

The control of entry regulations and retail pharmacy services in the UK

Volume 2 (Annexes A to I)

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A THE CONTROL OF ENTRY REGULATIONS IN ENGLAND, WALES AND SCOTLAND

Introduction and background

General

- A.1 The current regulatory system for NHS pharmaceutical services in England and Wales is contained in the **National Health Service (Pharmaceutical Services) Regulations 1992** ('the regulations'). The system controls the number and location of pharmacies wanting to hold pharmaceutical contracts to dispense NHS prescriptions. The regulations are secondary legislation made under section 41 - 43 of the **National Health Service Act 1977** as amended. In particular, section 41(2) introduces the concept that provision of pharmaceutical services must be 'necessary or desirable' in a neighbourhood. A similar framework exists in Scotland and Northern Ireland.
- A.2 All qualified pharmacists in England and Wales who are registered with the Royal Pharmaceutical Society of Great Britain (RPSGB) may dispense medicines. The dispensing premises must also be registered with the RPSGB which, therefore, holds two registers, one for individual pharmacists and one for registered dispensing premises.
- A.3 However, in order to dispense NHS prescriptions from their premises, an owner or prospective owner of a pharmacy (which may be a body corporate or an individual pharmacist) must apply to the local Primary Care Trust for a dispensing contract that enables 'entry' on to the local Pharmaceutical List.¹ The decision as to whether or not to grant an application for inclusion is determined under the regulations by the Primary Care Trust for the area and the decision on the application made on the facts of each individual case. In most cases, decisions are subject to appeal under Regulation 8 of the regulations to the Secretary of State who has delegated this responsibility to the Family Health Services Appeals Authority (FHSAA). In Wales, this responsibility is held by the National Assembly for Wales (NAFW).
- A.4 The current regulatory system was established in 1987 and amended in 1992.

England

- A.5 In October 2002 some local Health Authorities functions including pharmacy applications for NHS dispensing were devolved to Primary Care Trusts (PCTs).

¹ The Pharmaceutical List is a list of pharmacies contracted to dispense NHS prescriptions.

A.6 In deciding applications, PCTs are expected to follow the guidelines published by the Department of Health in 1992, HSG (92)-13 (the 1992 guidelines). The guidelines emphasise that there are no hard and fast rules and no quotas or norms are to be adopted when considering applications, and that each application is to be considered on its merit.

Wales

A.7 The NAFW is the devolved administration for health provision in Wales. Currently it operates under the same pharmacy regulations as England. The NAFW has fully devolved powers in health matters although as yet these have not been used to amend the regulations in Wales and so therefore the regulations are the same as in England. In Wales the 5 existing local Health Authorities are being replaced by 23 local health boards.

The tests under the regulations

A.8 This section examines the main parts of the regulations and the tests that are applied when applications are made under the regulations in both England and Wales.

A.9 Over time, the regulations have been tested through the courts. Judicial reviews have been sought in a number of cases leading to, what can be described as, the 'maturing' of the regulatory system through guidance from the courts.

Summary of the tests

A.10 The regulations set out the rules to be followed in determining applications for entry to the pharmaceutical list for dispensing NHS prescriptions in both non-controlled and controlled areas. Controlled areas are those that are rural in character. All other areas are classed as non-controlled. The main tests are as follows and are explained in more detail below:

Non-controlled areas

- Applications for a **new contract** - Regulation 4(4) the necessary or desirable test
Applications for **change of premises** other than minor relocation
Regulation 4(2)(b)(ii) subject to the necessary or desirable test Regulation 4(4)
- Applications for **minor relocation** Regulation 4(3)(a)
- Applications for **change of ownership** Regulation 4(3)(b)
- Application for **preliminary consent** Regulation 14

Controlled areas

- Applications to **dispense by doctors** (outline consent) – Regulation 20 and 21 subject to the **prejudice test** – Regulation 12(13).
- Applications for **preliminary consent** by **pharmacies** – Regulation 14 subject to the **prejudice test** – Regulation 12(13).
- Applications by **pharmacies** under the **necessary or desirable** test Regulation 4(4) (all pharmacy applications except minor relocations are subject to the necessary or desirable test).

A.11 The detailed operation of the rules under each test is discussed below.

The tests themselves

Non-controlled areas

APPLICATIONS FOR A NEW CONTRACT - REGULATION 4(4)

A.12 'An application in any case other than those specified in paragraph (3) shall be granted by the FHSA only if it is satisfied that it is **necessary or desirable** to grant the application in order to secure, in the **neighbourhood** in which the premises from which the applicant intends to provide the services are located, the adequate provision by persons included in the list of the services.... Specified in the application'.

A.13 A pharmacist applying to the PCT for admittance to its list must show that a new pharmacy is **necessary or desirable** for the **adequate provision** of pharmaceutical services in the **neighbourhood**.

A.14 The key terms in this test (as highlighted above) are not defined in the regulations. For example, '**neighbourhood**' is not defined and has been the subject of litigation and has led to the courts giving guidance on the interpretation of what constitutes a neighbourhood. Moreover, whether a particular neighbourhood has adequate provision of pharmacy services depends on the facts of a particular case and can involve geographical as well as other factors. For example, geographical characteristics such as lakes, rivers, hills, railways and major roads that directly affect the neighbourhood in question will be taken into account when deciding if there is already adequate provision and access in a particular area. The 1992 guidelines also include the following factors:

- the range of services provided by existing pharmacies, and
- evidence of local deficiencies in the services.

- A.15 The courts have provided guidance on the definition of neighbourhood². The key case was **R-v-FHSAA ex parte Boots the Chemist (1996)**³ better known as the **Cribbs Causeway case** when the court determined that a retail park could be a neighbourhood because no residential element was necessary.
- A.16 The courts were careful, however, not to give the concept of neighbourhood too wide a definition and in a Northern Ireland case, **Boots The Chemist (The Bangor case) (1994)**,⁴ the court held that the concept of neighbourhood for the purposes of regulating pharmacies has the same limitation as that of the concept of vicinity as defined in the regulations governing the licensing of premises selling liquor. Both concepts are limited to premises in the neighbourhood in the sense in which one speaks of being a neighbour of another.
- A.17 The necessary or desirable test is also an issue that depends upon the facts of each case. By way of a simple illustration, if a particular neighbourhood has only two pharmacies providing adequate services to half the community whilst the other half cannot gain access to either of the pharmacies because they reside on the other side of the neighbourhood or they are impeded by physical or geographical factors, any application for inclusion on the pharmaceutical list or indeed for change of premises is likely to succeed. The success of such an application will depend upon there being evidence that the community is lacking in adequate provision of pharmaceutical services and will gain greater access to such services if the application is granted. This type of application would, in all likelihood, be deemed 'necessary'.
- A.18 In some cases while it has not been deemed 'necessary' to grant an application, the courts have nevertheless felt that it was 'desirable' to do so. In **R-v-Northern & Yorkshire Regional Health Authority ex parte P J Norton (1995)**,⁵ Co-op chemists applied to open premises very close to Norton's premises. The local Health Authority granted the application on the basis that it was desirable because of the very high volume of patients the existing pharmacy served in an area that was still developing and that it would increase the services available and introduce an element of patient choice. The Norton appeal was dismissed by the Appeal Authority and ultimately dismissed by the Court of Appeal.

CHANGE OF PREMISES – REGULATION 4(2)(B)(II)

- A.19 This type of application is used where a pharmacy which is already on the pharmaceutical list wishes to relocate to other premises. However the relocation

² Cases referred to in this annexe were summarised from case notes compiled by the Family Health Services Appeal Authority.

³ QBD, [1996] 33 BMLR 1.

⁴ 4 February 1994, unreported in the High Court of Justice in Northern Ireland.

cannot be one which may be considered to be of a minor nature (see below) and thus the 'necessary or desirable' test is always applied to such cases (see above).

MINOR RELOCATIONS - REGULATION 4(3)(A)

- A.20 Where a pharmacy wishes to relocate the business to other premises, provided the relocation is minor, the PCT normally grants the application if it meets the following conditions:
- A.21 the move is within the same neighbourhood and is minor
- the same services are to be provided, and
 - there will be no break in provision between the old premises closing and the new premises opening.
- A.22 The PCT does not consult pharmacies likely to be affected by a minor relocation but does notify the parties (i.e. the applicant and others who may have filed an objection to the application) of the decision prior to granting the relocation. Such affected parties do have a right to appeal the decision within 30 days. It should be noted that the applicant also has a right of appeal if the application for minor relocation is refused. It should also be further noted that the applicant does not have to satisfy the 'necessary or desirable' test for a minor relocation. So again, the concept of neighbourhood plays a central part in minor relocation applications.
- A.23 The leading case on this issue is the case of **R-v-Yorkshire Regional Health Authority ex parte Suri & Gompels (1995)**.⁶ Here the court said that the definition of neighbourhood is primarily to be related to geography as well as physical and social factors. It would, therefore, seem that if a proposed minor relocation is over a short distance with no physical barriers or social factors for the users and the new premises serves essentially the same population as before, then the application will normally be granted.

CHANGE OF OWNERSHIP - REGULATION 4(3)(B)

- A.24 The owner of a pharmacy, who has the benefit of a NHS contract, cannot simply sell the contract and transfer the entry on the pharmaceutical list to the purchaser. The PCT has to grant the change and will only do so if it is satisfied that:
- the same services will be provided by the new owner (contractor), and

⁵ 6 June 1995, unreported QBD; affd (1996) CA transcript 53.

⁶ [1995] 21 BMLR 26 (upheld by the Court of Appeal (1995) 30 BMLR 78).

- there is no interruption of the provision of services by the change of ownership and no change to the location of the premises is involved.

A.25 If any of these conditions are not satisfied, the application will be refused. The PCT will advise all local pharmacies of the proposed grant of change of ownership, who may appeal (although the grounds of appeal are limited in change of ownership cases).

APPLICATIONS FOR PRELIMINARY CONSENT – REGULATION 14

A.26 These applications are used by pharmacists wishing to ‘test the waters’ before making a full application for a new contract under Regulation 4 in non-controlled localities, as well as for applications for additional premises/services or to relocate the premises. In non-controlled areas, the use of preliminary consents is a safeguard for applicants against investing substantial capital in premises only to find that no NHS contract will be granted. It is also a pre-requisite for some applications by pharmacists in controlled localities.

A.27 The application must be made in writing to the PCT and must contain enough information regarding the proposed location, types of services and other information so that the PCT can apply the ‘necessary or desirable test’.

A.28 The application for preliminary consent will be treated as if it is a full application to be included on the pharmaceutical list.

A.29 If the application is granted, the applicant must subsequently make a full application within 12 months (only one extension of time can be granted by the PCT). The full application should then be granted without the need to follow the normal procedures for dealing with full applications, provided the time limit has not expired and there are no changes to the proposed services granted in the preliminary application.

Controlled areas

A.30 Some areas are deemed rural in character and are classified as controlled localities. These are areas where GPs may have rights to provide dispensing services. Certain provisions of the regulations are designed to ensure that existing medical and pharmaceutical services are not adversely affected, particularly those provided by dispensing doctors.

A.31 Rurality is determined by the PCT under the provisions of Regulation 9. The question of rurality is a matter of observation and depends on the facts of each case. Many controlled areas have already been defined as such and PCTs with rural areas should already have determined maps of their districts with rural areas marked on them. The PCT’s decision on rurality can be appealed by the

local medical committee and/or local pharmaceutical committee. When an area is deemed rural in character it is then dealt with as a 'controlled' area.

APPLICATIONS TO DISPENSE BY DOCTORS (OUTLINE CONSENT) IN CONTROLLED LOCALITIES REGULATIONS 20 AND 21 SUBJECT TO THE 'PREJUDICE' TEST UNDER REGULATION 12(13).

- A.32 Regulation 12(13) is the test (known as the 'prejudice' test) for applications in controlled localities by those doctors wishing to dispense in rural areas. However, under Regulation 12(18) where an area is deemed to be rural, and an application from a doctor to dispense has been refused, the PCT will not entertain any further applications to provide similar services in that area for the next five years, unless it is satisfied of a significant change in circumstances affecting the controlled area.
- A.33 Similarly, if the application by the doctor is granted, the PCT will not entertain any applications to open a pharmacy in that area for the next five years, unless there is evidence of a significant change in circumstances affecting the controlled locality.
- A.34 An example of a significant change in circumstances would be a new development in the area accommodating a significant number of new residents with the overall effect of increasing the size of the local population requiring pharmaceutical services.
- A.35 When considering an application under Regulation 12, the PCT must first consider the 'prejudice' test Regulation 12(13). The PCT must refuse an application if its grant would prejudice the proper provision of general medical services, personal medical services, dispensing services or pharmaceutical services.
- A.36 Regulation 11 is the provision that determines which pharmacy applications are subject to the rural dispensing provisions under Regulation 12. When considering an application for a pharmacy to supply NHS pharmaceutical services relating to a controlled locality, the PCT has two distinct matters to decide:
- whether to grant the application would **prejudice** the proper provision of general medical services, personal medical services, dispensing services or pharmaceutical services in any area (the prejudice test Regulation 12(13)),
 - whether it is **necessary or desirable** under Regulation 4(4) to grant the application in order to secure in the neighbourhood the adequate provision of pharmaceutical services by persons on the pharmaceutical list (the necessary or desirable test).

- A.37 In addition any application for outline consent by a doctor will fail if the area is not within a controlled locality or is within one mile of any pharmacy.
- A.38 Both issues have to be considered in all applications for a controlled locality. However, under the second test the PCT would only be concerned with the provision of services by persons on the Pharmaceutical List and not with any services provided by dispensing doctors. In addition to this dispensing doctors who might be affected have no right to make representations in relation to the second test or participate in the process in any way should there be an oral hearing on the matter.
- A.39 The case of **R-v-Humberside FHSA ex parte Dr Moore & Partners**⁷ confirmed this subject to the proviso that this did not mean that the Health Authority could not consider any information received from dispensing doctors if it wished to do so, for example, in this case, written representations provided by doctors in the neighbourhood regarding the application.
- A.40 The rules and principles governing the way both pharmacists and dispensing doctors can practise in rural areas were developed over a long period before the regulations came into effect. Any area that was deemed to be a controlled area before the coming into effect of the regulations remained so and this position is reflected by Regulation 9 (1).
- A.41 Dispensing doctors are mainly found in market towns and other areas that are deemed 'rural' in character providing dispensing services for rural patients.
- A.42 A doctor proposing to begin or extend dispensing to patients living in a rural area must apply for outline consent (Regulation 21). Regulation 21 is the equivalent provision for dispensing doctors to preliminary consent for pharmacies and, in the case of controlled localities, dispensing doctors must apply for outline consent first. Dispensing doctors have a period of 12 months from the grant of outline consent to start dispensing before the grant lapses. The PCT will check whether the patients for whom the doctor intends to seek to dispense are more than one mile from a pharmacy with a NHS contract and whether the application passes the 'prejudice' test. If either of these proves not to be the case the application will fail.
- A.43 If on the other hand the application relates to an area where outline consent (under Regulation 21) has been refused in the previous five years, the application will not be considered, unless the PCT is satisfied that there has been a substantial change in circumstances affecting the area.

⁷ (No. 1 and No. 2),(1995) COD 343 (CA).

- A.44 When determining the question of rurality, geographical, physical and social factors play a large role in the determination of the issue.

APPLICATIONS FOR PRELIMINARY CONSENT BY PHARMACIES REGULATION 14 SUBJECT TO PREJUDICE TEST REGULATION 12(13).

- A.45 This is a form of application that pharmacies can make to dispense in controlled areas. Regulation 14 allows the pharmacy to apply for preliminary consent to be included in a pharmaceutical list when considering opening a pharmacy in a controlled area. See paragraph e. above on the mechanism of preliminary consent applications.
- A.46 By virtue of Regulation 14(3) if the application by the pharmacy is within a controlled locality, the prejudice test (Regulation 12(13)) must be applied. Thus Regulation 14(3) has the effect of applying the prejudice test to preliminary consent applications in controlled localities.

APPLICATIONS BY PHARMACIES UNDER THE NECESSARY OR DESIRABLE TEST REGULATION 4(4)

- A.47 All pharmacy applications except minor relocations are subject to the necessary or desirable test.
- A.48 Any pharmacist, **already on the Pharmaceutical List**, making an application to open a pharmacy in the vicinity of a dispensing doctor, does not have to satisfy the 'prejudice' test. The pharmacist merely has to satisfy the PCT of the 'necessary or desirable' test (**R-v-N Yorkshire FHSA ex parte Dr Wilson & Partners (1996)**).
- A.49 At present Regulation 11(1) means that a pharmacy application to provide pharmaceutical services in controlled localities can only be subject to the prejudice test if it is made under Regulation 4(2)(a) i.e. applications by people not currently included in the Pharmaceutical List. People who are already on the Pharmaceutical List apply under Regulation 4(2)(b) and so are not subject to the prejudice test.
- A.50 This leads to a situation whereby it is easier for a pharmacy already on the pharmaceutical list to open premises in a controlled locality because the application is made under Regulation 4(2)(b) which is not subject to Regulation 12 and hence the prejudice test. Therefore, the pharmacy which is already on the pharmaceutical list merely has to satisfy the necessary or desirable test under Regulation 4(4).

Administration of the system

England – initial applications

- A.51 The PCT considers each application for a NHS contract in controlled and non-controlled localities on its merits and in light of the current provision of services to the public.
- A.52 PCTs in England are directed by the 1992 guidelines, to reach decisions and to notify the parties on applications within 6 weeks from receipt of the application. Upon receipt of an application the PCT must notify:
- the local pharmaceutical committee
 - the local medical committee
 - any person whose name is on the Pharmaceutical List and whose interest might be affected if the application is granted.
- A.53 This consultation process does not apply to applications for a minor relocation 4(3)(a) and change of premises 4(3)(b).
- A.54 Local Pharmaceutical Committees (LPC) were established with the NHS in 1948 and are statutory bodies that have to be consulted by local PCTs about many issues concerning the terms of service and contracts of community pharmacies.
- A.55 Any of the above groups who have been notified have 30 days within which to make written representations to the PCT (see Regulation 5(1)).
- A.56 The Primary Care Trusts (PCT) have 30 days to determine an application and either grant approval outright, grant the approval subject to conditions or refuse approval. If an application is refused the parties involved are notified and are given a further 30 days to appeal.
- A.57 The PCT has a duty to consult to obtain the views/objections of other pharmacists in the neighbourhood. There is no such obligation to consult doctors (who do not appear on the Pharmaceutical List).

Pharmacy appeals - England

- A.58 Whatever the outcome of an application decided by the PCT, there is recourse for all those involved in the application process to an independent appeals system. Those people or groups of people who have been notified of the application **and** have made written representations to the PCT have a period of 30 days to make an appeal in writing. It should be noted that in applications concerning a minor relocation or change of premises no written representations

are allowed. In those applications where written representations are allowed, if representations are not made by the appropriate parties within the specified time scale then they will be debarred from appealing.

- A.59 The Family Health Services Appeal Authority (FHSAA) for England is based in Harrogate and administers the appeals system. It deals with the full range of applications that are appealed. The FHSAA's total annual expenditure for 2000/2001 was £755,000.⁸ The Board has a Chairman, Chief Executive, two non-executive Directors and one Executive Director. Three quarters of the Authority's workload is made up of pharmacy appeals and one quarter made up of other work such as NHS disciplinary appeals.
- A.60 Upon receiving appeals the FHSAA can deal with it in one of three ways: firstly, it can dismiss the appeal on paper i.e. summary dismissal (normally with vexatious/frivolous appeals); secondly, it can require detailed written submissions from the interested parties; or thirdly, it can refer the matter for an oral hearing. The FHSAA has to treat every appeal as a re-hearing and not merely a review. There are no legal grounds to cut down the right of appeal to a right to review. This was confirmed in the Northern Ireland case of **Cooper & Anglin (1991)**.⁹
- A.61 In the last three years the number of appeals has declined, from 493 appeals received in 1999 to 362 in 2001, a decrease of 131.

Wales

The initial application

- A.62 The five Health Authorities in Wales handle applications for entry to the Pharmaceutical List, at first instance. However, these will shortly be replaced by 23 local Health Boards which will then have responsibility for pharmacy entry controls.
- A.63 The NAFW has not issued separate guidance to the Welsh Health Authorities. They are expected to follow the 1992 guidelines (see above).

Pharmacy appeals - Wales

- A.64 A separate Welsh Appeals Authority was first established on 1 April 1996, prior to full devolution. The Appeals Authority is now established within the NAFW.
- A.65 The Appeals Office Committee of the NAFW deals with appeals in broadly the same way as the FHSAA in England. However, the Appeals Office Committee is

⁸ Family Health Services Appeal Authority Annual Report 1 April 2000 – 31 March 2001.

⁹ (1991) 10 NIJB 1.

not a designated appeals body in the same way as the FHSAA in England. In 2001/2002 only 21 appeals were received (see table below). The decision of the Health Authority is received and members of the Appeals Office Committee are invited to analyse the decision and provide written comments. A meeting is then called at which a final decision is made.

- A.66 The Appeals Office Committee deals with most appeals on paper but has a policy of oral hearings for applications made by doctors. The oral hearing committee is made up of a panel of qualified and lay members. A site visit is also always arranged in Wales to determine the neighbourhood when this is at issue.
- A.67 Appeals vary in the amount of time it takes for a decision to be made. Based on figures provided by the NAFW for 1999-2001, on average, it takes 10 months to process appeals without an oral hearing and 14.5 months for appeals that require an oral hearing.
- A.68 The Appeal Office Committee rely upon English legal cases for guidance.

Appeal statistics for England & Wales

- A.69 This section shows the breakdown of appeals received in both England and Wales by category of appeal for both controlled and non-controlled areas for the latest year for which data are available

England

TABLE A.1: FIGURES FOR 1 APRIL 2000 TO 31 MARCH 2001

Controlled areas	
Rurality	7
Dispensing doctors	9
Pharmacy (prejudice)	16
Pharmacy (necessary/desirable)	28
Others	1
Sub-total	61
Non-controlled areas	
Full applications	154
Minor relocation	83
Appliance applications	5
Oxygen applications	14
Others	3
Sub-total	259
Schedule 2 – Premises and hours	19
Removal from list	2
Total	341

Source: Appeal Authority Annual Report for 2000/01

Wales

TABLE A.2: FIGURES FOR 1 APRIL 2000 TO 31 MARCH 2001.

Controlled Areas	
Rurality	2
Dispensing Doctors	1
Pharmacy (all)	0
Sub total	3
Non Controlled Areas	
Full Application	11
Minor Relocation	6
Additional Services (Oxygen)	1
Sub total	18
Total	21

Source: Office Appeals Committee, NAFW

The current regulatory system in Scotland

Introduction and background

General

- A.70 Scotland's regulatory framework was established in 1987 with the introduction of the **National Health (Pharmaceutical Services) (Scotland) Amendment Regulations 1987**. These regulations were introduced as part of the Secretary of State's powers under the **National Health Service (Scotland) Act 1978** and after consultation with the council on tribunals in accordance with section 10 of the **Tribunals and Inquiries Act 1971**.
- A.71 Prior to the introduction of these regulations there was no regulatory framework to govern the entry of pharmacies into the market. In 1995 the Scottish NHS pharmaceutical regulations were consolidated into the NHS (Pharmaceutical Services) (Scotland) Regulations 1995 (the Scottish Regulations).
- A.72 The Scottish Regulations are similar to the regulations used in England and Wales with the same legal test for entry i.e. 'necessary or desirable'. However there are some differences in the Scottish regulations and these are discussed in more detail below.
- A.73 As in England and Wales, all qualified pharmacists in Scotland must be registered with the RPSGB in Scotland before they are allowed to undertake dispensing activities. The same position also applies to pharmacy premises.
- A.74 The regulatory process governs which pharmacies are granted NHS contracts before NHS prescriptions can be dispensed. Again the system is similar to the English and Welsh regulations. In Scotland the pharmacy applicant must apply to the relevant Island Health Board (IHB) or Health Authority (HA). The decision will be made by the IHB/PCT's Pharmacy Practice Committee and will be based on whether the applicant satisfies the legal test.
- A.75 The National Appeal Panel (NAP), the Scottish equivalent to the FHSAA in England, hears appeals. The full function of the NAP and the number of appeals dealt with is discussed in detail below.

Scotland

The tests under the regulations

APPLICATION FOR NEW CONTRACT (REGULATION 5(10))

- A.76 This regulation provides: 'An application... shall be granted if the board or primary care NHS trust 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'.
- A.77 The factors which Pharmacy Practice Committees (PPC) have to consider are: (a) what is the neighbourhood in which the premises are located? (b) What are the existing services in the neighbourhood?, (c) Are these services adequate or not?, (d) Is it necessary to grant the application in order to secure adequate provision of pharmaceutical services in the neighbourhood?, or (e) is it desirable to grant the application in order to secure adequate provision of pharmaceutical services in the neighbourhood?
- A.78 It is important to note that proposed pharmaceutical premises could be granted because they are necessary, or because they are desirable, or both.
- A.79 Like the regulations in England and Wales, the Scottish Regulations do not define the key terms.
- A.80 The concept of neighbourhood is not defined. Scottish PPCs and the NAP have relied on both English and Scottish cases for guidance.
- A.81 There has been some guidance from the Scottish courts on the concept of 'neighbourhood'.
- A.82 In the judicial review case of **Boots the Chemist Ltd (1999)**¹⁰ an application was made by Boots for a contract in respect of premises at a retail park in Inverness. Lord Nimmo-Smith said:
- 'Neighbourhood is not defined in the regulations and must therefore be given the meaning which would normally be attributed to it as an ordinary word of the English language. As the word is ordinarily understood, it has connotations of vicinity or nearness...the word neighbourhood in Regulation 5(10) of the Scottish Regulations means an area, which is relatively near to the premises in

¹⁰ Outer House, [2000] GWD 1-18.

question, which need not have any residents, and which can be regarded as a neighbourhood for all purposes’.

APPLICATION FOR MINOR RELOCATION (REGULATION 5(4))

A.83 The Scottish Regulations concerning minor relocations are similar to the regulations in England and Wales. The Scottish Regulations regulate those pharmacies that wish to move over short distances and which will essentially continue to serve the same population as before. The main differences are covered below under the heading ‘Differences from English regulations’.

A.84 Regulation 5(4) provides:

‘Where an application is made and-

- (a) the applicant intends to relocate to new premises, within the neighbourhood in which he provides pharmaceutical services, from premises already listed to him, and to provide from those new premises the same pharmaceutical services which he is listed as providing from his existing premises,
- (b) the Board is satisfied that the relocation is a minor relocation, and
- (c) the condition specified in paragraph (5) is fulfilled.

A.85 The condition referred to is that the provision of services provided by the applicant is not interrupted as a result of the minor relocation. There must not be a significant change in the neighbourhood population, therefore the move must be within the same neighbourhood as defined by the Board. Before the Board can satisfy itself that the move is a minor relocation it must seek the views of the Area Pharmaceutical Committee and the Chief Administrative Pharmaceutical Officer of the Board.

Differences from English regulations

MINOR RELOCATIONS

A.86 One important difference is the ‘appreciable effect’ rule contained in Regulation 5(6). The rule states that there must not be an appreciable effect on the pharmaceutical services provided by the applicant or any other person whose name is included on the pharmaceutical list of the Board.

A.87 This provision which is essentially an additional test, is absent from the English regulations.

PROVISIONAL PHARMACEUTICAL LIST

A.88 This provision under Regulation 6 is the Scottish equivalent of the English

provision governing preliminary consent. However, the Scottish system has one major difference, which distinguishes it from preliminary consent applications. Regulation 6(1) states that the application must specify the premises from which the pharmaceutical services will be provided. This means that the applicant must already have new premises to which he wishes to relocate.

Administration of the regulations

INITIAL APPLICATIONS

- A.89 Pharmacy Practice Committees deal with initial applications. There are 15 Health Boards in Scotland, each administering the system at local level. The Scottish Regulations state in paragraph 3 of schedule 3 that Health Boards must pass on the PPC's decision to applicants and interested parties in writing within 5 days of receiving notification from the PPC. The Board's letter must contain the decision, the reasons for the decision, and information about any right of appeal.

PHARMACY APPEALS IN SCOTLAND

- A.90 The NAP processes the appeals. The NAP is selected from a pool of people nominated by the Health Authority (HA), by the Scottish Department of the Royal Pharmaceutical Society of Great Britain and by the Scottish Pharmaceutical General Council (SPGC).
- A.91 The NAP is only convened to hear appeals presented to it. When an appeal is lodged it is sent to the NAP administrator with all relevant documents. The administrator then forwards copies of the documents to the Chairperson and to the Scottish Executive Solicitor who advises the NAP.
- A.92 The Chairperson can dismiss the appeal without a hearing if he/she considers there are no reasonable grounds for appeal or that the appeal is otherwise frivolous and/or vexatious, otherwise the appeal will be listed for an oral hearing. If an oral hearing is required then the 'panel' members will always attend a site visit to the applicant's premises or proposed premises, on the day of the oral hearing. During the site visit the panel members also carry out an assessment of the 'neighbourhood'.
- A.93 A Scottish Executive legal adviser sits in on all oral hearings to advise the panel. The NAP's decision and the reasons for it have to be notified to the relevant Health Board within 5 working days.
- A.94 The decision of the panel is final. The NAP's decisions can only be challenged through judicial review.

Appeal statistics

TABLE A.3: APPEALS RECEIVED FROM 1 JANUARY 2000 TO 31 DECEMBER 2000

Received in 2000	14
Brought forward from previous year	6
Decided in 2000	18
Carried forward to next year	2
Waiting times (weeks)	18
% of Appeals that were successful	33%
% of cases decided by an oral hearing	83%

Source: Scottish Executive

TABLE A.4: APPEALS RECEIVED FROM 1 JANUARY 2001 TO 31 DECEMBER 2001

Received in 2001	18
Brought forward from previous year	2
Decided in 2001	15
Carried forward for next year	5
Waiting times (weeks)	14
% of appeals that were successful	20%
% of cases decided by an oral hearing	67%

Source: Scottish Executive (Health Department)