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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

We believe it is essential that a clear definition of what is meant by "controlled remote, rural and island localities" is produced.

Any prejudice test must only be in relation to GMS services offered and not the dispensing element of the practice and should be clearly defined  
We also believe that it would have been more beneficial to define what is meant by 'controlled remote, rural and island' in the consultation as the definition will affect our overall view of the proposal.

We have concerns that the proposal is in breach of competition law.  
Paragraph 1.21 states that commercial considerations are not part of the decision-making process for pharmacy applications. By apparently seeking to protect dispensing GPs from pharmacy applications commercial considerations are being introduced to the regulations

**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

**Pending clear unequivocal guidelines on what is to be defined as controlled remote, rural and Island localities in a manner that best fits healthcare provision including Pharmacy and General Medical Services. We support the proposal that a regular review should be carried out and a minimum period of every three years seems reasonable. However we propose that the review is aligned with the transition towards a new statutory framework for NHS Board Pharmaceutical Care Services Planning.**

**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**

**We agree that all patients should receive quality pharmaceutical care.**

**We would like the Scottish Government and NHS Boards to recognise that all community pharmacists provide all aspects of clinical pharmaceutical care.**

**The majority of pharmaceutical services are often planned as oppose to acute requirements.**

**There should be a comprehensive feasibility study carried out and published. This study should incorporate other means of how people access pharmaceutical services for example using telehealth systems, visiting community pharmacies when they visit larger conurbations, towns or cities as part of their normal lives for the purpose of accessing other services.**

**Greater details of how NHS Boards would source and support qualified clinical pharmacists. We recommend that these pharmacists should be contracted from nearby community pharmacy contractors. Allowing patient choice in the pharmacy and pharmacist that would deliver the service in or from the conurbation most appropriate to their location.**

**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

The definition of 'interested party', who they would be, how they would engage the public to gather and demonstrate the balanced views of the community are required.

We recommend the "interested party" has a clear written mandate and guidance on how local opinion is gathered and represented in a balanced fashion.

We agree there consultation process needs to be improved. (See response to proposal 8)

If a decision is taken to increase patient representation by having a

community interested party representative then a number of issues must be considered:

- The representative will need to have been briefed on the pharmaceutical regulations and the processes and procedures that are part of them.
- how the community representative is chosen.

We do not support that 'interested party' should have the right to appeal the decision because the right to appeal is based solely on a legal challenge

There are already lay people on the panel and we would be keen to understand the impact on their role if the proposal for "interested party" is implemented.

#### 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 recommend that this is the role of a strong chairperson, experienced, well briefed and competent. This would ensure that the meeting is planned in such a way that all information is presented in a timely manner and parties have the opportunity to make appropriate representations which would prevent unnecessary discussion.

This facilitates a fair and timely hearing able to adapt to more complex applications without the introduction of artificial barriers which could in themselves introduce an injustice.

The meetings should be held during core business hours.

#### 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

Only one person should speak as they represent the generic view of the interested party whether 'public' or otherwise and all parties can choose who would speak on their behalf.

**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 recommend that NHS Boards should be responsible for carrying out the public consultation and remove that responsibility from the applicant.

This could include oversight of any consultation undertaken by the 'public interested party' to gain the views of other members of the public as part of the application process

The current process is flawed and does not work.

NHS Boards should set out their process for carrying out effective, transparent and fair public consultation.

**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 greater transparency, describing how decisions are made and should be as robust as any other regulated requirements involving public engagement.

### 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

We are not aware that NHS Boards take into account the financial viability of other primary care businesses such as GPs, dentists and opticians.

We do not support the proposal that NHS Boards should take into account the financial viability of pharmacy businesses

We do not believe NHS Boards have the competency, capability or expertise to assess ongoing financial viability of businesses.

We encourage NHS Boards to enforce the contractual arrangements that were agreed as part of a new 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

The definition of "a complex case" is required. Otherwise this timeframe specification is helpful.

We recommend the timescales should be extended to the appeals process. Time-scales must also apply to re-hearings by PPC if they have been sent back to them by the National Appeals Panel and that suitable trained person (s) must be available.

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 recommend the current practice should be reviewed and identify where improvements should be made. This might address specific issues concerning education and training requirements and streamlining processes

We support the proposal that a legal assessor should be present especially during deliberations.

