

## CONSULTATION RESPONSE FORM

We would thank the Scottish Government for providing the opportunity for comment on the proposed changes to the Control of Entry arrangements.

In addition to the proposals described in the consultation document, and following discussions within our Health Board, there was strong agreement to ask the Scottish Government to consider some important additional issues.

The comments made in our response follow significant experience in managing applications for entry to the Pharmaceutical List.

### Additional Comments

#### Comments on Consultation Document

| <u>Page</u> | <u>Para</u> | <u>Comment</u>  |
|-------------|-------------|---|
| 7           | 1.20        | As previously (in our response to the Review of the Control of Entry Arrangements carried out by the Scottish Government in 2010), we would ask the Scottish Government to consider the “necessary or desirable” test. Given Lord Nimmo Smith’s ruling regarding the appropriateness of deciding the legal test in two parts, if a Pharmacy Practice Committee (PPC) determines that a neighbourhood does not currently have access to adequate pharmaceutical services, then the inference is that the current services are not adequate. As a consequence it would be logical to suggest that the granting of a further contract is essential to redress this inadequacy. Our experience is that the issue of “desirability” is a source of confusion. We would request that the opportunity of this consultation is taken to review this matter. |
| 7.          | 1.21        | We note the narrative in the introduction of the consultation states that commercial aspects and the effect on neighbouring pharmacies income are not considered in the determination of new pharmacy applications. This is not consistent with current practice, both by PPCs and the National Appeals Panel (NAP). Scottish Executive Circular 1987(GEN)14 Para 18 states “A possible loss of income by an existing contractor, caused by the opening of an additional pharmacy is not of itself a relevant consideration.” Viability is however considered by PPCs on the basis of how this would affect the overall provision of services. The NAP has also used this consideration in a previous determination <sup>[1]</sup> . We would request that the opportunity of this consultation is taken to clarify this matter.                    |
| 7.          | 1.24        | Recent NAP decisions have shown that it is not sufficient for Health Boards to merely “identify the boundaries of the “neighbourhood” in which the premises named in the application are located”, but must explain in detail the reasons why the area within the defined boundaries constitutes a “neighbourhood”. We would request that the opportunity of this consultation is taken to clarify this matter and provide clear guidance to Health Boards.   |

#### Additional Considerations

##### 1. Applicant’s Public Consultation Process

Regulation 5 requires the Applicant to place an advert in a newspaper. The Regulations state “20 working days from the advert” It is not clear whether this timeframe should commence on the day the advert appears, or the day after. This lack of definition can cause difficulty for Health Boards when applicants are calculating their timescales. Applications have been rejected by this Health Board as being received out of time, when the applicant has counted the day the advert appeared as the first working day. We would request that the opportunity of this consultation is taken to clarify this matter.

2. **Schedule 2 – Form B**

At present this does not include the date of commencement of services. We have found it necessary to amend the form locally as this is a crucial piece of information for Health Boards. We would request that the opportunity of this consultation is taken to revise the documentation.

3. **Form A(1) – Part 2(b)(ii)**

Currently the regulations only require the applicant to provide documentary evidence where the response to Part 2(b)(ii) is “no” i.e. in cases where the applicant does not own or does not have a lease. There is no requirement for applicants who are in possession of the lease/ownership to provide evidence. If an applicant is required to document a negative response, we contend that the same should apply where the response is positive and would request that the opportunity of this consultation is taken to clarify this amend the documentation

4. **Appliance Suppliers**

Although the term “Appliance Suppliers” was previously removed from the Regulations, there is nothing within the current regulatory framework which shows that those wishing to solely supply appliances should undertake the same application process. We would request that the opportunity of this consultation is taken to clarify this matter.

5. **Training of new PPC members**

Recent determinations by the NAP preclude observers from being present in the “closed session” of the PPC deliberations. This has important consequences for Health Boards in respect of the training of new PPC members.

We would request that the opportunity of this consultation is taken amend the Regulations to permit PPC members to be present as observers during “closed sessions” as silent witnesses.

6. **Site Visits**

It is common practice for PPCs to undertake a site visit to the area around an applicant’s proposed premises. Currently the Regulations are silent on this issue and as such there are a variety of approaches across the country. The participation of GGC Board Officers in site visits has been challenged in the past.

It would be helpful if the Regulations could be amended to address this issue, by perhaps providing a minimum standard for visits and detail who can take part.

The NAP considers the presence of Health Board officers at the “closed session” of the PPC as being “a breach of natural justice” we therefore consider that the Regulations should address the matter of site visits and the roles of Health Board Officers.

7. **National Appeals Panel**

We would welcome further consideration of issues relating to the NAP.

Over the last three years since the new arrangements introduced it has been necessary to make fundamental changes to our PPC processes.

The current regulations allow the Chair of the NAP to remit applications back to the Health Board for reconsideration where he is satisfied that certain criteria have been met. The wording of the current regulations do not; however permit the NAP to hold an oral hearing and

indeed no NAP oral hearings have been held since the introduction of the new arrangements. We would request that the opportunity of this consultation is taken to address this matter.

**8. Non Contract Pharmacies**

We would welcome consideration on the matter of those registered pharmacies that are not included on the Pharmaceutical List.

Specifically, we request that the opportunity of this consultation is taken to provide clarification regarding the involvement of non-contract pharmacies in the handling of NHS prescriptions/dispensed medicines and the provision of other NHS services.

**9. Support for PPCs**

Given the complexity of the Control of Entry arrangements and the changes that result from experience, determinations and appeals, we consider that regular dialogue and training should be available to PPC members and Board Officers. We would request that the opportunity of this consultation is taken to provide ongoing and regular support. .

Training sessions could also foster a common approach and understanding between PPCs, the NAP and Scottish Government thus reducing the need to remit cases back to Health Boards because of procedural irregularities.

**10. Health Board Officers**

The role of Health Board Officers in the PPC process has been challenged and their presence in the PPC's closed session is considered by the NAP to be inappropriate. The NHS GGC PPC is of the strong opinion that the advice and support of Health Board officers is necessary in the closed session and we would request that the opportunity of this consultation is taken to amend the Regulations to permit this.

**Robert Gillespie**  
**Lead Pharmacist**  
**Community Care**

**Peter Daniels**  
**Chair**  
**Pharmacy Practices Committee**

## 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

We would broadly welcome this proposal; however feel that such a concept could only be introduced if it was underpinned by robust guidance on interpretation. It is unclear from the narrative in Point 6 whether the services to be taken into consideration are those generally expected by a population or those in existence at the point of considering an application. These can often be different and clarification would be required on this point if a "Prejudice Test" was to be introduced.

Consideration should be given to whether the application of a "Prejudice Test" could automatically debar a large majority of applications at the first stage without considering the greater benefits that would accrue to patients from the greater availability of a pharmaceutical care service. We would request that the opportunity of this consultation is taken to consider other options such as 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?

Yes

No

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

We disagree with the proposal of a three year review.

If the “controlled remote, rural and island localities” concept is to be a fundamental part of the application process then it would make sense to align any review period with the Pharmaceutical Care Services Plan, which is reviewed annually.

In addition, developments, once agreed can move quickly and a review period of one year may be more appropriate.

An annual review would ensure that the service remains responsive to patient need and adapts to a more proactive approach to managing the situation.

**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 with this proposal on the basis that the population across Scotland should have access to pharmaceutical care regardless of their location.

A flexible approach needs to be considered to accommodate options other than using Health Board employees from the managed service. Such options may include utilising the existing community pharmacy network.

If implemented, this proposal would require the provision of significant additional funding for Health Boards.

## 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

We recognise the importance of involving local communities in the application process.

We consider that proposal 4 would be difficult to administer and may not provide the PPC with a representative view from the community for the following reasons:

For most applications received by NHSGG&C, all existing contractors within a one mile radius of the applicant's proposed premises are consulted (other arrangements exist for

applications where the premises are located in more rural settings). This methodology is also used for the purposes of identifying those who are consulted in accordance with Paragraph 2 of Schedule 3, listed below:

- all elected representatives (except list MSPs) (average of 5.5);
- all community councils (average of 5.5);
- the PPF Group located within the relevant CHP/CHCPs (average of 1).

The complexity of the consultation imposes significant difficulty in identifying a single representative who can present balanced views of the communities who may be affected by an application. We also consider that it would be impossible to give the PPC assurance that a single Community Representative would be able to represent all views which can be opposing.

Notwithstanding the above, to avoid any perception of bias, we strongly believe that Heath Boards must not be involved in the selection of community representatives.

### **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**

It is our contention that 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.

- We cannot agree with the proposal to limit the time for presentations as in our opinion this would be unfair.
- Some applications are complex and imposing a time limit could be detrimental to the PPC's consideration of the case.
- Imposing a time limit could be cited as a reason for appeal.
- This issue could be addressed through the development of national guidelines for PPC Committees, applicants and interested parties.

### **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**

Our views regarding this proposal should be considered in the light of our reply to proposal 5 above.

If this proposal was implemented, 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 only permit the other representative to speak during the questioning section of the Hearing.
- We consider that the Regulations must continue to preclude the involvement of a solicitor, counsel or paid advocate from addressing the PPC.

**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**

- Pharmaceutical Care Plans are not currently developed to identify unmet need. We would consider that is an area that requires significant research.
- We consider that it would wholly inappropriate for Health Board Officers to be involved at the pre-application stage for the following reasons:
  - The consideration of applications is solely a matter for the PPC and not



Board Officers. Views expressed by Board Officers to an applicant could be cited as evidence at a hearing and may put the Committee in an invidious position if they did not agree.

- Any discussion between Board Officers and potential applicants has to be strictly limited to the provision of guidance of the application process to ensure that there is no suggestion of bias.
- In the interests of fairness, all interested parties should have the same opportunities as those afforded to applicants in respect to the pre-application stage and we consider that that this would be impractical.
- 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 as “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 same concerns could be raised if Board Officers were involved in any pre-application process.

### **Advertising**

We consider that it would be impractical to advertise in a newspaper and all circulating local news free-sheets and newsletters in the neighbourhood for the following reasons:

- The identification of all local news free-sheets and newsletters would be impractical given that there is no central register;
- The omission to include a notice in a publication could be cited as a reason for appeal.
- We would advise caution regarding the use of the term “neighbourhood” in this proposal. This has a specific meaning within the Regulations. The neighbourhood is a matter for the PPC solely to determine on the day of the Hearing.
- A previous exercise conducted for the Scottish Government showed that there was little response from either community groups or members of the public to Health Board notices placed in publications.
- We are concerned that if two advertisements are placed, members of the public would respond only to one advert and not both.

### **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**

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

## 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 disagree with this proposal for the following reasons:

- Applicants may be reluctant to provide financial information given that it would be shared with interested parties who may become competitors if the application was successful.
- 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.
- Notwithstanding our concerns above, if implemented:
  - The PPC would also need to consider the financial viability of the existing service providers.
  - Health Boards may also be at risk in situations where a decision is made to award a contract and where this business subsequently failed.

## 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 are broadly in favour of this proposal and believe that a timeframe of 6 weeks is generally appropriate for Health Boards, however there are occasions when a six week time limit may not be appropriate:

- PPC members are largely volunteers and may not be able to accommodate the need to hold hearings within a specified timeframe.
- In the past, NHS Greater Glasgow and Clyde were obliged to cancel an arranged meeting when the majority of the interested parties could not attend a hearing due to holiday commitments. In this case, legal advice was that a decision taken in the absence of a significant number of interested parties would be unsafe. This underlines fact that for situations outwith the control of the Health Board, it may not be possible to adhere to a strict lime limit.
- Timescales would also need to be extended where a Health Board received multiple applications within a short timescale. Applications impose a substantial administrative burden on Health Boards and a more flexible approach is required to address this situation.

This proposal does not address applications that have been considered by NAP and have been remitted back to the Health Board for further consideration. SG should take this opportunity to make specific provisions for this situation.

We cannot comment on the NAP timeframe.

### 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

We would agree with this proposal.

- In the absence of advice from Health Board officers, it is imperative that PPCs have access to technical advice in relation to the regulatory framework.
- Roles and responsibilities of the person providing advice to the PPC should be defined within national guidance. They should, for example, require to be present throughout the hearing and be familiar with the case and the associated documentation.