

Information/Guidance for Community Councils



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Introduction and Background

In June 2014, the Scottish Government published amendments to the legislation that cover the process to open a new community pharmacy.

This was done after an extensive period of consultation which saw nearly 100 individuals, groups and organisations comment on the government's initial proposals.

The result was a set of amendments, which aimed to make the process more transparent to the communities affected by an application.

One of the key changes was the introduction of a "nominated community representative" who will be drawn from the membership of the local Community Council (CC) covering the site of the proposed new pharmacy. The representative will be invited to provide a written response to the application and where a written representation has been submitted will be invited to attend the meeting which will hear the application. At this meeting, the representative will be able to make an oral representation on behalf of the community. The representative will also be able to appeal where they believe the pharmacy application process has not been followed, or where they disagree with the decision made by the Pharmacy Practices Committee (PPC).

This booklet aims to provide CCs with information on the application process and the Board's committee (PPC) that hears new pharmacy applications so as to allow them to fully engage with the process.

Further Information

Should you wish any further information on any aspect contained in this booklet, please contact:

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What is a New Pharmacy Application?

NHS pharmaceutical services (historically the dispensing of prescriptions but also the provision of certain services) can only be provided to the public with the permission of the Health Board (HB). The process for applying for a new pharmacy contract is governed by Pharmaceutical Regulations (National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 as amended).

Any pharmacist, partnership or company who wants to open a new pharmacy must submit an application to join the HB's Pharmaceutical List and applications can only be made by certain categories of people (the Medicines Act describes these categories). Intended applicants approach the HB about opening a pharmacy or relocating an existing pharmacy; the HB does not proactively seek applications (at this point in time).

Before a new application can be submitted and processed, the intended applicant will now have to undertake discussions with the HB, which may lead to a Joint Public Consultation being undertaken. After this consultation, a Consultation Analysis Report (CAR) is developed, which is sent to the PPC and is considered at the time of hearing assuming an application is formally made. Only after this point may the potential applicant submit a formal application to the HB.

When an Application is Submitted

Once the application is submitted (by using Form A – see **Figure 1** (Page 14) for more detail) the HB must follow the process laid out at Schedule 3 of the Regulations after it has carried out several checks to make sure the application can be processed.

At this point the HB will have identified the CC which will be included in the formal notification of the application. At this time, the CC will be asked for a nominated community representative to speak on its behalf.



Regulations - Schedule 3

Paragraph 1 of Schedule 3 requires the HB to send notification of an application to certain people/parties:

- the Area Pharmaceutical Committee (APC);
- the Area Medical Committee (AMC);
- other pharmacies in the area who the HB feel might be significantly affected if the application were granted;
- any HB whose boundary is within two kilometres of the proposed premises; and now
- a nominated community representative that covers the neighbourhood within which the applicant intends to provide pharmaceutical services, or any part of it.

The CC will have 30 days from the date of the formal notification to submit a written response to the application. This consultation is in addition to the joint public consultation exercise, which CCs might also have responded too. This does not preclude them from submitting a further written representation as part of the HB's formal consultation under this regulation as **failure to do so will exclude them from the next stage.**

In developing a CC response you might want to consider the "legal test" which is the measure against which the PPC will judge an application, and applications can only be granted where this test is met. The regulation states:

10) An application made..... shall be assessed in accordance with the procedures set out in Schedule 3, and shall be granted by the Board-

- (a) *only if it is satisfied that the provision of pharmaceutical services at the premises named in the application is necessary or desirable in order to secure adequate provision of pharmaceutical services in the neighbourhood in which the premises are located by persons whose names are included in the pharmaceutical list; and*
- (b) *if the boundaries of the neighbourhood within which the applicant intends to provide pharmaceutical services falls within any part of a controlled locality, only if it is satisfied that the granting of such an application, in its opinion, would not prejudice the provision of NHS funded services in the controlled locality.*

The key elements of this test are as follows:

- What is the neighbourhood of the proposed premises;
- What are the existing pharmaceutical services in the neighbourhood, or in any adjoining neighbourhood?
- Are these services adequate, and if not – why?
- Why is it necessary to grant the application?
- Why is it desirable to grant the application?

CCs should use this framework, along with the information provided in Form A, the CAR and any other documentation sent to them to develop a written response.

After the Board's formal consultation

Everyone consulted under Schedule 3, Para 1 who submits a written representation to the HB will be invited to attend the hearing of the PPC where the application will be considered. You will be given reasonable notice of the hearing and details of its time, venue and any special arrangements.

In advance of the hearing the HB will provide you with copies of:

- the Application, supplementary information and the HB guidance for those attending the hearing;
- the Consultation Analysis Report; and
- copies of the written representations submitted during the HBs formal consultation period.

On the day of the hearing you should attend the notified venue in plenty of time. Latecomers will not normally be admitted to the hearing room once the meeting has started.

In the unlikely event that that the hearing has to be re-arranged, the HB will endeavour to provide all parties with as much notice as possible.

Site Visit

The PPC collectively undertake a site visit to the Applicant's proposed premises. They tour the general area, may visit some of the current pharmacies, view actual and planned housing and road developments and "get a feel" for the demographics in the neighbourhood.



Who will be at the PPC hearing?

- the Application, supplementary information and the HB guidance for those attending the hearing;
- those people who submitted written representations during the HB's formal consultation process (the Interested Parties) under Regulation 3;
- the PPC members;
- support staff

In some instances the Applicant or one of the Interested Parties may choose to bring along someone to assist them in making their presentation and/or respond to questions.

This person can, if the Applicant or Interested Party wish, speak on their behalf.

These arrangements will have been made before the hearing so that the Chair is clear on who will be speaking. Anyone brought along to assist in the hearing will be asked to confirm that they are not appearing in the capacity of counsel, solicitor or paid advocate.

Occasionally the Chair will ask that an observer/s sit in on the proceedings. This is normally a new PPC member who needs to observe a hearing before sitting on one. All parties present will be asked for their agreement before the observer is admitted to the meeting room.

The Observer will take no part in proceedings and will be seated away from the meeting table (where this is possible).

The Pharmacy Practice Committee (PPC)

The PPC is a formal Committee of the HB and has delegated authority to consider all applications to provide pharmaceutical services within the Board's area and to determine whether an application should be granted, or not.

The Committee is made up of seven members:

- (a) The Chair - appointed by the HB; the Chair is a Board member but does not work for the HB. The Chair cannot be, or have ever been, a doctor, dentist, ophthalmic optician or pharmacist or the employee of a person who is a doctor, dentist, ophthalmic optician or pharmacist;
- (b) three are pharmacists of whom—
 - (i) one is a pharmacist who is appointed by the HB on the nomination of the APC, but who doesn't own or work for someone who owns a community pharmacy; and
 - (ii) two are pharmacists who are appointed by the HB on the nomination of the APC and who either own or work for someone who owns a community pharmacy; and
- (c) three are Lay persons appointed by the Board. These are ordinary members of the public, but cannot be or ever have been a doctor, dentist, ophthalmic optician or a pharmacist, or an employee of a person who is a doctor, dentist, ophthalmic optician or pharmacist.

Voting

Only the three Lay Members are allowed to vote. The Chair will only cast a vote where the decision is tied. All other members must leave the room prior to any decision taken by the Committee.

Support to the PPC

Officers from the Health Board and National Services Scotland will be in attendance at the PPC meeting solely in support of the Committee. They are not part of the Committee and do not have a vote.

The PPC hearing

A support officer will direct you to the meeting room and is there to answer any questions you might have about the process (before you enter the room). The PPC members will be in attendance on entering the room.

Who can speak?

The Chair will welcome you and explain that only one person will speak on behalf of the applicant and each interested party.

The Regulations allow for the applicant and any interested party to be assisted, and if so wished for that person to speak on their behalf. You should note however that the Regulations preclude anyone appearing in support to appear in the capacity of “solicitor, counsel, or paid advocate”. You will be asked at the beginning of the hearing to confirm that those taking part do not fall into any of these categories and should be aware that the hearing could be affected if there is a failure to clearly define the status of any individual taking part.

The Applicant will normally put their case forward in the form of a formal presentation. Interested parties can also adopt this approach, however this is not a requirement and you should not feel that you have to make a formal presentation. You should look at the arguments put forward and the statements contained in the written documents supplied by the HB to decide if you wish to develop a formal response. Should you decide not to make a formal statement, you will still be able to question the Applicant and the other Interested Parties and they along with the PPC will be able to pose questions to you as a representative of the CC.

While there is no time limit for Applicants and Interested Parties you should note that everyone present will have already had received (and read) the written submission and information surrounding the application. You should therefore aim to focus your contribution to points not already made.

Please note: the use of PowerPoint presentations/video evidence and/or pre-recorded interviews are strictly prohibited. Any Applicant/Interested Party appearing with such a presentation will not be allowed to proceed.



Procedure to Be Followed by PPC

While the process is a formal one, the Chair and Committee will want the Applicant and Interested Parties to have an opportunity to present their arguments in as informal an atmosphere as possible, while still keeping to the requirements of the formal process. However, it is important that all exchanges between those present are directed through the Chair.

The conduct of the meeting is very procedural and presentation of case and asking questions takes place in a prescribed manner. When stating your case, try to make it as concise as possible. If you have a pre-prepared statement which you intend to read from/refer to, please give a copy of this to the Secretariat as this will help with the production of the detailed notes of the hearing.

The procedure to be followed at the PPC will be:

1. The Chair will ask the PPC to declare any interest they may have in the application, or with persons associated with the application.
2. The applicant/s will present their case;
3. The interested parties will be offered the opportunity of posing questions to the applicant;
4. The Committee will question the applicant;
5. The interested parties in turn will present their case, if they wish;
6. The applicant will be offered the opportunity of posing questions to the interested parties;
7. The other interested parties will be offered the opportunity of posing questions to the other interested parties;
8. The Committee will question the interested parties;
(steps 5-8 will be repeated for each Interested Party until all parties have had an opportunity to put forward their case and respond to questions).
9. Each of the interested parties will sum up in turn (as a summary this should be kept to a minimum);
10. The applicant will sum up.

The hearing has two parts, an open and a closed session. The applicant, interested parties and support staff attend the open session after which the PPC goes into closed session during which their determination of the application will be made.

Before the end of the open session, the Chair will ask all present to confirm that they have had a full and fair hearing. The responses will be formally recorded as part of the record of proceedings.

After the Hearing

In accordance with the Regulations, the PPC's decision will be relayed to the HB within 10 working days. After which the decision will be formally relayed to the applicant and interested parties within 5 working days.

The statutory appeal period afforded by the Regulations (21 days) will not commence until the decision has been formally communicated. The formal communication of the decision will contain details on how an appeal can be made.

Only the Applicant or those who made written representations during the consultation period can appeal. This is why it is important for CCs to develop a written response and submit this to the HB within the timescales provided. Failure to do so will exclude you from making an appeal (if you feel the PPCs decision is flawed).

The HBs involvement in the process ends here and appeals are considered and determined by the National Appeals Panel (NAP).

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Glossary

The following list includes terms likely to be used during a PPC hearing.

Term	Abbreviation	
Acute Medication Service	AMS	Involves the electronic transfer of prescriptions between GPs and community pharmacists for acute conditions plus provision of any associated advice.
Applicant		A person, partnership or company wishing to obtain an NHS community pharmacy contract.
Area Medical Committee	AMC	Local consultative Committee set up by Health Board.
Area Pharmaceutical Committee	APC	Local consultative Committee set up by Health Board.
Chronic Medication Service	CMS	Allows patients with long term condition to register with a community pharmacy of their choice for provision of pharmaceutical care as part of a shared agreement between the patient, community pharmacist and GP.
Community Representative		Person nominated by one or more Community Councils from amongst their elected members to make representations at PPC.
Consultation Analysis Report	CAR	Report produced jointly by the Health Board and intended Applicant which details the findings from the public consultation.
Contractor Pharmacist		Pharmacist whose name is included in the pharmaceutical list or is an employee of a person whose name is so listed and is appointed by the Area Pharmaceutical Committee.
Controlled Locality		An area within a Health Board, which is remote or rural in character, and which is served by a dispensing doctor.
Interested Parties		Any persons or organisations, other than the applicant, who are entitled to appeal against a PPC decision.
Lay members		Persons nominated to service on the PPC, who are not employed by, or who themselves are not/have never been a doctor, dentist, ophthalmic optician or pharmacist.
Legal Test		The test that the PPC has to determine pharmacy applications.
Minor Ailment Service	MAS	Allows eligible patients to register with a community pharmacy to enable them to consult with a community pharmacist for certain minor conditions direct from the pharmacy.
Minor Relocation		Where a pharmacy seeks to relocate position where the move is not significant – see Regulation 5 (6) of the pharmacy regulations for full details.
National Appeal Panel	NAP	The body which hears appeals against PPC decisions.
Non Contractor Pharmacist		A pharmacist whose name is not included in any pharmaceutical list and who is not the employee of a person whose name is so listed and is appointed by the Area Pharmaceutical Committee.
Pharmaceutical Care Services Plan	PCSP	A document prepared by the Health Board annually, comprising a summary of the pharmaceutical services provided in the area of the Health Board, together with an analysis of where in its area it believes there is a lack of adequate provision of pharmaceutical services.

Term	Abbreviation	
Pharmaceutical List		A list maintained by the Health Boards which records the names of pharmacies, the premises from which they provide community pharmacy services, the nature of the service provided and the days and hours which the premises are open.
Pharmacy Practice Committee	PPC	A committee appointed by a Health Board to consider applications for contracts to dispense NHS prescriptions.
Public Consultation		Formal 90 working day consultation with local communities who may be affected when an application is made to open a community pharmacy.
Public Health Service	PHS	A service provided by community pharmacies supporting patients with their self care and provision of advice and information on health issues as well as smoking cessation and sexual health services.
Public Partnership Forum	PPF	A network of Groups and individuals through which the Health & Social Care Partnership (HSCP) engages and communicates with people in their area.
Site visit		A visit by the PPC who will be present at the hearing to the area where the premises which are the subject to the application, are located.
Written Representations		Representations made to the PPC in writing and within the appropriate timescales by those entitled to do so, giving details of objections or support to the application.

Useful Links

Community Pharmacy

<https://nhsnss.org/services/practitioner/pharmacy/>

National Appeal Panel

<http://www.shsc.scot/meetings/national-appeal-panel/>

Scottish Neighbourhood Statistics

<http://www.gov.scot/Topics/Statistics/sns>

The National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009

http://www.legislation.gov.uk/ssi/2009/183/pdfs/ssi_20090183_en.pdf

The National Health Service (Pharmaceutical Services) (Scotland) Amendment Regulations 2011

http://www.legislation.gov.uk/ssi/2011/32/pdfs/ssi_20110032_en.pdf

The National Health Service (Pharmaceutical Services) (Scotland) (Miscellaneous Amendments) Regulations 2014

http://www.legislation.gov.uk/ssi/2014/148/pdfs/ssi_20140148_en.pdf

Figure 1

Section 1 - Applicant's details

Section 1 seeks:

The name of the person/partnership/body corporate that is making the application. This will normally be the party who will own the pharmacy (if the application is granted).

The address given at Section 1 should be the preferred mailing address. For a body corporate, this should be the registered address of the company.

FORM A (1) Regulation 5(2)

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

(Please delete words/sections which do not apply)

TO ...INVERTOSH..... 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) Mrs A N Body

of (correspondence address and name of company if relevant)

21 South End Street
Wolverbridge
INVERTOSH
IH32 9RS

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 Anne Norma Body

A named Superintendent Pharmacist must be supplied.

Section 2 – Premises Details

Section 2 gives:

Details of the premises from which the Applicant intends to establish the pharmacy, and the pharmacist who will be in charge of the premises.

- (a) Must show the full postal address of the proposed premises (if already constructed);
Where the application relates to premises that are not already constructed, the Board will require sight of a plan showing the exact location of the premises.
- (b) Where the answer to questions 2(b) i, ii or iii is “No” – the Applicant will be subsequently required to provide details on Form B before inclusion in the List can be confirmed (if the application is granted).

2. Premises details

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

14 Woodend Street
Wolverbridge
INVERTOSH
IH32 8BP

(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
AS SOON AS APPLICATION PROCESS IS COMPLETE

*** (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).

- (c) Should show the full name and General Pharmaceutical Council (GPhC) Registration Number of the pharmacist who will be in charge of the pharmaceutical aspects of the business.

Section 4 (b) – Applicant’s Assessment

The Applicant’s Assessment must include:

- (a) A description of any adjustments the applicant intends to make to the premises (see Equalities Act 2010 for details).
- (b) A description of the boundaries of the proposed neighbourhood, along with a map.
- (c) A detailed assessment of the current provision in the neighbourhood described by the applicant of services for which the applicant believes there is not currently adequate provision by **persons on the Pharmaceutical List**, and evidence in support of that belief

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.

Will make all reasonable adjustments to ensure compliance with 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.

**North: From Woodend Street (A84) following trunk road to junction with South Street (A85);
East: South Street (A85) following road south across railway line to Woodend Park at its junction with High Street;
South: High Street travelling west to junction with Beith Road; and
West: Beith Street following north over railway line to junction with Woodend Road.**

(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.

The current provision does not provide an adequate level of service to the neighbourhood given that it operates from cramped premises with no consultation room.

In addition, the significant redevelopment to the south of High Street (which includes 150 new residential dwellings and a primary school) will place significant pressure on the current services.

(v) Describe the pharmaceutical services you will provide.

**Minor Ailment Service;
Chronic Medication Service;
Acute Medical Service;
Public Health Service.**

Additional Services (at the HBs discretion):

- Opiate Substitution Therapy (Methadone and Buprenorphine);
- Injecting Equipment;
- Palliative Care;
- Advice to Care Homes.

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

1st November 2015

- (d) A description of the pharmaceutical services that the applicant intends to provide
- (e) The date by which the applicant intends to commence the provision of services

(f) The hours in each day the applicant intends to provide such services

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

Mon – Fri: 9.00am – 6.30pm
Saturday: 9.00am – 2.00pm
Sunday: 11.00am – 3.00pm

(viii) 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.

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Section 5 – Declaration

The applicant must sign, print their name and date the application before submission.

5. I/We undertake to provide the services as detailed in the 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.*

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