rec'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

Agree in principle with the introduction of a prejudice test in addition to the adequacy test. Being able to take into account the impact on existing NHS services in the locality when considering an application to open a pharmacy would be advantageous to a Board, however tight criteria/guidance in relation to how the prejudice test should be applied and how the NHS Board will deem an area as controlled remote, rural etc will be required to ensure consistency of approach across all Health Board areas. Clarity regarding the appeals process will be required particularly around the ability of and criteria for any appeal by a local community.

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

However there was considerable variation within NHS Ayrshire & Arran regarding the frequency of review.

In practice in rural Scotland it is very unlikely that there will be significant change in infrastructure to affect the designation.

On one side Community Pharmacy and Primary Care Contracts and planning felt that three years was too long.

In contrast the GP respondents felt that three years did not allow enough time for robust financial planning of businesses and suggested a wider review of 5 -10 years.

A helpful compromise was suggested around a longer timeline unless there are demographic changes that would prompt an earlier review. Such changes would be picked up in the Pharmaceutical Care Services Plan

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

There is general support for the principal that patients should have access to NHS Pharmaceutical Services.

Initiatives such as this would benefit patient care and encourage greater interprofessional working.

Each case would have to considered individually and take into account situations where patients are designated to be dispensed to by GPs due to locality and availability of branch practices. In such cases patients can attend the main practice in a locality where there is a community pharmacy. Scottish Government should provide Boards with advice on how this would be dealt with as it does not seem to make sense to develop additional services when there is already local access.

Such pharmacists could be salaried and dedicate a certain amount of time to a Practice as directed by the Board. These salaried pharmacists would be employed by the Board and attached to a practice / locality as required.

Clarity around how such arrangements would be funded is required.

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

There is general agreement within this proposal on the assumption that safeguards would be included to ensure the views are representative and not those of any individual or pressure group.

A suggestion was the expansion of the role of the local PPF's to include public consultation. This would allow relationships between the PPF and various local groups in the area to be developed. If the PPF was the forum from which a nominated representative was secured this would allow the

PPF's to become highly skilled at gathering the views of the community and would also allow their representative to be trained and become familiar with the proceedings at a PPC hearing and become skilled at representing local views. There would be clarity of communication and would take into account the local knowledge that the PPF will have in respect of appropriate local groups to consult with.

There was agreement that 30 days would be inadequate and suggest 60 or even 90 days is more appropriate.

There needs to be a defined mechanism for public consultation which may need, in very remote areas, to include funded public meetings or other mechanisms ensure any opinions are truly representative of the wider community and not that os a single person.

Community Pharmacy colleagues were concerned about the limited knowledge communities may have about the diversity and standards of pharmaceutical services that are being proposed and the potential benefits and asked that a requirement for objective awareness raising be included.

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 support this proposal but feel that structured in depth training for PPC Chairs is imperative. This training should be undertaken on a national basis to ensure a consistent approach by all PPC's . This training should cover all aspects of Chairing a PPC from submission of additional material by applicants or interested parties at the Hearing and what information should be considered at a re-hearing and a maximum time allowed for a presentation.

Also a guidance/protocol for Chairs document should be established taking into account that in some Health Board areas hearings are not held regularly and therefore some Chairs are not as skilled as others.

Consistency of approach is paramount as it is well known that applicants already compare processes in different Board areas.

Stakeholder engagement in establishing the updated process would be helpful and should include NHS Bodies, Professional Bodies, Representative Groups (BMA, the Dispensing Doctors Association, and Community Pharmacy Scotland) and public groups (Patients Association)

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

In general this inclusion is to be welcomed. It offers the opportunity for fuller and more democratic debate. Clarification would be required regarding the capacity in which the assistor can appear/speak at the Hearing. An unintended consequence could be that applicants with significant financial backing could appoint legal counsel to act as their assister. This could give the applicant, or those opposing, an unfair advantage. There is a danger the PPC could develop into a legal argument.

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 are supportive of the pre-application stage and the link to the Pharmaceutical Care Services Plan (PCSP) Caution is required to ensure that the pre application stage does not affect the impartiality of the PPC.

In order for this to work NHS Boards the PCSP requires to be robust and fit for purpose and be able proactively determine areas of unmet need. This will require Scottish Government input.

We are concerned regarding the requirements for applicants to carry out this level of advertising and feel that this may discourage small independent pharmacies.

Also further concern at cost to NHS Board for advertising.

Specifically our GP Community felt that other affected parties (dispensing medical practices) should be involved in the discussion of unmet need prior to a full hearing. The GPs contend that in rural areas the services of dispensing doctors should be considered equivalent to NHS Pharmaceutical Services and the very presence of a dispensing doctor determines that need is unmet is not upheld in future.

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

Currently all public views are supplied to the Committee in full as part of their papers and it is noted in the PPC report that the Committee have had sight of them but would support this process being more formally minuted especially if the public representative is to be given the right of appeal. This is also an area which needs to be reinforced at any training events for PPC Chairs. Guidance is required for Boards to know the criteria for assessing the public response, and also what weight should be applied to the various areas of response. This needs to be consistent across Boards.

The ability of a Community to appeal if they feel their views have not been adequately heard should be clarified.

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** ☒ and **No**

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

This is a complex issue as the applicant should have considered economic viability as part of their business plan. Financial viability will be affected by the infrastructure of any higher company and / or the range of pharmaceutical services on that can be provided now and in the future. The immediate financial viability should not be a consideration of the NHS Board rather the consideration should be on the impact of the existing infrastructure and how this can be supported.

Approval of a poorly viable pharmacy, if that pharmacy were to close, would damage the PPC credibility and fail to secure long term provision.

Economic viability would also have to consider the potential impact on other pharmacies and also any GP Dispensing arrangements.

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

Agree that the implementation of a time frame from end of consultation period to date of hearing.

If a 6 week target is finally agreed there may need to be more trained PPC members to allow such tight timescales to be met.

Would require definitive guidance on what would constitute a complex case.

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

As experienced NHS Board Officers are not permitted to carry out this function and as the process for hearings becomes more complex independent legal support is desirable. We have concerns regarding the source of this independent legal support as it is hard to envisage that the CLO could support all PPC's for all Boards. NHS Boards may have to procure this support locally where legal expertise in this matter may be limited. In addition this adds significantly to the cost and could impact of the timescales.

Is this a good use of NHS funds. Perhaps greater clarity re process regarding the hearings would make it appropriate for a suitably trained NHS Board officer to be present to clarify hearing processes.

This requirement seems to conflict with the pre hearing where the NHS Board will consider where there is unmet need or not. If the NHS Board agrees to allow the application to progress this is itself could influence the PPC

For completeness, and in the spirit of consultation and engagement, we have included general comments received by the GP Community.

These comments, in particular Paragraph 1.35 are not shared by the wider NHS Board, The Area Pharmacy Professional Committee, Community Pharmacy or Primary Care Development.

Para 1.35 talks about ensuring that people living in remote, rural and island communities should have access to appropriate NHS Pharmaceutical Services and NHS primary medical services that are no less adequate than would be the case in non-rural areas.

We would support this and suggest that as part of consideration of "adequacy" it be recognised that the services provided by dispensing doctors are at the very least considered the equivalent of NHS Pharmaceutical Services. Dispensing practices provide the full range of services from the provision of medicines, the checking of medicines, minor ailment service, emergency contraception etc., as do pharmacists. Indeed the only service not provided in many cases is the sale of OTC medication.

Para 1.36 states that the Scottish Government is committed to ensuring that where patients living in communities have serious difficulty in obtaining their medicines that the dispensing service provided by their GP practice will continue to be available to the communities they serve.

We would support this assertion that the services we provide be maintained. The difficulty will be in the definition of 'serious difficulty'.

Para 1.37 states that, "The Scottish Governments Action Plan for NHS pharmaceutical care (Prescription for Excellence) gives a firm commitment to explore ways in which rural communities and dispensing GP practices can be further supported by a pharmacist working with the GP practice, and how this can be provided to patients alongside the dispensing service offered by their GP."

We would support working alongside but would ask how this is to be funded – who pays for the pharmacists support in rural areas – cost would wipe out GP practice income from dispensing if burden fell on practices and as such would have the same detrimental impact upon other services as the loss of dispensing. The current arrangement of HB employed pharmaceutical advisors visiting and supporting all GP practices would we believe with some additional resource provide this link.

Para 1.4 states "As discussed in the Action Plan for pharmaceutical care, Prescription for Excellence, in future there will be a shift in emphasis away from the system of Control of Entry for pharmacy applications to one that is based on identified need by NHS Boards. NHS Board Pharmaceutical Care Services Plans will be central to how NHS Scotland plans, provides and delivers pharmaceutical care and medicines to its communities." The devil will be in detail – who is to be involved in drawing up plans , will the LMC, and local dispensing GPs be on group to develop plan?