

rec'd 19/2
ack'd 20/2

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Annex B

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

In principle, we believe that the proposal will make the system more robust.

However, we do need more clarity on how '*controlled, rural and island localities*' will be defined.

The prejudice test is a welcome introduction which we believe will provide evidence and support a transparent model – which in turn will make the appeals process less subjective.

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

In our view, three years is a reasonable period of time and, that conducting a review in anything less than 3 years will be unnecessary and inefficient.

This review should include any planned developments.

It also should take into consideration the NHS Board's Pharmaceutical Care Services planning strategy.

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

In principle we do not oppose this proposal, however we would need to understand how this would be funded and work in practice before we could fully support it.

The requirement for a dispensing GP practice to employ a qualified clinical pharmacist to ensure the quality and governance of providing a pharmaceutical service would be a positive step; we envisage that this person would be sourced from the existing community pharmacy network.

There is an opportunity here to consider how the two contracts could be aligned to support greater collaboration, utilisation of skills and integration of care which better supports patient care.

Solutions such as information technology and telecare could also support the provision of Pharmaceutical Care for such communities.

We firmly support the view that pharmaceutical care and the supply of medicines should not be separated.

We would also suggest the introduction of some form of premises inspection and

regulatory body for dispensing practices, including some form of initial premises approval to ensure suitability and appropriate clinical conditions for providing pharmaceutical care, in line with the requirements for a community pharmacy dispensary.

In terms of providing safe supply, we would expect to see the same levels of governance and regulation as applies to community pharmacy.

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 believe that this proposal would add an unnecessary level of complexity to the already open and public consultation process. To fulfil this role and the powers in decision making that the proposal suggest, the representative would need to have a clearly defined role and be able to stand up to legal challenge.

The nominated representative would potentially be subject to lobbying from other interested parties which could negate the transparency of the current process and it would potentially be difficult to retain knowledge and expertise required in terms of keeping up with regulations and how they are applied.

We believe it is preferable to retain the transparency of the process and maintain consultation with the wider community; after all, lay people already play a key part as members of the panel.

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

We do not support the proposal to limit the time allowed for oral representations to be made during PPC hearings although we support that better time management of the PPC Hearings should be the overall objective.

The effectiveness of the Chair is critical to the effective running of PPC hearings, and they should be clear as to the requirements in organisations giving clear and concise oral representations.

Restricting representative's time in the provision of oral representation could potentially lead to grounds for appeal following a decision should they feel that they haven't had the opportunity to put their case forward.

A whole day is set aside for hearings and, we believe that this is adequate time for all representatives to be heard if proceedings are managed well by an effective Chair.

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

We do not support this proposal.

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

We do not support this proposal; a pre-application stage is unnecessary and adds complexity and bureaucratic burden to both the applicant and the NHS Board. Any need for NHS Pharmaceutical Services must be identified through the Pharmaceutical Care Plan, which should be developed in a robust, transparent and
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accessible way. If the Pharmaceutical Care Plan is robust, and reviewed within the required timescales, then we believe that the need for pre-application is unnecessary.

During the application phase, public consultation is already undertaken to facilitate responses from residents and others affected by the application. There is no evidence to support the current process in terms of vigour or the ineffectiveness of it.

The addition of further levels of consultation and advertising being placed in regulation adds additional cost to all parties; the current regulations are clear in the requirements for PPCs in considering applications in terms of the necessary and desirable test and taking into account public views.

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 support this proposal as it adds a greater level of transparency to the process, outlining the reasons for the decision being taken. The 'test' is the determining factor in any decision being made, not the perceived desire for a pharmacy.

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

Whilst we understand the desire to secure sustained provision, we do not support the proposal to introduce a financial viability check as part of the application process.

Financial risk is undertaken by the applicant and there are sanctions and specifications which address the failure to deliver services which have been contracted already in place.

We believe that this would add yet another layer of process and bureaucracy to the process, it is also unclear as to who would be placing the judgment on financial viability of a business and despite this, there would be no guarantees as businesses can fail for a number of reasons which would not be apparent at the time of application.

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 the proposed timescales which gives the NHS an incentive to deal with applications promptly, there needs to be more clarity around which circumstances would deem to be considered complex cases and how long the timeframe would be extended.

The NAP should take a proactive role and determine appeals rather than push back to PPCs on multiple occasions, a consequence of this is that the PPC may run out of suitably trained panel members to hear the applications.

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

We support this proposal of a suitable qualified and experienced independent legal assessor to support the PPC deliberations.

NAP is only hearing any appeals where there has been a flaw in the process.

Ultimately decisions are being made by individuals who may not fully comprehend what they are being asked to decide on, and the possible consequences of their decisions.

The provision of an independent legal assessor will undoubtedly help to support relevance and improve consistency in the decision making process involving lay members however; it does not in any way obviate unqualified lay members making business affecting decisions.