

# Response from Boots UK Ltd

## 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

While we agree that it would be desirable to define zones (“controlled remote, rural and island localities”) where dispensing by GP practices would be considered in place of the provision of pharmaceutical services by community pharmacies. By definition, dispensing by GPs would not be considered outside these zones, once established, and there would need to be a mechanism to review designations in light of population growth or movement (see Q2).

We believe that the following definitions would be acceptable for defining localities:

- Very remote rural
- Remote rural
- Very remote small towns

However, we do not agree that “Remote small towns” should be included. These can be up to 10,000 population, under the Scottish Government definition, and in our opinion, a town of that size would be able to support up to three viable community pharmacies, making dispensing by GPs unnecessary.

We are unsure about the use of “accessible rural” as being suitable for dispensing by GPs. These areas are defined by their proximity to larger settlements (which would themselves be able to support community pharmacies) and the residents of such areas would be expected to visit those towns regularly, enabling them to access NHS pharmaceutical care when needed.

In terms of a “prejudice test”, we agree that this would be useful but we note that the test itself is not defined within the consultation paper. A successful test would have to cover potential impacts on both general medical services and the provision of NHS pharmaceutical care. In particular, the test would have to show that losing dispensing income would not affect the provision of

medical services in the locality (although, as the consultation acknowledges, such services are funded separately and should not be affected in any case). This should be considered in any future revision of the GMS contract in Scotland. The Scottish Government should consider using wording from existing “prejudice tests” included within community pharmacy contractual frameworks in other administrations, as the workings of these are well understood and supported by extensive experience. This would help reduce legal costs by lowering the chances of such decisions going to appeal.

**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**

Where such areas have been agreed (see Q1), we agree that reviews should be **at least every three years**. This process should be linked to the updating of Pharmaceutical Care Services (PCS) plans.

A key element of any review should be an examination of whether the defined locality still meets the criteria for “rurality” (ie, has the population grown, shrunk or moved) and whether a full NHS pharmaceutical service, from a community pharmacy, would be a viable option.

There should be a presumption against retaining “rural” designations where there is clear evidence of population spread or improved transport links.

**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 believe that local community pharmacy contractors should be offered the opportunity to provide pharmaceutical care services (using suitably qualified clinical pharmacists) to supplement dispensing by GP practices. This would enable supply and service to go hand-in-hand. Community pharmacies are already serving local communities and providing pharmaceutical care services to patients of dispensing practices would be an extension of this.

NHS pharmaceutical services could be provided by a mixture of home visiting/deliveries, in-pharmacy provision and/or telehealth/video-links, as appropriate.

In our experience, patients from areas in which a dispensing service is provided by GP practices also visit larger towns, cities and retail destinations where community pharmacies are located. They should be made aware of their entitlement to receive NHS pharmaceutical care at such locations.

## 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 type of community representative should be designated as the “**public interest party**” (to distinguish them from those parties which have a financial or material interest in any decision). Naturally, public interest parties should not have any such financial, material or personal interest in the applications under discussion, and this should be clearly declared.

There should only be one public interest party able to take part in each discussion or debate around an application. This person should have a duty to present information or arguments on behalf of all groups that had made representations (other than the directly interested parties themselves). Arguments would need to be presented in an even-handed manner, with both “for” and “against” cases set out for the panel or committee to consider.

The public interest party representative would need be educated and informed on the Control of Entry process and regulations, and be clear about the limits of the debate (ie, that discussions should be concerned only with the specific application and not wider issues of health policy).

**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 believe that it would be inappropriate to set time limits on oral representations. Any experienced and competent PPC chair should be able to ensure that all sides have a fair and proportionate time to present their arguments and that time is not wasted on unnecessary discussions.

Since the applicant has to establish the burden of proof (ie, that the proposed pharmacy is “necessary or desirable”) and rebut any arguments against this, we feel that this will naturally mean that the applicant ends up speaking for longest. The chair should ensure that all others have sufficient time. The Scottish Government may wish to issue guidance to PPC members and chairs, but we do not feel that this should be proscriptive. Standardised processes should help reduce the risk of judicial reviews.

**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 continue to believe that it is important that no paid or legal advocacy is used in hearings, in order to minimise costs for all parties.

If a suitably trained or experienced person is chosen as the “public interest party” (see Q4, above) then community groups should not need additional persons speaking on their behalf. The public interest party would have a duty to be even-handed and make representations on behalf of all community groups.

All groups would retain the right to make written submissions which can be drafted with expert advice.

**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**

In our experience, such advertising (at the application stage) has proved ineffective and generally produces very little response. We do not believe that requiring advertising at a pre-application stage would represent value for money for businesses or the NHS. The NHS Board should already be identifying potential unmet needs through its PCS planning.

If the Scottish Government does wish to pursue this option, then we believe that it would be more cost-effective to require the NHS Board to run the advertising and responses stage, with input from local public interest groups, with potential applicants funding the process through the payment of a fee at a set tariff rate.

### **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 processes that increase transparency in public decision making. All decisions should be written up clearly.

### **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 do not believe that it is appropriate for NHS Boards to be making decisions on the long-term financial viability of applicants or their specific applications. These are commercial risks which are borne by the applicant and/or its financial backers. Such judgements are best left to commercial organisations with a direct financial interest in the long-term viability of the proposed pharmacy and which would suffer the losses if a business failed.

The viability of a community pharmacy is not entirely dependent on NHS income. Pharmacies also gain income from direct transactions with patients, the scale of which will vary depending on the proposed location. Such (commercially sensitive) information would not be disclosed during the application, and might increase or decrease over time for reasons beyond the control of the NHS Board (eg, the opening of non-pharmacy retail competitors or the state of major local employers).

Pharmacies draw their custom from a wide area, which, in some cases, can extend well beyond the NHS Board area in which they are situated or include a high level of passing or seasonal trade.

Instead, NHS Boards should have powers to enforce the contractual arrangements that have been entered in to with regard to service continuity and agreed opening hours, including penalties for failing to meet them. This would be a better way of protecting the interests of patients and taxpayers.

### 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

These timescales would be acceptable to Boots UK Ltd, as long as there is provision for extension where circumstances are outside the control of the applicant or the NHS Board.

### 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 would expect that if the PPC chair was able to take expert or legal advice on the processes then this should lead to better decision making and thus fewer appeals, reducing costs for all involved.

In practice, all advice should be provided directly to the PPC chair to ensure the authority of the process and avoid any influence on the process itself.