

## CONSULTATION RESPONSE FORM Pharmacy Administration Leads Group (PALG)

### 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?

No

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

This proposal assumes that the GMS contract introduced in 2004 as an interim model is still appropriate in 2014, but if that is the case then the introduction of a 'Prejudice Test' would be welcomed as it is recognised that there will always be certain locations where a community pharmacy business would not be sustainable. In such locations dispensing GPs are needed and require a degree of security.

However, the use of the designation '*controlled remote, rural and island locality*' requires careful consideration and the PALG disagree with this classification. We would strongly suggest that a more appropriate designation would be '*controlled locality*'. There are many pharmacies providing pharmaceutical services in localities which are remote, rural and island. In addition there are remote, rural and island locations where there may be a need for a community pharmacy and where an application would not impact on other NHS provided services provided by dispensing GPs.

It should be the responsibility of Boards to identify their '*controlled localities*' taking into consideration population spread and numbers, geography, access to services and the sustainability of a community pharmacy in that area, not just because the location is remote, rural and island.

Consideration should be given as to whether the introduction of a "Prejudice Test" could automatically debar applications at the initial stage without considering the benefits to patients who would access pharmaceutical care service. Options for consideration could be satellite clinics, partnership working, remote robotic dispensing and shared premises.

##### 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?

No

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

The PALG disagree with the proposal of a three year review.

If the *"controlled locality"* concept is to be a fundamental part of the application process then the review period should be aligned with the Pharmaceutical Care Services Plan, which is reviewed annually.

An annual review would ensure that the service remains responsive to patient need and adopts a more proactive approach to managing the situation whilst ensuring the ongoing provision of GP dispensing services where they are needed, taking into account the requirements of "Prescription for Excellence"

### 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

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

All people should have access to NHS pharmaceutical and primary medical services that are no less adequate than would be the case in all parts of Scotland. We agree that where there is a GP dispensing service this should be supplemented with pharmaceutical care in line with patient need.

The introduction of clinical pharmacists, providing pharmaceutical care as described within "Prescription of Excellence" is to be welcomed but this is very ambitious and would incur additional Board costs with no clear sources of funding. The PALG suggest that this care could be undertaken by all pharmacists although clearly

defined standards would be needed for both the pharmaceutical care provided by the pharmacist and also for the dispensing service provided by the GP practice, and how the two services work together.

There should also be pharmacist input into the governance arrangements for the safe and secure handling of medicines in dispensing practices.

It may be appropriate to consider pharmaceutical care being delivered remotely from a community pharmacy in another location by using available technologies e.g. Face Time or Skype.

## **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?**

**No**

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

Although the PALG agrees with this proposal in principle it is difficult to see how this could be implemented in practice and may not provide the PPC with a representative view from the community.

On receiving an application for a new contract, Boards are required to undertake a consultation exercise and at the time of application, the "neighbourhood" has not been defined as this is a matter for the PPC to do at the time of the oral hearing.

It is therefore necessary for the Board to ensure that the scope of the consultation is sufficient to include those who may have an interest in pharmaceutical services in the wider neighbourhood relative to the proposed pharmacy.

There are various methods used by Boards to determine who should be consulted but typically the consultation involves multiple stakeholders including, but not restricted to:

- elected representatives;
- community councils;
- PPF Groups located within CHP/CHCPs.

It is often necessary to consult over a wide geographical area and some areas have many community councils and community groups. It is our experience that these different communities can hold strongly opposing views, but often without a clear regard or understanding of the Regulations regarding contract applications or an obvious individual to represent them all.

However if this proposal is implemented then it is our recommendation, although with some reservations that an elected member of the local authority council in the proposed neighbourhood would be called upon to represent the views of the community. Generally local councillors have been better able to understand the Legal Test and the workings of the PPC and do receive feedback directly when applications are received.

We consider that it may not be possible to identify all community groups who consider that they have views that should be taken into consideration and that the omission to include a community group in the consultation process may be cited as a reason for appeal. Hence the consultation methodology would have to be clearly defined within the Regulations.

We consider that any process to select community representatives would have to be transparent and subject to strict governance and to avoid any perception of bias Boards must not be involved in the selection of community representatives. The methodology applied to identify and select community representatives would also have to be clearly defined within the Regulations.

In addition we feel that as an 'interested party' the community representative having 30 days to make written representations about the application to the Board is unrealistic and 60 days would be more appropriate.

**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?**

**No**

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

Every party attending an oral hearing of a PPC should feel confident that they have received a full and fair hearing. Limiting the time for contributions may be prejudicial to the applicant and interested parties in presenting their perspective and may give grounds for appeal so this proposal would need to be built into the Regulations for our answer to be 'Yes'.

Our experience has shown that the issues raised at pharmacy applications can be complex and contentious and these require to be fully explained. Applicants who are familiar with the process recognise the dangers of losing the focus of their arguments with a long presentation and adopt a concise approach. We would also recognise that in the case of other applications, the arguments cannot be condensed and longer presentations are necessary.

Placing a time limit on a presentation could be cited as a reason for appeal if the aggrieved party considers that they had been disadvantaged, and in the past appeals have been upheld by the NAP for this reason.

It is however recognised that some hearings can be dominated by the interests of a single party and as such we agree that it is in the best interests of all involved for such situations to be avoided. We feel however that this can be addressed through the development of national guidelines for PPC Committees, applicants and interested parties. This would need to clearly define how PPCs are conducted and, for example allow the Committee to deal with unnecessary repetition in a fair and appropriate manner. There would be a requirement for additional training for the Chair and PPC members.

**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**

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

The current restriction produces an artificial barrier to communication in the oral hearing and this change should facilitate a smoother and speedier flow of responses from the interested parties. However, it would be necessary to clearly define the roles of the principle and assisting representative.

For practical reasons and in the interests of brevity, we consider that only one nominated representative of each applicant/interested party should be permitted to present their case to the Committee. We consider that it would be appropriate to permit the other representative to speak during the questioning part of the Hearing.

We would also suggest that the Regulations continue to preclude the involvement of a solicitor, counsel or paid advocate from addressing the PPC. No party should have an advantage due to the level of assistance they are able to enlist for the hearing.

**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?**

**No**

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

We consider that it would be wholly inappropriate for Board officers to be involved at the pre-application stage unless this requirement is built into the Regulations. The consideration of applications is currently a matter for the PPC, not the Board officers who must administer the process of applications in transparent way that is

seen to be fair to all parties. Any discussion between Board officers and potential applicants has to be strictly limited to the provision of guidance on the application process.

The participation of Board officers at a pre-application stage to discuss the merits or otherwise of the case may not be consistent with the view taken by the PPC when considering the application at the oral hearing, and could expose these officers to accusations of bias.

We consider that it is not appropriate for Board officers to have the ability to halt an application on the basis of their view that there is no unmet need.

In the interests of fairness, we would contend that interested parties should have the same opportunities as those afforded to applicants in respect to the pre-application stage and that this would be unmanageable.

Any views expressed by Board officers to an applicant could be cited as evidence at a hearing and may put the PPC in an invidious position if they took a different view to that of the Board officers.

It also should be noted that the relevant Board officers may not be present at the hearing to verify or clarify statements attributed to them.

It should be noted that in the past, the NAP has determined that the presence of Board officers at the "closed session" of the PPC was "a breach of natural justice" citing that their presence might be construed as bias or the suggestion of bias and should be avoided at all costs. We consider that the NAP will take a similar view to the involvement of Board officers at the pre-application stage unless this process is part of the Regulations with clear definitions of what is required from the Board.

In respect of the second element of the proposal, it would be extremely difficult to show that a notice had been advertised in "all "publications" circulating in a community. This information is not routinely held in a central location and it would be highly unlikely that an applicant, or the Board, would have information on all the local news free-sheets and newsletters in circulation in a neighbourhood. In addition, the omission to include a notice in a publication could be cited as a reason for appeal.

The use of the term "neighbourhood" in this proposal is confusing as this has a specific meaning within the Regulations. The neighbourhood is a matter for the PPC solely to determine at the Hearing and not for Board officers to prejudge.

Any requirement on Boards to advertise applications must be clearly defined within the Regulations.

In terms of the proposal that "NHS Boards will also be required to undertake the same level of advertising in relation to its consultation activities". Since the introduction of the provision that Boards should consult with the public, some Boards have advertised in the press, at considerable cost, but have experienced little response from either community groups or members of the public. In addition, we believe that this proposal could lead to duplication and significant cost. If the applicant and the Health Board were to advertise in the same publications there is a concern that those members of the public who choose, would respond only to one advert and not both.

The suggestion does not reflect the current use of social media resources. Consideration should therefore be given to using the latest news section of NHS websites, Twitter and Facebook.

The applicant should have to convince the PPC that they have taken sufficient and appropriate steps to gauge public opinion e.g. a representative public survey in addition to the advertisement as currently required. This should be tailored to the community in question and not restricted by Regulation.

**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**

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

We recognise the importance of clear and accurate reports of PPC decisions and would support the development of national guidance on this matter.

We would contend, however that the views of the community should not be subject to different or additional consideration from the views of the applicant and the interested parties.

We would also support further consideration of the process regarding the applicant's public consultation exercise.

At present, the applicant is only required to provide a summary of the responses received in response to their public consultation exercise.

To avoid the perception of bias, we would recommend that all responses should be sent to the Board instead of the applicant.

If there is any change to allow public opinion to influence the PPC decision, then where public opinion has been influenced in a prejudiced way this needs to be able to be taken into consideration and it is important that it is clear to the public what the decision was based on.

**[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?**

**No**

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

It is the opinion of the PALG that assessing the financial viability of a community pharmacy business requires specific business and financial expertise that the members of the PPC do not have.

The current application process does not require the applicant to provide financial or business information and financial viability doesn't just depend upon NHS business but on other business such as OTC sales e.g. a large retail pharmacy will not be so dependent upon NHS business.

In any case, we believe that it would be impractical for NHS Boards to make such a judgement given the limited information available at the time of the Hearing and the number of variables that are impossible to evaluate.

To add to this complexity, it may naturally follow that consideration should also be given to the financial viability of existing providers.

Any judgement made could easily be used as the basis of an appeal.

In addition, Health Boards may also be exposed in situations where a decision is made to award a contract and where the business subsequently fails.

### **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**

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

The PALG are broadly in favour of this proposal and believe that a timeframe of 6 week is generally appropriate for Boards with some proviso. We believe it inappropriate to comment on the NAP timeframe to meet this proposed deadline.

Historically, Boards have experienced difficulties in forming a PPC e.g. during the summer months when diary commitments are dictated by the holiday arrangements of members, the applicant and the interested parties, and particularly during repeat applications when members of the PPC have been "borrowed" from other Boards.

Consideration should also be given to extending timescales when a Board receives multiple applications within a short time period.

We believe this proposal should also take into consideration timescales associated with applications that have been considered by the PPC, where an appeal has been lodged and the application has been remitted back to the Board by the NAP for reconsideration (i.e. where there is no further public consultation).

### **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?**

**No**

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

It is the general view of the PALG that the roles and responsibilities of the person(s) acting in a supporting and advisory capacity, including providing advice and guidance to the PPC should be defined within the Regulations. Board officials have successfully undertaken this function for many years and provided that they are not present during the private deliberations of the PPC then we would propose that this continues. These officials have built up knowledge and experience over a number of years and the independent legal assessor would not necessarily have a better understanding of the Regulations. In addition the legal assessor would increase the cost of holding oral hearings considerably and could cause delays.