

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?

No

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

Consideration should be given to whether the application of a "prejudice test" could automatically exclude applications at the first stage without considering the greater benefits that would accrue to patients from the greater availability of a pharmaceutical care service. Scottish Government could perhaps look at options for partnership working, remote robotic dispensing and shared premises.

We would question the concept that GP practice income received for dispensing should not be subsidising the delivery of PMS. It may be that any "test" should put the onus on the medical practice to explain why loss of dispensing income would destabilise their delivery of PMS.

If a pharmacy is necessary then it will be operated by regulated pharmacists and technicians within regulated premises. Dispensing practices and dispensers are not regulated. Safety should be the paramount consideration, and in consideration of safety emergency supplies may have to be made from the GP practice.

In many areas dispensing GP practices are managed by the Health Board. The actual situation experienced in the Northern isles in recent years is that when new doctors come in to an independent practice the cost of stock and the resultant debt make taking on a small independent dispensing practice unattractive. In recent years incoming doctors have often preferred to be employed, meaning the repeat medicines can be supplied from more distant pharmacies without any impact on the sustainability of the GP practice.

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

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

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

An annual review would ensure that the service remains responsive to patient need. Review of controlled localities would be required periodically to reflect the changing nature of the population, access, provision of NHS services, advances in technologies will have an impact, medicines are already being supplied using CMS from pharmacies in the Northern Isles, and the dispensing doctor only supplies acute medicines

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

We agree with this proposal in principle on the basis that the population across Scotland should have access to pharmaceutical care regardless of their location. In particular people living in remote, rural and island areas should have access to NHS pharmaceutical services

There should also be pharmacist input into the governance arrangements for the safe and secure handling of medicines in dispensing practices. However please the present legislation does not allow a clinical pharmacist to have direct input into the dispensing process, in a dispensing practice so this proposal does not address a fundamental concern. At the present time the accountability for dispensing in dispensing practices sits with the doctors from the practice.

The most affordable option for clinical input is to develop the community pharmacy contract in line with “ Prescription for Excellence” using CMS as the platform for the provision of pharmaceutical care to those most in need. Introduction of additional pharmacists would have a significant financial impact which needs to be recognised in financial allocations.

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

When an application is lodged, the “neighbourhood” has not been defined as this is a matter for the PPC to do at the time of the hearing so this adds a legal question around whether a locality is a neighbourhood.

The PPC already receives views of local community under current legislation and it is difficult to see how one individual could adequately represent divergent groups without bias. There is a real danger that emotion may cloud rational assessment (as has been experienced in recent cases). In the remote context most community

concerns, in our experience are based around the potential loss of the GP practice. GP practices have lobbied the public, and the public often understandably feel they need to support the practice. It is difficult to know in these circumstances how representation can be fair.

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

Issues raised at pharmacy applications can be complex and contentious and these require to be fully explained. 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 frameworks. Each application has its own individual circumstances and the standard framework must be flexible enough to accommodate these.

In our experience, with a good chair many potential problems of this nature can be avoided.

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 system is sometimes embarrassing for participants with whispered conversations between interested parties and their assistants. The framework for how hearings should be conducted should also include clear guidance on who can, and importantly cannot, assist the applicant and interested parties.

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 disagree with the first element of this proposal regarding the pre-application stage as Pharmaceutical Care Plans are not currently developed to identify unmet need. Consideration of applications is solely a matter for the PPC.

Boards should be free to choose which medium best reaches the population. This suggested approach is not needed in the islands where there is excellent local radio and newspaper coverage.

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? No

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

Lack of guidance under current regulations means that the PPC does not know the criteria for assessing public responses nor what weight should be applied to them.

Again, the public are likely to often be led by the desirability of a new pharmacy rather the Legal Test which currently may overrule the views of the community.

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

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. So this is complex territory. Long time viability of what is an independent business is outside of the expertise of PPCs. PPC's do not have the skills to make the judgement on viability. Large chains may well choose to open a pharmacy speculatively even if it is unlikely to be profitable initially. And a Pharmacy can be made viable by introducing other elements e.g a post office.

Boards have a responsibility to meet unmet identified pharmaceutical care needs, which may or may require a pharmacy. If a pharmacy is shown to be necessary and desirable then it should be allowed to open.

The Pharmaceutical Care Services Plan, if designed to draw on community planning and local economic development plans would discourage any uneconomic applications.

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

Reasonable timeframe is welcomed.

In the islands, Boards can have difficulty in identifying dates when sufficient members of the PPC are available for oral hearings and therefore they should be allowed longer than 6 weeks from the end of the consultation period to make a decision. However we would like to see NAP decisions made within a time period of 6 weeks.

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

The inclusion of an independent legal assessor would make it even more difficult to set a suitable date for a hearing which could lead to a longer delay in hearings being carried out.

The independent legal assessor would not necessarily have any better understanding of the regulations than the Board officials supporting the PPC. If Health Board officers continue to be excluded from PPC hearings, then PPCs must have access to technical advice in relation to the regulatory framework. In the island context a legal assessor could prove very expensive addition.