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 this response NHS pharmaceutical services relates to National Health Service (Pharmaceutical Services)(Scotland) 2011.

NHS Grampian broadly supports the proposal for controlled localities

The changes proposed do nothing to further define desirable within the test of necessary or desirable and so does not help NHS Boards in the application of the desirability test.

NHS Grampian is broadly supportive of the additional prejudice test for controlled localities. However, there is a need for guidance in the application of such a prejudice test and the perspectives of such a test i.e. that the test is a valid and reliable assessment of any prejudicial impact on other NHS services rather than an assessment of the impact on the business model or profitability of primary care contractor services. Such a prejudice test should not be restricted to GP dispensing practices; i.e. if the prejudice test for dispensing practices is to be applied at an individual practice level rather than across a network of provision, or within a defined geography / neighbourhood, then the same should be applied to a community pharmacy contractor.

NHS Grampian believes the addition of the prejudice test will add some needed stability to dispensing provision from general practices but the downside may be to stifle applications to provide full pharmaceutical services in these areas. NHS Grampian would like to see a framework applied within which it is able to plan for the full range of primary care services, including all, four primary care contractor groups, in an integrated way based on objective assessment of population need and within the context of community locality planning. Such an approach fits with the original aspirations of the pharmaceutical care service plan and would allow Boards to invite proposals from contractor providers to deliver care to meet identified needs and choose provision on the basis of how well a contractor or group of contractors
Fees and payments for the supply of pharmaceuticals should be undertaken within the same financial remuneration frameworks, from a joint global sum and be delivered to the same standards. There is a need to ensure that professional leadership, support, training and development for dispensing practices is in place in relation to their provision of pharmaceuticals.

NHS Grampian recognises that whilst dispensing income was not designed to cross subsidise general medical services this cross subsidisation is a reality. Standardised assessment of the level of cross subsidy and therefore the potential risk to general medical services if dispensing income is lost is required if equitable application of the regulations are to be undertaken.

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

Regular review will be vital and this should be undertaken to standardised timescales and in a standardised way. There will also be a requirement to define the exceptional circumstances within which such timescales will need to be shortened and earlier review to take place along with the decision making responsibilities for making such changes.

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
Whilst equity of healthcare access for people living in remote, rural and island areas to NHS pharmaceutical services and NHS primary medical services that are no less adequate than would be the case in other parts of Scotland is an aspiration there needs to be careful definition of adequacy. There is also a need to not restrict the NHS Board in carrying out its responsibilities in terms of assessing need for and providing services within the finances available to it.

NHS Grampian supports the proposal to supplement dispensing practices with qualified clinical pharmacist input. However the resourcing, both in terms of funding and in recruitment, remain potential challenges. It also remains unclear as to how this potentially impacts on the adequacy test as by definition Boards will be required to enhance dispensing practice based dispensing services to full pharmaceutical services if equity of services is to be achieved. This would lead to a dual contractor approach to the delivery of pharmaceutical services in rural parts of Scotland. If this is the intention then again there is a need to address the issue of fees and payments for the provision of pharmaceuticals being undertaken within the same financial remuneration frameworks, from a joint global sum and be delivered to the same standards. There is a need to ensure that professional leadership, support, training and development for dispensing practices is in place in relation to their provision of pharmaceuticals.

In supporting the proposal for clinical pharmacist input NHS Grampian supports a flexible approach to the delivery of such input and for Boards to take mixed approaches as appropriate e.g. through a primary care practice pharmacist model, managed service input or through local contracting with individual pharmacists or contractors. One model might be for a group of community pharmacy contractors to support a group of dispensing practices by providing pharmaceutical care services to their patients and this would fit well with the vision for services laid out in Prescription for Excellence and Grampian’s own Pharmacy 2020. The mechanism of input should also reflect the innovative delivery of services, particularly the use of IT where appropriate and make use of the range of skills available not just in pharmacists but also within pharmacy technicians.

An area that does require strengthening is the governance and professional support for dispensing practices in relation to their dispensing services. Ideally these arrangements should be the same as those for other pharmaceutical services and national and local initiatives to support such services should be open to both pharmaceutical and general practice providers (this would include training, materials, infrastructure payments etc).

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

<table>
<thead>
<tr>
<th>The move to give local communities a greater voice in deliberations is welcomed by NHS Grampian. However, there is a need to ensure that the bodies recognised as representing the local community are defined i.e. all NHS Boards could for example use community councils. There is also a need to further define local community geography in terms of territory in order to include appropriate consultation and representation from communities.</th>
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<tr>
<td>In addition there is a need to make sure that such public representation is</td>
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<tr>
<td>a) Informed and input is supported in terms of fully understanding the remit of the PPC and responsibilities of the NHS Board</td>
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<td>b) not a route to raise expectations that a community’s view will necessarily be the same as the outcome of the PPC deliberations</td>
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<td>Overall NHS Grampian would repeat that a more sustainable route to future planning of pharmaceutical services (including those dispensing focussed services delivered from GP practices) is one based in pharmaceutical care service planning. Such planning should be integrated within a wider primary care service planning</td>
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approach adopted through locality planning. This approach would ensure broader consideration of population need and include a route for the community voice to be heard. This move to a prospective planning approach would also help avoid the harmful effects on local professional and public relationships that are sometimes part of the existing application process where a community’s dispensing practice are threatened by a pharmacy application.

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

There is already a standardised process for hearings to take place and it is appropriate that no one person or organisation should dominate such a hearing.

However NHS Grampian feels that a crude time limit would not be appropriate, particularly as we seek to include new input such as those of the local community.

NHS Grampian is of the view that revised guidance to NHS Boards regarding the proceedings of the PPC meetings may help Boards in assuring interested parties that all NHS Boards are operating in the same way. This guidance should be developed through the NHS Board PPC Administrators Group which is, and has been, working on sharing best practice between Board PPCs.

Scottish Government should the consider the development of standardised information packs to support applicants and interested parties attending PPCs. This information could include a description of how the hearing takes place, reinforce the need for clarity and accuracy in presenting information etc.

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

Whilst understanding how such a proposal has arisen NHS Grampian would have concerns regarding such an approach

a) Further professionalisation of PPC proceedings may be at odds with a commitment to hearing the community voice. There is the potential for a local community council to be speaking on behalf of their community against a professional legal or pharmaceutically trained advisor to an applicant.

b) This approach takes the PPC proceedings further down the quasi legal road rather than placing it within NHS Board planning arrangements as it should be.

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

NHS Grampian agrees that there should be a pre-application stage where the applicant engages with the Board. NHS Grampian has done this in the past to provide unbiased support for applicants in navigating the process.

However, the NHS Board cannot at a pre-application stage and without the full PPC
process being undertaken, make a decision that a pharmacy would not receive a contract.

There is also a significant flaw in the approach whereby the NHS Board is required to redefine the neighbourhood. This definition is for the applicant to make and for the PPC to validate. What, for example, would be the validity of a public consultation undertaken by the applicant for a neighbourhood geography which is later challenged by interested parties or the PPC itself.

Overall this proposal exemplifies why maintaining the control of entry system alongside prospective pharmaceutical care service planning is not appropriate. The principle of applicants speaking to NHS Boards to consider how their application might meet pre assessed local needs, that have been laid out in the Board’s pharmaceutical care service plan, is welcome but this approach is in effect made less powerful by the continued reliance on control of entry for contractual award.

Rather than proposing an assessment of urgency of pharmaceutical need NHS Grampian would support a prioritisation of need. Prioritisation is a standard part of needs assessment and all NHS Board Pharmaceutical Care Service Plans should include prioritised actions to meet local needs.

NHS Grampian believes that Boards should undertake the consultation process on behalf of applicants with a suitable fee charged to applicants to fully cover the costs. There is potential to consider whether a successful application should lead to a refund of the fee.

Whilst the attempt to widen consultation is welcomed such consultation should be in line with other Board processes for consultation and not set a different level of requirement upon PPC processes in isolation.

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

It is important that the views of the community are considered in PPC discussions. However, views of the community are not part of the adequacy or prejudice test to a greater or lesser extent than any other interested party. So while supportive of published decisions include narrative explaining the outcome of a pharmacy application, and in particular to respond to the views put forward of all interested parties not just the community, NHS Grampian does not support a requirement where the community view is held above all other views, either in decision making or in recording deliberations.
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

NHS Grampian warmly welcomes the proposal to consider the sustainability of services. As with the assessment of prejudice in terms of other services there is a need to consider how such viability is defined e.g. full business plan for the proposed contractor business.

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

NHS Grampian supports explicit timescales for decision making. Delays cause anxiety and should be avoided. Currently PPC hearings are held within 30 days of the end of the consultation (consultation recommends within 42). NHS Grampian would seek standardised guidance as to what good cause for delay is.

With regard to appeals NHS Grampian notes that the appeal process is to be given twice the length of time to review a decision as for the original decision to be made. NHS Grampian feels that the NAP should be under the same time constraints as NHS Boards in order to speed processes of decision making up.

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

PPCs do need access to appropriate advice during their deliberations. The recent and current presumption by NAP that Board Officers are in some way biased and are able to exert undue influence on PPC decision making is a clear indication that the legalistic approach to planning of pharmacy services leads to a poorer approach to planning services than a prospective planning approach, with appropriate input from Board and communities, would provide. In the past technical advice has been provided for by the Board Officers and supported by the CLO.

NHS Grampian agrees the need for the PPC to have access to legal advice and that such advice should be separate to advice to NAP. NHS Grampian has concerns over the funding of such advice and the availability of such advice given that PPC hearings have to take place within a set timescale and are dependant on a minimum panel of members to be present; i.e. the hearings are difficult to timetable already and if NHS Grampian were to rely on the availability of a small centralised legal resource then this would likely make setting a date for hearings even more difficult.

Moving to a Pharmaceutical Care Service Planning approach should remove this need and replace the entire control of entry process. NHS Grampian would reiterate earlier comments that such professionalisation and increasing legal input to PPC procedures takes the planning of pharmaceutical services further away from the planning of other services in NHS Grampian.
**Additional Comments** Community Pharmacy Services

NHS Grampian broadly supports the proposals made in this consultation. However, NHS Grampian also strongly believes that the control of entry approach to the award of community pharmacy contracts for NHS services (even amended as proposed) is outdated and does not fit with the integrated models of care delivery aspired to within NHS Scotland and NHS Grampian.

The national commitments made to locality planning within the context of health and social care integration offer a real opportunity to consider the planning of all services afresh.

Since the Scottish consultation on control of entry in 2003, the development and piloting of pharmaceutical care service planning in 2005/6 it has been clear to NHS Boards that there is a better way to plan pharmaceutical services than relying on contractor driven applications.

The continuation of control of entry arrangements limits the application of such plans. With such application limited by the control of entry process, development of these plans has also been overly cautious.

NHS Grampian considers that an approach that places pharmaceutical care service planning within the broader context of primary care services will better allow the delivery of the aspirations of Scottish Government and NHS Grampian for pharmaceutical care in the community as outlined in Prescription for Excellence. In short, control of entry is an outdated mode of planning for services, should be abolished and replaced with a prospective planning model for NHS Board communities within a short timeframe.

Once such service plans were in place this would allow prospective contractors to propose to the NHS Board how they would meet the needs identified in the NHS plan. NHS Boards would then be able to assess the most appropriate and sustainable proposals for delivery or in the absence of such a proposal agree the priority of delivery via an alternative approach e.g. managed service. This would move us away from a 'first past the post' approach to applications and award of contracts.