

Scottish Government Health Directorate  
Pharmacy and Medicines Division  
1 East Rear  
St Andrew's House  
Regent Road  
Edinburgh  
EH1 3DG

14 February 2014

### **Control of Entry Arrangements**

Dear Mr O'Donnell,

Thank you for the opportunity to respond to the Control of Entry (Pharmacy Applications) and Dispensing GP Practices consultation proposals.

The Royal Pharmaceutical Society is the professional leadership body for pharmacists in Scotland, England and Wales leads and supports the development of the pharmacy profession for public and patient benefit. This response comes from the Scottish Pharmacy Board which is the elected body of pharmacists representing all sectors of pharmacy practice in Scotland.

This consultation is addressing only one part of the control of entry regulations and we are concerned that changes could be made in isolation without due regard to the future needs of the Scottish population as reflected in current Scottish Government policies, including The Public Bodies (Joint Working) Bill and, in particular, Prescription for Excellence – A Vision and Action Plan for the right pharmaceutical care through integrated partnerships and innovation. We are concerned that there are some elements of the current regulations, which could prevent new ways of working and stifle both innovation and the use of new technologies, which have the potential to particularly benefit remote and rural populations. It would therefore be advantageous to examine the regulations more widely through a comprehensive review to ensure they are fit for the future as outlined in the above policy documents.

Prescription for Excellence rightly advocates closer collaboration between health professionals. Our joint working with the Royal College of General Practitioners (RCGP) has already begun this process and there are many examples of GPs and pharmacists working locally together for patient benefit. We would also like to have further discussions with dispensing doctors to find agreeable solutions to providing pharmaceutical care for the rural populations.

Dispensing is only one aspect of the NHS services provided by community pharmacies. Communities benefit in many ways by having another health professional nearby and access to a full community pharmacy contract. This includes public health services such as smoking cessation and emergency hormonal contraception, access to medicines, the minor ailment service and chronic medication service, supporting self care and long term conditions. Patient safety and preventative health care are at the core of a pharmacist's role and contribute to shifting the balance of care in the community, freeing up GP and hospital time. We consider these aspects of provision to be necessary and desirable for any community wherever possible to improve patient care and maximise NHS resources.

We are concerned that the proposed introduction of a prejudice test would shift public policy away from recognising this need and that it seems to be suggesting that a dispensing service may be considered adequate in order to sustain a business model rather than the option of providing comprehensive patient care on an equitable basis to all Scottish citizens.

We are happy to discuss any aspect of our response or the professional issues raised by the consultation proposals in more detail if this would be helpful.

Yours faithfully,

A handwritten signature in dark ink, appearing to read 'Alex MacKinnon', with a long horizontal flourish extending to the right.

Alex MacKinnon  
Director for Scotland  
Royal Pharmaceutical Society

## 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?

No

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

We fully support the need for dispensing doctors in remote and rural areas where there is no possibility of providing a full NHS pharmacy service and are delighted to see an acknowledgement of the requirement for pharmaceutical care to be provided in addition to dispensing.

There are certain anomalies in the current control of entry regulations which need reviewed to ensure that pharmaceutical care is provided as much as it is practical on an equitable basis to all citizens in Scotland.

We have concerns over the introduction of a prejudice test as mentioned in the current consultation as a standalone amendment and would prefer a more comprehensive review of the current regulations which examines how they fit with the new Ministerial action plan "Prescription for Excellence." . We would expect that any changes made now to the current regulations would provide health boards with as much flexibility as possible to provide pharmaceutical care in new ways, aligning with the principles outlined in the Ministerial action plan.

The regulations at the moment preclude and stifle innovations recommended in the Ministerial action plan which advocates a truly person centred approach rather than service driven. Ideas such as pharmacy group practice, multidisciplinary working in a variety of settings and easy relocation to adapt to changing local needs are not easy to implement under current regulations Health boards currently do not have enough flexibility to provide local solutions for local situations whether urban or rural

With regard to the prejudice test it is not clear in the consultation if the income from dispensing would be taken into account when looking at the viability of dispensing doctor practices. If this was the case then the prejudice test would automatically disadvantage the residents of the area from having a community pharmacy were one to apply. Had this been in place several areas

in the highlands which are now very happy to have a community pharmacy would have been disadvantaged.

It is our understanding that the payments for dispensing are in addition to those for standard General Medical Services (GMS). If the GMS contract payments are not sufficient to recruit General Practitioners (GPs) to an area and provide an adequate service this needs to be addressed by health boards. Dispensing payments should not be used as an incentive to recruit GPs and to subsequently deprive local residents of a full pharmacy service.

The health board has access to all payments made to contractors and is therefore in a position to consider the impact of any reduction in income in comparison to similar non dispensing practices.

The interests of the local residents should be foremost and the health board should be reviewing local pharmaceutical needs regularly within their Pharmaceutical Care Services Plan (PCSP). Variation in the standard of the PCSP across health boards needs to be addressed. More emphasis should be placed on the requirement for every health board to have a robust PCSP in place. The plan is a key working document to ensure that the local population has access to the appropriate range of NHS services, making the best use of NHS resources and providing full medical and pharmaceutical services in the most cost effective manner.

### **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 X

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

NHS boards should review their population needs periodically as part of their PCSP. This plan should identify areas of need which would be the only areas where applications should be considered.

Three years seems a reasonable interval but there should be flexibility to adapt to any major local changes within that period.

### **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

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

We agree with this proposal in so far as everyone should have access to equitable pharmaceutical care but believe there may be many ways of approaching this, both within the managed service and using existing pharmacy contractors and health boards should give due consideration to all the available options. There are already examples of different ways of working across the Highland and Islands.

In some areas, such as Orkney, the doctors have refused to take on complete responsibility for dispensing and so the health board has found other solutions, which have proved more cost effective.

Multidisciplinary groups working in collaboration should explore the options available for their communities and services should be commissioned according to the way forward integrating health and social care. The regulations should be amended and made more flexible to accommodate different and new ways of working as suggested in "Prescription for Excellence" based on safe, effective and person centred care.

The pharmaceutical care and contribution of a pharmacist attached to a GP surgery is an excellent addition to the primary care team and will ensure safe, cost effective, evidence based prescribing. However, NHS pharmaceutical services comprise much more than can be provided by an individual pharmacist and the population should have access to the advantages of all aspects of the community pharmacy NHS contracted services wherever possible.

The minor ailment service frees up more expensive GP time and public health services are a welcome addition to the preventative care of any community. Access to over the counter medicines is invaluable in encouraging self care. In addition, pharmacy services are available for more extended hours than GPs providing more cover in the out of hours period.

Where a full NHS pharmaceutical service is not possible locally health boards should explore all possibilities to provide their rural populations with as comprehensive a service as possible, using existing services wherever possible to make best use of NHS resources and provide patient choice which is often denied to those in remote and rural areas.

This could include:

- The use of IT to provide services using existing contractors remotely.

- Part time and /or peripatetic pharmacists and /or satellite pharmacies.
- Use of existing contractors to provide non urgent care and allowing dispensing doctors to provide urgent and acute care.
- Use of NHS dispensing resources to fund new ways of working to provide pharmacist input, giving patients the advantages of the skill sets of both professions and freeing up GP time for complex care .

The term clinical pharmacist can be misleading. This care could be provided by any pharmacist. There needs to be a flexible approach to allow local solutions.

In addition to providing pharmaceutical care there should be pharmacist input into dispensing practices to provide training and ensure adequate patient safety processes are in place, as currently there is little regulation in these practices. Pharmacy technicians are now registered professionals and could assist with supporting practices in many areas.

## **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

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

We support greater involvement from the community who is indeed the major stakeholder in any decision, but there must be strict governance around this so that representatives are impartial and well informed on all aspects of the application. Choice of representative would be crucial to ensure clear understanding e.g. local councillors or community council representatives.

The public have in some instances been subjected to misinformation. No-one likes change and where a pharmacy has never been available there can be a lack of understanding as to the advantages a pharmacy will bring to the community, providing much more than a dispensing service. Where there has been no misinformation advertised locally the public opinion is very supportive of a pharmacy application. An example of this to examine is Bonar Bridge.

Our understanding is that despite adverse publicity it is almost unheard for medical services to be affected locally to any degree and if they have there are usually other confounding factors such as imminent retiral.

Having greater transparency and accurate information available to the community would help alleviate any unnecessary anxieties around threatened loss of GMS services.

### 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?

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

This proposal covers several separate issues and so it is difficult to answer either yes or no:

- We strongly support a standard process nationally to minimise any variation.
- Ensuring a fair hearing and controlling the timing of any meeting is the responsibility of the chairperson.
- Limiting times could be unfair or discriminatory to some parties as

each application and its circumstances are different.

Understanding of all aspects of the application process can be challenging even for those within the pharmacy profession but particularly for lay representatives. Training must be available to support a standardised process for all members of the panel.

**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?

No

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

The person speaking should be well informed of their case and should not require another voice.

Allowing others to speak could result in legal representation being used which could disadvantage some parties and add unnecessary costs to the process for all parties.

**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?

No



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

Applications should only be considered if they align with the health board PCSP for the area.  
The PCSP is publically available so applicants can assess local need. If the PCSP was robust and comprehensive this would give good indication of areas which needed more input and allow health boards to actively pursue applicants for these areas .  
Applicants can already consult informally with health boards on specific points relating to a proposal.

The Pharmacy Practices Committee (PPC) hearing should be the forum for all aspects of the application to be explored. A pre-application stage would add yet another layer of beaurocracy and applicants could still submit applications with the view that a broader hearing might be more productive.

It is unreasonable to be too prescriptive about the exact nature and amount of advertising required. It might result in technical hitches to the proceedings if there were claims that one avenue of advertising had been missed.

There should be a consensus at the hearing as to the effectiveness of the publicity and having community involvement would help ascertain this. There needs to be governance about the nature of any publicity to avoid unnecessary confusion and anxiety within the local population. This should be restricted in content to facts and avoid speculation and scaremongering which could prejudice any outcome.

Looking at historic examples, the main reason for any public negativity is the threat of losing medical services. In areas where this has not been raised as a potential threat then the community is generally positive about the addition of a community pharmacy in their area.

**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

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

We would support a move to have more transparency over any decisions. The report from the PPC should encompass all aspects of the rationale for the panel decision and transparency to foster confidence should be encouraged.

The eventual outcome of any panel decision should be what is best for the patients and the public who should be reassured that their opinion has been taken into account and that their interests in receiving services equitable with other parts of the country have been at the heart of any decision.

## 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?

No

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

The financial viability is not for the Health Boards to decide. This is a business matter and could change at any moment depending on personal and commercial circumstances. Some of the aspects informing financial viability are separate to the NHS contract and would most likely be commercially sensitive.

We fully appreciate the level of disappointment the community would experience if a pharmacy was not sustained when they have had a full NHS pharmaceutical service available. However, applicants would not be applying unless they had carried out their own due diligence and assessment. If that situation should arise it would be for the health board to consider the alternatives, using a flexible approach as we have outlined above.

## 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

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

Three months seems a reasonable time frame and would provide a focus for organising hearings but inevitably there will be circumstances where this is not possible and therefore we agree with the option to extend in complex cases.

Finding suitable members for the appeals panel can be even more challenging than for the initial application. There is currently no timeframe for the appeals process which can severely hold up resolutions. So any agreed timeframes should also apply to the appeals process.

### 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?

No

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

Having a legal assessor available for every PPC area would be difficult and could cause unnecessary expense and delay.

Adequate standardised training and procedures for all PPCs should increase efficiency and reduce appeals.

Chairpersons in particular should have appropriate training and expertise and could move to other hearing areas to provide independence.