

Dear Colleague

NHS (Pharmaceutical Services) (Scotland) Amendment Regulations 2011 (SSI 2011/32)

Provision on Control of Entry to Pharmaceutical Lists

1. The National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 determines the process to be followed when applications are made to NHS Boards to provide NHS pharmaceutical services. The 2011 Amendment Regulations (SSI 2011/32) make a number of changes to the Control of Entry arrangements and processes for inclusion on the pharmaceutical list. The Regulation Amendments can be found at www.legislation.gov.uk/ssi/2011/32/contents/made
2. This circular informs NHS Boards of :
 - the amendment Regulations coming into force; and
 - the revised Control of Entry Arrangements.
3. Attached at **Annex 1** is an overview of the amendment regulations.
4. **Annex 2** provides guidance to Boards relating to the amended arrangements and processes and also includes 3 appendices;
 - **Appendix A** – PPC and NAP constitution and function;
 - **Appendix B** – Public Consultation Advice; and
 - **Appendix C** – PPC Minute Proforma
5. **Annex 3** provides guidance for applicants, including;
 - **Appendix 1** - Applicants assessment requirements;
 - **Appendix 2** – Application Forms

31 March 2011

Addresses

For action

NHS Boards, Chief Executives

Directors of Pharmacy

For information:

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6. The Guidance will be kept under review and we are happy to consider any comments or suggestions for future amendments.

Action by NHS Boards

7. NHS Boards are asked to draw the contents of this circular to the attention of all staff involved in dealing with matters relating to control of entry arrangements and to distribute copies of **Annex 3** and **Appendix 1** and **2** to each person on your pharmaceutical list.

Yours Sincerely

A handwritten signature in blue ink that reads "Bill Scott". The signature is written in a cursive, slightly slanted style.

Professor Bill Scott
Chief Pharmaceutical Officer

NHS (Pharmaceutical Services)(Scotland) Amendment Regulations 2011

Overview

The National Health Service (Pharmaceutical Services) (Scotland) Amendment Regulations 2011 amend the provisions for the control of entry application process. The amendments follow the consultation *Review of the Control of Entry Arrangements* and the recommendations made in the subsequent summary report. The revised procedures will apply to applications for entry to the pharmaceutical list received on or after 1 April 2011.

The regulations below amend the NHS (Pharmaceutical Services)(Scotland) Regulations 2009 (the Principal Regulations).

Regulation 4 amends Regulation 5 (Pharmaceutical List) of the Principal Regulations to provide for an applicants consultation and assessment of the application, as detailed below.

Applicants Consultation

The amendments provide that an applicant, except where applying for a minor relocation or change of ownership, shall be required to seek views from the public within the area to which their application relates. This is for the purpose of assessing whether the neighbourhood has adequate provision of pharmaceutical services by persons on the pharmaceutical list of some or all of the pharmaceutical services that the applicant intends to provide. ie If the application is to open new premises, this should be advertised in a local newspaper circulating within the neighbourhood in which the applicant intends to provide services. If relocating, this should be advertised in the current premises. Advertising of the applicant's intentions should be for a continuous period of at least 20 days and in the case of a relocation, should make clear that the existing premises will close if the application is successful. An application must then be lodged within 20 days of the completion of the consultation.

Applicant's Assessment

The amendments provide for an 'applicants assessment.' The applicants assessment is for the purpose of ensuring the Board has sufficient information for making a decision on the application and will also help to show evidence of the commitment of the applicant.

Application Form A (for use by pharmacists/by persons other than pharmacists) and Form A(MR) have been replaced by Form A(1) and A(2). Form A(1) is to be used by anyone applying to either relocate (minor or other than minor) or to open new premises. Form A(2) is to be used when applying to take over ownership of existing premises on the pharmaceutical list.

Application Form A(1) provides for the completion of the applicant's assessment whereby the applicant is asked specific questions so as to provide sufficient detail information to inform the Board. Boards shall disregard already listed premises when an applicant is applying to relocate i.e. the premises to be relocated should not be considered as providing pharmaceutical services when considering adequacy, by those on the pharmaceutical list, in the area.

An application for change of ownership (Form A(2)) does not require an applicant's assessment.

The regulation also replaces the word 'appreciable' with 'significant' in relation to minor relocations which responds to some concerns that the previous wording stifled Boards' ability to grant minor relocations.

Regulation 6 amends Regulation 15 of the Principal Regulations so that Boards are obliged to publish Pharmaceutical Care Services Plans. Boards also have to monitor their Pharmaceutical Care Services Plan annually to reflect changes in service provision or patient needs.

Regulation 8 amends Schedule 3 in the Principal Regulations increasing the period from 5 days to 10 days in which the Board is required to give notice of the application to the Area Pharmaceutical Committee, the Area Medical Committee, any person whose name is on the pharmaceutical list, or provisional list, who may be significantly affected if granted, and any Board whose boundary is within 2 kilometres of the proposed premises.

The amendment also requires that dispensing doctors in the neighbourhood where the application has been made are given written notification. This will ensure that they are aware from the outset that an application is to be considered by the Board and can discuss with the Area Medical Committee if they wish to do so.

Boards will now be required to publish decisions about applications on their websites alongside the reasons for the decision. This will ensure the process is as open as possible and that potential applicants can consider whether previous applications have been made in a given area.

Grounds of appeal are clarified such that an appeal is available where the Board has erred in law in its application of the provision of the regulations or there has been; a procedural defect; a failure to properly narrate the facts or reasons upon which the determination of the application was based; or a failure by the Board to adequately explain the application of the provisions of the regulations to the facts stated.

The Chair of the National Appeal Panel may dismiss an appeal if there are no reasonable grounds for appeal or the appeal is frivolous or vexatious. The role of the National Appeal Panel Chair is being strengthened such that they 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 remit the appeal onto the NAP if a point of law has been raised. This responds to concerns that the National Appeal Panel previously heard most appeals afresh and in so doing was becoming regarded as the main decision making body, rather than the Boards' Pharmacy Practice Committees.

Regulation 9 amends Schedule 4 of the Principal Regulations to amend the structure of the Pharmacy Practices Committee and the National Appeal Panel. These amendments are detailed below.

Pharmacy Practice Committees

The PPC shall continue to consist of 7 members unless the application is for premises in a neighbourhood or an adjacent neighbourhood to the location of a dispensing doctor, in which case an additional member will be appointed by the Board from persons nominated by the Area Medical Committee ensuring wider representation on the committee. The

amendments also provide that only lay members are now entitled to vote reinforcing the independence of the decisions made. The non-contractor pharmacist shall no longer be nominated by the Royal Pharmaceutical Society but by the Area Pharmaceutical Committee ensuring consistency with appointments to the National Appeal Panel and reinforcing independence.

National Appeal Panel

Nominations for membership shall no longer be provided by the Royal Pharmaceutical Society Great Britain or by the general body of pharmacy contractors. Panel members will be selected from nominations put forward by the Board. The Scottish Ministers, following consultation with all Health Boards shall appoint a Chair. As appeals are to be more focussed on errors in law, the amendment regulations provide that the Chair shall be an advocate, a solicitor or a solicitor-advocate but shall not be nor previously have been a health professional or an employee of a person on the pharmaceutical list. A substitute Chair will be appointed in the event that the Chair is unable to attend hearings.

The National Appeal Panel will now consist of 3 members, the Chair, a non-contractor pharmacist and a lay member, who is not nor has been a health professional. All members shall have the right to vote.

ARRANGEMENTS FOR CONTROL OF ENTRY TO PHARMACEUTICAL LISTS

General

1. The National Health Service (Pharmaceutical Services) (Scotland) Amendment Regulations 2011 (SSI 32/2011) amends the National Health Service (Pharmaceutical Services)(Scotland) Regulations 2009, the principal regulations, in relation to the arrangements for the control of entry to a Health Board's Pharmaceutical List as required by the National Health Service Act (Scotland) 1978.
2. The amendment Regulations follow the consultation *Review of the Control of Entry Arrangements* and the recommendations made in the subsequent summary report and will come into force on 1 April 2011.
3. The Regulations provide for prospective community pharmacy owners to submit applications to Health Boards to provide NHS pharmaceutical services. The Health Boards have powers to deal with change of ownership and minor relocations (see paragraphs 8-12 below) without the establishment of a Pharmacy Practices Committee (PPC).
4. For new applications, the Board must consider whether the application is valid as if not, they can determine that the application need not be considered by their PPC [i.e. where the applicant has not provided sufficient information in their applicant's assessment]. If applications are valid the Board is required to establish a Pharmacy Practices Committee (PPC) to consider applications and to decide whether such applications are necessary or desirable to ensure the adequate provision of pharmaceutical services in a Board area. Scottish Ministers will arrange for the National Appeal Panel (NAP) to be convened to consider any appeals against the decisions of a Health Board's PPC. The constitution and functions of a PPC and the NAP are described in **Appendix A**.
5. The objective of these Regulations is to provide a mechanism whereby the number of premises providing NHS pharmaceutical services is determined as closely as possible by reference to the need of local population for those services, for example as outlined in the Board Pharmaceutical Care Services Plan (PCSP). The NHS needs of the local community are to be the main determinant of whether an additional community pharmacy or relocation is to be approved.
6. There is no predetermined target number of community pharmacies, either nationally or for individual Health Board areas. In some areas, there is already prima facie evidence of an overabundance of community pharmacies and a rationalisation of the number of premises would not necessarily reduce access to services. Indeed, it should not necessarily be regarded as obligatory to replace a community pharmacy which is closed with another. In other areas, there may be a need to increase access to pharmaceutical services but above all, a flexible approach should be adopted. Local needs will change over time and a pattern of service provision must adapt accordingly.

Applications to open community pharmacies

7. All applications, whether for new or in respect of existing premises, must be submitted to Health Boards on the relevant application form (Form A (1) or A (2) of Schedule 2 of the Regulations) and must specify the premises from which the proposed

services are to be provided. The applicant must state all NHS pharmaceutical services it is proposed, will be provided.

Change of ownership of existing community pharmacy

8. An applicant wishing to apply for change of ownership must complete application form A(2). The Regulations provide that the buyer of an existing pharmacy should be included on the relevant pharmaceutical list provided that the premises are on the pharmaceutical list at the time of the sale and there is no interruption or reduction of the pharmaceutical services to be provided.

9. It is preferred that there should be no change or interruption to services provided or to the hours of opening. However, we are aware that in some instances there may be a valid reason for a short interruption to services or the applicant may wish to provide additional services or increase the opening hours. The applicant must detail any possible changes from the current provision and provide explanation. It will be for the Board to consider and decide whether this is acceptable. Any proposed change to opening hours must take into account the Board's Hours of Opening Scheme. If the Board is content with the proposal it may issue form (C) confirming acceptance of the application and inclusion on the pharmaceutical list without establishing a PPC.

10. It should be made clear to the applicant what services have been accepted. Any proposal to alter services will be considered by the Board as a change notice and the applicant should be advised accordingly following consideration.

Applications for minor relocation of an existing community pharmacy

11. On receipt of an application for a minor relocation (which must be made on Form A(1)), the Board should seek and take into account the views of the Area Pharmaceutical Committee and the most senior pharmaceutical adviser. Subject to the Board being fully satisfied that the relocation is minor, the Board may approve the relocation without the reference to its PPC, if and only if:

a. the population of the neighbourhood served by the new premises is essentially the same as that served by the existing premises, and the NHS services to be provided are not being reduced, and

b. there would be no significant effect on the pharmaceutical services provided by the applicant or any other person whose name is on the Board's pharmaceutical list i.e. no other existing community pharmacy would suffer significant detriment to an extent which would prejudice the continuing ability to provide the NHS services it already provides, and

c. the applicant agrees to cease the provision of services at the current premises before commencing the provision of services at the new premises and that person provides NHS pharmaceutical services without interruption or has reached agreement with the Board for a short-term arrangement under its Hours of Service Scheme.

12. This provision is intended to permit the acquisition of new premises e.g. on expiry of a lease or when the existing location is affected by a compulsory purchase order or to permit a contractor to move to better premises or respond to changing patterns of patient need such as changes in local shopping habits, without need for a new application. It is the fulfilment of the above conditions which render the relocation "minor".

Applications deemed non-minor

13. If the Board receives representations or advice from its officials, including the relevant professional officers, or by some other method, and forms the opinion that the relocation is not minor, the application shall be refused and the applicant advised accordingly. If the applicant still wishes to relocate, they will have to make a new application, undertaking all steps as necessary.

Applications for new community pharmacies (or non-minor relocations)

14. On receipt of an application for a new community pharmacy, a Board must determine whether it is complete and as such constitutes a valid application which they need consider. The Board must determine whether the applicant's assessment meets the requirements in Regulation 5 (2C). This includes the applicant's assessment of current provision of services in the area and – where there has been a rejected application in the previous 12 months – the applicant's evidence of significant change. In both these instances, Boards will need to make their own judgement as to whether the applicant has, as provided for in Regulation 5 (2B), met the requirements of Regulation 5 (2C) and in so doing provided sufficient detail which would assist them in making a determination about the application.

15. If a Board judges that this is not the case, they should seek any missing information from the applicant. If they do so, this information must then be provided to the Board within 5 working days. If not, and the Board remain of the view that the applicant has not provided sufficient detail which would assist them in making a determination about the application, it shall be refused. In either granting or refusing the application, the Board must provide strong/robust written reasons for doing so.

16. Within 10 working days of receipt of a complete and valid application for a new pharmacy which meets the requirements of Regulation 5 (2C), (or within 10 working days of receipt of the additional information referred to in paragraph 14 above) the Board will invite representations from the following groups/ persons:

- its Area Pharmaceutical Committee;
- its Area Medical Committee;
- any person on the Board's Pharmaceutical List whose interests may be significantly affected if the application is approved; and
- any other Health Board whose boundary is within two kilometres of the proposed premises.

17. A Health Board receiving such an invitation must within 5 working days, invite representations from its own Area Pharmaceutical Committee, Area Medical Committee and any person on the Pharmaceutical List whose interests may be significantly affected if the application is approved. All of the above are able to offer written representations to the Board considering the application and must do so within 30 days from the date on which the notification was sent to them.

18. The 30 day period allowed for submission of written representations runs from the date of dispatch of the notification. Any person or organisation who does not offer representation at this stage has no right to offer representations to any subsequent stage or to appeal against any decision taken by the Board's PPC.

Dispensing Doctor

19. At the same time as inviting representations as above, if the application is for an area in which a dispensing doctor is located the Board shall also notify the dispensing doctor of the application. The dispensing doctor is not entitled to send written notice of interest or comments direct to the Board, but is able to do so through their Area Medical Committee.

20. The Board should also prepare and begin a 60 day consultation of the public to whom services may be provided. In doing so, they should consider the public consultation guidance provided at **Appendix B** which is intended to increase consistency across the country. Boards may wish to consider at this point setting a provisional date for a potential PPC hearing.

Missing information

21. If, when the application was lodged, the applicant was unable to provide information such as the GPhC registration details of the premises (premises must be registered with the GPhC under the provisions of the Medicines Act), the name of the pharmacist in charge of the premises or the date on which the applicant proposes to commence services, then the Board should seek that information by issuing form (B) of Schedule 2 of the Regulations following provisional approval of the application. The application may be considered on the understanding that any missing information will be provided prior to an applicant's inclusion on the pharmaceutical list.

Pharmacy Practice Committee

22. The Board is then required to refer all relevant applications, together with any representations received, to its PPC. It will be the responsibility of the PPC to decide whether the services from the premises as proposed by the applicant are necessary or desirable to secure the adequate provision of pharmaceutical services in the neighbourhood of the said premises. It will be for the PPC, on behalf of the Board, to determine this, in whatever manner it considers appropriate. Whilst it may be desirable it is not necessary for the PPC to hear oral representations in making their determination. There may be a number of factors which suggest to the PPC that oral representations are not necessary i.e. the PPC's robust and justifiable position that adequate provision of pharmaceutical services is secure in a neighbourhood.

23. The main issue for the PPC to consider is whether the current provision of NHS pharmaceutical services in the given neighbourhood is adequate and if not, whether the proposed services are necessary or desirable to secure adequate services. A fully mechanistic approach to such a decision is not appropriate and the use of ratios, quotas, norms, averages or simple measures of distance in determining adequacy is limited. Any or all such measures may be relevant as indicators but no single measure should be used as a determinant. PPCs should have reference to its Board's Pharmaceutical Care Services Plan when considering need for pharmaceutical services within the proposed area. Each decision must be firmly based on the facts of the local circumstances. A possible reduction in income by an existing community pharmacy caused by the opening of an additional pharmacy, is not itself a relevant consideration, unless it could affect the continued viability of the other pharmacies in the neighbourhood – thus affecting the security of the adequate provision of pharmaceutical services. Similarly, a possible reduction in income by an existing dispensing GP is not a relevant consideration.

Decisions of PPC and appeals

24. Health Boards should do everything in their power to ensure that PPC decisions are reached quickly. It should be exceptional for a PPC decision to take longer than a month to be made after completion of the public consultation and for a NAP decision to take longer than 3 months from the date of the lodging of the appeal.

25. The PPC should offer written notification to the Board within 10 working days of arriving at their decision. This written notification should be robust and clearly outline;

- the procedures followed;
- the facts and reasons considered when the PPC determined the application; and
- an explanation as to how those facts were applied in line with the provisions of the Regulations (e.g. how the facts supported the determination as to what constituted the neighbourhood and, for instance, that there is currently adequate provision of pharmaceutical services in that neighbourhood from persons on the pharmaceutical list.)

26. Support material, including a decisions pro-forma, has been prepared to support PPCs. The proformas provides a template for writing up reports. (See **Appendix C**). Boards and PPCs should also consider the written reports of the NAP which are available on the SHSC website www.shsc.scot.nhs.uk/national_committee_services as these are prepared in consultation with Central Legal Office.

Health Board action following PPC decision

27. Within 5 working days of being notified by their PPC, the Board must in turn, notify the applicant - and others as outlined under paragraph 5 of the Regulations - of the full decision, and advise them of any right of appeal. Boards are also required to publish the full decision about the application on its website, within 5 working days of this notification.

Appealing a decision

28. The applicant and others eligible to appeal must notify the Board within 21 days of receipt of notification of the decision. They must state the grounds for the appeal. No late appeals should be permitted in any circumstances, unless for lawful reasons. Appeals will be considered by a National Appeal Panel (NAP). The Board must therefore forward all appeals together with relevant case papers to the Chair of the NAP within 5 working days of receipt. The inclusion of proposed new entries on the Board's Pharmaceutical List can not be effected until the period during which appeals may be lodged, has elapsed or until any ensuing consideration of appeals, has been completed. Form (D) in Schedule 2 should be used to advise persons of the date of their inclusion on the Board's provisional pharmaceutical list.

29. The NAP must provide written notification to the Board within 5 working days of reaching their decision informing them of the full decision. In turn, the Board must then, within 5 working days, notify the applicant and others as outlined in paragraph 1 of the Regulations, of the full decision.

30. The Health Board shall respect the independence of the NAP and accept the decision of the NAP as final and binding on the Health Board.

Commencement of services

31. Where a need has been identified and a PPC has determined that additional premises are to open, the Board - in the interests of patients - should ensure that this happens as soon as possible. Subject to paragraph 28, the person's name will be added to the pharmaceutical list on the date specified in the Board's final formal notification to them (form (C)) and they become bound by the Terms of Service from that date.

32. It is recognised that applicants cannot always commit themselves entirely before applying for new premises, but nevertheless the Board has a duty to patients and should ensure as far as possible that the applicant opens the premises and provides services within 6 months of the Board's notification that the application was approved. If the applicant fails to provide the services within 6 months of the Board's notification of inclusion on the pharmaceutical list (as in form (C)), their name shall be removed from the list unless the following exception applies;

- the applicant must be able to provide evidence which satisfies the Board that circumstances out with their control - which they could not reasonably have anticipated at the time of the application being considered - have prevented the opening.

33. If they can satisfy the Board of this, then the Board may extend the period by a further period not exceeding 9 months. This is intended as a one-off extension to cover circumstances clearly beyond the person's control (e.g. entirely unpredictable planning or building work). The person must satisfy the Board that they are actively pursuing the intention to provide services.

34. Regulations also provide for removal of a contractor's name from the pharmaceutical list if the Board determines that the person has not provided pharmaceutical services for the preceding 6 months. Before taking that action the Board is required to give the person 28 days notice of its intention to do so, afford the person the opportunity of making written representations, and consult with the Area Pharmaceutical Committee.

Requests to the Board for Information

35. Boards are now required to publish a Pharmaceutical Care Services Plan (PCSP) and to ensure it is updated annually. The PCSP should comprise of a summary of the pharmaceutical services provided in the area of the Board together with an analysis by the Board of where it believes there is a lack of adequate provision of pharmaceutical services. Boards are also required to publish the outcomes of previous applications in their area, detailing the reasons for the decisions made.

36. However, it remains possible that a prospective applicant will make informal preliminary inquiries to a Health Board. The Board should make every endeavour to supply reasonably promptly any relevant information over and above that already available if it is not of a confidential and sensitive nature and is readily available. Directing the enquirer to the PCSP and previous applications may be sufficient.

37. However, the Health Board, PPC or the National Appeal Panel is not bound by any such information given. Applications will be considered based on the information provided at the time. It is not a given that an application will be approved if the Board has identified a potential shortage of services in an area.

Transitional arrangements

38. The Regulations include transitional arrangements which provide that any application in progress before 1 April 2011 must be considered in line with the Regulations extant before 1 April 2011. This includes any appeal made relating to an original application which was made prior to 1 April 2011.

PHARMACY PRACTICES COMMITTEE

Constitution

1. Each Health Board is required by Regulation to establish a Pharmacy Practices Committee (PPC). Its membership, as defined in Regulations is a chair whom shall be a member of the Health Board, 3 pharmacists and 3 lay persons.
2. The Board shall, subject to the provisions of Schedule 4 Part 1 of the Regulations make standing orders in respect of:
 - a. the terms of office of members of the PPC and the filling of casual vacancies;
 - b. procedures of the PPC; and
 - c. the making of reports.
3. In the event that the application being considered is in a neighbourhood where there is a dispensing doctor, a further member may be appointed by the Area Medical Committee.

Functions

4. Each Health Board shall delegate to its PPC, its function to assess and determine the need for additional contracts or services under Regulation 4. It shall delegate this function unconditionally and must refer all such applications to the PPC, but the Health Board's procedures may allow for the making of reports to the PPC on a need for proposed additional pharmaceutical service(s). The Health Board shall arrange for provision of secretarial services for the PPC.
5. The PPC is established to consider whether a new or relocated pharmacy should be admitted to the Board's Pharmaceutical List. It should consider this matter by reference to the NHS service being provided by those contractors already on the pharmaceutical list. It may be, however, that in considering applications, the PPC may discover information or form a view on more general policy matters relevant to the work of other committees or of the Health Board itself. The PPC may offer advice, comment or provide information to the Health Board on such other matters if it so wishes but that advice cannot be binding.
6. It is not a function of the PPC to consider the need for dispensing doctors.
7. Regulation 10 of the Health Boards (Membership and Procedure) (Scotland) Regulations 2001 (SI 2001/302) allows Health Boards to appoint Committees for the exercise on behalf of the Board of any of the Board's functions subject to such restrictions or conditions as the Board may think fit or Scottish Ministers may direct. Under these powers Boards may delegate additional functions to their PPC if so desired. Health Boards should note that the provisions of the Pharmaceutical Services Regulations in respect to the membership quorum and voting rights apply only when the PPC is considering applications under Regulation 4. If additional functions are delegated, Health Boards will need to make such appropriate arrangements as are required.

Membership – Chair

8. A Board should appoint a lay Chair and a Vice Chair neither of whom may be a member of, or an employee of a member of the healthcare professions.

Membership - Lay Members

9. Where practicable, it is desirable that the Board appoint persons who are not members or employees of members of a health care profession.

Membership - Pharmacist Members

10. In appointing pharmacist members and deputies the Board will wish to ensure a broad spread of membership both geographically and by type (e.g. independent/multiple) of pharmacist appointed. Ministers believe that any appointing body should have a choice of candidates. The Area Pharmaceutical Committee should therefore be asked to supply to the Board a list of not less than 6 pharmacists included in the pharmaceutical list of the Health Board (or pharmacists employed by those on the list) who are willing to serve as members or deputy members of the PPC. They should also be asked to supply a list of 3 pharmacists who are not included in any pharmaceutical list nor employed by someone on the list and who are willing to serve as members or deputy members of the PPC. Where there are an insufficient number of eligible pharmacists available in an area the list may include any pharmacist in the appropriate categories in Scotland who is willing to serve as a member or deputy member. The Health Board will appoint pharmacist members from the list as follows:-

- a. two pharmacy contractors or employees there of and
- b. one pharmacist who is not a pharmacy contractor or an employee thereof.

Membership – Area Medical Committee Nomination

11. The Area Medical Committee should be asked to supply to the Board a list of not less than 3 persons who are willing to serve as members or deputy members of the PPC should an application relating to an area served by a dispensing GP be made.

Membership – Deputies

12. Deputies are to be appointed for all members except the Chair. A deputy must meet the criteria, as set out above, applicable to the member or members for whom he/she is to act as deputy.

Membership - Appointment of Women Members

13. Ministers are keen to increase the number of women involved in public duties. Therefore full consideration should be given to the nomination of female candidates.

Membership – Experience

14. Previous experience in planning the provision of health services maybe useful to the PPC's work especially in complex cases and Health Boards may like to consider this in making appointments from among the membership of the Board.

Quorum

15. The quorum is the Chair (or Vice-Chair if acting as Chair), 2 lay members (or deputy members) and 2 pharmacist members (or deputy members) of whom one is not included in a pharmaceutical list. At the commencement of the meeting, there must be an equal number of lay and pharmacist members. But the pharmacy members and/or employees thereof and any nominee of the Area Medical Committee will be required to withdraw immediately before a decision on an application takes place.

16. Only the lay members are entitled to remain and to vote.

Procedure at Meetings and Oral Hearings

17. The PPC's proceedings must be, and be seen to be, scrupulously impartial. No person who has any interest in the outcome of the application may take any part in the proceedings at any stage and members of PPCs have a duty to declare their interests under Health Boards' standing orders and it is the recommended procedure that suitable arrangements are made for such members to make general declarations of interest. Any member who anticipates an interest in any application to be considered should declare it prior to the meeting in order that arrangements may be made for the attendance of a deputy. The Chair (or the vice-Chair acting as Chair) of the PPC as required by Regulations, at the beginning of every meeting must ascertain that no member or deputy member present has any interest in any of the applications, and no member claiming such interest may take part in the consideration of that application.

18. "Interest" means any direct or indirect personal interest which includes pecuniary interest whether or not arising from any NHS contract. For example, any employee or associate of the applicant and any trader (whether or not in contract with the NHS) in any similar or related line of business would have an interest as would any NHS contractor likely to be affected by the outcome of any application. In cases of doubt (e.g. a significant shareholding) members and deputy members will wish to avoid any suggestion of bias by disqualifying themselves from consideration of the application(s) in question.

Oral Hearings

19. The PPC may hold oral hearings and /or conduct site visits, if it deems this to be desirable. Where a PPC decides to hold oral hearings, it should give reasonable notice (normally not less than 10 days) so that all those with an interest who might wish to attend have an opportunity to do so. The same rules as apply to Discipline Committee Hearings on privacy, will also apply to PPC meetings. Persons appearing at a hearing of the PPC may be assisted by some other person but that other person may not appear in the capacity of council, solicitor or paid advocate nor shall that other person be entitled to speak on behalf of the person appearing at a hearing.

20. In formulating its decision as to the need for additional pharmaceutical services, a PPC will need to take account of a number of factors. Some are listed below. The list is not comprehensive and conversely not all of these factors will necessarily be relevant in each case. The PPC should normally consider:

- a. The pattern of natural communities and the normal patterns of travel. Primary care services should be provided as part of the normal fabric of people's lives and the PPC should consider where, how often and how easily people travel about the neighbourhood of the premises in order to consult a general practitioner, to go to

work, shops, school, to visit other health care premises or pursue leisure activities. Reasonable provision has no absolute measure and will depend on what is reasonable in the circumstances. For example, a distance which would be regarded as excessive in some environments, will be quite acceptable in others;

b. Existing patterns;

1. The number and location of existing pharmacies with NHS contracts and the possible effects on the NHS services they provide; the range of NHS services provided by them, their hours of service and any scope for amendment of those hours of service;

2. The numbers of prescriptions dispensed and, as far as this can be ascertained, their usual sources. To a very considerable extent, this will be the number and location of general medical practitioner surgeries, and the size of the practice prescribing lists but it is common for prescriptions to be dispensed at a distant pharmacy, convenient to the patient's place of work, family shopping areas etc and this should be borne in mind;

3. Local demography especially the presence of any group which makes above average use of primary care services and seasonal trends. Special regard must be had to the requirements of the Equality Act 2010 in considering applications:

- the need to eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Act;

- advance equality of opportunity between people who share a protected characteristic and those who do not;

- foster good relations between people who share a protected characteristic and those who do not.

4. Ease of access to a pharmacy should be a factor for consideration. Distances, especially distances from doctors' surgeries to pharmacies, are relevant but should not be taken alone because for example, pharmaceutical services now include MAS, CMS etc., removing the need to always see a GP or visit a GP practice. Regard should be given to acceptable travelling distances within the local environment (see a. above), patterns of private and public transport, the features of local geography including natural or man-made barriers;

5. Evidence of a local deficiency in the service, e.g. complaints which have been upheld by the Health Board, or unwillingness of existing contractors to fulfil a stated need.

c. Anticipation of future developments;

1. Known fixed/firm plans for the development and/or expansion of new centres of population, e.g. new or developing housing estates or for changes in the pattern of population, e.g. slum clearance;

2. Known fixed/firm plans for changes in the number and/or source of prescriptions, e.g. changes in the number and location of doctor's surgeries or the development of health centres and/or the appointment of additional doctors in that neighbourhood;

3. Known fixed/firm plans for developments which would change the pattern of local social traffic and therefore access to services, e.g. shopping centres;

4. Health Board plans for the development of services, e.g. community care;
5. The Board's Pharmaceutical Services Care Plan; and
6. Local population projections.

Voting

21. Immediately before any decision is made the pharmacist members, and/or employees thereof, and if relevant, the Area Medical Committees nominee, must withdraw and should a vote be necessary, the question shall be determined by a majority of votes of members remaining. The Chair shall not vote in the first instance; they will have a casting vote if the votes cast are equal.

Reports

22. After consideration of all the information presented to them, including that obtained at any oral proceedings, the PPC shall prepare a report relevant to each application. The report should properly narrate the facts and full reasons upon which the determination of the application was based. The report will state such relevant facts as appears to the PPC to have been established and the inferences which the PPC drew from those facts. The report will contain the decision of the PPC on the applications considered. All reports will, on completion, be passed to the Health Board for action. The pro forma attached at Annex 3 provides a template for the report.

Summary – PPC

23. The PPC is concerned only with NHS contract services and the provision of NHS pharmaceutical services must only be considered.

24. Above all a flexible approach should be adopted. Local needs will change over time and the pattern of service provision must adapt accordingly. The provisions must not be allowed to fix rigidly the pattern of service obtaining on the commencement date nor do they create an oligopoly for existing contractors. At all times, the governing principle will be to provide the local population with reasonable and adequate access to the full range of NHS pharmaceutical services.

NATIONAL APPEAL PANEL

Constitution

25. Scottish Ministers will arrange for a National Appeal Panel (NAP) to be established and will appoint the Chair of the NAP after consultation with all Health Boards. The Chair is required to be an advocate, a solicitor or a solicitor-advocate but shall not be nor previously have been a health professional nor have been an employee of a person on the pharmaceutical list. Non-pharmacist members except the Chair, will be appointed from lists provided for that purpose by Health Boards except that no such member hearing a specific case should be from a Health Board which has previously considered or commented on the application regardless of whether the member has an interest. The panel of pharmacist members will be drawn from lists provided by the Board from nominations made by the Area Pharmaceutical Committee. Nominations for the NAP will have a term of 3 years with power for co-option and reappointment. The same rules as to declaration of interest etc will apply to the NAP as they applied to the PPC.

26. The composition of a NAP will be smaller than that of a Health Board PPC; it will comprise a legally qualified Chair, a pharmacist not on the Pharmaceutical List and a non-pharmacist member. All members are entitled to vote.

Function

27. It is not the function of the NAP to simply substitute one judgement for another, i.e. to conclude that if they had been the PPC they would have reached a different decision. It is the function of the NAP to reverse decisions which are obviously wrong. It is therefore intended that the NAP shall adopt the following criteria: No appeal should be heard by the NAP unless it can be shown that:

a. there was a procedural defect at the earlier stage (e.g. a failure to consult a person or body with a clear interest); or

b. there was a failure by the Board to properly narrate the facts or reasons upon which their determination of the application was based; or

c. there was a failure by the Board to explain how the provisions of the Regulations have been applied in relation to the facts set out in the application.

d. the Board has erred in law in its application of the above provisions – a, b, or c.

28. Any notice of appeal should contain a precise statement detailing any circumstances detailed in paragraph 27 which has occurred or an other point of law which the appellants contend that the Board's decision is wrong.

29. The Chair after considering the notice of appeal and the decision of the Board shall either:

a. dismiss the appeal if in the opinion that;

(i) the notice discloses no reasonable grounds of appeal; or

(ii) the appeal is otherwise frivolous or vexatious; or

b. remit the decision back to the Board if the Chair is of the opinion that any of the circumstances detailed in paragraph 27 have occurred;

and the Chair's decision is final.

30. Where the Chair remits the decision back to the Board, he must provide advice as to how it may remedy the defect or failure which has led to the decision to remit and the Board shall then reconsider the application.

31. In any case where the Chair deems an appeal is justified, the NAP shall be convened and the Panel shall thereafter determine the appeal.

32. The NAP should determine its own procedure and may hold oral hearings and/or make local visits if it considers these to be necessary. The rules on representation before a PPC and on privacy will apply equally to the NAP's proceedings.

33. The National Appeal Panel shall determine an appeal as it thinks fit and its decision in respect of an appeal shall be final.

Quorum

34. The National Appeal Panel will no longer convene with a quorum of members. All three members must be present for the hearing to take place. In the event that a member is unable to be present, the hearing will require to be rescheduled.

Control of Entry to the Pharmaceutical List - Public Consultation

Background

1. The NHS (Pharmaceutical Services) (Scotland) Regulations 2009, as amended, require NHS Boards to undertake a formal 60-day consultation with local communities who may be affected when an application is made to open a community pharmacy. This guidance document is intended to improve good practice and consistency across Scotland. It is a key element of the pharmacy application procedures that NHS Boards engage with local communities as part of the process. People who may be affected by any changes to the local provision of the full range of pharmaceutical services should be kept fully informed about the application process, how NHS Boards arrive at decisions and how their views are taken into account.

Local Community Views and Consultation

2. As part of the application process, the Scottish Government amended the law in 2009 to ensure that Boards consulted the public and have regard to the views offered. This ensures that local communities are involved in the application process.

3. Our overarching aim is to ensure that the public are involved in the process where they wish to be and where it may affect them and are helped to fully understand the process and associated issues. This guidance material is intended to provide help to Boards in achieving that.

What NHS Boards can do to inform the public

4. NHS Boards have a key role in engaging with local communities, when a pharmacy application is made, to provide clear information and advice. While most applications are likely to be routine and may not generate much interest to local communities, it is recognised that applications in some areas can cause concern to some.

5. This Guidance summarises some of the issues relating to Control of Entry which might help local communities in forming views about pharmacy applications and which might help NHS Boards in seeking the views of local communities. In particular, it may be helpful to ensure the public are informed about:

- The full range of services which are available through community pharmacy, and how those services are integral to overall primary care service provision;
- The provisions and requirements set out in the Pharmaceutical Services legislation as it applies to pharmacy applications;
- The application process, how decisions are made, and by whom;
- To what extent NHS Boards are able to take account of local views and concerns.

6. The Board should seek information from the public which would aid their decision making in relation to the application. The key question(s) for consultation with the public could cover:

- their interpretation of the neighbourhood in question;
- their views as to whether the pharmaceutical services provided from persons on the pharmaceutical list is currently adequate;
- their views about whether approval is required to ensure such services are adequate.

Sections of the following text might be useful in helping to compile material to share with the public. Clearly however, NHS Boards will need to consider their local circumstances.

What services do Community Pharmacies provide?

It appears many people believe that the local community pharmacy (or 'chemist') is where they take their GP prescriptions to collect their medicines. However, modern community pharmacies offer a much more comprehensive range of services which are highly valued by many, but may not be recognised by those who have not had ready access to a community pharmacy e.g. those in very rural or remote areas where there has been no community pharmacy. As part of the integrated primary care team, GPs and pharmacists can be most effective in terms of providing high quality patient care when they work with each other.

Pharmacists have a wide knowledge in the science and use of medicines, and can help patients get the most from their medicines while minimising the risks associated with taking medicines particularly in relation to how certain medicines can interact with others. In addition, patients can get expert advice from a community pharmacy without the need to make a GP appointment.

The Right Medicine: A Strategy for Pharmaceutical Care in Scotland (published by the Scottish Executive in February 2002) outlined a commitment to work with the pharmacy profession to improve the public's health, provide better access to care, deliver better quality services for patients, users and carers, and develop the pharmacy profession. Four core pharmaceutical services have been introduced in response to that strategy and commitment:

Minor Ailment Service (MAS): through which certain groups of patients can register with the community pharmacy of their choice to enable them to consult with a community pharmacist for certain minor conditions direct from the pharmacy. The pharmacist advises, treats or refers the individual according to their needs.

Public Health Service (PHS): through which community pharmacy is used to support self-care and provide advice and information on health issues. This includes a smoking cessation service to help those who wish to stop smoking and a sexual health service which includes free access to Emergency Hormonal Contraception (EHC).

Acute Medication Service (AMS): this is the dispensing of acute or 'one-off' prescriptions but supported by the electronic version of the prescription, to increase patient safety, improve data collection and payment processes.

Chronic Medication Service (CMS): through which more use will be made of the professional skills of community pharmacists in the management of long-term conditions, in partnership with the patient and their GP. CMS is the final element of the new community pharmacy contract and is in the process of implementation.

The introduction of these services are part of a long term strategy to enable pharmacists to use their extensive training and skills and move focus away from just the provision of medicines towards the provision of patient centred care as part of the wider primary care team. Together these services will play an important part in shifting the balance of care by:

- improving access for the public as they do not need an appointment to see their pharmacist for a consultation;
- reducing unnecessary workload on GP and nursing colleagues therefore freeing up their time to see patients with more serious complaints;
- helping to address health inequalities; and
- making better use of the workforce by more fully utilising the skills of community pharmacists.

Applications

A 'pharmacy' can be opened by anybody, anywhere in the country. However, if someone wishes to provide NHS pharmaceutical services to the public, they can only do so with permission of the relevant NHS Board and must therefore apply to that Board to provide the services from premises they have identified. Applications to open a pharmacy to provide NHS services can be made by any individual, partnership or company, subject to the conditions specified in the Medicines Act.

When an application to open a pharmacy is made, NHS Boards are required by law to consider the application. This will require the establishment of a Pharmacy Practices Committee (PPC) to act on their behalf in considering applications. This committee is discussed further below. In considering the application, the PPC will consider the pharmaceutical services already provided in the area, the pharmaceutical services to be provided and any representations received by the Board and also any other information available which is relevant to the consideration of the application.

Under the law, the PPC consists of 7 members (a chair, three pharmacists and three non-pharmacist (lay) members) unless the application is for premises in a neighbourhood served by a dispensing doctor, in which case an additional member will be appointed by the Board from persons nominated by the Area Medical Committee ensuring wider representation on the committee. The three non-pharmacist (lay) members are entitled to vote reinforcing the independence of the decisions made. The pharmacists shall be chosen from persons nominated by each Board's Area Pharmaceutical Committee again reinforcing independence.

The "legal test"

The PPC of an NHS Board must consider whether an application to open a community pharmacy is "necessary or desirable" in order to secure the adequate provision of NHS pharmaceutical services by persons on the pharmaceutical list in the neighbourhood in which the related premises are located.

The arrangements made by Boards with community pharmacists must comply with Regulations made under the NHS (Scotland) Act 1978. Those Regulations (the NHS (Pharmaceutical Services) (Scotland) Regulations 2009 as amended) set out the ways by which persons can apply to provide NHS pharmaceutical services and set out the terms and conditions under which those services will be provided.

It is the role of the 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 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”.

An application for inclusion in the Pharmaceutical List, is essentially an application to provide NHS pharmaceutical services from identified premises in the relevant 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 pharmacies that wish to provide NHS pharmaceutical services; a non-NHS ‘pharmacy’ can be opened anywhere by anybody.

Application Process

As above, an application may only be granted if the Board’s Pharmacy Practices Committee (PPC) is satisfied that it is “necessary or desirable”¹ 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 considered in a different way under the control of entry.

It is important to note that whilst NHS pharmaceutical services can be provided from premises selling other items and services, such other commercial aspects are not a consideration of the arrangements when NHS Boards are determining whether an application should be granted. Similarly, the effect on neighbouring pharmacies’ income unless the granting of the application is likely to lead to adequacy not being secured by reason of their viability, or the presence of dispensing GP surgeries, is not a consideration. The arrangements focus on securing the adequacy of NHS pharmaceutical services from persons on the pharmaceutical list that are provided to patients in the neighbourhood and whether an application must be approved to secure adequate provision is available.

On receipt of an application to which the control of entry rules apply, the Board must first notify a number of parties about the application. The Area Medical Committee, the Area Pharmaceutical Committee and any persons already included in the pharmaceutical list whose interests might be affected if the application were granted are entitled to make representations to the Board and thereafter must be given notice of the Board’s decision. If representation has been made, such persons and the applicant are entitled to appeal against the decision and those appeals are determined by an independent body - the ‘National Appeal Panel’ (NAP).

The NHS (Pharmaceutical Services)(Scotland) Amendment Regulations 2011 now require NHS Boards to notify a dispensing GP if there has been an application to open a pharmacy in the area within which they dispense. A Board’s Area Medical Committee is the avenue for all GPs to offer any representations regarding an application and the AMC also has a subsequent right of appeal if they offer representations.

The key aspect of the application process is the legal test. The Board’s PPC must consider applications in line with this ‘test’. In short, this requires the PPC to:

- Identify the boundaries of the ‘neighbourhood’ in which the premises named in the application are located (this will vary greatly e.g. in a city this may only be a street or

¹ See section 27(3)(c) of the 1978 Act and regulation 5(10) of the 2009 Regulations

two whilst in a more rural setting, it could be a whole village(s)), and particularly identify the reasons why this area constitutes a neighbourhood;

- Consider and agree whether the current provision of NHS Pharmaceutical services from persons on the list 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.

National Appeal Panel (NAP)

The role of the National Appeal Panel (NAP) is to consider appeals against decisions made by Pharmacy Practice Committees (PPCs). The NAP considers appeals both from applicants who have been refused entry to the pharmaceutical list or permission for relocation of premises, and from other contractors or the AMC (as determined in the Regulations) who may object when applications for entry to the Pharmaceutical List have been successful.

The NAP hears appeals against decisions made by the PPCs of NHS Boards. Where an appeal is made, it is necessary to ensure members of the hearing are experienced and knowledgeable in relation to pharmaceutical services and that any such appeal is heard by representatives from out with the NHS Board that made the original decision. Decisions taken by the NAP are final, but subject to possible Judicial Review.

Under the terms of the NHS (Pharmaceutical Services) (Scotland) Amendment Regulations 2011, nominations for membership shall be selected from nominations put forward by the Area Pharmaceutical Committees of NHS Board. The Scottish Ministers, following consultation with all Health Boards, shall appoint a Chair who shall be an advocate, a solicitor or a solicitor-advocate but shall not be, nor previously has been a health professional or an employee of a person on the pharmaceutical list. A substitute Chair will be appointed in the event that the Chair is unable to attend hearings.

The National Appeal Panel will now consist of 3 members, the Chair, a non-contractor pharmacist and a lay member, who is not nor has been a health professional. All members of the NAP have the right to vote.

PPC [Insert reference]

**Pharmacy Practices Committee
Minutes of a Meeting held on**

[Insert date and time of meeting]

PRESENT: [Insert names of those present]

IN ATTENDANCE: [Insert names of those in attendance]

1. APOLOGIES

Section 1 – Applications under Regulation 5(10)

2. APPLICATION FOR INCLUSION IN THE BOARD'S PHARMACEUTICAL LIST

Case No: PPC [Insert reference]
Mr AB, [Insert address]

The Committee was asked to consider an application submitted by Mr AB to provide general pharmaceutical services from premises situated at [Insert address] under Regulation 5(10) of the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 as amended.

The Committee had to determine whether the granting of the application was necessary or desirable to secure the adequate provision of pharmaceutical services in the neighbourhood in which the Applicant's proposed premises were located.

The Committee, having previously been circulated with all the papers regarding the application from Mr AB, agreed that the application should be considered by oral hearing.

The hearing was convened under paragraph 3(2) of Schedule 3 to the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 as amended ("the Regulations"). In terms of this paragraph, the PPC "shall determine an application in such a manner as it thinks fit". In terms of Regulation 5(10) of the Regulations, the question for the PPC is whether "the provision of pharmaceutical services at the premises named in the application is necessary or desirable to secure adequate provision of pharmaceutical service in the neighbourhood in which the premises are located by persons whose names are included in the Pharmaceutical List."

The Applicant was represented in person by Mr AB ("the Applicant"), assisted by Mr CD. The Interested Parties who had submitted written representations during the

consultation period and who had chosen to attend the hearing, were Mr EF of CH Ltd, and Mr HI, trading as HI Pharmacy, (“the Interested parties”).

The Chair asked the Applicant and the Interested Parties to confirm that they were not attending the Committee in the capacity of solicitor, counsel or paid advocate. They confirmed that they were not.

Prior to the hearing, the Committee had as a group, visited the vicinity surrounding the Applicant’s proposed premises, the existing pharmacies, GP surgeries and facilities in the immediate area and surrounding areas of: [Insert areas].

The Committee noted that the premises were constructed/not constructed/had been leased/purchased/were subject to conditional contract, dependent on the Committee’s decision on the application.

The procedure adopted by the Committee at the hearing was that the Chair asked the Applicant to make his submission. There followed the opportunity for the Interested Parties and the Committee to ask questions. The Interested Parties would then make their submissions. There followed the opportunity for the Applicant and the Committee to ask questions of the Interested Parties in turn. The Interested parties and the Applicant were then given the opportunity to sum up.

The Applicant’s Case

Mr AB stated (to include the description of the proposed neighbourhood and reasons why the granting of the application would secure adequacy of pharmaceutical services to the neighbourhood) [Insert precise statement or as presented].

Questions from Mr EF to the Applicant

[Insert precise or as presented].

Questions from Mr HI to the Applicant

[Insert precise or as presented].

Questions from the Committee to the Applicant

[Insert precise or as presented].

The Interested Party’s Case – Mr EF of CH Ltd

Mr EF stated (to include the description of the proposed neighbourhood and reasons why he objected to the application) [Insert precise or as presented].

Questions from the Applicant to Mr EF

[Insert precise or as presented].

Questions from Mr HI to Mr EF

[Insert precise or as presented].

Questions from the Committee to Mr EF

[Insert precise or as presented].

The Interested Parties' Case – Mr HI trading as HI Pharmacy

Mr HI stated (to include the description of the proposed neighbourhood and reasons why he objected to the application) [Insert precise or as presented].

Questions from the Applicant to Mr HI

[Insert precise or as presented].

Questions from the Mr EF to Mr HI

[Insert precise or as presented].

Questions from the Committee to Mr HI

[Insert precise or as presented].

Summing up

The Applicant and Interested Parties were then given the opportunity to sum up.

Mr HI stated [Insert comment].

Mr EF stated [Insert comment].

Mr AB stated [Insert comment].

DECISION

Having considered the evidence presented to it, and the Committee's observation from the site visit, the Committee had to decide firstly, the question of the neighbourhood in which the premises to which the application related, were located.

The Committee considered the various neighbourhoods put forward by the Applicant, the Interested Parties, and the APC in relation to the application, as well as comments received from the public consultation. The Committee took into consideration, the Committee's obligations in terms of the Equality Act 2010 – the need to eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Act;
advance equality of opportunity between people who share a protected characteristic and those who do not;
foster good relations between people who share a protected characteristic and those who do not.

Neighbourhood: the Committee considered that the neighbourhood should be defined as follows:

North:

East:

South:

West:

(Description below provides an example of level of description)

The Committee agreed that Main Road, was a boundary, not in terms of any difficulty in crossing the road, but because the area beyond this was of a different topography being mainly taken by the Botanic Gardens. The residential element to the north of Main Road was affluent flatted accommodation as opposed to student accommodation. The River Scot was both a physical boundary and marked the edge of a different neighbourhood. Donald Road was a major trunk road dissecting the city from the centre above the River Donn. Bolton Road was a busy shopping thoroughfare. The main university buildings lay on one side of the street, with the other bounding an area of flatted accommodation, beyond which was residential accommodation at the more affluent end of the scale.

Adequacy of Existing Provision of Pharmaceutical Services and Necessity or Desirability:

Having reached that decision, the Committee was then required to consider the adequacy of pharmaceutical services within that neighbourhood, and whether the granting of the application was necessary or desirable to secure adequate provision of pharmaceutical services in that neighbourhood.

The Committee noted that within the neighbourhood as defined by the Committee there were X pharmacies. These pharmacies provided a comprehensive range of pharmaceutical services including NHS core services and supplementary services. The Committee considered that the level of existing services to/and within the defined neighbourhood, provided satisfactory access, for those resident in the neighbourhood, to pharmaceutical services. The Committee therefore considered the existing pharmaceutical services in the neighbourhood were adequate.

The Committee was satisfied that no evidence had been produced by the Applicant, or had been made available to the Committee via another source, which demonstrated that the services currently provided to the neighbourhood were inadequate.

Having regard to the overall services provided by the existing contractors within the vicinity of the proposed pharmacy, the number of prescriptions dispensed by those contractors in the preceding 12 months, and the level of service provided by those contractors to the neighbourhood, the Committee agreed that the neighbourhood was currently adequately served.

In accordance with the statutory procedure the Pharmacist Contractor Members of the Committee, and Board Officers were excluded from the decision process:

DECIDED/-

The PPC was satisfied that the provision of pharmaceutical services at the premises of the Applicant was not necessary or desirable in order to secure adequate provision of pharmaceutical services in the neighbourhood in which the premises were located by persons whose names are included in the Pharmaceutical List and in the circumstances, it was the unanimous decision of the PPC that the application be refused.

XYZ as Chair of the PPC:

Date:

Control of Entry to the Pharmaceutical List - Guidance for Applicants

NHS (Pharmaceutical Services) (Scotland) Amendment Regulations 2011 – Schedule 2 (www.legislation.gov.uk/ssi/2011/32/contents/made)

1. All applications to provide pharmaceutical services, whether from new or existing contractors, must be submitted on the relevant application form as listed in Schedule 2 and must specify the premises from which the proposed services are to be provided. The applicant must state all pharmaceutical services to be provided and may also detail any additional services they are willing to provide if required. Please note it will be for the Board to decide whether they wish to accept any or all of the proposals.

Application for Change of Ownership

2. An applicant wishing to apply for change of ownership must complete application form (A2) as listed in Schedule 2. It is preferred that there should be no change or interruption to services provided or to the hours of opening. However we are aware that in some instances there may be a valid reason for a short interruption to services or the applicant may wish to provide additional services or increase the opening hours. The applicant must detail any possible changes from the current provision and provide explanation. It will be for the Board to consider and decide whether this is acceptable. Any proposed change to opening hours must take into account the Boards Hours of Opening Scheme.

Application for Relocation (Minor)

3. An applicant wishing to apply for a minor relocation must complete the required parts of application form (A1) as listed in Schedule 2.

4. As above, for change of ownership, it is not intended that services should change, be interrupted or the hours of opening changed. A full explanation should be given if there is deemed to be a possibility that services will be interrupted, services changed or hours of opening altered, again in line with the Boards Hours of Opening Scheme. The applicant may wish to extend opening hours, provide additional services or may require a short interruption for example to transfer IT systems. It will be up to Boards whether or not to accept the proposals.

Application for Relocation (other than Minor)

5. An applicant wishing to apply for relocation, other than minor, must complete the required parts of application form (A1) as listed in Schedule 2. Prior to the application being lodged the potential applicant must undertake a pre-consultation exercise with the members of the public that the relocation may have an impact on.

6. This will allow the applicant to gauge the views of the local population to inform the Board as part of the revised application process and gives the public early notification of a potential relocation. Further information on the pre-consultation exercise can be found at paragraphs 13 to 18 below.

Application for new contract other than change of ownership and minor relocations.

7. An applicant wishing to apply to provide pharmaceutical services must complete the required parts of application form (A1) as listed in Schedule 2. Prior to the application being lodged, the potential applicant is now required to undertake a pre-consultation exercise with the public within the area to which the application will relate.

8. This will allow the applicant to gauge the views of the local population to inform the Board as part of the revised application process and gives the public early notification of a potential application. Further information on the pre-consultation exercise can be found at paragraphs 13 to 18 below.

9. You will wish to take into account the Boards Pharmaceutical Care Services Plan (PCSP) which will be published on the Boards website. The PCSP will give a summary of the pharmaceutical services provided in the area of the Board together with an analysis by the Board of where it believes there is a lack of adequate provision of pharmaceutical services.

10. You should also take into account the outcomes of previous applications in the area, available on the Boards website. If applying to open a pharmacy in an area where an application has been rejected within the previous 12 months, you will be required to provide evidence of any significant change that has occurred in your view making it either necessary or desirable that an application is now granted in order to secure adequate provision of pharmaceutical services in the area.

11. If when the application is lodged the applicant was unable to provide some information such as the registration details of the premises or details of the responsible pharmacist, then the Board will seek this additional information on form (B) as listed in schedule 2.

12. However, the Health Board or the PPC is not bound by any such information given. Applications will be considered based on the information provided at the time. It is not a given that an application will be approved if the Board identified a potential shortage of services in an area.

Applicants Pre-Consultation Exercise

13. Applicants must, except where applying for a minor relocation or change of ownership, undertake a pre-consultation exercise within the area to which their application will relate to. The exercise is for the purpose of gauging public opinion and assessing whether the neighbourhood has adequate provision of pharmaceutical services of some or all of the pharmaceutical services that the applicant intends to provide.

14. If relocation is other than minor, the applicant should display a notice of their intentions in their current premises. The notice should detail the proposals; where the new premises will be located, when will services be provided, what services will be provided, opening hours etc. A closing date and address for returning comments should be included.

15. If the application is to open new premises, they should note their intentions through publication in a local newspaper circulating within the neighbourhood in which the applicant intends to provide services. The advertisement should contain details on the proposals; where the premises will be located, what services will be provided and proposed opening hours. A closing date and address for returning comments should also be included.

16. Advertising of the applicants intentions should be for a continuous period of at least 20 working days and in the case of relocation, make clear that the existing premises will close if the application is successful. (If it's a minor relocation the existing premises will not be included in the assessment of adequacy in the area.)

17. The application must be lodged within 20 working days of the pre-consultation exercise being concluded.

18. In the case of appliance suppliers, they should advertise within the area they will be providing services. It is understood that an appliance suppliers neighbourhood in which they propose to provide services may encompass a large part of the country. If this is the case the applicant may also wish to advertise their intention in a relevant topical publication.

Applicant's Assessment

19. The revised application process provides for an 'applicant's assessment.' The applicant's assessment is for the purpose of ensuring the Board has sufficient information for making a decision on the application.

20. Form A(1) is to be used by anyone applying to either relocate (minor or other than minor) or to open new premises. It allows for the completion of the applicants assessment whereby the applicant is asked specific questions so as to provide sufficient detailed information to best inform the Board.

21. Form A(2) is to be used when applying to take over ownership of existing premises on the pharmaceutical list.

22. Detail of information required on each form for the applicants assessment is detailed at **Appendix 1**. Copies of the Application Forms are included at **Appendix 2**.

Applicant Assessment Requirements

Form A(1)

Application for New Premises

Applicants applying to open new premises are required to complete Parts 1, 2, 4(b) and 5. A full applicants assessment is required including the following;

- Provide confirmation that premises may be used for provision of pharmaceutical services, if the applicant does not already own or hold a lease for the premises;
- Describe any adjustments they intend to make to ensure the premises comply with section 29 (Provision of Services) of the Equalities Act 2010 (www.legislation.gov.uk/ukpga/2010/15);
- Describe the services they currently and will continue to provide. The applicant has the opportunity to list additional services they are willing to provide if the Board requires it;
- Provide the date that services will commence at the new premises;
- Detail the hours they currently and will continue to provide. Applicants may wish to extend their current provision of hours. This will be for the Board to consider whether it necessary;
- A description of the boundaries of the neighbourhood;
- An assessment of current services in area for which you believe there not to be adequate provision;
- Detail of the consultation undertaken and a summary of views of the people within the neighbourhood; and
- Whether there has been a previous application in the same are within the past 12 months and if so detail what significant change has occurred so that it is now deemed necessary or desirable to grant an application in that area.

Applicants applying for relocation are required to complete Parts 1, 2 and 5. Part 3 allows the applicant to detail whether the application is minor and why. Depending on whether the application is minor or other than minor determines whether Part 4(a) or (b) should be completed.

Relocation (Minor)

Part 3 requires the applicant to detail why the relocation is considered to be minor eg. the applicant intends to relocate within the neighbourhood in which the applicant already provides pharmaceutical services from the premises already listed, and to provide from those new premises the same pharmaceutical services which the applicant currently provides at their existing premises. The provision of services should not be interrupted except for any period in line with the Boards Hours of Service Scheme or any such period as the Board for good cause may allow. If the services will be interrupted the applicant is required to provide as much detail as possible eg how long and why. It will be for the Board to determine whether this is acceptable.

Part 4(a) requires the applicant to;

- Provide confirmation that premises may be used for provision of pharmaceutical services, if the applicant does not already own or hold a lease for the premises
- Describe any adjustments they intend to make to ensure the premises comply with section 29 (Provision of Services) of the Equalities Act 2010 (www.legislation.gov.uk/ukpga/2010/15);
- Describe the services they currently and will continue to provide. The applicant has the opportunity to list additional services they are willing to provide if the Board requires it.
- Provide the date that services will commence at the new premises.
- Detail the hours they currently and will continue to provide. Applicants may wish to extend their current provision of hours. This will be for the Board to consider whether it necessary.

The applicant has the opportunity to provide additional information regarding further services or amended opening times. However, it is for the Board to decide whether they wish to accept some, all or none of these changes.

Relocation (other than Minor)

If the application is for a relocation, other than minor, applicants are required to complete Part 4(b). The information required is detailed above under Application for New Premises.

Form A(2)

Applications for Change of Ownership

An application for change of ownership (Form A (2)) does not require any form of applicants assessment as the premises already exist and are providing a pharmaceutical service in the area.

The applicant is required to provide confirmation of the Responsible Pharmacist, when services will commence, what services are to be provided and opening hours. If the applicant proposes to amend the opening hours or provide additional services they should detail clearly what changes are proposed and why. It is for Boards to consider whether some, all or none of these changes are acceptable and may accept the application based on current provision with no proposed changes.

Application for Inclusion in the Pharmaceutical List to Provide Pharmaceutical Services – Relocation or New Application

(Please delete words/sections which do not apply)

TO HEALTH BOARD

1. Applicant’s details

I am/we are applying as an Individual/ a Pharmacist/ a Corporate Body. (* If applying as Corporate Body please also provide Superintendent Pharmacist details below)

I/We (name of person making application)

of (correspondence address and name of company if relevant)

apply to have my/our name(s) included in the pharmaceutical list. The application is in respect of:

- (a) the relocation of the premises from which I/we provide pharmaceutical services specified in Part 4. (Please complete Parts 2, 3, 4 (a) or (b) and sign and date the application at 5).
- (b) the opening of new premises for the provision of pharmaceutical services specified in Part 4. (Please complete Parts 2, 4 (b) and sign and date the application at 5).

* Superintendent Pharmacist is

2. Premises details

(a) The premises from which I/we propose to provide pharmaceutical services are/will be at—

(b) the premises from which it is proposed to provide pharmaceutical services are—

(i) already constructed Yes No

(ii) already in our possession (lease or ownership) Yes No

** (iii) registered by the General Pharmaceutical Council in my/our name(s)

Yes No N/A

If the answer to (iii) is yes, state reference number.

If the answer to (iii) is no, give date of application for registration.

*** (c) If applicable the Responsible Pharmacist at the said premises will be—

Name

GPhC Registration No.

If the application is for a relocation please proceed to Part 3, if not please proceed to Part 4(b)

3. Relocation Details

(a) To be completed only by persons whose names are included in the pharmaceutical list applying under Part 1(a)

(i) the premises in the Board's area from which I am/we are currently providing pharmaceutical services are at—

(ii) the relocation is for the following reasons:

If the relocation application is considered to be minor please complete (iii) and then proceed to Part 4(a). If relocation is other than minor please proceed to Part 4(b)

(iii) **To be completed only if the applicant considers relocation to be minor.** A minor relocation is one where there will be no significant change in the neighbourhood population served, and other circumstances are such that there will be no significant effect on the NHS pharmaceutical services provided by the applicant or any other person on the Board's list.

I/We consider the relocation fulfils the criteria for minor relocation because:—

It is preferred that services will be continuous however if the service will be interrupted please state why and for what period below.

If the application is for a minor relocation please proceed to Part 4(a)

If the application s for a relocation other than minor or for a new application please proceed to Part 4 (b).

4.

Part 4(a) – Additional information. To be completed by persons applying for a minor relocation.

Please note, the NHS Board may reject your application if they do not consider that you have provided sufficient detail.

(i) If the answer to 2(b)(ii) is no, please provide written consent from the person who may grant such possession that the premises may be used for the provision of pharmaceutical services.

(ii) Describe any adjustments you intend to make to the premises to ensure you will comply with the duties incumbent upon you, as the provider of pharmaceutical services, under section 29 of the Equalities Act 2010.

(iii) Please provide a description of the pharmaceutical services you currently and will continue to provide, along with detail of any further services you propose to provide if relocation is successful.

(iv) Please provide the date you intend to commence the provision of the services detailed above if relocation is successful.

(v) Please detail the hours in each day that you currently and will continue to provide such services, along side any intention to extend hours (taking into account the Board's Hours of Service Scheme.)

Please proceed to Part 5

Part 4(b) – Applicant’s Assessment. To be completed by persons applying for a relocation other than minor or to open new premises.

(i) If the answer to 2 (b)(ii) is no, please provide written consent from the person who may grant such possession that the premises may be used for the provision of pharmaceutical services.

(ii) Describe any adjustments you intend to make to the premises to ensure you will comply with the duties incumbent upon you, as the provider of pharmaceutical services, under section 29 of the Equalities Act 2010.

(iii) Describe the boundaries of the neighbourhood, where you intend to provide pharmaceutical services, which your application proposes to cover.

(iv) Provide an assessment of the current provision, in the proposed neighbourhood, for which you believe there not to be adequate provision and evidence to support that view.

(v) Describe the pharmaceutical services you will provide.

(vi) State the date you intend to commence the provision of the services detailed above.

(vii) State the hours in each day that you intend to provide such services (taking into account the Board's Hours of Service Scheme.)

(viii) Provide details of the consultation conducted and a summary of views from people within the neighbourhood that the application affects.

(ix) Has there been an application to provide pharmaceutical services in the neighbourhood that encompasses the same or substantially the same area encompassed by the neighbourhood as stated at 4(ii) above within the previous 12 months?

Yes No

If yes, please provide evidence of the significant change that has occurred that means in your view that it is now necessary or desirable that an application be granted in order to secure adequate provision of pharmaceutical services in the neighbourhood to which the application relates. **If the answer is no please proceed to Part 5.**

5. I/We undertake to provide the services as detailed in this Form and undertake to provide such of these services as may be approved by the Board in accordance with the terms of service for the time being in operation.

Signed

Print Name

Date

NOTES:

(1) An application on Form A (1) will be required by any person already included or who wishes to be included in the pharmaceutical list to undertake to supply pharmaceutical services from additional or alternative premises. A person wishing to be included on the list to provide pharmaceutical services from premises already on the list should complete Form A (2).

(2) *Please note that medicines cannot be dispensed from the premises until they are registered by the General Pharmaceutical Council. Although an application to be included in the pharmaceutical list can be considered in advance of such registration, registration details and any other information required but not given at the initial application stage must subsequently be provided on Form B before inclusion in the list is confirmed.*

(3) ***Premises need only be registered with the General Pharmaceutical Council if the intention is to dispense medicines from the premises.*

(4) ****Responsible Pharmacist details should be provided if full pharmaceutical services are being provided.*

(5) *Payment cannot be made for NHS services provided before the date of entry in the pharmaceutical list recorded in Form C as issued by the Board.*

Application for Inclusion in the Pharmaceutical List to Provide Pharmaceutical Services – Change of Provider

(Please delete words/sections which do not apply)

TO HEALTH BOARD

1. Applicant’s details

I am/we are applying as an Individual/ a Pharmacist/ a Corporate Body. (*If applying as Corporate Body please also provide Superintendent Pharmacist details below)

I/We (name of person making application)

of (correspondence address and name of company if relevant)

apply to have my/our name(s) included in the pharmaceutical list. The application is in respect of the provision of services from premises from which the pharmaceutical services specified in Part 4 below are already provided (complete Parts 2, 3, 4 and 5 and sign and date the application at 6.

*Our Superintendent Pharmacist is

2. Premises details

(a) The premises from which I/we propose to provide pharmaceutical services are at—

(b) **if applicable the Responsible Pharmacist at the said premises will be—

Name

GPhC Registration No.

3. Date commencing

I/We undertake to provide the pharmaceutical services specified at Part 4 from the said premises from (date)

and it is proposed that the premises will be open during the following hours (taking into account the Board's Hours of Service Scheme.)

4. Services to be provided

I/We propose to continue to provide the following pharmaceutical services as may be approved by the Board in accordance with the terms of service for pharmacists.

5. Application Details

(a) The name of the person who is currently providing services from the premises named in Part 2(a) is—

(b) There will be no change in the pharmaceutical services provided and the provision of services by me/us will be continuous/interrupted.

It is preferred that services will be continuous however if the service will be interrupted please state why and for what period below.

6. I/We undertake to provide the services as detailed in this Form and undertake to provide such of these services as may be approved by the Board in accordance with the terms of service for the time being in operation.

Signed

Print Name

Date

NOTES:

(1) An application on Form A (2) will be required by any person already included or who wishes to be included in the pharmaceutical list to undertake to supply pharmaceutical services from premises from which pharmaceutical services are already provided. Any person already included or who wishes to be included in the pharmaceutical list to relocate current premises or to provide services from new premises should complete Form A (1).

(2) Please note that medicines cannot be dispensed from the premises until they are registered by the General Pharmaceutical Council. Although an application to be included in the pharmaceutical list can be considered in advance of such registration, registration details and any other information required but not given at the initial application stage must subsequently be provided on Form B before inclusion in the list is confirmed.

*(3) **Responsible Pharmacist details should be provided if full pharmaceutical services are being provided.*

(4) Payment cannot be made for NHS services provided before the date of entry in the pharmaceutical list recorded in Form C as issued by the Board.

Notification of Information Not Given on Form A1/A2

(Please delete words/sections which do not apply)

TO HEALTH BOARD

1. I/We (name of person making application) []

Of (correspondence address and name of company if relevant)

[]

to be included in the pharmaceutical list to provide pharmaceutical services from premises as specified in Form A (1) or (2).

2. The premises are now—

(i) constructed Yes [] No []

(ii) leased/conveyed to me/us and I/we took possession of them on []

(iii) registered by the General Pharmaceutical Council in my/our name with effect from []

(iv) The reference number is []

3. *If applicable, the Responsible Pharmacist at the said premises will be—

Name []

GPhC Registration No. []

4. I/We undertake to provide the services as detailed in Form A 1/A 2 and undertake to provide such of these services as may be approved by the Board in accordance with the terms of service for the time being in operation.

Signed []

Print Name []

Date []

NOTIFICATION OF DATE OF ENTRY ON PHARMACEUTICAL LIST

To [applicant(s)]

Your name(s) and premises (Insert Details)

have been included in the Board's pharmaceutical list, to provide the following pharmaceutical services

from (insert date)

Signed

Date

On behalf of Health Board

Notification of Date of Inclusion in Provisional Pharmaceutical List

To [applicant(s)]

I acknowledge receipt of Form A (1)/A(2) applying for your name to be included in the pharmaceutical list to provide the following services

from (provisional date)

Entry of your name in the pharmaceutical list cannot be confirmed until you have submitted Form B as respects the matters in relation to which you were unable to make affirmative statements in paragraphs 2(b) of Form A(1) or, as the case may be, unable to complete 2(b) of Form A(2).

The information required is

Signed

Date

On behalf of Health Board

NOTE:—

Provisional entry in the list does not entitle you to dispense medicines or appliances from the premises nor to receive payment for the provision of pharmaceutical services under the NHS.