

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 X

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

A prejudice test would be welcomed but it should be called *controlled locality* rather than *controlled remote, rural and island locality*. Boards should be able to identify their controlled localities in relation to spread of the population, geography, access to services, sustainability of a community pharmacy in that area and not just remote, rural and island.

There are many pharmacies providing pharmaceutical services in localities which could be described as 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. Clarity and consistency around a "Prejudice Test" could prove valuable in local decision making.

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 X

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

Formalised review at least every 3 years seems very reasonable. Given that neighbourhood circumstances can at times change within a 3 year period, there may be a need for ad hoc review so the statement of a minimum of 3 years is welcomed. The demarcation of “controlled remote, rural and island locality” needs to be carefully defined so it is clear in all minds and practical to apply. In line with our comments in proposal 1 we would prefer the title “controlled locality”.

Finally we believe this review should be aligned with the Pharmaceutical Care Services Plan. Although this plan currently requires updating annually, it is more practical to update this on the same basis as the review of controlled localities i.e. a minimum of every 3 years.

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 X

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

We agree that the equity of access to pharmaceutical care should be available to all patients within NHS Scotland; however the challenges of delivering personalised care to remote populations should not be underestimated. Such requirements would also need to be met flexibly - contracting of the pharmaceutical care may be appropriate in some areas, while directly employed staff could provide the service in other areas. Creative use of technology may provide solutions that meet the needs of many patients.

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 X

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

This concept does facilitate local representation which we would wholeheartedly support, and the explanatory notes give several examples of who the local representative may be. However it is challenging to ensure an appropriate community representative can be defined on all occasions. It is our view that the Boards should not be responsible for selecting local representatives.

We also have a difficulty in seeing how one individual could adequately represent divergent groups (e.g elderly forum -v- mother and toddler group) without bias. It is important that the concept of local representation is addressed but it must be done in a way that ensures balanced views are obtained, and also ensures lobbying by other interested parties does not affect this representation.

The views of local representatives should be formed by evidence and not opinion. Regulations should be developed to encourage this.

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 X

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

There is already a standard process which is followed in the management of PPC Hearings and this is governed by the Chair of the meeting. A good Chair will also ensure that no one person or organisation is able to dominate the entire hearing.

However limiting the time for oral representations through the Chair, can be the source of appeal, if a party believes they have been unjustly treated. Therefore building this into regulations would remove this risk.

Limiting presentation time would also encourage a clear focus on the main issues surrounding the application rather than a wide range of unnecessary detail. This we believe can only lead to an improved hearing process.

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 X

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

If as outlined in Proposal 5 time is limited for oral representations, then there is a strong incentive on the parties to ensure focussed and effective presentations.

As long as the existing regulation exclusions apply, precluding the involvement of solicitor, counsel or advocate, then a coherent presentation of the case can improve the decision making process.

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 X

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

We believe that Health Boards should be proactive in planning pharmaceutical service provision in its' area served. We believe however that this should be achieved via their Pharmaceutical Care Service Plans rather than through direct discussions with applicants. Applicants should be able to interpret PCSPs and use it to argue their case. This will however require PCSP to be developed with a sharper focus on determining and identifying unmet pharmaceutical need. This will require guidance and support from SG. But an active and useful PCSP, is preferable to this proposal.

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 X

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

Many Boards try to do this by placing the notes of the meeting in the public domain. However the development of a clear methodology to do this in regulation would, we believe, aid transparency

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 X

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

We see this as an extremely complex area, and are doubtful about the ability of NHS Boards to make this judgement. The current application process does not require the applicant to provide financial or business information. It has been our experience that applicants are often reluctant to provide such information given that it may be shared with interested parties who would, if the application were granted, become competitors.

Additionally the financial viability of the business may not be wholly dependent on the NHS pharmacy contract e.g. a Veterinary Pharmacy may give strong financial support to a business within a large farming community.

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 X

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. A NAP timeframe of 3months also seems generally reasonable.

However there are times when delays may be required for legitimate reasons, not necessarily driven by the complexity of the case. As long as reasonable and explained delays are acceptable then this proposal is supported.

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 X

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. This would reduce the number of appeals against decisions where the appeal was based on instances where the PPC were charged in not correctly applying the regulations