetings are conducted. A strong chairman will ensure that all parties have the opportunity to make appropriate representations and will prevent unnecessary discussion. However, we agree that imposing a time limit on participants, which reflects the number of participants attending, may be appropriate for the sake of expediency.

**Proposal 6:**

The Scottish Government proposes that going forward those assisting in oral representations by the applicant, the community and other interested parties in attendance are able to speak on behalf of those they are assisting.

Do you agree with this proposal? Yes  No

Please tell us the reason for your answer in the box below

This brings the Scottish regulations into line with those elsewhere in Britain.

**Proposal 7:**

The Scottish Government proposes that going forward those applying to open a pharmacy, for the purpose of providing NHS pharmaceutical services, should first enter into a pre-application stage with the NHS Board to determine whether there is an identified unmet need in the provision of NHS pharmaceutical services.

This would assist NHS Boards in determining the urgency of the demand for NHS pharmaceutical services identified by the applicant. NHS Boards Pharmaceutical Care Services Plans would need to reflect an assessment of service gaps and where need is most urgent.

Where an application proceeds, the applicant must be able to provide evidence to the NHS Board and the affected communities that every effort has been made to publicise the intention to open a community pharmacy and to consult and obtain responses from residents in the associated neighbourhood. Also, the notice must be advertised in a newspaper and all circulating local news free-sheets and newsletters in the neighbourhood in order to reach the vast majority of residents.

NHS Boards will also be required to do the same level of advertising in relation to its consultation activities.

Do you agree with this proposal? Yes  No

Please tell us the reason for your answer in the box below

**Pre-Application Stage**

The implication of this proposal is that if no identified unmet need has been found then the application will not proceed. We believe, again, that this could represent anti-competitive practice on the part of the Scottish Government. Furthermore, if decisions are being made against PCSP then these must be robust documents that have been subject to public and interested party scrutiny and for which there is a robust appeals process. It is our understanding that these provisions are not currently within the regulations.

If the PCSP is accurate and publicly available then unmet needs will be obvious and the need for this stage of the process is unnecessary. Implementing this proposal would have the effect that any innovation in service delivery would be blocked and any applications which seek to meet a need which may occur in the future would also be prevented.

### **Advertising**

This element of the proposal is unworkable as currently described. There are a number of fundamental flaws with the proposal including:

1. What is the definition of a free-sheet? Does it include the gardening club, Women's Institute, school or cub-scout newsletters? The extent of this definition will govern whether the suggestion is workable or not.
2. What would happen if the advertisement was placed in six free-sheets but a seventh was overlooked?
3. What geographic area should the advertisement cover? The distribution will vary between city and rural environments and it would be inappropriate for a consultation notice for an application in Renfrew to have to be placed in papers covering the whole of Glasgow.
4. Publication dates of free sheets and newspapers will vary. Some will be daily, weekly, fortnightly, monthly and even quarterly. This may mean that applicants cannot fulfil this element of the regulations within the regulatory time-period for the advertisement to be placed and the results to be sent to the Health Board.

This proposal simply adds cost into the application process for no appreciable benefit. If asking the public for their comments on an application is considered to be fundamental it may be better for applicants to pay a fee and either the Health board or Community Council use that money to conduct the survey. In this way the results could be seen to be more independent than is currently the case.

### **Proposal 8:**

**The Scottish Government proposes that going forward NHS Boards specify to what extent the views of the community have or have not been taken into account in their published decisions on the outcome of a pharmacy application.**

**Do you agree with this proposal?**

Yes

No

**Please tell us the reason for your answer in the box below**

This proposal needs to be clarified as it is not clear what the outcome may look like. If the intention is that, within decision notifications, there is reference made to the comments that the public have made we would have no issue with this proposal provided that public comments are equally weighted with the other regulatory requirements.

### **Securing NHS pharmaceutical services**

### **Proposal 9:**

**The Scottish Government considers that NHS Boards should be able to take into account how NHS pharmaceutical services would be delivered in practice in the long term after an application has been received. This includes taking into account the financial viability of the pharmacy business proposed. This is an important factor in securing these services in the long term.**

**Do you agree with this proposal?** Yes  No

**Please tell us the reason for your answer in the box below**

We question the ability and legitimacy of this proposal:

1. We question what capacity there is at Health Boards to be able to undertake an assessment of financial viability. Many NHS employees will be unaware of the complexities of financing and running a commercial business and therefore we do not believe that the Health Board will be properly resourced to undertake this activity.
2. It is unclear what criteria will be used in making the assessment. For example, is financial viability to be assessed on NHS income or NHS and non-NHS income? If the latter we believe that this is outside the remit of the Health Board.
3. How will financial viability be measured? Will it be based on the individual contract or the body corporate as a whole? The viability of an application by Rowlands Pharmacy will be very different to that of a sole trader. How will this distinction be made?
4. What is the definition of long term? Is it 1 year, 5 years, 10 years, 20 years? When determining budgets and other financial models for new pharmacies it is notoriously difficult to get even the first year correct let alone what might happen in 5 years time (or more).

### **Timeframes for reaching decisions**

#### **Proposal 10:**

**The Scottish Government proposes that going forward the regulatory framework would require NHS Board PPCs to make a decision within 6 weeks of the end of the public consultation process and the NAP to make a decision within 3 months upon receipt of an appeal (or appeals) being lodged.**

**In more complex cases the timeframe would be made extendable where there is a good cause for delay.**

**Do you agree with this proposal?** Yes  No

**Please tell us the reason for your answer in the box below**

We agree with this proposal but have three suggestions to enhance it:

1. There should be a definition of what a 'complex case' actually is.
2. Time-scales must also apply to re-hearings by PPC if they have been sent back to them by the National Appeals Panel.
3. Where an application has been sent back to the PPC once, has been re-heard and appealed again (and the appeal has been upheld), the NAP must hear the application as there are clearly problems at the PPC preventing them from hearing the case properly.

### Expert advice and support to PPCs during deliberations

#### Proposal 11:

**The Scottish Government proposes that going forward the regulatory framework would make provisions for the appropriate role of an independent legal assessor acting in a supporting and advisory capacity, including providing advice and guidance on technical and legal aspects of the application process during PPC deliberations.**

Do you agree with this proposal?

Yes

No

**Please tell us the reason for your answer in the box below**

One way to control costs may be to have the chairman be a legally qualified person – this would avoid both chairman and legal assessor costs.