Applications to provide NHS Pharmaceutical Services

A consultation on the Control of Entry Arrangements and Dispensing GP Practices

December 2013
Scottish Government



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Ministerial Foreword Alex Neil MSP, Cabinet Secretary for Health and Wellbeing



Applications to provide NHS Pharmaceutical Services and Dispensing GP Practices - A Consultation

It is almost three years since the Scottish Parliament last amended the Regulations which govern pharmacy applications in Scotland.

In April 2011, the National Health Service (Pharmaceutical Services) (Scotland) Amendment Regulations (SSI 2011/32) came into force. In particular, these amended Regulations placed new duties on NHS Boards to recognise GP dispensing practices as key stakeholders in the pharmacy application process in remote, rural and island communities.

NHS Boards are now required to notify dispensing GP practices of any application to open a pharmacy if the proposed pharmacy is in, or near, a location where a GP practice is currently providing a dispensing service to its patients.

Dispensing GP practices affected by a pharmacy application are now entitled to send written notice of interest or comments through their Area Medical Committee (AMC) to the NHS Board. In addition, NHS Boards shall appoint an additional member to the NHS Board's Pharmacy Practice Committee from persons nominated by the AMC where the pharmacy application directly affects a dispensing GP practice. This is to ensure appropriate representation on the Committee and that consideration of the issues regarding the affected dispensing GP practices are taken into account in the overall process.

The principal purpose of this consultation is to ensure that the regulatory framework for pharmacy applications and related processes, and the powers which allow NHS Boards to put in place arrangements with GP practices to dispense medicines to their patients, remain fit for purpose.

That is why I announced an immediate review of these regulatory frameworks to help ensure that they continue to best meet the health needs of rural communities. This consultation marks the next stage of that review.

This consultation also explores improvements in the pharmacy application process more generally. This includes improvements in the public consultation process for both the applicant and the NHS Board; improvements in engagement of the community; and increased transparency and improvements in the overall decision-making process.

I hope that you will take this opportunity to carefully consider these proposals. The issues are complex and reach further than the circumstances in which a GP practice should or should not continue to dispense to its patients.

I look forward to hearing your views on the issues and proposals discussed in this consultation.

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Applications to provide NHS Pharmaceutical Services

A consultation on the Control of Entry Arrangements and GP Dispensing Practices

Section 1: Context

- 1.1 In September this year, the Cabinet Secretary for Health and Wellbeing, Alex Neil MSP, announced that he would immediately review the regulatory frameworks that support the pharmacy applications process and the powers given to NHS Boards to make arrangements with GP practices to dispense NHS medicines to patients registered on their practice lists.
- 1.2 The review was announced amid increasing concerns from some dispensing GP practices and the rural communities they serve that pharmacy applications in these areas, if successful, would destabilise local services provided by the GP practices concerned and the long term sustainability of the practices themselves.
- 1.3 At the time of publication, there are over 100 GP practices across Scotland who are required by Scottish Ministers to provide a dispensing service to their patients where the NHS Board has established that those patients would otherwise have serious difficulty in obtaining NHS dispensed medicines and appliances from a registered pharmacy.
- 1.4 These dispensing GP practices are in locations where the historic absence of a community pharmacy would suggest that prospective community pharmacy owners have considered a pharmacy to be unviable or at best marginal in terms of on-going business operation. In these circumstances, dispensing GP practices play an essential and vital role in the provision of NHS medicines.
- 1.5 In addition to the remuneration for the delivery of primary medical services, these practices receive funding for the dispensing of medicines to their patients.
- 1.6 Normally, NHS pharmaceutical services are provided through a registered community pharmacy. There are currently some 1,240 registered community pharmacies across Scotland providing NHS pharmaceutical services. They are mainly based in the high streets of our towns and cities.
- 1.7 The Scottish Government policy remains committed to the principle that, wherever possible, people across Scotland should have access to NHS pharmaceutical services provided by a registered community pharmacy.

Prescription for Excellence

- 1.8 Prescription for Excellence¹, our Vision and Action Plan for pharmaceutical care, recognises that dispensing doctors play an essential role in the dispensing and supply of medicines to patients in rural communities. It is committed to the principle that collaborative working, wherever possible, between GPs and pharmacists provide the best care for patients making full use of their differing clinical skills and expertise.
- 1.9 Going forward NHS pharmaceutical care provision (the clinical skills of a pharmacist other than dispensing) should complement and support dispensing doctors and their patients. That is why *Prescription for Excellence* includes in its actions that the Scottish Government will work with patients, dispensing doctors and appropriate stakeholders to explore how rural communities can be further supported in terms of NHS pharmaceutical care.

Provision of pharmaceutical services

- 1.10 Section 27 of the National Health Service (Scotland) Act 1978² ("the 1978 Act") provides the primary legislation that places a duty on every NHS Board to make arrangements for their resident populations to provide pharmaceutical services. This includes that permission to open a new community pharmacy should be granted where it is necessary or desirable in order to secure adequate provision of NHS pharmaceutical services by a community pharmacy in the neighbourhood where the proposed premises are located.
- 1.11 Any registered pharmacist or corporate body (such as a retail pharmacy business) can open and run a pharmacy anywhere in the country provided it is registered with the General Pharmaceutical Council³ (the regulatory body for pharmacists, pharmacy technicians and pharmacy premises in Great Britain). This does not require permission from a NHS Board. If the registered pharmacy wishes to provide NHS pharmaceutical services, it must seek entry onto the pharmaceutical list of that NHS Board.
- 1.12 Section 28 of the 1978 Act⁴ sets out the persons with whom a NHS Board may arrange the provision of NHS pharmaceutical services. Generally, arrangements may only be made with a registered pharmacist, or a person/corporate body lawfully conducting a retail pharmacy business in accordance with the Medicines Act 1968⁵, who undertakes that medicines will be dispensed by, or under the direct supervision of, a registered pharmacist.
- **1.13** The current regulations regarding GPs⁶,⁷, only allow NHS Boards to authorise them to dispense where patients would otherwise have serious difficulty in

¹ http://www.scotland.gov.uk/Resource/0043/00434053.pdf

http://www.legislation.gov.uk/ukpga/1978/29/section/27

³ http://pharmacyregulation.org/about-us

⁴ http://www.legislation.gov.uk/ukpga/1978/29/section/28

⁵ http://www.legislation.gov.uk/ukpga/1968/67/section/69

⁶ http://www.legislation.gov.uk/ssi/2004/115/schedule/5/paragraph/44/made.

⁷ http://www.sehd.scot.nhs.uk/publications/DC20050815ssi2004 116.pdf. (See Schedule 1, Paragraph 15)

obtaining drugs or appliances from a pharmacist because of distance, inadequacy of means of communication or other exceptional circumstances.

Current arrangements for considering applications

- The arrangements made by NHS Boards with community pharmacists must comply with Regulations made under the 1978 Act. Those Regulations (the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009⁸ - "the 2009 Regulations") set out the ways persons can apply to provide NHS pharmaceutical services. The Regulations also set out the terms and conditions under which those services will be provided.
- In April 2011, the Regulations were amended placing new and additional duties on NHS Boards. They included, for example, the requirement of NHS Boards to:
 - notify dispensing GP practices of any application to open a pharmacy if the proposed pharmacy is in, or near, a location where a dispensing GP practice is currently providing a dispensing service to its patients. Dispensing GP practices affected by a pharmacy application are now entitled to send written notice of interest or comments through their Area Medical Committee (AMC) to the NHS Board;
 - appoint an additional member to the NHS Board's Pharmacy Practice Committee nominated by the AMC where the pharmacy application directly affects a dispensing GP practice. This is to ensure appropriate representation on the Committee and that consideration of the issues regarding affected dispensing GP practices are taken into account in the overall process;
 - undertake a 60 day public consultation when an application is received; and
 - publish decisions about applications on their websites alongside the reasons for the decisions. This is to help ensure the process is as open as possible and that potential applicants are aware of previous applications in a given area.
- In addition, applicants are required to advertise locally their intention to 1.16 provide NHS pharmaceutical services and seek the views from the public within the area to which their application relates. Applicants are also required to provide the NHS Board with an assessment of the public involvement exercise and a summary of the feedback received.
- The amended Regulations also strengthened the role of the National Appeal Panel (NAP) such that it may remit the decision back to the Board for consideration if it is the opinion of the Chair that the appeal is process based, or if a point of law has been raised.

8 http://www.legislation.gov.uk/ssi/2009/183/contents/made http://www.legislation.gov.uk/ssi/2011/32/contents/made

The role of the NHS Board

- 1.18 It is the role of the NHS Board, in whose area the pharmacy is located, to administer the arrangements set up by the 1978 Act and related Regulations. This includes a requirement that NHS Boards must prepare lists of the persons with whom they have made arrangements for the provision of NHS pharmaceutical services and the premises from which they will provide those services. The list that Boards prepare is known as their "pharmaceutical list".
- 1.19 An application for inclusion in the pharmaceutical list is essentially an application to provide NHS pharmaceutical services in the relevant NHS Board's area. The procedure for consideration of applications is set out in the 2009 Regulations and is explained in more detail below. These Regulations apply only to registered pharmacies that wish to provide NHS pharmaceutical services.
- 1.20 An application may only be granted if the NHS Board's Pharmacy Practices Committee (PPC) is satisfied that it is "necessary or desirable" to approve the application in order to secure the adequate provision of NHS pharmaceutical services in the neighbourhood in which the premises are located. Cases of 'minor relocation', or where a new provider applies to take over existing arrangements for the provision of services, are excepted from this aspect of the control of entry Regulations ("the 2009 Regulations").
- 1.21 It is important to note that whilst NHS pharmaceutical services are normally provided from commercial premises, the commercial aspects are not a consideration when NHS Boards are determining whether an application should be granted. Similarly, the effect on neighbouring pharmacies' income is not a consideration.
- 1.22 On receipt of an application to which the 2009 Regulations apply, the NHS Board must first notify a number of parties about the application. These parties include relevant local NHS committees (such as the Area Pharmaceutical Committee and Area Medical Committee) and persons already included in a pharmaceutical list whose interests might be affected if the application were granted. These parties are entitled to make representations to the NHS Board and thereafter must be given notice of the NHS Board's decision.
- 1.23 These parties and the applicant are entitled to appeal against the decision and those appeals are determined by an independent body - the 'National Appeal Panel'.
- 1.24 The key aspect of the process is a legal test under which the NHS Board Pharmacy Practice Committee (the PPC) must consider all applications. In summary, this requires the PPC to:

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¹⁰ See section 27(3)(c) of the 1978 Act http://www.legislation.gov.uk/ukpga/1978/29/section/27

- Identify the boundaries of the 'neighbourhood' in which the premises named in the application are located (this will vary greatly depending on the locality - e.g. in a city this may only be a street or two, whilst in a more rural setting, it could be a whole village(s));
- Consider and agree whether the current provision of NHS pharmaceutical services in that neighbourhood is adequate and;
- If the current provision is not adequate, consider and agree whether it is necessary or desirable to approve the application to secure the adequate provision of NHS pharmaceutical services in the neighbourhood.
- 1.25 Under the 2009 Regulations, when an application to open a new pharmacy is made, the NHS Board's PPC will consider: the pharmaceutical services already provided in the neighbourhood; the pharmaceutical services to be provided at the premises named in the application; any representations received by the Board; any information available to the Board which, in its opinion, is relevant to the consideration of the application; any public consultation responses received; and the NHS Board pharmaceutical care services plan.
- 1.26 An application should be granted only if the PPC is satisfied that the provision of NHS pharmaceutical services at the premises named in the application is necessary or desirable in order to secure adequate provision. In terms of the 1978 Act, the fact that there is a dispensing GP practice in the area is not a factor which the PPC can consider.
- 1.27 Where a pharmacy application is approved in an area served by a dispensing GP practice, the NHS Board would need to consider whether any patients would still have serious difficulties in collecting their medication. Where they decide that patients would still face serious difficulty, they may choose to instruct the GP practice to dispense to those patients.

Dispensing GP Practices

- 1.28 Under the terms of "the 1978 Act", NHS Boards are required to make and administer arrangements for the provision of NHS pharmaceutical services as well as primary medical services to people in their area.
- 1.29 NHS Boards must assess the needs of patients based on their individual circumstances. It is for the NHS Board to determine whether any patients will have serious difficulty in obtaining their medicines and to take steps to ensure they can receive that medication. Where a patient would have serious difficulty in having their prescribed medicines dispensed, NHS Boards can instruct GP practices to dispense medication to patients.
- **1.30** A patient on the dispensing list of a GP practice can choose to have their medicines dispensed from the practice dispensary or to have a prescription issued to present at a community pharmacy of their choice.

Patient list sizes and dispensing

- 1.31 There are currently just over 100 dispensing GP practices in Scotland 86 are independent GP practices under contract to their local NHS Board to provide both NHS primary medical services and the dispensing of NHS medicines to some or all of their patients. The remainder are directly managed (or salaried) practices provided and managed by a NHS Board.
- 1.32 Most are located in the Highlands and Islands (64), NHS Dumfries & Galloway (13) and NHS Grampian (10). They account for around 10% of GP practices and around 4% of the population.
- 1.33 Registered patient list sizes range from around 130 to 14,900, with an average of 2,180 registered patients. Dispensing GP practices are not necessarily required to provide dispensing for all their registered patients. The dispensing list sizes vary from around 130 to 4,500. The percentages of patients being dispensed to range from 100% in 66 practices, with 90-99% in 9 practices, to less than a third of patients in 14 practices.
- 1.34 These figures may include practices with more than one location (i.e. with branch surgeries), so the number of patients being dispensed to from a discrete location by each practice may be smaller. In some cases it is the viability of branch surgeries which can concern local communities when an application to open a community pharmacy is made.

Going forward

- 1.35 Scottish Government remains clear 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.
- 1.36 It 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.
- 1.37 The Scottish Government's Action Plan for NHS pharmaceutical care (*Prescription for Excellence*¹¹) 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.
- 1.38 The Action Plan reinforces that the skills and knowledge of the GP and of the pharmacist complement each other and together produce the best advice and care for patients and outcomes from their medicines.

¹¹ http://www.scotland.gov.uk/Resource/0043/00434053.pdf

NHS Board Pharmaceutical Care Services Plans

- **1.39** NHS Boards currently produce a Pharmaceutical Care Services Plan (PCSP) for their areas. These are intended to fulfil two main functions:
 - To provide a comprehensive picture of the range, nature and quality of pharmaceutical care provided within the NHS Board area; and
 - To identify needs and gaps in the provision of pharmaceutical care within the NHS Board area.
- 1.40 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.
- 1.41 Over the course of the next three years and beyond, NHS Board Pharmaceutical Care Services Plans will have implications for existing arrangements for service provision, and where and how it is provided. Plans will need to consider population needs, which include public health and health inequalities.
- 1.42 NHS Board Pharmaceutical Care Services Plans will have the statutory underpinning of both primary and secondary legislation and will be the main vehicle for the planning, procuring and provision of NHS pharmaceutical care. This will be particularly important in remote, rural and island areas of Scotland and the continuing role of essential dispensing by GP practices and how this can be enhanced and supplemented with clinical pharmaceutical care.
- 1.43 It is therefore important to recognise that the proposals set out in this consultation will be reviewed as we make the transition towards a new statutory framework for NHS Board Pharmaceutical Care Services Planning.
- **1.44** As part of the actions set out in *Prescription for Excellence*, the Scottish Government will consult on the statutory powers of NHS Board Pharmaceutical Care Services Plans and its impact on existing planning arrangements including dispensing doctors.

Amending Legislation

1.45 The proposals discussed in this consultation document would give effect to changes to Regulation 5 of and paragraph 3 and 4 of Schedule 3 to the NHS (Pharmaceutical Services) (Scotland) Regulations 2009; Paragraph 44, Schedule 5 of the NHS (General Medical Services Contracts) (Scotland) Regulations 2004; and Schedule 1, Paragraph 15 of the NHS (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004.

Section 2: Consultation Issues

The stability of NHS services in remote, rural and island areas

- 2.1 The Wilson and Barber Review¹² described how changes brought about by applications to open a community pharmacy under the current "control of entry" framework have caused significant concerns for some local communities, and have, on occasions, undermined the professional partnership between pharmacists and GPs.
- 2.2 In recent years the application, or approval, to open a pharmacy where there is an existing dispensing GP practice, has attracted high profile campaigning and lobbying to protect the dispensing GP practice concerned. It is strongly contended by dispensing GP practices and their patients that the income generated from dispensing medicines subsidises staff costs and other services offered by the practice, and the impact of opening a pharmacy would destabilise the viability of the practice and the healthcare hub they provide for their communities. The additional funding for providing a dispensing service within these practices is intended to remunerate for delivery of that service.
- 2.3 The consultation proposals in Part 1 aim to address this issue by offering a new approach to how NHS Boards consider pharmacy applications in remote, rural and island areas. It describes how existing primary legislation could be used to introduce amended regulations that would designate certain geographical areas as 'controlled remote, rural and island localities' for the purpose of considering new community pharmacy applications.
- 2.4 This approach involves additional legal tests which would include considering the impact that the opening of a new pharmacy might have on existing NHS services in the neighbourhood of the proposed pharmacy, including those NHS services provided by any dispensing GP practice and its branch surgeries where they exist.
- 2.5 The proposals in Part 1 also consider the importance of NHS Boards monitoring demographic changes and related changes in healthcare needs in these 'controlled remote, rural and island localities'. This is crucial in terms of ensuring that NHS pharmaceutical and primary medical services are able to respond to changing population and clinical care priorities; that the pharmaceutical care provided is safe, clinically effective, and deliver the best health outcome for patients from the medicines prescribed to them.

The wider pharmacy applications process

2.6 The issues 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.

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¹² http://www.scotland.gov.uk/Resource/0043/00430209.pdf

Public consultation and the community voice

- 2.7 It is also clear that there is a need to look again at the public consultation aspects of the pharmacy application process more generally. The Scottish Government is aware of concerns in some communities that the application process is not transparent or robust enough, with decisions taken behind closed doors. In addition they feel that their views and representations are not given sufficient weight in the decision-making process.
- 2.8 There is also a need to consider whether communities through a nominated representative should be given 'interested party' status and be invited to submit written and give oral representations at NHS Board Pharmacy Practice Committee (PPC) hearings alongside other interested parties.
- 2.9 The proposals in Part 2 of this consultation seek to introduce improvements in the consultation process undertaken by the applicant, and by the NHS Board upon the receipt of a pharmacy application. They also aim to give greater weight to community involvement and public engagement in the overall applications process including giving rights to members of the community or their representatives to make representations to the PPC. The proposals also aim to provide a greater balance of those permitted to make representations at PPC hearings so that no single party or person (the applicant or those affected by the application) is able to dominate the entire hearing.
- 2.10 The proposals in Part 2 also seek to place a greater responsibility on the applicant and the NHS Board to demonstrate the extent to which the views of the local community have been taken into account. This is particularly important when an NHS Board publishes its decision on the outcome of pharmacy applications.
- 2.11 Looking to future arrangements in relation to the planning of NHS pharmaceutical services, the proposals also consider a first stage in the application process whereby the prospective applicant should enter into a preapplication stage with the NHS Board. This is to help determine whether there is an identified unmet need in the provision of NHS pharmaceutical services. This new approach will introduce a shift in emphasis away from a largely applicant driven procedure to one where NHS Boards' Pharmaceutical Care Services Plans will have a greater role.

Securing NHS pharmaceutical services

2.12 We also want to ensure the rights of patients to receive reliable and sustainable NHS pharmaceutical services into the future. NHS Boards should be able to take into account how pharmaceutical services would be delivered in practice in the long term after an application has been received. This is central to NHS Boards ability to secure NHS services for the communities they serve.

Timeframes for reaching decisions

- 2.13 There has also been a growing case to look at timeframes for PPCs and the National Appeal Panel (NAP) to reach decisions. Applicants, NHS Boards and interested parties alike have expressed concerns about the perceived excessive time and resource involved in the application process. This includes, for example, from the time it takes from the application being submitted to the PPC hearing and decision, through to decisions of the NAP where appeals have been lodged and referred back to Boards for further action.
- 2.14 The length of the overall process can sometimes be a source of great anxiety for the community and the applicant, as well as costly in terms of the resource invested.
- 2.15 The proposals in Part 2 seek to address this by considering the introduction of a statutory timeframe within which PPCs and the NAP are obliged to reach decisions. It is recognised, however, that a balance needs to be struck to ensure that shorter timescales do not affect the quality of decisions that might lead to additional unnecessary appeals.

Expert advice and support to PPCs during deliberations

- 2.16 The constitution of the PPC largely consists of lay members and members who are generally not expert in the legal framework governing pharmacy applications and the associated legal tests. This is compounded by the infrequent need to convene a PPC in most NHS Board areas, and the turnover and availability of those willing and prepared to serve as members.
- 2.17 NHS Boards and their PPC Chairs have become concerned that this causes practical difficulties in how the PPC carries out its responsibilities when it withdraws from the open hearing to consider the evidence in detail and members casts their votes on the merits of the application.
- 2.18 In the past such expert advice and support has been provided by NHS Board officers, but there is a view that such advice and assistance to PPC members in the course of their private deliberations could amount to actual or perceived bias in the decision-making of the PPC. NHS Boards are trying alternative approaches to dealing with this issue, but are concerned that they have added to the overall timescales for PPCs in reaching a decision and can bring about additional costs and pressure on resources.
- **2.19** The proposal in Part 2 looks to bring about a more practical solution for NHS Boards in the form of a supporting independent legal assessor.

CONSULTATION PROPOSALS PART 1

CONTROL OF ENTRY (PHARMACY APPLICATIONS) AND DISPENSING GP PRACTICES

The stability of NHS services in remote, rural and island areas

- 1. The Scottish Government recognises the vital role that dispensing GP practices play in the dispensing and supply of medicines to patients in remote, rural and island communities. It is committed to ensuring that where patients have serious difficulty in obtaining (from a pharmacist) any drugs, medicines or appliances, required for their treatment that the dispensing GP practice will continue to fulfil this vital role.
- The Scottish Government notes concerns that sometimes the impact of opening a community pharmacy in some rural communities could potentially impact on other NHS provided services or destabilise the overall disposition of NHS primary medical and pharmaceutical services. It is also aware of concerns about the impact on the viability of the dispensing GP practice and the staff it employs.
- 3. Whilst the income GP practices receive for dispensing is not intended to subsidise the delivery of primary medical services, the Scottish Government considers that in the circumstances it is reasonable that a degree of stability be provided for dispensing practices whilst the way ahead in the context of *Prescription for Excellence* is developed.

Areas of a 'prescribed description' and 'prescribed criteria'

- 4. Therefore, based on existing powers under Section 27(4)(d) of the NHS (Scotland) Act 1978, 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. These are areas that would be deemed by NHS Boards as rural in character taking account of the Scottish Government's Urban/Rural Classifications such as "remote small towns", "accessible rural", "remote rural", "very remote small towns" and "very remote rural" These areas will usually have one or more dispensing GP practices and branch surgeries within the locality.
- In a 'controlled remote, rural and island locality' the NHS Board Pharmacy Practices Committee (the PPC), in addition to the test of 'necessary or desirable' (the adequacy test), will need to consider whether the application to open a pharmacy in the locality would adversely impact on the provision of existing NHS services in the locality. This would be known as the 'Prejudice Test'.

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¹³ http://www.scotland.gov.uk/Topics/Statistics/About/Methodology/UrbanRuralClassification

- 6. In general, this means that nothing must be done which would compromise the ability of people to access existing NHS pharmaceutical services, dispensing services or primary medical services. Prejudice arises where the pharmaceutical services or primary medical services that people can rightly expect to be provided by the NHS would, in some respect, cease or otherwise be curtailed or withdrawn without the replacement of those services potentially affected.
- 7. If the NHS Board PPC concludes that the opening of a pharmacy would affect NHS provided or contracted services in this way, then the application would be rejected regardless of whether it would otherwise be necessary or desirable in order to secure the adequate provision of pharmaceutical services in the locality.

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 🗌 |
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| Please tell us the reason for your answer i | n the box below | |
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- 6. Changes can occur that may affect the designation of an area as a 'controlled remote, rural and island locality'. This can happen where an urban area is expanding into the surrounding countryside, or where there has been a substantial development permitted in what may have been deemed a 'controlled remote, rural and island locality'. An example of this could be where a housing development has been built or is in the process of being built and the population of a village has increased or will increase as a consequence with increases in shopping, leisure and other facilities usually found in non-rural areas.
- 9. In addition NHS services need to be able to respond to changing healthcare needs and priorities both locally and nationally that may require some local NHS service reconfiguration to deliver appropriate and clinically effective service provision with available resources.

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 🗌 |
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| Please tell us the reason for your answer in th | e box below | |
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- 10. It follows, therefore, that NHS Boards need to have the appropriate freedoms to discharge their statutory duty to secure and provide both the NHS pharmaceutical services and NHS primary medical services needed by their local communities.
- 11. The circumstances in which GP practices are required to dispense to their patients should also be kept under review by the NHS Board.
- 12. As discussed above, it is important that NHS services are responsive to population changes and changing healthcare needs and priorities both locally and nationally. It is therefore important that 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 so that patients get the best possible outcomes from their medicines.

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 🗌 |
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CONSULTATION PROPOSALS PART 2

WIDER PHARMACY APPLICATION PROCESSES

1. 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. These will be routine considerations for all applications.

Public consultation and the community voice

- 2. Under Paragraph 1 of Schedule 3 to the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009, the NHS Board must notify the Area Pharmaceutical Committee ('the APC'), the Area Medical Committee ('the AMC'), any person named on the pharmaceutical or provisional pharmaceutical lists whose interests the Board considers the granting of that application may significantly affect and any Board within a 2km boundary of the proposed premises. These are known as 'interested parties'.
- 3. The Scottish Government acknowledges that there is a need to consider whether communities through a nominated representative should be given 'interested party' status and be invited to submit written and give oral representations at NHS Board Pharmacy Practices Committee (PPC) hearings alongside other interested parties.
- 4. The NHS Board could invite 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. The representative would be required to present a balanced viewpoint from the local community.
- 5. This approach is intended to address concerns that the application process is not transparent or robust enough, and to give sufficient weight to views of the community in the evidence gathering and decision-making process.
- 6. 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.

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 be considered in statute 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 🗌 |
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| Please tell us the reason for your answer in t | the box below | |
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7. In the interest of fairness during meetings where the NHS Board PPC decides to take oral representations, in order to achieve a greater balance of those permitted to make representations, the Scottish Government is considering the case that no one single party or person (the applicant or those affected by the application) is able to dominate the entire hearing.

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 t | he box below | |
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| | | |
| The 2009 Regulations set out that the applicant making oral representations can be assisted in meetings by another person. However, a person in a capacity of counsel, solicitor or paid advocate behalf of the person they are assisting. | naking represent n who assists ca | ations at the |
| Going forward the Scottish Government is considerable this rule so that those assisting can speak on be assisting. This case is strongest for those assist behalf of the community. | half of those the | / are |
| Proposal 6: | | |
| The Scottish Government proposes that goin in oral representations by the applicant, the cinterested parties in attendance are able to sthey are assisting. | community and | other |
| Do you agree with this proposal? | Yes □ | No 🗌 |
| Please tell us the reason for your answer in the box below | | |

- 10. It is also clear that there is a need to look again at the public consultation aspects of the pharmacy application process. The Scottish Government is aware of concerns in some communities that the application process is not transparent or robust enough, with decisions taken behind closed doors, and that their views given during the consultation process are not given sufficient weight in the decision-making process.
- 11. Under the current process, the community is entitled to participate in two consultations, namely, the consultation the applicant requires to complete and the public consultation of the NHS Board. In addition, the PPC is directed to have regard to any consultation responses when considering whether the application meets the test of necessity or desirability.

- 12. At present a person who wishes to be included in the pharmaceutical list for the provision of pharmaceutical services must make an application to the NHS Board in which the area of the application relates.
- 13. Within twenty working days prior to making the above application, the applicant must complete a consultation with the communities affected. The aim is to assess whether the neighbourhood to which the application relates has adequate provision of some or all of the pharmaceutical services the applicant intends to provide. Notice of the consultation must be given by being published in a newspaper circulating in the neighbourhood of the application.
- 14. On receipt of the application the NHS Board must take reasonable steps to consult with the public who may receive pharmaceutical services as a result of the application. This should normally take place over a 60 day period.
- 15. Going forward the Scottish Government considers the case for placing two requirements on the applicant. The first is that the applicant should enter into a pre-application stage with the NHS Board to determine whether there is in fact an identified unmet need in the provision of pharmaceutical services. This represents a shift away from a largely applicant driven procedure to one where NHS Boards Pharmaceutical Care Services Plans will have a greater role.
- 16. It would also assist NHS Boards in determining the urgency of the demand for NHS pharmaceutical services identified by the applicant. Therefore, NHS Boards' Pharmaceutical Care Services Plans would need to reflect an assessment of service gaps and where need is most urgent.
- 17. The Scottish Government considers this to be an important first step towards the aims set out *Prescription for Excellence* where NHS Board Pharmaceutical Care Services Plans will be the main statutory vehicle through which NHS Scotland plans, provides and delivers pharmaceutical care and medicines to its communities.
- 18. Secondly, the applicant will also be required to provide evidence that they have taken positive steps to consult with the community in compiling their assessment of need. This means that notice of the consultation must be given by being published in a newspaper circulating in the neighbourhood of the application. The notice must also be advertised in all circulating local news free-sheets and newsletters in the neighbourhood in order to reach the vast majority of residents the applicant intends to provide services to. A similar requirement will be placed on NHS Boards for their consultation exercise.
- 19. The purpose of this is to actively consult and engage with residents in the neighbourhood in which the applicant intends to provide pharmaceutical services in order to obtain their views.

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 th | e box below | |
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- 20. With regard to the public consultation undertaken by the NHS Board, communities have expressed concerns that it is not always clear how, or if, their views have been taken into account and what part they have played in the NHS Board PPC decision.
- 21. The current 2009 Regulations direct PPCs to have regard to any consultation responses when considering whether the application meets the test of necessity or desirability. They are also required to publish decisions about applications on their websites alongside the reasons for the decision.

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 | |
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| Securing NHS pharmaceutical services | | |
| The Scottish Government is committed to protecting receive reliable and sustainable NHS pharmaceutical viability of the proposed pharmacy is a key factor in for the local community concerned. | al services. T | he financial |
| NHS Boards should therefore be able to actively take pharmaceutical services would be delivered in praction an application has been received. This is central to secure NHS services in the communities they serve | tice in the long NHS Boards | g term after |
| Proposal 9: | | |
| The Scottish Government considers that NHS Be take into account how NHS pharmaceutical serving practice in the long term after an application be included taking into account the financial viability business proposed. This is an important factor services in the long term. | ices would b nas been rec ty of the pha | e delivered eived. This rmacy |
| Do you agree with this proposal? | Yes 🗌 | No 🗌 |
| Please tell us the reason for your answer in the | box below | |
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Timeframes for reaching decisions

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24. There has also been a growing case to look at timeframes for PPCs and the National Appeal Panel (NAP) to reach decisions. Applicants, NHS Boards and interested parties alike have expressed concerns about the sometimes excessive time and resource involved in the application process.

- 25. The length of the overall process can sometimes be a source of great anxiety for the community and the applicant, as well as costly in terms of the resource invested to see the application process through to fruition.
- 26. The Scottish Government aims to address this by considering the introduction of a statutory timeframe within which PPCs and the NAP are obliged to reach decisions. The Scottish Government considers that there may be a case to 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 by 'interested parties'.
- 27. However, a balance would need to be struck to ensure that statutory timescales would not affect the quality of decisions that might lead to additional unnecessary appeals. In more complex cases the timeframe would be made extendable where there is a good cause for delay. This would apply to both PPC and NAP 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 | |
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Expert advice and support to PPCs during deliberations

- 28. The constitution of the PPC largely consists of lay members and members who are generally not expert in the legal framework governing pharmacy applications and associated legal tests
- 29. This is compounded by the infrequent need to convene a PPC in most NHS Board areas, and the turnover and availability of those willing and prepared to serve as members.

- 30. NHS Boards and their PPC Chairs have become concerned that this causes practical difficulties in how the PPC carries out its responsibilities when it withdraws from the open PPC hearing to consider the evidence in detail and members casts their votes on the merits of the application.
- 31. In the past advice and support has been provided by NHS Board officers, but there is a view that such advice and assistance to PPC members in the course of their private deliberations could amount to actual or perceived bias in the decision-making of the PPC.
- 32. The Scottish Government is of the view that NHS Board PPCs should have access to an independent legal assessor to provide technical support and guidance to the PPC regarding due process and adherence to the necessary considerations required to assess the legal tests set out in primary and secondary legislation.

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 t | he box below | |
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A consultation on the Control of Entry Arrangements and Dispensing GP Practices

The Scottish Government is inviting responses to its consultation on *Control of Entry Arrangements and Dispensing GP Practices*. The consultation will start on 12 December 2013 and will run until 20 February 2014.

Responding to the consultation

See **Annexes B and C** for questionnaire/ respondent form. We are inviting written responses to this consultation by 20 February 2014. Please send your response **with the completed Respondent Information Form** to: ControlofEntry2013@scotland.gsi.gov.uk

or

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

If you have any queries please email as above or call 0131 244 2524.

We would be grateful if you would use the consultation questionnaire provided or could clearly indicate in your response which questions or parts of the consultation paper you are responding to as this will aid our analysis of the responses received.

The Scottish Government's Consultation Process

Further information is provided at **Annex C**

A list of bodies to which this consultation has been sent is provided at **Annex E**

This consultation, and all other Scottish Government consultation exercises, can be viewed online on the consultation web pages of the Scottish Government website at http://www.scotland.gov.uk/consultations.

The Scottish Government has an email alert system for consultations (<u>SEconsult</u>: http://www.scotland.gov.uk/consultations/seconsult.aspx). This system allows stakeholder individuals and organisations to register and receive a weekly email containing details of all new consultations (including web links). SEconsult complements, but in no way replaces SG distribution lists, and is designed to allow stakeholders to keep up to date with all SG consultation activity, and therefore be

alerted at the earliest opportunity to those of most interest. We would encourage you to register.

Handling your response

We need to know how you wish your response to be handled and, in particular, whether you are happy for your response to be made public. Please complete and return the **Respondent Information Form** (see Annex C), included with this consultation paper, as this will ensure that we treat your response appropriately. If you ask for your response not to be published we will regard it as confidential, and we will treat it accordingly.

All respondents should be aware that the Scottish Government are subject to the provisions of the Freedom of Information (Scotland) Act 2002 and would therefore have to consider any request made to it under the Act for information relating to responses made to this consultation exercise.

Next steps in the process

Where respondents have given permission for their response to be made public and after we have checked that they contain no potentially defamatory material, responses will be made available to the public in the Scottish Government Library by 12 March 2014 and on the Scottish Government consultation web pages by 20 March 2014. You can make arrangements to view responses by contacting the SG Library on 0131 244 4552. Responses can be copied and sent to you, but a charge may be made for this service.

What happens next?

Following the closing date, all responses will be analysed and considered along with any other available evidence to help us reach decisions on what changes are required. We aim to issue a report on this consultation as early as possible in Spring 2014 and to make changes to Regulations as soon as is practicable.

Comments and complaints

If you have any comments about how this consultation exercise has been conducted, please send them in the first instance to the address details overleaf for the attention of Brian O'Donnell.

Respondent Information Form

Please complete the Respondent Information Form, which is provided alongside the questionnaire. **It must be returned with all responses.**

CONSULTATION RESPONSE FORM

Consultation Proposals - Part 1Control of Entry (Pharmacy Applications) and Dispensing GP Practices

The stability of NHS services in remote and rural areas

| Proposa | I 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 belo | ow | |
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| Proposal 2: | | |
| The Scottish Government proposes that the designation 'controlled remote, rural and island locality' should be really Boards so that NHS provided or contracted service population changes, and changing healthcare needs an and nationally. It is proposed that the review should be minimum of every three years. | eviewed peri es are respor d priorities b | iodically by nsive to ooth locally |
| Do you agree with this proposal? | Yes 🗌 | No 🗌 |
| Please tell us the reason for your answer in the box below | ow | |
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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 | | | | | |
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Consultation Proposals - Part 2Wider 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. No 🗌 Do you agree with this proposal? Yes Please tell us the reason for your answer in the box below **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

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 | | | | | |
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| Proposal 7: | | | | | |
| The Scottish Government proposes that going forward a pharmacy, for the purpose of providing NHS pharmached should first enter into a pre-application stage with the whether there is an identified unmet need in the provise pharmaceutical services. | ceutical serv NHS Board t | vices, | | | |
| This would assist NHS Boards in determining the urge NHS pharmaceutical services identified by the applical Pharmaceutical Care Services Plans would need to ref service gaps and where need is most urgent. | nt. NHS Boa | rds | | | |
| 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 to its consultation activities. | of advertisin | g in relation | | | |
| Do you agree with this proposal? | Yes 🗌 | No 🗌 | | | |
| Please tell us the reason for your answer in the box be | low | | | | |
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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 | | | | | |
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| Securing NHS pharmaceutical services | | | | | |
| Proposal 9: | | | | | |
| The Scottish Government considers that NHS E into account how NHS pharmaceutical services in the long term after an application has been reinto account the financial viability of the pharman important factor in securing these services in | would be delivered eceived. This includacy business propo | in practice les taking | | | |
| Do you agree with this proposal? | Yes 🗌 | No 🗌 | | | |
| Please tell us the reason for your answer in the | box below | | | | |
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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 | | | | | | |
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| Expert advice and support to PPCs during del | <u>liberations</u> | | | | | |
| Proposal 11: | | | | | | |
| The Scottish Government proposes that going framework would make provisions for the applegal assessor acting in a supporting and adv providing advice and guidance on technical a application process during PPC deliberations | propriate role of an inc isory capacity, includ nd legal aspects of th | dependen ing | | | | |
| Do you agree with this proposal? | Yes □ | No 🗌 | | | | |
| Please tell us the reason for your answer in the box below | | | | | | |
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Annex C

Respondent Information Form

A CONSULTATION ON THE CONTROL OF ENTRY ARRANGEMENTS AND DISPENSING GP PRACTICES



Please Note this form **must** be returned with your response to ensure that we handle your response appropriately

| 1. Name/Organisation Organisation Name | | | | | | | | |
|--|--|--|--------------------------------------|------|------------------|--------------------------|--|--------------------------------------|
| Title | Mr 🗌 Ms | s Mrs[| ☐ Miss ☐ | Dr | ☐ Plea | ase tick a | as appr | opriate |
| Surr | name | | | | | | | |
| Fore | Forename | | | | | | | |
| 2. Postal Address | | | | | | | | |
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| Pos | stcode | | Phone | | | Email | | |
| 3. Pe | ermissions | - I am res | ponding as. | | | | | |
| Individual | | I | 1 | Grou | o/Organi | sation | | |
| | | | Please tick | as a | appropriat | е | | |
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| (b) | Where con requested, responses | nfidentiality , we will ma | ke your o the public | | | re you co be mad | | or your response ble? |

| | | Please tick ONE of the following boxes | | | Please tick as appropriate ☐ Yes ☐ No | | |
|---|-----|--|----|--|--|--|--|
| ١ | | | | | | | |
| | | Yes, make my response, name and address all available | | | | | |
| | | | or | | | | |
| | | Yes, make my response available, but not my name and address | | | | | |
| | | | or | | | | |
| | | Yes, make my response and name available, but not my address | | | | | |
| į | | | | | | | |
| | (d) | We will share your response internally with other Scottish Government policy teams who may be addressing the issues you discuss. They may wish to contact you again in the future, but we require your permission to do so. Are you content for Scottish Government to contact you again in relation to this consultation exercise? Please tick as appropriate Yes | | | | | |
| | | | | | | | |

THE SCOTTISH GOVERNMENT CONSULTATION PROCESS

Consultation is an essential and important aspect of Scottish Government working methods. Given the wide-ranging areas of work of the Scottish Government, there are many varied types of consultation. However, in general, Scottish Government consultation exercises aim to provide opportunities for all those who wish to express their opinions on a proposed area of work to do so in ways which will inform and enhance that work.

The Scottish Government encourages consultation that is thorough, effective and appropriate to the issue under consideration and the nature of the target audience. Consultation exercises take account of a wide range of factors, and no two exercises are likely to be the same.

Typically Scottish Government consultations involve a written paper inviting answers to specific questions or more general views about the material presented. Written papers are distributed to organisations and individuals with an interest in the issue, and they are also placed on the Scottish Government web site enabling a wider audience to access the paper and submit their responses¹⁴. Consultation exercises may also involve seeking views in a number of different ways, such as through public meetings, focus groups or questionnaire exercises. Copies of all the written responses received to a consultation exercise (except those where the individual or organisation requested confidentiality) are placed in the Scottish Government library at Saughton House, Edinburgh (K Spur, Saughton House, Broomhouse Drive, Edinburgh, EH11 3XD, telephone 0131 244 4565).

All Scottish Government consultation papers and related publications (e.g., analysis of response reports) can be accessed at: http://www.scotland.gov.uk/consultations

The views and suggestions detailed in consultation responses are analysed and used as part of the decision making process, along with a range of other available information and evidence. Depending on the nature of the consultation exercise the responses received may:

- indicate the need for policy development or review
- inform the development of a particular policy
- help decisions to be made between alternative policy proposals
- be used to finalise legislation before it is implemented

Final decisions on the issues under consideration will also take account of a range of other factors, including other available information and research evidence.

While details of particular circumstances described in a response to a consultation exercise may usefully inform the policy process, consultation exercises cannot address individual concerns and comments, which should be directed to the relevant public body.

¹⁴ http://www.scotland.gov.uk/consultations

EQUALITY IMPACT and BUSINESS REGULATORY IMPACT ASSESSMENT INFORMATION

Equality Impact Assessment Information

The public sector equality duties require the Scottish Government to pay "due regard" to the need to:

- eliminate discrimination, victimisation, harassment or other unlawful conduct that is prohibited under the Equality Act 2010;
- advance equality of opportunity between people who share a protected characteristic and those who do not;
- foster good relations between people who share a relevant protected characteristic.

These three requirements apply across the "protected characteristics" of age; disability; gender reassignment; pregnancy and maternity; race; religion and belief; sex and sexual orientation.

In effect, this means that equality considerations are integrated into all functions and policies of Scottish Government Directorates and Agencies.

A key part of these duties is to assess the impact of all of our policies to ensure that the Scottish Government do not inadvertently create a negative impact for equality groups, and also to ensure that the Scottish Government actively seek the opportunity to promote equality of opportunity and to foster good relations

The Scottish Government has not identified any potential negative impact on any equality group of the proposals in this consultation exercise. Indeed, in so far as these proposals are intended to safeguard the provision of local NHS services, it considers that the proposals are supportive of the interest of all equality groups in the same way as they are supportive of the care needs of the wider population.

The Scottish Government welcomes your feedback regarding the equalities impact of the proposals presented in this paper, and the effect they may have on different sectors of the population.

Business Regulatory Impact Assessment Information

The Scottish Government is committed to consulting with all parties potentially affected by proposals for new legislation, or where any regulation is being changed significantly. All policy changes, whether European or domestic, which may have an impact upon business or the third sector organisations should be accompanied by a Business Regulatory Impact Assessment (BRIA).

The BRIA helps policy makers to use available evidence to find proposals that best achieve the policy objectives, whilst minimising costs and burdens. Through consultation and engagement with business, the costs and benefits of the proposed

legislation can be analysed. It also ensures that any impact on business, particularly small enterprises, is fully considered before Regulations are made.

The Scottish Government welcomes your views regarding the impact that the proposals presented in this paper may have on businesses.

The Scottish Government has identified potential impact on 3 business interests in this consultation.

- 1. In respect of dispensing doctor practices these proposals are intended to provide short term stability, which in term would enable the practices concerned to provide a continuum of care to patients. There are no proposals at the present to change the funding envelope for the contractors concerned.
- In respect of persons wishing to apply to open a community pharmacy these
 consultation proposals may in some circumstances involve increased
 preparation, but are intended to help deliver better decision making by NHS
 Board Pharmacy Practice Committees which is an objective that is beneficial
 in respect of all parties.
- 3. In respect of individual professional pharmacists these proposals hold out the prospect of some potential increased need for professional pharmacists to support dispensing doctors to provide services to patients consistent with local plans which may be developed by NHS Boards. This may enable pharmacists concerned to enter into arrangements with NHS Boards.

CONSULTATION DISTRIBUTION LIST

Clerk of the Health and Sport Committee

All Scottish MEPs

All Scottish MPs

All MSPs

SG Library

SPICe Library

6 Legal Deposit/Copyright Libraries

Chief Executives, NHS Boards

Chief Executives, Special Health Boards

Directors of Finance, NHS Boards

Directors of Finance, Special Health Boards

NHS Boards Chief Pharmacists / Directors of Pharmacy

Association of Community Health Partnerships Scotland

Department of Health, England

Health and Social Care Department, Wales

Department of Health, Social Services and Public Safety, Northern Ireland

CoSLA

Chief Executives, All Scottish Local Authorities

Community Council Liaison Officers, All Scottish Local Authorities

General Medical Council

General Pharmaceutical Council

Royal Pharmaceutical Society of Great Britain

Community Pharmacy Scotland

National Pharmacy Association

Pharmacists' Defence Association

Royal College of General Practitioners

BMA Scotland, Scottish General Practitioners Committee

Dispensing Doctors Association

Scottish Public Services Ombudsman

National Appeal Panel Chair

Scottish Healthcare Service Centre

Scottish Health Council

Equality and Human Rights Commission

Scottish Patients Association

Alliance Scotland

Voluntary Health Scotland

NHS Boards have been asked to circulate the consultation link to:-

- Community Pharmacy Contractors
- GP Dispensing Practices
- Area Medical Committees
- Area Pharmaceutical Committees
- PPC Chairs
- Any other groups with an interest.



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