

# **The NHS (Pharmaceutical Services) Regulations 2005**

## **Information for Primary Care Trusts**

**INFORMATION FOR PRIMARY CARE TRUSTS (CONTROL OF ENTRY) REVISED FEBRUARY 2007**

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## Executive Summary

This Guidance has been produced to assist Primary Care Trusts in the assessment and determination of applications to provide NHS pharmaceutical services. It incorporates reforms effective from 1 April 2005 to the regulatory system and further amendments to the Regulations effective from 5 July 2005 and 19 January 2007. It also provides information on the appeals process.

The NHS Act 1977 requires Primary Care Trusts to approve an application from a chemist only where it is necessary or desirable<sup>1</sup> in order to secure the adequate provision of NHS pharmaceutical services in the neighbourhood. This is known as “control of entry”. Control of entry was introduced originally in 1986 and new Regulations introduced from April 1987.

The NHS (Pharmaceutical Services) Regulations 2005 derive from this legislation. The Regulations apply to “chemists” which includes not only pharmacies but also appliance contractors.

In summary, the main reforms to the Regulations introduced in April 2005 comprised:

- Introducing new criteria of ‘competition and choice’ to the current regulatory test (see *Chapter 3*)
- Four exemptions to the regulatory test (see *Chapter 4*):
  - Pharmacies based in approved retail developments over 15,000 square metres or more retail leasehold gross floor space away from town centres
  - Pharmacies that intend to open for no less than 100 hours per week
  - Applications from members of a consortia wishing to establish new One Stop Primary Care Centres
  - Wholly mail-order or internet based pharmacy services
- Streamlining and modernisation of the application and decision-making process. These include:
  - Primary Care Trusts can invite applications from contractors (a non-regulatory change)
  - Reworking the application form to reflect the new criteria that Primary Care Trusts use in assessing applications (see *Chapters 2 and 3*).
  - Primary Care Trusts being allowed to set a fixed date for the receipt of applications. (see *Chapter 3*)(again, a non-regulatory change)

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<sup>1</sup> From 1 March 2007, the relevant legislative provision is set out in Chapter 7 of the NHS Act 2006. This Act consolidates various NHS enactments.

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- Primary Care Trusts being required to reach a decision on an application within four months of the due date for receipt, unless there is good cause or in the case of a minor relocations less than 500m or changes of ownership, when the Primary Care Trust must reach a decision within 30 days. (*see Chapter 3*)
  - Primary Care Trusts consulting widely with patient, consumer and local community groups that have a direct interest in local pharmaceutical services provision. There is an administrative minimum consultation period of 45 days (*see Chapter 3*).
  - A streamlined procedure in which the Primary Care Trust does not consult before making its determination for all minor relocations under 500m, but Primary Care Trusts having the discretion to override this where there is good cause (*see Chapter 3*).
  - After a successful minor relocation, the applicant being required to trade from the new premises for a minimum 12-month period before a further application for a minor relocation can be accepted; unless the applicant shows there is good cause (*see Chapter 3*).
  - Removing the restriction which prevented minor relocations across Primary Care Trust boundaries (*see Chapter 3*).
  - Retaining the concept of preliminary consent for a pharmacy application, but reducing the maximum period for grant of such consent to six months (*see Chapter 3*).
  - Reducing the maximum period of grant for full consent to nine months (a grant shall be for six months which the Primary Care Trust can extend by up to a further three months at its discretion).
  - Enabling Primary Care Trusts to have the discretion to require the applicant to commence pharmaceutical services within a given period not exceeding three months unless there is good cause (*see Chapter 3*).
  - Retaining the longstop discretion for Primary Care Trusts to decide competing applications of equal merit based on 'the first past the post' (*see Chapter 3*).
  - Combining appeals for a change of ownership with appeals concerning minor relocations (*see Chapter 3*).
- Other guidance and advice:
    - The reforms to the control of entry regulations were introduced at the same time as the introduction of the new community pharmacy contractual framework.

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Separate guidance is available on the new framework on the Department's website. In addition, new requirements on pharmacy contractors and pharmacists to declare information about their suitability to provide NHS services were introduced. Further advice for Primary Care Trusts on these "fitness to practise" procedures and for managing their pharmaceutical lists, including admission of chemists (providers of pharmaceutical services and appliance contractors) is available on the Department's website. Existing contractors had until 3 October 2005 to comply with these requirements. Ongoing fitness to practise issues must be reported by contractors within seven days.

## 1. Introduction

### Status of Advice

- 1.1 The primary purpose of this guidance is to help all those working in Primary Care Trusts with the task of making decisions relating to the provision of pharmaceutical services in England from 1 April 2005. We also intend it to be of assistance to all others who are affected by such decisions.
- 1.2 The law on the subject is complex and contained in Acts of Parliament, the Regulations and reported decisions of the courts – known as “case law”. This guidance is designed to provide staff at all levels with information on the relevant provisions and interpretations of those provisions. It is also intended to provide practical advice in relation to the operation of the statutory provisions.
- 1.3 Although there is a lot of detailed reference in notes to the legal provisions, the rules themselves are not, in the main, set out “verbatim” in this guidance. In order to make the guidance easier to read, the detailed rules have, in most cases, been paraphrased. However, all those responsible for administering or applying the law must bear in mind that it is the law that must be applied, not the interpretation that is set out below.
- 1.4 **This document’s legal status is that it is an analysis of the rules of law together with appropriate notes of guidance, designed to assist decision-takers in reaching decisions within the framework of the law. It is not an authoritative statement of the law.** In practice, there is no substitute for referring to the law itself, or seeking professional advice as to what the law says and how it applies in particular circumstances. It is essential to understand that decisions must be taken in accordance with the law, and not simply taken based on the analysis and advice contained in this guidance (or indeed any other commentary on the law).

### Previous guidance and transitional arrangements

- 1.5 This guidance originally replaced an earlier guidance note, contained in document HSG(92)13, for applications received from 1 April 2005 onwards. However, Primary Care Trusts should continue to retain that previous guidance until all applications received up to and including 31 March 2005 and any appeals which result from decisions on such applications have been finally dealt with. It also replaces the earlier versions of this Guidance published in April and August 2005.

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### The new regulations

- 1.6 The National Health Service (Pharmaceutical Services) Regulations 2005, SI 2005/641 replaced the National Health Service (Pharmaceutical Services) Regulations 1992, SI 1992/662. They set out the legal requirements in full in conjunction with SIs 2005/1015, 2005/1501 and 2006/3373 which have amended SI 2005/641. There have been other - mostly consequential - amendments to these regulations in other statutory instruments since April 2005. These include SI 2005/3315, 2006/552, 2006/913 and 2006/1501.

### Background to the control of entry reforms to the regulations

- 1.7 On 17 January 2003, the Office of Fair Trading (OFT) published its report "The control of entry regulations and retail pharmacy services in the UK." This was the first report under the White Paper "Opportunity for All in a World of Change". The OFT advises where laws and regulations bar competition, distort markets or hold back innovation and progress. The OFT recommended abolition of the current statutory controls on pharmacies which can dispense NHS prescriptions to improve competition, reduce prices for medicines sold over the counter and improve access to, and the quality of, pharmacy services.
- 1.8 On 17 July 2003, the Government published its response to the OFT report covering England. The Government also published its response to the Health Select Committee report on the same topic. In summary the Government decided not to implement the OFT recommendation in full but to move cautiously in that direction and introduce a balanced package of reform measures to open up the market and to modernise the current regulatory system.
- 1.9 On 29 August 2003, the Government consulted on proposals to reform and modernise the NHS (Pharmaceutical Services) Regulations 1992. It also set up an expert Advisory Group chaired by Anne Galbraith, chair of the Prescription Pricing Authority, to advise on how best to implement the proposed measures. The Advisory Group reported in January 2004. The Executive Summary was published in March 2004 and the full report was published in March 2005.
- 1.10 On 18 August 2004 and in a further written statement to the House of Commons on 7 September 2004, the Government announced details of its proposals for implementing these measures. The full text of the announcement on 7 September is at Annex A. In summary, these comprise:
- introduction of competition and choice to the regulatory test
  - four exemptions to that test
  - streamlining the application and decision-making process.

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### Linked developments

- 1.11 The reforms to the system are also linked to other changes affecting community pharmacy services:
- (a) the introduction of a new contractual framework
  - (b) reforms to NHS rural dispensing; and
  - (c) the introduction of “fitness to practise” requirements on chemist “providers” (i.e. sole proprietors/partners including in limited liability partnerships and bodies corporate (companies) and their directors and superintendent pharmacists.
- 1.12 Separate draft guidance has been prepared in relation to the new contractual framework and final guidance on “fitness to practise” procedures. A further version of the contractual framework guidance will be available in due course and published on the Department’s website.
- 1.13 Primary Care Trusts will wish to note at this stage that the procedures for dealing with applications to be admitted to the pharmaceutical list dovetail closely with the procedures to follow under “fitness to practise”.

## 2. Background to and overview of the Regulatory System

2.1 The NHS Act 1977 was amended in 1986. In essence, Sections 41-43 set out the main provisions governing:

- The powers the NHS has to govern arrangements for pharmaceutical services;
- The regulations to underpin these arrangements – including control of entry and
- various provisions about those authorised to provide services, including remuneration arrangements.

2.2 Regulations were introduced from April 1987 which were subsequently replaced by the NHS (Pharmaceutical Services) Regulations 1992. These in turn have now been superseded by the NHS (Pharmaceutical Services) Regulations 2005 (referred to as the “Regulations” from now on) and three main sets of amending regulations – SI 2005/1015, SI 2005/1501 and SI 2006/3373. Copies are available from HMSO bookshops or can be found on The Office of Public Sector Information website<sup>2</sup>. All these regulations are made under the NHS Act. The Regulations apply to “chemists” which includes not only pharmacies but also appliance contractors. From 1 March 2007, the NHS Act 2006 consolidates various NHS enactments including pharmaceutical provisions. This updates the language and does not change the law. The main provisions are set out in Part 7 of the Act. Where stated, the references to the primary legislation in this document will be updated in a later edition.

### Duties of Primary Care Trusts

2.3 Pharmaceutical services are those services which are defined in the NHS Act 1977, *Section 41*. They include:

- the provision of proper and sufficient drugs, medicines and appliances which are ordered by doctors;
- the provision of proper and sufficient drugs and medicines which are ordered by dentists; and
- the provision of such other services as may be prescribed in the regulations.

2.4 Originally, the underlying policy objective of the legislation was that there should be a distinction between those who *prescribe* drugs and

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<sup>2</sup> <http://www.opsi.gov.uk/stat.htm>

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those who *dispense* drugs. This principle has, however, always been subject to exceptions, most notably in rural areas – which are known in the Regulations as “controlled localities.” It is increasingly less distinct as more health professionals, including pharmacists, are able to qualify as prescribers in order to improve access to, and choice of, services for patients.

- 2.5 Nonetheless, arrangements for the provision of pharmaceutical services within the National Health Service remain the responsibility of Primary Care Trusts, acting also under the terms of Section 41 of the 1977 Act. This states that:

“It is the duty of every Primary Care Trust, in accordance with regulations, to arrange as respects their area for the provision to persons who are in that area of [pharmaceutical services]”.

- 2.6 More detailed regulations relating to the arrangements for securing the provision of these services are made under the authority of *Section 42* of the National Health Service Act 1977. This provides (as amended by Section 43 (2) of the Health and Social Care Act 2001):

“(1) Regulations shall provide for securing that arrangements made by a Primary Care Trust under Section 41 above will

(a) enable persons for whom drugs, medicines or appliances mentioned in that section are ordered as there mentioned to receive them from persons with whom such arrangements have been made; and

(b) ensure the provision of services prescribed under subsection 1(e) of that section by persons with whom such arrangements have been made”.

- 2.7 The section goes on to state that regulations may be made to deal with the process of creating a pharmaceutical list, removing persons from that list and setting the qualifications of those entitled to be entered on the list.

- 2.8 Section 42 also specifically provides that, save in prescribed cases, any application to provide pharmaceutical services shall:

“shall be granted only if the Primary Care Trust is satisfied, in accordance with the regulations, that it is necessary or desirable to grant it in order to secure in the neighbourhood in which the premises are located the adequate provision by persons included in the list of the services, or some of the services, specified in the application”.

- 2.9 This is what is commonly termed the “**control of entry**” test. More information is given below at paragraphs 2.12 et seq.

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- 2.10 The drugs, appliances and chemical reagents to be supplied within the NHS and payments for such are identified in the *Drug Tariff*. This is a monthly publication compiled under regulation 56 by the Prescription Pricing Division, a part of the NHS Business Services Authority. It performs this function on behalf of the Department of Health and National Assembly for Wales. The Drug Tariff is available from The Stationery Office.<sup>3</sup>
- 2.11 The regulations contemplate two modes of provision of pharmaceutical services:
- (a) by chemists and
  - (b) by doctors (see Chapter 6 of this guidance)

### The “control of entry” test (or “necessary or desirable” test)

- 2.12 As mentioned above, “control of entry” is shorthand to describe the system whereby Primary Care Trusts assess under regulation 12 only whether the grant of an application is necessary or desirable for a new pharmacy to dispense NHS prescriptions in order to secure adequate pharmaceutical services in a particular neighbourhood.
- 2.13 Once an application is received, the Primary Care Trust invites, as soon as practicable, a range of interested local parties to give views.
- 2.14 Views have to be made known to the Primary Care Trust within 45 days of the date the notification is sent out. This is extended from the previous 30-day period for consultation<sup>4</sup>.
- 2.15 Primary Care Trusts determine applications under regulation 24 and are generally free to determine them as they see fit. However, regulation 12(2) requires Primary Care Trusts to take account of certain particular factors. These include
- whether any of the services proposed are already provided within the neighbourhood;

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<sup>3</sup> The exhaustive list of appliances that may be supplied under the Regulations is set out in Part IX of the Drug Tariff. Any drug/medicine may be supplied unless it is included in the selected list set out in Schedule 1 to the NHS (General Medical Services Contracts) (Prescription of Drugs etc) Regulations 2004, which is reproduced in Part XVIII A of the Drug Tariff.

<sup>4</sup> The terms “notification”, “consultation”, “inviting views” are used interchangeably in this guidance. The Regulations (see, for example, regulation 23) refer to “notification of applications”.

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- whether there are any local pharmaceutical services provided including under a pilot scheme which are the same as any in the application;
  - whether the recipients of pharmaceutical services already have a reasonable choice regarding the services or the range of persons already on the pharmaceutical list in the neighbourhood (these are the new criteria of “competition and choice” referred to above)
  - other information the Primary Care Trust considers relevant;
  - any representations received from those invited to give views.
- 2.16 In taking account of these factors, Primary Care Trusts are to disregard any services in the neighbourhood which are provided by a distance selling chemist – in practical terms this means a chemist operating a wholly mail-order or internet based pharmacy.
- 2.17 Primary Care Trusts can make decisions based on the written documentation received or may decide to hold an oral hearing. If they decide to hold an oral hearing, they must give at least fourteen days’ notice to the applicant and to those who have sent in views. If a Primary Care Trust receives more than one application, it can consider them together in relation to each other. There are now time limits for deciding cases.
- 2.18 Once a decision has been made, the Primary Care Trust notifies the applicant and those who have sent in views giving a statement of the reasons for the decision and the rights of appeal.
- 2.19 Similar procedures apply where a Primary Care Trust determines
- whether or not an area is “controlled” (i.e. rural in character) under regulation 31;
  - applications to open a pharmacy in a controlled locality under regulation 33; and
  - applications to be given preliminary consent for inclusion in the Primary Care Trust list under regulation 40. Preliminary consent is outlined further in the next chapter.

### **Rural dispensing**

- 2.20 The “control of entry” system applies equally to urban and rural areas. However, where a Primary Care Trust has determined that an area is “controlled” (i.e. rural in character), provided certain conditions are met, doctors as well as pharmacies can dispense NHS medicines. GPs may, in general, dispense NHS prescriptions only with NHS approval

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and only to their own patients who live in such controlled localities and more than 1.6 km from a pharmacy. The main purpose is to ensure patients in rural areas who might have difficulty getting to their nearest pharmacy can access the medicines they need.

- 2.21 A GP who wishes to apply to dispense to patients need only show that to do so would not prejudice the proper provision of medical or pharmaceutical services locally (the “prejudice” test). There is no “control of entry” test.
- 2.22 A pharmacy wishing to open in a rural area must pass both the “prejudice” and “control of entry” tests.
- 2.23 Further information on rural dispensing including a series of reform measures introduced from 1 April 2005 is in Chapters 5 and 6 of this guidance. The same transitional arrangements (see paragraph 1.5) apply to rural applications as to non-rural applications.

### **Appeals against Primary Care Trust decisions on pharmacy applications**

- 2.24 Under the Regulations, Primary Care Trust decisions are appealable to the Secretary of State for Health who has delegated this responsibility to the National Health Service Litigation Authority (NHSLA). The appellate function is undertaken by the NHSLA’s Family Health Services Appeal Unit, based in Harrogate. More information about their work is available on the website at <http://www.fhsaa.nhs.uk/fhsaasha>
- 2.25 The main provisions regarding pharmacy appeals are set out in regulation 29. There are also appeals mechanisms in relation to decisions on determining “controlled” (rural) areas and on applications in respect of rural areas which are broadly similar. These are set out in regulation 38.
- 2.26 An appeal has to be made to the Appeal Unit within 30 days from the date on which the Primary Care Trust decision letter is sent. The appeal should contain a concise statement of the grounds of appeal. Appeals may be sent by letter or by fax.
- 2.27 An appeal can generally only be made by the applicant or by a pharmacist who has been notified of the decision by the Primary Care Trust. An appeal cannot be made, for example, by a local representative committee (e.g. LPC or LMC). The Primary Care Trust decides who is or who is not in its opinion affected by the decision. Where more than one appeal is received in relation to a decision, the Appeal Unit can determine them at the same time.

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- 2.28 Control of entry appeals are determined by the Pharmacy Committee of the Appeal Unit. Some other types of appeal are determined by a senior officer of the Appeal Unit.
- 2.29 The Appeal Unit's deliberations are not limited to simply reviewing the Primary Care Trust decision. It will reconsider the application *de novo* (i.e. from the beginning).
- 2.30 The majority of cases are decided based on correspondence with the Appeal Unit and other documentation related to the original decision. Occasionally, e.g. if there are material differences in the facts presented by the parties, the Appeal Unit will convene a panel to hold an oral hearing. The Appeal Unit gives interested parties including the Primary Care Trust at least 14 days' notice of the hearing. Interested parties can attend with any representatives they wish to accompany them.
- 2.31 The Appeal Unit's target is to ensure all appeals are processed within 26 weeks. For those appeals determined without an oral hearing, the target is to process appeals within 15 weeks.
- 2.32 Whilst there are standard complaints procedures as apply to any NHS body, there are no further powers for review of an appeal decision once it has been issued. The Appeal Unit's decision can only be set aside by the High Court.

### 3. Entry onto a pharmaceutical list: general provisions

#### Introduction

- 3.1 This chapter deals with procedures relating to all areas in England **other than** “controlled” or rural localities (for which see Chapters 5 and 6). See Chapter 4 for further information on applications for one of the new exemptions from the test.

#### Applications

- 3.2 In order to be able to provide pharmaceutical services under the NHS, the Regulations provide that persons<sup>5</sup> (other than doctors and dentists) must be included in a pharmaceutical list. Primary Care Trusts are required to prepare lists of such persons, whose applications to be included in a pharmaceutical list have been granted. The pharmaceutical list must state the address of the premises from which the service is provided, details of the days on which and times at which the premises are required to be open to provide such NHS pharmaceutical services and indicate which directed services the chemist has undertaken to provide. The pharmaceutical list should be available for public inspection (*regulation 4*).

#### Setting a date for receipt of applications

- 3.3 Primary Care Trusts can fix a date for the receipt of applications. Setting a date is not obligatory. Where a Primary Care Trust decides it wishes to do so it should determine the date and make this public (e.g. by publishing the designated date on their website). Primary Care Trusts may find it more convenient to designate a normal working day, and a specific day during the month (e.g. the first Tuesday, the third Thursday) rather than to designate a precise date - “the 3<sup>rd</sup>”, “the 19<sup>th</sup>” etc. Primary Care Trusts may also wish to avoid specifying Mondays or Fridays to avoid a clash with public holidays. Primary Care Trusts are free to change this designated date but should give adequate notice via their website or however the date has been publicised. Three months’ notice should usually be sufficient. For more information about this, see paragraph 3.133 below.

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<sup>5</sup> Whilst this is the term used in the Regulations, the provisions of Part IV of the Medicines Act 1968 in fact restrict the ownership of pharmacies (whether providing NHS services or not) to registered pharmacists, or partnerships of pharmacists, or bodies corporate which employ registered pharmacists.

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### Applications to provide pharmaceutical services

- 3.4 To be included in a pharmaceutical list, the person must apply to the relevant Primary Care Trust. The procedures to be followed and the legal tests which must be satisfied in determining such applications together with rights of appeal are set out in the regulations and outlined below (*regulation 5*).
- 3.5 Once a person has been included in the pharmaceutical list, he is required by the Regulations to submit a further application if he wishes to:
- (a) open *additional premises* in the area of the Primary Care Trust from which to supply the same or different pharmaceutical services (*regulation 5(1)(b)(i)*); or
  - (b) *change the premises* from which the pharmaceutical services are supplied to other premises within the area (*regulation 5(1)(b)(ii)*); or
  - (c) provide from existing premises, *services other than those already listed* in relation to the applicant (*regulation 5(1)(b)(iii)*).

The exact procedure to be followed and tests to be satisfied in determining these applications depends on the precise details of the application that is being made.

### Form of application (*regulation 5(1)*)

- 3.6 The regulations require applicants to supply all the minimum information listed in Part I of Schedule 4 of the Regulations, and if the applicant is not already included in the Primary Care Trust's pharmaceutical list, he must provide the information and undertakings specified in Part 3 of Schedule 4. Primary Care Trusts may find it helpful to list these information requirements on their websites. It is also open to Primary Care Trusts to make available an information pack about the Primary Care Trust area and the needs required as identified in their pharmaceutical needs assessment. A model application form is available on the Department's website and is at Annex D. Primary Care Trusts may find this useful and they can adapt it to suit their needs and make available on their website. Where they do so, Primary Care Trusts may wish to consider pre-populating parts of the application form where possible to help applicants. **Primary Care Trusts should note that applicants are not compelled to use a particular application form as long as the minimum information required under the regulations is provided.** Primary Care Trusts may wish to log the day and time applications are received and keep papers in separate files to enable clear audit trails of how applications progress.

## Preliminary consent applications (*regulation 40*)

### Period of consent

- Preliminary consent can, from 1 April 2005, only be granted for six months
- There is no extension to this period.

- 3.7 Where a person is not yet in a position actually to provide pharmaceutical services or to alter the services currently provided, but is planning to do so, the regulations provide for the possibility of that person making a “preliminary consent” application.
- 3.8 This type of application may be appropriate, for example, for those contemplating setting up business in a particular area, but who cannot yet point to the actual premises from which they intend to provide those pharmaceutical services. An example of this might be where a new housing estate or shopping development is still being developed, and the specific premises have not yet been constructed or leased/bought.
- 3.9 The decision as to whether or not to apply for preliminary consent is one for the applicant alone. It is **not** a requirement of the regulations that an application for preliminary consent must precede an ordinary application.
- 3.10 Any preliminary consent application to provide pharmaceutical services should be treated as if it were a full application to be included in a pharmaceutical list (*regulation 40(3)*). Decisions are appealable.
- 3.11 If the Primary Care Trust is satisfied that the application satisfies the regulatory test, preliminary consent will be granted. An application may be granted in respect of only some of the services specified in it (for example if the supply of appliances has been proposed, but there is already adequate provision from other chemists).
- 3.12 Where a Primary Care Trust grants preliminary consent to an applicant, the preliminary consent is effective for a maximum period of six months from the date of its final grant. No extension to this period can be granted (*regulation 40(4)*).
- 3.13 Once granted and during the period of grant (or any appeal dealt with) the Primary Care Trust cannot go back on, or in any way revise its decision to grant preliminary consent, other than for fitness to practise reasons. The Primary Care Trust will need to bear this in mind if it receives, during this period, another application from another contractor relating to the same neighbourhood.

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### **Making a full application once preliminary consent has been granted (*regulation 41*)**

- 3.14 The use of preliminary consent is designed to help speed up the application process. Where the applicant has been granted preliminary consent, the applicant will have to complete the full application when he is able to specify the premises from which it is proposed to provide services. The applicant must do so before the expiry of the grant of preliminary consent. Alternatively, he may choose to submit a further application for preliminary consent (e.g. because the details of the premises are still not known) at which point the process begins again. When submitting the full application, he can amend the services to be provided only to the extent that it does not affect the basis on which his preliminary consent application was granted.
- 3.15 The receipt of a full application, therefore, should not be the occasion to re-examine decisions made at the preliminary consent stage nor does it introduce further opportunities to appeal against those decisions. The full application when received should be granted without following the normal procedure for dealing with full applications only if the following conditions are met:
- (a) the date of the full application for inclusion in the pharmaceutical list falls within a maximum period of six months from the date of the final grant of the preliminary consent (*regulation 41(1)(a)*). (Once full consent is granted, applicants then have six months in which to open, unless granted further extension of up to three months by the Primary Care Trust (see below));
  - (b) the pharmaceutical services the applicant proposes to provide are the same as specified in the application for preliminary consent (*regulation 41(1)(b)*);
  - (c) the premises specified in the full application are in the same location for which the preliminary consent was granted (*regulation 41(1)(c)*).
- 3.16 Where the location of the premises is different from that for which the preliminary consent was granted, the full application should be treated as if the application were one under regulation 5(1)(b)(ii) to change the premises.
- 3.17 The Primary Care Trust will need to be satisfied that the location of the premises has been defined sufficiently precisely in the application to enable the Primary Care Trust to determine whether the application meets the conditions for automatic grant of full consent. If it has not, further information should be sought from the applicant before continuing to consider the application (see section G in Annex D).

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### Form of application

- 3.18 Applicants wishing to apply for preliminary consent should provide the same information as required in Part I of Schedule 4 of the Regulations (a model application form is at Annex D) and if the applicant is not already on the pharmaceutical list of the Primary Care Trust, the notification and declarations specified in Part 3 of Schedule 4. Applications should be completed as fully as possible. See paragraph 3.6 above for more information (*regulation 40(2)(c)*).

### Inviting applications

- 3.19 This is not a regulatory matter but it is open to Primary Care Trusts to adopt a proactive role to generate business interest in meeting the needs for pharmaceutical services in a neighbourhood by inviting applications. Primary Care Trusts will have consulted Local Pharmaceutical Committees on how best to meet such needs as part of their pharmaceutical needs assessment. This assessment can be used to identify gaps or deficiencies in service provision for which the Primary Care Trust wishes to invite expressions of interest from providers.
- 3.20 Primary Care Trusts may therefore wish to publicise the need for such services as appropriate, e.g. by placing advertisements in relevant trade journals inviting applications. Primary Care Trusts who have set a date for the receipt of applications should ensure sufficient time is allowed between placing the advertisement and the closing date. Primary Care Trusts should ensure that any advertisement is phrased in such a way that it does not imply that the outcome of any applications that are subsequently received in response has been pre-determined.
- 3.21 An example of such an advertisement is at Annex E.

### Determining the application (*regulation 24*)

#### Jurisdiction

- 3.22 Having received a valid form of application, the relevant Primary Care Trust must first be satisfied that it is one over which it has jurisdiction to reach a determination. That is to say, the Primary Care Trust must check that it has the power to make a determination in relation to the application which has been submitted. The first check should be that the proposed premises are within the boundaries of the Primary Care Trust.

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- 3.23 The Primary Care Trust should also check that the application is made by a person entitled to make the application. Primary Care Trusts should reject at once any applications from individuals who are not pharmacists; or bodies corporate that do not comply with the requirements of the Medicines Act 1968, section 71.<sup>6</sup> Applicants need to bear in mind that from 19 January 2007 PCTs need to ensure they have sight of relevant documents supporting applications under an amendment to regulation 24 (2) (a). Therefore, a PCT should not determine an application (nor include a successful applicant on its pharmaceutical list) unless it has checked the fitness to practise information supplied with that application. This is particularly relevant for a superintendent pharmacist since it had been the case previously that a superintendent pharmacist did not have to have been appointed at the time of the application, though he had to be appointed before the final inclusion of the body corporate on the pharmaceutical list. As superintendent pharmacists are required to make fitness to practise declarations (see separate guidance) and Primary Care Trusts then need to carry out checks, the PCT cannot decide an application nor the body corporate be included on the list if successful until these checks are completed.
- 3.24 Similarly, applications from persons or bodies corporate that have been professionally disqualified from providing pharmaceutical services should also be rejected.

<p>3.25 Under regulation 11 (2) a Primary Care Trust <b>must refuse</b> any application from a pharmacist which does not offer to provide all of the essential services within the new contractual framework for community pharmacy. This rule does not apply to applications from appliance contractors.</p>
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- 3.26 This is included to ensure the application meets the minimum essential levels of NHS service required of all pharmacy applicants under the new contractual framework including ensuring safe pharmacy systems ("clinical governance") and continued professional development for staff.

### General rules

- 3.27 Two further general rules apply to the determination of all classes of application:
- **Partial grants** – the Primary Care Trust may grant the application either in respect of some or all of the services specified in the application. This does not apply to the provision of essential services under the pharmacy contractual framework which all pharmacies had to agree to provide from 1 April 2005. However, it

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<sup>6</sup> These are (i) that the body corporate must appoint a superintendent pharmacist; and (ii) that the business must be carried on under the personal control of a pharmacist. .

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can apply to the provision of dispensing services by an appliance contractor.

- **Language qualifications** – if the applicant is registered under the provision of the Pharmacy Act 1954 section 4A<sup>7</sup>, then the Primary Care Trust must additionally be satisfied that the applicant's knowledge of English is of the level necessary, in the interests of him/herself and his/her customers, for the provision of pharmaceutical services. This applies to all applications<sup>8</sup> (*regulation 11(1)*).

### Types of decision

3.28 The type of decision that the Primary Care Trust will be required to make will depend on the type of application that has been submitted. There are five types of application:

- minor relocations
  - 500m or more
  - less than 500m
  - cross-boundary less than 500 m or 500m or more
- change of ownership
- change to services
- applications for preliminary consent (see above)
- all other applications

#### Minor relocations (*regulation 6*)

Primary Care Trusts will wish to note that

- the “necessary or desirable” test does not apply
- the Court of Appeal has established certain criteria for minor relocations. In essence a minor relocation must be within the same neighbourhood, involve a short distance and must have no physical barriers between the premises
- there is to be no interruption in service provision except as the Primary Care Trust for good cause allows
- the applicant must trade from the new premises for a minimum 12 months before any further minor relocation may be sought
- from April 2005 there is a new facility to approve all minor relocations under 500 metres without the need for notification. Decisions must be made within 30 days. These decisions are appealable.

<sup>7</sup> inserted by SI 1987 No 2202 Art 2(4); it provides for those qualified by a European diploma to be registered.

<sup>8</sup> This test does not actually apply to minor relocation applications, applications for changes of ownership where the applicant is already on the list or to temporary chemists applying on behalf of suspended chemists.

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- Primary Care Trusts have the discretion to override the granting without consultation, where there is good cause, if they believe there are reasons why a consultation should take place .
- there is a new permission for minor relocations to take place across Primary Care Trust boundaries as long as the criteria are met. (*regulation 7*)
- for applications for minor relocations of 500 metres or more, the Primary Care Trust is obliged to give notice of applications and allow 45 days for representations before determining the application (see 3.31 below).
- minor relocations for applicants who have been granted an application under the exemption for approved retail areas (*regulation 6(1A) and 7(1A) – as amended by SI 1501*) are not allowed outside the approved retail area (whether over or under 500 metres in distance). However, minor relocations within the same approved retail area are permitted.

### *Minor relocations – 500 metres or more*

3.29 Minor relocation applications are made where the applicant intends to change the premises from which he is providing pharmaceutical services at the time of the application (or where for reasons beyond his control, such as fire, he is not currently providing services but is entered on the pharmaceutical list in respect of those premises). The change must be **within the same neighbourhood** from which pharmaceutical services are to be provided. Primary Care Trusts should not treat an application as a minor relocation application, unless the applicant has completed the application form on this basis (*regulation 6*).

3.30 The “necessary or desirable” test **does not** apply to minor relocations. However, for an application to fall into this category, the applicant must show under regulation 6 that:

- i. the services to be provided from the new premises are the same as those provided at the existing premises;
- ii. the proposed move is “within the neighbourhood”;
- iii. the change of premises is a “minor relocation”; and
- iv. there are no barriers which would change the accessibility of the new premises, i.e. a railway line, a main road without obvious crossing points.
- v. The provision of pharmaceutical services will not be interrupted except for such a period as the Primary Care Trust may for “good cause” allow.

(*regulation 6(1)(a)*)

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- 3.31 Primary Care Trusts should, under regulation 23 etc, notify all interested parties of the proposal as they would for a conventional application and allow 45 days for representations (*regulation 6(2)*). The same applies where the minor relocation is across a Primary Care Trust's border (*regulation 7(2)*). Provided the conditions for a minor relocation are met and, in addition, the Primary Care Trust is satisfied that the provision of pharmaceutical services will not be interrupted, except for such period as the Primary Care Trust may for "good cause" allow, then the Primary Care Trust must grant the application (*regulation 6(1)(b)*). What constitutes "good cause" is ultimately for the Primary Care Trust to assess on the facts of the case. For example, there may be a temporary delay in handing over the premises to the new leaseholder. Alternatively, the applicant may request a short interruption to transfer stock and supplies from the old to the new premises and test computer systems etc before opening.
- 3.32 In accordance with case law (see Annex C for more information), in assessing whether an application is a minor relocation or not, Primary Care Trusts may wish to consider a sequence of key questions. If the answer at any stage to these is "no" then the application for a minor relocation will fail. If it does, the applicant should be asked if he wishes to resubmit the application as a major relocation. If he does, it must be dealt with in the same way and following the same procedures as a new application under regulation 12(2). Interested parties can then be notified if that is the case, so that they can respond if they wish. If the applicant disagrees with the Primary Care Trust's view, he can appeal within 30 days.
- i) **Are the proposed premises in the same neighbourhood as the existing premises or not?**
  - ii) **Can the proposed distance be considered "minor" in relation to the neighbourhood in question?** For example, in relatively sparsely populated areas or where retail facilities may be strung out for a considerable distance, a relocation may still be "minor" which would not be the case in more densely populated areas. In the late 1990s, the FHSAA (SHA), the predecessor to the Appeal Unit, found that it tended not to grant appeals for a minor relocation where the distance involved was more than 800 metres. However, that is only an indication and should not be taken as a "norm". In all cases, Primary Care Trusts should undertake site visits to determine the facts.
  - iii) **Will access by patients or potential patients to the pharmacy be the same at the proposed site as it is at the current site?** In other words, Primary Care Trusts must consider whether there are any physical barriers or other geographical, transport or communication factors which mean that access for patients or potential patients to the proposed site is going to be affected by the move.

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- 3.33 Once granted, regulation 5(5) requires the applicant to trade for a minimum period of 12 months from the new premises before any further application for a minor relocation can be made unless the Primary Care Trust for good cause allows the applicant do so before the end of that period – for example, on grounds of health and safety. In addition, in some cases, a successful “minor relocation” applicant may find that, subsequent to the grant of the application, he is in fact unable to open in the new premises which were proposed in the application. For example, the freeholder of the premises has changed their mind about agreeing to lease the premises to a pharmacy. The applicant may therefore seek to apply again, once more using the “minor relocation” procedure.
- 3.34 If the proposed location of the revised premises is still **within the neighbourhood** of the original premises and is at such a distance from the original premises as still to fall within the definition of “minor relocation”, then the subsequent application may be dealt with in the same way as a minor relocation application.
- 3.35 In some cases, however, an applicant – currently dispensing from premises A – who has been unable to open in the premises – premises B – which were considered in the first application, puts in a second application to open in alternative premises – premises C. In such cases, the premises specified in the second application – premises C – must still be within such distance as would qualify as a “minor relocation” from *premises A*, from which the application is currently providing pharmaceutical services. If the second application relating to premises C was within the scope of “minor relocation” from premises B, but not premises A, the application could **not** be dealt with as a minor relocation. The only way such an application could be valid as a minor relocation application would be if the applicant actually opened for business at premises B and traded for the minimum period of 12 months, before submitting the application relating to premises C.
- 3.36 If the relevant conditions are not met, the application can be treated as a major relocation and the criteria set out under regulation 12(2) applied - see paragraph 3.32 above.

### *Minor relocations - less than 500 metres (regulation 6(3))*

- 3.37 The initial procedure is similar to that set out in paragraphs 3.29 – 3.36 above applies to applications for minor relocations less than 500 metres by the most practicable route by foot. Primary Care Trusts should note in particular that even though the distance is less, the change must still be **within the same neighbourhood** from which pharmaceutical services are to be provided.

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- 3.38 However, in this instance the Primary Care Trust shall approve the application **without giving any other party notice, and without hearing oral representations** provided of course all the other conditions are met, and shall do so within 30 days (*regulation 6(3)*). For example, the applicant agrees to provide all essential services and the Primary Care Trust agrees there is no reason to challenge the application on the grounds that it is a move to a new neighbourhood. Primary Care Trusts should still undertake site visits to ensure the maximum distance of less than 500 metres has not been exceeded. The distance should be calculated by reference to the most practicable route. If granted, the Primary Care Trust will amend the entry in its list from the date the applicant notifies the Primary Care Trust it has moved and is trading from those new premises (normally at least 30 days after the Primary Care Trust has approved the relocation). The Primary Care Trust should delete the entry in respect of the previous trading address. As long as the Primary Care Trust is satisfied that the application meets the requirements for this new regulatory freedom, there is no need to assess or consult in the usual way. A chemist must comply with the requirement to provide pharmaceutical services from that new address for a minimum 12 months before submitting a further application for a minor relocation unless good cause intervenes.
- 3.39 Primary Care Trusts can still challenge an application for a minor relocation of less than 500 metres where it believes there is good cause. "Good cause" could be where the Primary Care Trust does not agree the move would be within the same neighbourhood. Alternatively, there may be inadequate communication links to the proposed new site which would change the availability of pharmaceutical services in the neighbourhood. For example, the pharmacy wishes to move across a busy road and there is no obvious means of pedestrian access to the new site. Again, Primary Care Trusts should reach their decision on their assessment of the facts of the case before them. A decision not to treat an application as one for less than 500 metres can be appealed only by the applicant. (*regulation 6(3) to (5)*).
- 3.40 Primary Care Trusts should note that where an applicant has successfully applied for an exemption to the "necessary or desirable" test in relation to an approved retail area, he cannot since 5 July 2005 subsequently apply for a minor relocation outside that retail area – even if the distance involved is under 500 metres (*regulation 6(1A) – SI 2005/1501*). A contractor can only minor relocate within the approved retail area.

### *Cross-boundary minor relocations (regulation 7)*

- 3.41 The 1992 Regulations did not allow for minor relocations across a Primary Care Trust boundary (e.g. a pharmacy could not cross the street if this meant it would transfer from the area of one Primary Care Trust to the area of another Primary Care Trust). However, the system

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has changed so that this is become possible from April 2005 under regulation 7. The conditions are the same as for a minor relocation within a Primary Care Trust's boundaries. In addition, the applicant must agree to the original Primary Care Trust removing his name from its list (*regulation 7(1)(b)*). If these conditions are not met, the same procedure as set out in paragraph 3.32 can be followed. If the applicant agrees it should be treated as a major relocation the criteria set out under regulation 12(2) should be applied. If the applicant does not agree, again, such a decision is appealable.

- 3.42 The criteria set out in paragraphs 3.29 – 3.40 above for relocations less than 500 metres also apply here. Pharmacies wishing to be considered for a cross-boundary minor relocation should apply to the relevant Primary Care Trust covering the address of the new premises. The receiving Primary Care Trust will wish to assure itself that the contractor is providing the same services (*regulation 5(1)(c)*) and therefore needs formally to approve the application. The receiving Primary Care Trust should also ensure that any fitness to practise conditions in force at the time of the change carry forward to the new premises (*regulation 21(10)*). It shall also notify the Primary Care Trust in which the premises currently are located of its decision and the date from which services at the new address are to commence and those others listed in *regulation 27(1)(a)*. The current listing for the contractor should then be deleted on the day services at the new address begin.
- 3.43 Primary Care Trusts should note that where an applicant has successfully applied for an exemption to the “necessary or desirable” test in relation to an approved retail area and that approved retail area straddles Primary Care Trust boundaries, he cannot subsequently apply for a minor relocation outside that approved retail area (*regulation 7(1A) – SI 2005/1501*).
- 3.44 For an example of the process of handling relocation applications, see Annex B, Illustrative flowchart 2.

### *Notification*

- 3.45 Once an application has been determined, there are still duties on the Primary Care Trust to notify the outcome of the decision (*regulation 27(1)(a)*).

### *Appeal*

- 3.46 The decisions of Primary Care Trusts are appealable (*regulation 6(5) and 7(6)*). This includes minor relocations under 500m (as amended by SI 2006/3373 from 19 January 2007). More information on these is given at paragraphs 3.162 onwards.

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### Change of ownership (*regulation 8*)

- 3.47 The second category of application to be considered occurs where a person applies to provide services at premises from which services are, at the time of the application, currently provided by another person who is already on the list. Such applications must be made where the person currently providing the service and who is on the list wishes to sell or otherwise transfer ownership of the pharmacy to another. Primary Care Trusts will wish to note that in situations where Company A has taken over Company B by buying its shares and Company B continues to trade this is not a change of ownership. All that has happened is that the issued share capital is in new hands. However, if the directors of Company B have also changed, then this information needs to be sent to the relevant Primary Care Trust(s) together with information about the directors' and superintendent pharmacist's fitness to practise. The key test is whether the legal identity of the contractor has changed. More information is given on this in Annex A at page 3.
- 3.48 In any change of ownership application, if the applicant has qualified to have his/her name registered under the Pharmacy Act 1954, section 4A (qualification by European Diploma), the Primary Care Trust must also be satisfied that the applicant has the necessary level of knowledge of English (unless the applicant is already on the pharmaceutical list) (*regulation 11(2)*).
- 3.49 The Primary Care Trust must also be satisfied that the same services will be provided by the new applicant as were provided by the person formerly on the pharmaceutical list (*regulation 8(1)(a)*). If the Primary Care Trust considers there has been a change of circumstances and either wants to discontinue certain services, or commission new ones, these should be the subject of separate negotiations once the change of ownership has been agreed (*regulation 8(1)(b)*).
- 3.50 In addition, the applicant must show that the provision of pharmaceutical services will not be interrupted, except for such period as the Primary Care Trust may for "good cause" allow (*regulation 8(1)(b)*).

### Notification

- 3.51 Once an application has been determined, there are still duties on the Primary Care Trust to notify the outcome of the decision (*regulation 27(1)(a)*). Notices of determination for applications for change of ownership must be sent within 30 days of the date of receipt of the application.

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### *Appeal*

- 3.52 The decisions of the Primary Care Trust are appealable (*regulation 29(2)*).

### **Minor relocations and changes of ownership**

- 3.53 As a practical matter, it is often the case that a minor relocation application is associated with a change of ownership application. They are, however, two distinct matters and should be the matter of separate applications and separate decisions. The minor relocation application can only be granted to the person currently providing services from existing premises. A change of ownership application can only be granted to a person in relation to premises from which services are being provided. It follows, therefore, that it is not possible for a pharmacist who has obtained permission to minor relocate, to transfer ownership to another person before he has actually completed the relocation and opened for business at the new site. If he wishes to transfer ownership before moving, the change of ownership must take effect first, and then the new owner can apply for permission to effect a minor relocation.

### **Change to services**

- 3.54 An application from a new owner to provide different pharmaceutical services to those currently provided is to be treated as if it were an application for inclusion in the pharmaceutical list for the provision of new services.

### **All other applications**

- 3.55 All other applications (with the exception of exemptions to the control of entry test and discussed in Chapter 4), falling outside the scope of the special cases above, are to be granted by the Primary Care Trust only if the control of entry test is satisfied.
- 3.56 This test, as set out in the NHS Act 1977 (and repeated in regulation 12) provides that the application:

“shall be granted only if the Primary Care Trust is satisfied, in accordance with the regulations, 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 a pharmaceutical list of the services, or some of the services, specified in the application.”

(*regulation 12(1)*)

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- 3.57 This provision raises three distinct issues, each of which must be determined properly. Experience of cases heard by the courts in the past suggests that keeping each of these matters separate in a disciplined fashion can help prevent pitfalls and legal challenge. The three issues are
- (a) Neighbourhood
  - (b) Adequacy
  - (c) Necessary or desirable

### Neighbourhood

- 3.58 **Neither the NHS Act nor the Regulations define the term “neighbourhood”.** This is essentially a matter of fact and degree for the Primary Care Trust to determine based on the evidence. The Primary Care Trust’s pharmaceutical services needs assessment should assist here since it will provide evidence of the need for services in a given area. However, Primary Care Trusts may have completed their pharmaceutical needs assessment based on a number of localities which may or may not be co-terminous with the “neighbourhood” to be served by the pharmacy applicant. Whilst the model application form invites applicants to set out their understanding of the neighbourhood in question, it is a matter for the Primary Care Trust to determine based on what they find. Site visits will therefore help Primary Care Trusts come to a decision.

Over the years, the courts have established a number of principles in relation to what constitutes “neighbourhood”. [*Examples from case law are included at Annex C*]

- 3.59 From these cases, certain aspects which will help Primary Care Trusts determine the appropriate “neighbourhood” include
- (a) it can be defined by physical, geographical or social factors
  - (b) what is a neighbourhood in a rural area or small town is going to be different from a neighbourhood in a suburban or urban area
  - (c) a neighbourhood does not have to comprise a resident population – this is important in relation to considering applications for pharmacies in shopping developments which do not meet the criteria for an automatic exemption.
- 3.60 In summary, the Primary Care Trust and only the Primary Care Trust decides what constitutes a “neighbourhood” for the purposes of the application. This will always be a decision based on the Primary Care Trust’s assessment of the facts of the case. Such decisions can of course be appealed. The Primary Care Trust is entitled to take into account representations about the neighbourhood from the applicant, from those it has invited to make comments (including those received

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by a neighbouring Primary Care Trust where the application is close to that Primary Care Trust's area) but is not bound to accept them.

### Adequacy

- 3.61 Having determined the neighbourhood, a Primary Care Trust moves on to consider the question of the adequacy of service provision within that neighbourhood.
- 3.62 Securing adequate provision is **the key** requirement for Primary Care Trusts. If a pharmaceutical needs assessment has determined that access to pharmacy services for a given neighbourhood is wholly adequate or wholly inadequate then an application is likely to fail or succeed accordingly.
- 3.63 It must be stressed however that the test is **not** one of assessing whether current provision is "wholly adequate". The Court of Appeal did find this to be a useful starting point since if provision were "wholly adequate" that would be the end of an application. However, Lord Justice Laws in *R v FHS Appeal Authority ex parte Lowe* in 2001 set out certain tenets which Primary Care Trusts will find helpful in constructing their assessment. They link closely to the concept of "necessary or desirable" discussed below.
- (a) The grant of an application is only possible for the purpose of securing adequate provision of services in a neighbourhood;
  - (b) The concept of adequacy is a question of degree. There is a spectrum or "sliding scale" of adequacy where conclusions are reached along a line between the extremes of adequacy and inadequacy. Logically therefore it is reasonable to find that such conclusions can vary over time. What may have been adequate 24 months ago may no longer be adequate now - or vice versa.
  - (c) Therefore, whilst "adequacy" is the first question to be addressed, the true question is to determine the point, on the facts, at which an application lies on the sliding scale or spectrum of adequacy.
  - (d) It may fall at the wholly adequate or inadequate point, be marginal or somewhere between the two. The Primary Care Trust may therefore conclude it is desirable to grant the application in order to secure adequate provision.
  - (e) However, whilst there may be some slippage between what is marginal and the two extremes, the judgment to be made is an "emphatically pragmatic" one.

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- 3.64 In summary, therefore, the concept of “adequacy” of service provision in a neighbourhood is for the Primary Care Trust to determine on the facts of the case. Such determinations may vary over time. A Primary Care Trust can start by asking whether provision is wholly adequate or inadequate. It can then proceed to consider whether it is desirable to grant an application to secure adequate provision.

### **The new criteria of ‘choice’ promoting competition**

#### **Background to the changes**

- 3.65 Historically, the general character of the precepts of the overall test had, under the 1992 Regulations, led to a situation where, unless exceptions to the test were specified, the tendency was for a Primary Care Trust to refuse an application (or for an affected contractor to appeal successfully against a Primary Care Trust decision to grant an application) rather than for an application to be approved. Thus, it could be more difficult for a new applicant to “pass” the test if, for example existing affected contractors opposed the application, or if the Primary Care Trust considered the advantages and disadvantages of granting an application were evenly balanced.
- 3.66 Whilst there are no quotas or “target average” number of pharmacies, the overall number of pharmacies between 1994/95 and 2004/05 providing NHS services in England barely changed. It decreased slightly from 9,771 to 9,742 whilst the number of items dispensed rose by around 40%. In the same period, the number of full applications in non-controlled localities that Health Authorities and Primary Care Trusts in England and Wales considered varied between 257 and 535 per year. The percentage of those granted varied between 19% and 29% per year. This percentage of approvals may in part be attributable to a number of applications for the same site where the Primary Care Trust grants just one. It may involve an existing contractor who is moving some distance within the Primary Care Trust’s area.
- 3.67 The changes introduced from in April 2005, supported by this updated guidance for Primary Care Trusts, aimed to achieve a more even balance in deciding whether to approve or to refuse applications in future. In the first year of the reformed regime, there were 876 full applications including exemptions received by Primary Care Trusts of which 339 or 39% were approved<sup>9</sup>. It nonetheless remains the case that the overriding objective is to determine an application in relation to the overall effect it will have on access to services for patients and not the overall effect it will have on other contractors.

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<sup>9</sup> The Department published a review of progress on the operation of the reformed regime on 11 January 2007. This is available on the Department’s website.

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- 3.68 In assessing whether or not there is adequate provision of pharmaceutical services in a neighbourhood, explicit criteria of choice were introduced to the assessment. These criteria were not necessarily all new and Primary Care Trusts may already have taken some into account. However, from April 2005, clearer emphasis has now been placed within the regulations on certain key factors associated with promoting more choice for patients in order to promote more competition.
- 3.69 These factors are:
- the level of access
  - choice and diversity in the neighbourhood
  - innovation in service delivery
  - services to specific populations/to meet disease needs
  - the overall longer-term impact.
- 3.70 These criteria were introduced by virtue of Section 42(3)(k) of the NHS Act 1977. This allows for regulations to include provision as to criteria which are to be applied when making decisions under the Regulations. The criteria are defined in regulation 12(2)(b) (as amended by SI 2005/1015). This states that Primary Care Trusts shall have regard in particular to
- “whether the recipients of pharmaceutical services already have a **reasonable choice** with regard to
- i. the pharmaceutical services or directed services provided in the neighbourhood in which the premises named in the application are located, by persons included in the pharmaceutical list; and
  - ii. the persons included in a pharmaceutical list from whom such recipients may obtain pharmaceutical services or directed services in the neighbourhood in which the premises named in the application are located.”
- 3.71 Primary Care Trusts should note that these new provisions include the term “reasonable choice” but do not include the term “competition” (for legislative drafting reasons) and that these provisions are still within the overall test of adequacy. Nonetheless, they enable Primary Care Trusts to take into account additional factors when determining adequacy. This is to help meet the commitment, as set out in the NHS Improvement Plan and in *Building on the Best: Choice, Responsiveness and Equity in the NHS* to expand patient choice within primary care. So just as Primary Care Trusts have previously had particular regard to the current availability of services in the neighbourhood, so they now also have particular regard to the choice of services and of providers in the neighbourhood.

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- 3.72 The overall aim is fully in line with the overall objective of the regulations. That is to ensure adequate access to pharmaceutical services for patients. These new criteria, by promoting more competition, aim to improve the choice of where patients may obtain services. In turn, this will mean more choice in where patients can get advice for self-care, and access the range of services which pharmacies will increasingly provide through the new contractual framework.
- 3.73 These new criteria also assist Primary Care Trusts in assessing the characteristics of current service provision and the benefits that may accrue from granting an application. Primary Care Trusts should therefore have adopted these factors as part of their overall assessment of an application.

### **Applying the new criteria**

#### **Checklist of factors to be considered under “choice” promoting more competition**

- √ What is the current level of access within the neighbourhood to the NHS pharmaceutical services which the applicant proposes to provide?
- √ What is the extent to which services in the neighbourhood already offer a choice to patients which may be improved by the provision of additional facilities?
- √ What is the extent to which there is a reasonable choice of providers in the neighbourhood which may be improved by additional providers?
- √ What is the extent to which current service provision in the neighbourhood is adequately responding to the changing needs of the community it serves or to local Primary Care Trust delivery plans designed to meet primary care policy objectives?
- √ What is the extent to which the applicant proposes to improve service provision in the neighbourhood through innovation or new directions in delivery?
- √ What is the extent to which the application will meet the need for specialist or other services which improve the provision of, or access to, services such as for specific populations or vulnerable groups?
- √ What is the PCT's assessment of the overall impact on the neighbourhood in the longer-term?

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### **The current level of access within the neighbourhood to the NHS pharmaceutical services which the applicant proposes to provide**

- 3.75 Primary Care Trusts should consider the extent to which access is already available to the services which the applicant will provide. This information may already be available from the pharmaceutical needs assessment and can include all categories of service delivery (essential and directed services which covers advanced and local enhanced services). It should also take into account the times at which and days of the week on which all such services are normally available in relation to the expected and actual demand for such services. It should also consider whether there are any exceptional local factors affecting access such as seasonal factors, or planned developments which are likely to increase or decrease the demand for these services.

### **The extent to which services in the neighbourhood already offer a choice to patients which may be improved by the provision of additional facilities**

- 3.76 Primary Care Trusts should consider the extent to which patients have a choice of services in the neighbourhood which the applicant proposes to provide and what benefits or detriment may accrue from the grant or refusal of the application. Primary Care Trusts may wish to take account of prescribing trends and data to help their assessment. The extent to which these meet current and anticipated or projected demand will be important factors to bear in mind. For example, the Primary Care Trust may find that the choice of the full range of essential and directed services within the neighbourhood that the Primary Care Trust has determined are required, is restricted because of significant pressures on current providers. For example, a large volume of routine dispensing means that current providers are offering no or a limited range of directed services to meet needs. In this case, the neighbourhood could benefit from the introduction of a greater diversity and choice of service provision.

### **The extent to which there is a reasonable choice of providers in the neighbourhood which may be improved by additional providers**

- 3.77 Primary Care Trusts should assess the extent to which there is a reasonable choice of providers of services in a neighbourhood. For example, a neighbourhood with one provider but a high demand for diverse or more accessible services which are not being met may benefit from an additional provider of services who can cater for these needs. This may be an existing provider seeking to expand his business. Alternatively, it could be a brand new provider where an existing provider is unable to expand his current range of services to meet these needs. Exceptions to this may also apply. For example, a Primary Care Trust may receive an application for a pharmacy within a rural "controlled" locality which may not support the entrance of a

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competitor. Alternatively, the Primary Care Trust is already supporting a pharmacy in a more isolated location (for example, through commissioning specific services from that pharmacy or through Essential Small Pharmacy Local Pharmaceutical Services) in order that patients can continue to access the services they need. Equally, Primary Care Trusts should be alive to the overall impact that a grant of an application may have on access to services (see paragraph 3.80 below). Primary Care Trusts should note that a choice of provider does not necessarily mean a straightforward choice between Company X and Company Y. For more information see Appeal Case No 13085 dated 27 July 2006 on the NHSLA's website at [www.nhsla.com](http://www.nhsla.com).

**The extent to which current service provision in the neighbourhood is adequately responding to the changing needs of the community it serves or to local Primary Care Trust delivery plans designed to meet primary care policy objectives**

- 3.78 Primary Care Trusts should consider whether the current level of service provision adequately responds to the changing healthcare needs of patients, or to the Primary Care Trust's delivery plans for improvements to primary care service provision which it has identified. This may include whether current services in the neighbourhood are adequately responsive to changing needs within the neighbourhood. For example, the characteristics of the population are gradually shifting - for example, in terms of age, gender or ethnicity. Alternatively, there are diverse populations who would benefit if services were developed which helped them secure better access to healthcare services to meet their particular requirements. Alternatively, the Primary Care Trust has identified a need for pharmaceutical services which are delivered in such a way that they make a better fit with or promote greater synergy of service provision with other healthcare providers in the neighbourhood and which are currently not available.

**The extent to which the applicant proposes to improve service provision in the neighbourhood through innovation or new directions in delivery**

- 3.79 A Primary Care Trust may find that current service provision is not responding flexibly to the needs of the neighbourhood it serves. An applicant may propose imaginative or innovative techniques and approaches to maximise service delivery to meet those needs. This might for example be through the provision of services which specifically focus on helping patients with certain longer-term medical conditions to meet health goals and national public sector agreement targets.

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### **The extent to which the application will meet the need for specialist or other services which improve the provision of, or access to, services for example to specific populations or vulnerable groups**

- 3.80 Primary Care Trusts will also consider the extent to which the application proposes services or means of delivery which will offer greater benefits by closing gaps in the current provision of services within a neighbourhood. Alternatively, it may determine that a community served within the neighbourhood would benefit from improved access and choice resulting e.g. from improved geographical position or services for that neighbourhood. Examples of this might include improved access to pharmaceutical services for people in deprived areas, to certain minority ethnic groups e.g. through improved language facilities, for people with disabilities, or services for patients with specific local healthcare needs (e.g. respiratory disease in industrial areas, substance misuse).

### **The assessment of the overall impact on the neighbourhood in the longer-term**

- 3.81 Primary Care Trusts will wish to consider the likely impact the application would have on the provision of services in the neighbourhood in the longer term particularly in relation to local delivery plans drawn up from requirements identified in a Primary Care Trust pharmaceutical needs assessment. Of special consideration here would be any detrimental impact on future overall access and choice of pharmacy services, or on the quality of such services.
- 3.82 An example of this would be an application which would secure an unjustifiably large proportion or virtual monopoly of NHS pharmaceutical service provision within the neighbourhood or more widely within the Primary Care Trust area. Applications to run GP-surgery based pharmacies or which would increase market penetration for one or two existing pharmacy companies may be such examples, although there will be exceptions, for example where it is proposed to incorporate a pharmacy within a primary care centre. Also relevant is whether grant of the application would distort the pattern of the local market or would have a significant impact on access to services for vulnerable population groups (e.g. the elderly, housebound, disabled) or a significant impact on the quality of services available generally or to specific population groups.
- 3.83 Primary Care Trusts should therefore, in determining the overall impact of an application, take account of all relevant factors. It is unlikely that such an assessment will always be clear-cut. Rather it is likely to comprise a statement of advantages and disadvantages based on the facts and a judgment, taking account of all relevant circumstances, as to whether an application should be granted or not.

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3.84 Such factors may include

- The likely effect on access to essential and directed services in the neighbourhood (which can include the effect on access to services provided by contractors outside that neighbourhood – see paragraph 3.86 below);
- The likely demand for such essential and directed services in the future, taking account of any known local factors which would affect demand;
- The likely effect on local pharmaceutical services (if any);
- The current pattern and level of service provision (including the current pattern and level of choice and competition) and an assessment of the likely effect on future provision if the pharmacy application is either refused or approved; and
- The likely impact on patients who currently use the services and whether approval or refusal of the application is likely to benefit patients in the longer term or to adversely affect their access to adequate services, or the quality of such services.

### The “necessary or desirable” criteria

3.85 As mentioned above, regulation 12(2) sets out how a Primary Care Trust goes about deciding whether the regulatory test is satisfied. This includes a provision from the previous Regulations that the Primary Care Trust shall have regard in particular to

“(a) whether or not the following services are already provided by persons in the neighbourhood in which the premises named in the application are located-

- i. any pharmaceutical services specified in the application provided by persons included in a pharmaceutical list, or any directed services the applicant agrees to provide if his name is included in a pharmaceutical list, or
- ii. any local pharmaceutical services provided under a pharmacy pilot scheme which are of the same description as any pharmaceutical services specified in the application.”

3.86 This means that Primary Care Trusts will take into account and in particular will consider the extent to which services (whether essential, or directed (advanced or enhanced)) are already available in the neighbourhood. This includes services provided under a local pharmaceutical service scheme. It can, following the *Holme on Spalding Moor* appeal case (see Annex C), include services which are provided to the neighbourhood from contractors outside it.

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- 3.87 In deciding the question of necessity or of desirability, it remains very important that Primary Care Trusts treat each application on its merits, on a case-by-case basis. Applications received at the same time for the same location can still be considered together. Primary Care Trusts should not restrict their discretion in any way by setting pre-determined numbers or formulae for making their assessment. Therefore, Primary Care Trusts should not adopt norms, quotas or use national average figures as an absolute or comparative guide (for example the number of pharmacies per million population locally compared to the national average). Nor should Primary Care Trusts establish fixed rules for example by basing decisions on the average, or median, distance from another NHS chemist locally or nationally. Doing so could increase the risk of successful legal challenge.
- 3.88 Primary Care Trusts are therefore urged to be flexible but consistent in their approach. In particular, Primary Care Trusts will wish to ensure that their decisions allow for developments to reflect changing local factors, needs and circumstances.
- 3.89 Primary Care Trusts may find that, having conducted a pharmaceutical needs assessment, they have addressed these questions. They may also have addressed them when considering the question of adequacy above.
- 3.90 The range of additional factors which historically Primary Care Trusts have taken account of in assessing necessity or desirability are set out in the table below. More information about the factors to be taken account can be found in Annex A (Frequently Asked Questions).

### **Necessary or desirable factors**

The factors which a Primary Care Trust may consider in determining whether an application is “necessary or desirable” are likely to include the following:

- demographic data (age, gender, ethnicity) and projections
- known health problems and any particular local needs
- the views of local patient and consumer groups, residents’ or tenants’ associations, parish councils etc
- environmental (e.g. communication and availability of public transport) or seasonal factors (e.g. holidaymakers)
- social factors such as deprivation indices
- local authority plans (e.g. for regeneration, new housing developments, improved transport links)
- local business profile (e.g. new businesses starting up, whether there are commuters coming in during the day – or commuters leaving the neighbourhood to work elsewhere),
- the existing availability of pharmaceutical services, the extent of services provided and evidence of any deficiencies (e.g. complaints)
- the Primary Care Trust’s plans for development of primary care services

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(for example as set out in Local Delivery Plans).

### Procedures for dealing with applications

3.91 The procedures to be adopted by the Primary Care Trust in reaching its decision are set out in detail in the following paragraphs. These provisions apply also to “preliminary consent” applications. The relevant procedures are listed in *regulation 22* including those applying to rural (“controlled”) localities.

#### Giving Notice of the Application

- 3.92 The first step is that the Primary Care Trust must, as soon as practicable<sup>10</sup> after receipt of the application, give notice<sup>11</sup> to
- (a) The Local Pharmaceutical Committee
  - (b) The Local Medical Committee
  - (c) any person included on the Primary Care Trust’s pharmaceutical list and whose interests might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted.
  - (d) similarly, any LPS chemist whose interests might, in the opinion of the Primary Care Trust, be significantly affected;
  - (e) any other Primary Care Trust which has GPs in appropriate cases, or persons included in their pharmaceutical list, who might be affected.<sup>12</sup>
  - (f) Any Primary Care Trust, any part of whose area is within 2 km of the proposed premises.

<sup>10</sup> This phrase is not defined in the regulations. As a guide Primary Care Trusts should initiate consultation within as short a time as is reasonable bearing in mind the overall time limits for deciding applications. Primary Care Trusts should note that any long delay could attract the criticism of the Health Service Ombudsman as an example of maladministration.

<sup>11</sup> While there is no prescribed form for such notice, although it must be in writing and could therefore be done by letter, the right of recipients of any such notice to make representations must be made clear.

<sup>12</sup> Primary Care Trusts who have to notify another Primary Care Trust of the fact that they are considering an application must be aware that the 45 days period for receiving representations will, in practice, have to be extended slightly. The reason for this is that where an “outside” Primary Care Trust is thus notified, that “outside” Primary Care Trust must in turn notify similar groups including the Local Pharmaceutical Committee, and the Local Medical Committee for its area, together with any person on the pharmaceutical list whose interests might, in their opinion, be significantly affected if the application were granted. This is set out in regulation 23 (3). The notice must tell them that any person so notified may make representations to the Primary Care Trust to which the application was originally made within 45 days from the date on which the notification (from the “outside” Primary Care Trust) was sent. Staff in the “outside” Primary Care Trust should therefore send to the first Primary Care Trust a copy of the letter to the parties, which gives the date for a reply.

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- (g) Local patient forums serving the area and representatives of any other patient, consumer or community group that the Primary Care Trust considers has an interest in the provision of pharmaceutical services in the neighbourhood.

*(regulation 23(2))*

It is up to the Primary Care Trust to determine who else it will consult. More information for example on notifying internet or mail-order applications is given in Chapter 4. However, it may wish to consult local community interests, such as consumer or neighbourhood groups where this seems appropriate. Recipients have at least **45 days** or such longer period as the Primary Care Trust allows in which to make comments to the Primary Care Trust (*regulation 23(3)*). However, the Primary Care Trust may take account of information received after that date under its general powers to consider information it considers relevant. This includes, for example, where a Primary Care Trust invites views from a neighbouring Primary Care Trust. Where Primary Care Trusts have set a date for the receipt of applications, they may want to alert local groups as to when they might be asked to comment on any applications received.

- 3.93 Any Primary Care Trust sent a copy of an application for inclusion in a pharmaceutical list is to be asked specifically if any part of the location specified in the application is within 1.6 km of a rural “controlled” area.
- 3.94 Concurrently, or as notice of applications is being prepared, the Primary Care Trust should carry out a series of checks. These are listed in *regulation 24(2)* and essentially comprise:
- as far as reasonably practical, a check on the information provided in the application form and ensure it has sight of all relevant documents before it makes a determination;
  - initiating checks as to the “fitness” of the applicant (for more information on this see the separate guidance on fitness to practise);

### Considering applications and sharing papers

- 3.95 The procedure under which a Primary Care Trust considers applications is for the Primary Care Trust to determine (*regulation 24(1)*). However, papers are to be copied to the bodies and persons whom the Primary Care Trust is required to notify of the application and they are to be given 45 days to comment in writing. It is considered good practice to enclose the complete application form or other correspondence provided about the application (but not fitness to practise declarations) when inviting views so that those notified can make informed representations. Comments received by the Primary

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Care Trust from any of these parties should also be copied to the others including the applicant. Further comments following this action would be an indication of serious conflict and clearly point to the need for a hearing in order that the issues and arguments can be aired.

### Preparing for the decision

- 3.96 Primary Care Trusts must act with the utmost probity when preparing to make decisions on applications i.e. the principle of fairness. This means primarily that information provided by or submissions made on behalf of one side, and which is material to the issue to be decided, must be shown to the other side in order that such information or submission can be challenged. See paragraphs 3.123 - 3.132 below.

### Evidence

- 3.97 The next step is that the Primary Care Trust must determine the evidence it should take into account in coming to a decision on any application.
- 3.98 The regulations do provide certain ground rules about the information which decision-takers must take into account in reaching their decisions:
- as noted above, in considering any application (other than a minor relocation or change of ownership application), the Primary Care Trust shall have regard in particular to whether or not any of the pharmaceutical services specified in the application are already provided by persons included in the pharmaceutical list in the neighbourhood in which the premises named in the application are located (*regulation 12(2)(a)*). However, it has been held by the courts that this is not an overriding factor but one of many (see the case of *ex parte Baker* cited in Annex C).
  - The Primary Care Trust shall now have regard in particular to whether the recipients of pharmaceutical services already have a reasonable choice with regard to the range of pharmaceutical services or of providers of such services in the neighbourhood (*regulation 12(2)(b)*).
  - The Primary Care Trust shall also have regard for any information available to it which, in its opinion, is relevant to the consideration of the application. What is relevant is not laid down in regulations, but is a matter for the judgement of the decision-taker. It must relate to the issue(s) to be determined arising from the application (*regulation 12(2)(c)*). Logically, therefore, it must relate to the provision of NHS pharmaceutical services and those services alone. It should not for example take into account factors such as the range or prices of over the counter medicines and related products.

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- Although the burden of proof is on the applicant to produce the evidence required to satisfy the Primary Care Trust that the statutory tests relevant to their application are met, Primary Care Trusts should note they are not limited to information provided in the application form or in any representations made by the applicants or those commenting on or objecting to the application. A Primary Care Trust is entitled to make its own enquiries and gather its own evidence should it feel the need to do so. In particular, the Primary Care Trust is entitled to use its own management information such as dispensing figures. On the extent to which such information needs to be disclosed to the parties, see below the section on “fairness”.
- The Primary Care Trust shall have regard to representations received from any of the parties or bodies to whom notice of the application has been sent (*regulation 12(2)(d)*). In addition, it must consider evidence and representations submitted, even by those with whom the Primary Care Trust is not obliged to consult.

3.99 Although these ground rules appear in the regulations, Primary Care Trusts should note that they are only matters to which the Primary Care Trust is “to have regard”: they are not conclusive of those matters. However, in recording its decision, Primary Care Trust should be clear what information and factors they have had regard to in respect of these categories of evidence.

3.100 A further point to bear in mind is that a Primary Care Trust is not limited to these categories of additional information. For example, one result of an application being made may be that a petition is organised amongst the residents of a particular community or from the patients of a particular surgery. Even though it might not fall within any of the categories of information listed above, the Primary Care Trust may consider it. Of course, such petitions may be biased and seek to advance a particular point of view. The Primary Care Trust will therefore need to weigh the value of such evidence received carefully.

3.101 Similarly, care should be taken with any supporting evidence submitted, such as the results of a market research survey, the patterns of consumer activity or the likely use to be made of the pharmacy, were the application to be granted.

3.102 The Primary Care Trust itself may seek the views of other groups not formally listed in the regulations. An example might be a local neighbourhood council or residents’ association.

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3.103 Other types of information that are likely to be of assistance include:

- the pattern of natural communities and normal patterns of travel
- other developments such as new highways, or shopping centres
- local authority plans or outline planning permissions.

3.104 This is purely indicative. The list is not comprehensive; nor will each of the items of information be relevant to every application. However, it provides an indication of the kinds of information that are likely to help determine applications.

3.105 Primary Care Trusts should note, however, that conclusions cannot be reached on any factors or on the overall application without some evidence on which to base a finding of fact.

### Deciding the procedure

3.106 It is for the Primary Care Trust to decide the procedure it will adopt to determine the application. Here, the Primary Care Trust has, under the regulations, a broad discretion as to the procedure to be adopted: regulation 24 (1) merely states that the Primary Care Trust may determine an application “in such manner as it thinks fit”.

3.107 In particular, it is specifically provided that the Primary Care Trust may decide the application without hearing any oral representations, if it considers that oral representations are unnecessary. Where it decides that a hearing is not necessary, it is good practice for the Primary Care Trust to make and record a formal decision to that effect. Primary Care Trusts should not assume that holding an oral hearing would reduce the likelihood of an appeal. Whether in the circumstances an oral hearing would be desirable is entirely a matter for the Primary Care Trust. However, oral representations may be helpful in situations where the submission in the papers reveal major disagreements as to the factual basis on which an application is being made and/or opposed.

3.108 *Regulation 24(3)* states that the decision as to whether a hearing should be arranged is for the Primary Care Trust, not the parties, to determine. Certainly, a request for a hearing should not automatically trigger the establishment of a hearing. A Primary Care Trust may wish to convene a special Pharmacy Panel to determine the application without a hearing. Again, where it does so it is good practice to make a formal decision to that effect and to notify interested parties.

### Hearings (*regulation 24(3)*)

3.109 If a hearing is to be held, the regulations provide that at least fourteen days' notice must be given to both the applicant and any person who was required to be notified of the application *and from whom it has received representations*.

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- 3.110 The procedure to be adopted at any such hearing is stated to be such as the Primary Care Trust in question may determine (*regulation 24(5)*).<sup>13</sup>
- 3.111 Where there is an oral hearing, the regulations do not prescribe the number of persons who should be involved in the hearing. Thus, there is no prohibition on a single person holding the hearing. It is, however, good practice for the Primary Care Trust to appoint at least a three-person tribunal to consider any application.
- 3.112 The chairman or chairwoman should be legally qualified. If this is not possible, a person with considerable experience of such forms of inquiry should be appointed.
- 3.113 Although the regulations provide that the actual decision is to be taken by the Primary Care Trust, in practice pharmacy decisions are usually delegated to a properly authorised committee or officer. Therefore, the committee holding the hearing will, in practice, usually make the decision on behalf of the Primary Care Trust.
- 3.114 The applicant and any other person who has made representations may be assisted at any hearing in the presentation of his representations by some other person. However, *regulation 24(4)* prescribes that “no person shall be entitled to be heard in the capacity of counsel or solicitor”. Thus while formal legal representation is not permitted, the rules do not actually prevent representation being provided by a person who happens to be professionally qualified as a lawyer, as long as he is not acting as such on the day of the hearing.

### Principles of administrative law

- 3.115 Whether a hearing is held, or the application is dealt with solely based on the papers submitted, the process for making the determination must be in accordance with the fundamental principles of administrative law.
- 3.116 These principles, in brief, are:
- (a) that the decision-taker must not be “biased”, and
  - (b) that the procedure must be “fair”.

#### “Bias”

- 3.117 Bias in this context means that no decision-taker must have a personal or financial interest in the outcome of the hearing. The boundaries of

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<sup>13</sup> This is a slightly unusual formulation in administrative law, since such matters are often left to the chairman of the hearing panel or tribunal. However, Primary Care Trusts do have a power to delegate functions to committees or officers, so, assuming that proper delegation to the committee or chairman is made, the outcome is effectively the same.

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this principle are not always clear. Obviously, a decision-taker who was related to, was a personal friend or a business associate of an applicant, or knew an objector well should not be involved in any decision-making process.

- 3.118 Similarly, a person with a personal shareholding (other than a small minority shareholding in a public limited company) in a company applying for or objecting to an application – or indeed in any retail pharmaceutical company – should not take part in the decision-taking process. However, the fact that the decision-taker’s pension fund, as part of its overall portfolio of equity investment, might have invested in such a company would not debar that person from determining an application – the interest in the outcome of the application would be too remote. Further information about the position of Primary Care Trust panel members and officers etc and the declarations they should make is given in Annex A on page 6.
- 3.119 There is one specific regulation that is relevant in this context. **No person who provides or assists in providing** primary medical services under Part I, or pharmaceutical services under Part II or as a Local Pharmaceutical Services provider under Part I, of the National Health Service Act 1977 can take part in any decision under these regulations. Thus, all doctors, chemists and their staff are excluded from taking part in any decision, irrespective of where they practice in this country. The full list is in *regulation 24(6)*. It includes for example directors and beneficial shareholders of companies, or officers and trustees of APMS providers or employed by the Primary Care Trust for the purpose of providing medical services.<sup>14</sup>
- 3.120 Whilst the wording of this regulation does not, however, prohibit such persons from giving professional advice to the decision-takers on any particular application, Primary Care Trusts should take particular care about seeking views from representatives of local contractor committees when reaching their decisions. This would give those representatives a potential second opportunity to make representations about an application which other interested parties would not be able to enjoy or challenge. It is therefore **essential** that any such person withdraws before the process of considering the outcome of an application and voting commences. This extends to representatives of local contractor committees whether they are a contractor or not who should have no part in decisions on applications (see also “Fairness” below).
- 3.121 Failure to observe this requirement **could result in the determinations being successfully challenged by way of judicial**

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<sup>14</sup> Similarly, it is good practice that where a Primary Care Trust has or could be alleged to have an interest in the outcome of an application (for example, the Primary Care Trust is a minority shareholder in a LIFTCo), the officers associated with that interest should not be involved in the decision. In these circumstances, Primary Care Trusts may wish to consider inviting officers of neighbouring Trusts to assist in decisions.

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**review** on the grounds of procedural irregularity, with all the resultant expense and delay that such proceedings inevitably involve.

3.122 To sum up, it is essential that Primary Care Trusts act with the utmost probity when making decisions on applications.

*“Fairness“*

3.123 In this context, fairness means primarily that information provided by or submissions made on behalf of one side, and which is material to the issue to be decided, must be shown to the other side in order that such information or submission can be challenged.

3.124 It is clear that if a failure to show a document has actually had no adverse effect on the other side, or which added nothing to information already known to the other side them, notwithstanding the general principle, a Court may conclude there has been no breach of the “fairness” principle.

3.125 Decision-takers must therefore have procedures for assembling and copying to the other parties, the actual application, together with the submissions and representations made thereon.

3.126 A problem can arise in this context where one party, as part of its submission provides confidential commercial information<sup>15</sup>, say on the level of dispensing activity or profitability of an existing pharmacy, and then requests that such information should remain confidential to the Primary Care Trust. The Primary Care Trust may be in some difficulty as to whether it would be fair to take such evidence into account.

3.127 In some cases, the party providing the information may agree that the other side should have sight of that commercially sensitive information, based on the giving of undertakings that commercial advantage will not be taken as a result of the provision of such information.

3.128 However, such agreement may not be forthcoming. Then the decision-taker will have to decide what to do with the evidence submitted. In some cases, the problem may be able to be resolved on the basis that the evidence is simply not relevant to the issue to be determined.

3.129 If the Primary Care Trust is of the view that the information is apparently material to the issue to be decided, and at the same time is clearly commercially sensitive, then it may need to consider whether, under the provisions of Human Rights Act 1998, it is in the public interest that the information should be released to other parties. This Act incorporates the provisions of the European Charter on Human Rights. Public authorities are prevented by law from acting in a way

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<sup>15</sup> Such information should be distinguished from the management information held by the Primary Care Trust, which, as suggested above, should be taken into consideration where relevant.

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that is incompatible with a Convention right. Article 6 enshrines the right to a fair trial.

- 3.130 The courts have determined that, notwithstanding the general principle that information should be disclosed to all the parties to proceedings, there are exceptions to this proposition. This includes where such disclosure would affect the interests of other persons. In one case<sup>16</sup>, the Court accepted the force of the argument that the duty to be fair to one party could not be interpreted so as to involve disproportionate unfairness to another through the enforced disclosure of commercially confidential information.
- 3.131 Primary Care Trusts should also bear in mind that they may be asked to disclose information received in connection with applications under the provisions of the Freedom of Information Act which came into force on 1 January 2005. More information is available at [www.foi.nhs.uk](http://www.foi.nhs.uk). It is clear that commercially confidential information can be exempted from disclosure where there is no overriding public interest.
- 3.132 The problem the Primary Care Trust faces in this matter is whether commercially confidential information can be taken into account at all in its decision. As a general approach, Primary Care Trusts should bear in mind that the overall objective of any procedure - whether by way of hearing or by written representations - is that there should be fairness. In cases where commercial information will be relevant, but is not disclosed, the Primary Care Trust may be able to provide the general gist of the information, without disclosing the full commercial detail, and reach a decision on that basis. However, if even this is not possible, then it appears to follow that the principle of fairness means that the information so provided should not be taken into account by the Primary Care Trust.

### **Multiple applications**

- 3.133 In some cases there may be more than one application relating to the provision of pharmaceutical services in a particular neighbourhood (e.g. where the building of a substantial new housing estate has been announced or built, a new doctors' surgery or superstore is planned or has opened). This may particularly be the case where Primary Care Trusts have specified set dates every month for receiving applications. Where Primary Care Trusts have done this, they may wish to publicise whether they will treat applications received prior to this date as received on the specified date and give a common time of, for example, 0001 hours, or whether they will record the actual time and date the application is received (see also paragraphs 3.134 - 3.138 below).

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<sup>16</sup> *R v Monopolies and Mergers Commission ex parte Elders* [1987] 1 WLR 1221.

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- 3.134 Under *regulation 24(7)*, where it thinks fit, the Primary Care Trust has a discretion to consider together two or more applications.<sup>17</sup>
- 3.135 Notice in writing must be given to all the applicants and all the parties entitled to be notified of the applications.
- 3.136 While considering similar applications together may be good practice and thus desirable in principle, Primary Care Trusts should not do this where it would result in considerable delay to the determination of any particular application and bearing in mind the overall timescale set for determining applications. Thus, a Primary Care Trust may be notified informally that an application is to be expected in relation to the provision of service in a neighbourhood for which another application has already been received. *Regulation 23(2)* provides that the Primary Care Trust must give notice of an application “as soon as is practicable”. To delay the consideration of an application received on the basis that a further application may be received in the future could lead to serious delay and run the risk of legal or other challenge.
- 3.137 In this way, the power on the part of Primary Care Trusts to consider applications together is not capable of being exploited by potential applicants who seek effectively to “block” consideration of earlier applications.
- 3.138 When a Primary Care Trust properly determines to consider two or more such applications together, it may, of course, reject all of them. However, if it determines to grant one of them, the determination to grant such applications should be based on a consideration of all the evidence provided to the Primary Care Trust about the competing claims of the applicants.
- 3.139 In such cases, a favourable determination should not be made simply on the grounds that one particular application was received before another. It should be made on the basis that the range and quality of services specified in the application in question is to be preferred. If the application form does not provide sufficient information as to how the quality of services to be provided is to be assured, Primary Care Trusts may wish to seek further information from the applicant either in writing or by way of an oral hearing. However, where all other things are equal, Primary Care Trusts can ultimately determine competing applications on the basis of the time the first application was received. This is known as “the first past the post” principle.
- 3.140 In recording the reasons for its decision, the Primary Care Trust should identify the factors which led it to favour one application over another. These might include, for example, taking into account:

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<sup>17</sup> As the regulation specifies “in relation to each other” it is unlikely that it would be appropriate to consider together applications relating to different neighbourhoods, albeit adjacent ones.

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- the range and availability of services to be provided;
- the times at which such services are to be available;
- there is a realistic prospect that services will be provided (for example, the applicant has secured or will secure the relevant premises);
- access for the disabled; or
- the provision of staff with specialist language or interpreter skills

where these are relevant factors.

3.141 In addition, although the regulations do not provide for this, if more than one application is made to provide pharmaceutical services in a location adjacent to the boundaries of more than one Primary Care Trust, and the Primary Care Trust receiving the application is required to pass details on to the neighbouring Primary Care Trust(s), it may be sensible for the Primary Care Trusts involved to establish a joint arrangement to consider and determine such applications. This is to ensure that there is neither over-provision nor under-provision of pharmaceutical services in such a location.

### Timescales for completing determinations

3.142 Primary Care Trusts should aim to determine all applications where there is a need to notify others in **four months** unless there is reasonable cause for any longer period (for example where consideration of an application has been deferred on “fitness to practice” grounds). For applications which do not need to be notified first e.g. minor relocations of under 500m or changes of ownership these should be determined in 30 calendar days (*see regulations 6 (3), 7(3), 8 and 27 (2) as amended*).

### Notification of decisions

3.143 Once a Primary Care Trust has completed its determination – whether or not to grant the application wholly or in part, the Primary Care Trust is to give notice in writing of its decision. This must be done “as soon as practicable” and in any event within four months of the date of receipt of the application, under regulation 27(1), unless there is “good cause”.

3.144 In minor relocation cases over 500 metres, including between neighbouring Primary Care Trusts, notice of the determination should be sent to the applicant and those who made representations to the Primary Care Trust (see new regulation 27(1)(za) from 19 January 2007). For minor relocations under 500 metres, in change of ownership

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cases<sup>18</sup>, applications following suspension, and applications to return to the list after the provision of local pharmaceutical services, notice of the determination is to be sent to the following:

- (a) the applicant;
- (b) any person already included in the pharmaceutical list and whose interests might, in the opinion of the Primary Care Trust be significantly affected by the decision;
- (c) any LPS chemist on the list of the Primary Care Trust whose interests might be significantly affected;
- (d) the Local Pharmaceutical Committee;
- (e) the Local Medical Committee;
- (f) any Primary Care Trust any part of whose area is within 2 km of the premises;
- (g) any Patients' Forum serving the locality of the premises; and
- (h) any other patient, consumer or community group the Primary Care Trust considered had an interest in the application.

*(regulation 27(1)(a) as amended)*

3.145 In the case of any other application for inclusion on the list, including those applying for one of the four exemptions, the notice of the decision must be sent to the following:

- (a) the applicant
- (b) any person who had to be given notice of the application and who actually made representations within the prescribed time period to the Primary Care Trust. This includes representations received from those from outside the Primary Care Trust area.

*(regulation 27(1)(b))*

3.146 In addition, where the Primary Care Trust has been required to notify another Primary Care Trust that an application has been made (on the grounds that any parts of its area is within 2 km of the premises stated in the application) for any of the applications listed in paragraph 3.143 above, that latter Primary Care Trust has the responsibility under regulation 27(3) of notifying the decision in writing to the following:

- (a) the Local Pharmaceutical Committee for its locality;
- (b) the Local Medical Committee for its locality;
- (c) any person whose name is included in the pharmaceutical list and whose interests might, in the opinion of that Primary Care Trust be significantly affected by the decision;
- (d) any LPS chemist on the list of the Primary Care Trust; and

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<sup>18</sup> The same rules also apply to notification of change of premises cases under reg 39(6). This is where the Primary Care Trust has granted an application and the contractor then notifies a change of premises which the Primary Care Trust accepts are in effect a minor relocation.

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- (e) any Patient's Forum and other patient, community or consumer groups which the Primary Care Trust considers has an interest in the provision of services in the neighbourhood

3.147 All notices of decisions must contain:

- (a) a written statement of the reasons for the decision; and
- (b) a statement of the rights of appeal for those entitled to appeal (see below)

*(regulation 27(1))*

### *Statement of reasons*

3.148 Primary Care Trusts can find that the making of a statement of reasons causes difficulty. A simple statement, for example, that an application is granted "because it is necessary" is simply the conclusion, not a reason for arriving at that conclusion. It is thus not adequate. The Primary Care Trust must explain why it reached the conclusion it did. Apart from being bad decision-making, failure to give proper reasons will unjustly disadvantage those who are actual or potential appellants.

3.149 The regulations do not actually state that the Primary Care Trust should make a statement of the findings of material facts which have led to its determination. However, it would be good practice so to do, particularly in a case in which there was a substantial conflict of evidence.

3.150 The letter notifying the decision should make clear that each of the issues which were required to be determined by the statutory provisions relevant to the particular application has been considered by the decision-taker.

3.151 For example, the decision letter should make clear: what the "neighbourhood" was for the purpose of the decision; why the provision of pharmaceutical services in a particular neighbourhood was or was not adequate; or why a proposed service was or was not "necessary" or "desirable". Examples of decision letters are available on the NHS Primary Care Contracting website at [www.pcc.nhs.uk](http://www.pcc.nhs.uk). It is also helpful to the parties notified if Primary Care Trusts make reference to the relevant regulations they considered as part of the decision.

### *Statement of appeal rights*

3.152 Those entitled to appeal are outlined below. The decision letter must contain a statement of those who do have the right of appeal.

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### *Refusal or imposition of conditions*

- 3.153 Where a Primary Care Trust refuses an application or imposes conditions on an applicant on the ground of their “fitness to practise” further notifications have to be given. These are set out in the guidance on “fitness to practise” (*regulation 26(6)(b)*).

### **Effect of Grant of Application (*regulation 39*)**

- 3.154 Even though an application may be granted, it is important to stress that the successful applicant is not automatically to be included on the pharmaceutical list. He must actually show that he is committed to providing the services in question.
- 3.155 In the case of full applications, the successful applicant must, at least fourteen days before the expiry of the period of six months from the date on which the granting of his application was notified to him by the Primary Care Trust, give notice to that Primary Care Trust that he will within fourteen days start to provide the services in respect of which the application was made, at the premises to which the application related (*regulation 39(2)*). Primary Care Trusts should bear in mind that under *regulation 39(10)* the date for inclusion in the list has certain limits. An applicant cannot be included in a list until the day after 30 days has expired from the date the Primary Care Trust's decision is given. An exception to this, as a result of an amendment introduced under SI 2006/3373, is where a Primary Care Trust agrees to a lesser period. One example of when this might happen is where an applicant who has been granted the right to provide services by virtue of one of the four new exemptions, confirms they are not going to appeal the decision and are ready to start providing services sooner than the usual 30-day period. Otherwise, the date to be included on the list is the date of the last appeal concerning an application and the 30 days' gap does not apply in these circumstances.
- 3.156 The period of six months may be extended by the Primary Care Trust for up to another three months if there is good cause. The required notice is to be given on the form set out in Schedule 4 Part II (see Annex D) (*regulation 39(2)(b) and (4)*).

### **Notice of requirement to commence services**

- 3.157 *Regulation 39(3)* permits a Primary Care Trust in writing to require an applicant granted consent to commence the provision of services. The notice should specify the date on which services are to commence. This date may not be earlier than the day that is 30 days after the application was granted or the date the last appeal concerning the application was determined. It must not be less than 28 days beginning with the date the notice is issued, or later than three months from the date the notice is issued. The relevant date must be within the period

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for which consent has been granted (or extended on application). Such notices are appealable.

- 3.158 The form for applicants to notify the commencement date is included in the Regulations at Schedule 4 Part II. Primary Care Trusts may wish to pre-populate the form with the information about the premises and services to be provided. Applicants can then confirm their agreement.
- 3.159 In cases involving a minor relocation across a Primary Care Trust boundary, where the contractor advises that he is about to commence services at his new premises, that Primary Care Trust notifies the Primary Care Trust covering the contractor's existing premises within 14 days of receiving the notice from the contractor. (*regulation 39(12)*).

### Notification of change of premises

- 3.160 If the applicant cannot for some reason go ahead with the original premises specified in the application, but during the six month period (or as extended) notifies the Primary Care Trust of his intention to provide the same pharmaceutical services from other premises in the same neighbourhood and the change of premises would only be a "minor relocation", then the Primary Care Trust may amend the premises in the original application. There is no extension to the original six or nine month period as appropriate.
- 3.161 Notification of the decision is to the same persons as must be notified following the granting of a minor relocation application.

### Appeals

#### Who has the right of appeal?

- 3.162 The right to appeal against a decision of a Primary Care Trust varies slightly depending on the type of application which has been determined. Appeal rights have been clarified in the amendments to the regulations introduced from 19 January 2007 under SI 2006/3373.
- 3.163 Where a Primary Care Trust has determined either:
- (a) a minor relocation application under 500 metres;
  - (b) a change of ownership application;
  - (c) an application following suspension;
  - (d) an application concerning the right of return to the list; or
  - (e) where the Primary Care Trust has made a decision as to whether or not to amend the premises named in the original application, the following have the right to appeal:
    - the original applicant

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- any person on the pharmaceutical list or any LPS chemist who was notified of the decision by the Primary Care Trust (or a neighbouring Primary Care Trust) on the grounds that his/her interests might be significantly affected by the decision. (*regulation 29(2)*)
- 3.164 Appeals against decisions on change of ownership can be combined with appeals concerning minor relocations. An applicant can appeal against a Primary Care Trust decision where it decides to override the automatic approval of minor relocations under 500 metres.
- 3.165 For other types of application (new premises, additional premises and additional services, minor relocations over 500 metres or where the Primary Care Trust has determined a relocation under 500 metres is to be treated as one over 500 metres), the right of appeal extends to the applicant, and to any person on the pharmaceutical list or any LPS chemist who was notified of the original application and who had made representations to the Primary Care Trust relating to the application within the prescribed time period. It should be noted, however, that the right of appeal **does not** extend to any others who did make representations e.g. a parish council or community group. Nor does it extend to those who were required to be so notified but who did not in the event make representations.
- 3.166 Where the Primary Care Trust has determined to refuse to allow an extension to the period within which an applicant is required to notify the Primary Care Trust that he will start to provide pharmaceutical services, then the applicant alone has the right of appeal (*regulation 29(5)*). Similarly only the applicant has a right of appeal regarding a Primary Care Trust's determination in respect of one of the four exemptions from the control of entry test (*regulation 29(3)*). Primary Care Trusts will therefore wish to bear in mind that a person other than the applicant who wishes to challenge these kinds of decisions has recourse only to a Judicial Review (see also for example Chapter 4 paragraph 4.74).

### To whom is the appeal made?

- 3.167 Regulation 29 (5) states that the right of appeal is to the Secretary of State. However, this function has been delegated to the NHS Litigation Authority (NHSLA). All appeals and representations should be sent direct to the Family Health Services Appeal Unit of the NHSLA. Primary Care Trusts should advise potential appellants accordingly.

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The address is:

Family Health Services Appeal Unit  
NHS Litigation Authority  
30 Victoria Avenue  
Harrogate  
North Yorkshire  
HG1 5PR

Tel: 01423 535415; Fax: 01423 522034

e-mail: [mail@fhsaa.nhs.uk](mailto:mail@fhsaa.nhs.uk)

website: [www.nhsla.com/fhsau](http://www.nhsla.com/fhsau)

### Procedure relating to appeals

#### Notice of appeal

- 3.168 Any notice of appeal must be in writing, and must be made within 30 days from the date on which the notice of the decision was sent by the Primary Care Trust to the applicant (*regulation 29(2)(b)(a)*).
- 3.169 This 30 day time limit may be extended for such longer period as the Appeal Unit may for “reasonable cause” allow. Thus, the time limit is a strict one and it is up to the appellant to demonstrate that “reasonable cause” exists (*regulation 29(6)(b)*).
- 3.170 In such a case where the Primary Care Trust has considered two or more applications together under the rules set out above, and the Appeal Unit receives appeals against two or more such applications, then the appeals must also be dealt with on the same basis. Where a Primary Care Trust decides not to consider applications relating to a particular area together, nevertheless the Appeal Unit itself has the power to consider them together at the appeal stage, should it so determine (*regulation 29(7)*).
- 3.171 There is no prescribed form on which the notice of appeal is to be made. It could therefore be perfectly properly made, for example, in the form of a letter. However, whatever form is chosen, the notice of appeal must contain a concise statement of the grounds of appeal. Although these do not have to be in the nature of formal legal pleadings, they must give a clear indication of what the appeal is about and the basis for it (*regulation 29(9)*).

#### Consideration of the appeal: next steps

- 3.172 On receipt of the appeal, the Appeal Unit considers the notice of appeal.
- 3.173 If it is of the opinion that it discloses no reasonable grounds of appeal, or that the appeal is otherwise vexatious or frivolous, it may at once

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determine the appeal by dismissing it. If it is not of such opinion, then it sends a copy of the notice of appeal to those parties specified in the Regulations (*regulation 29(10)*).

3.174 In the case of an appeal against a determination relating to:

- a minor relocation application (including between neighbouring Primary Care Trusts);
- a change of ownership application;
- a decision as to whether or not to amend the premises named in the original application;
- a right of return to the pharmaceutical list; or
- a refusal to allow an extension of the period within which notification of the commencement of the provision of services must be made

the notice of appeal must be sent to:

- (a) the applicant;
- (b) any person already included in the pharmaceutical list and any LPS chemist whose interest might, in the opinion of the Primary Care Trust be significantly affected by the decision;
- (c) the Local Pharmaceutical Committee
- (d) the Local Medical Committee
- (e) any Primary Care Trust, any part of whose area is within 2 km of the premises; and
- (f) any Patient Forum serving the locality of the Primary Care Trust; and
- (g) any other patient, consumer or community groups that the Primary Care Trust considered had an interest in the provision of services in the neighbourhood.

*(regulation 29(11)(a))*

3.175 The reason why this list is rather long is that, in these categories of case, the original application may not have been given wide circulation. Moreover, although the decision must have been announced to a wider group, the actual rights of appeal are relatively closely defined. Thus, this process of circulating the notice of appeal gives a wider group the opportunity to make representations about the appeal.

3.176 In the case of a decision on any other application, where the original application was sent to a widely defined group who therefore have had one opportunity to make representations, the notice of appeal is to go only to:

- the applicant;
- Any person who was required to have been notified of the original application and who, within the prescribed time limits did in fact make representations to the Primary Care Trust.

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*(regulation 29(11)(a))*

3.177 In the case of an appeal against a suspension from the list (see “fitness to practice” guidance) or temporary provision of services during a period of suspension, the notice of appeal is only to go to

- the applicant; and
- the suspended chemist.

*(regulation 29(11)(c))*

3.178 Any person to whom a copy of the notice of appeal has been sent has **30 days** within which to make written representations to the Appeal Unit. The period is to run from the date on which of the notice was sent *(regulation 29(12))*.

3.179 Before reaching a decision, the Appeal Unit may require an oral hearing to be held. Where this is to happen, one or more persons are appointed to hear the appeal and report to the Appeal Unit. The procedure for the hearing is to be determined by the persons so appointed *(regulation 29(13) – (15))*.

3.180 The regulations state that notice of the hearing is to be sent to the appellant and any person to whom a copy of the notice of appeal was sent not less than 14 days before the date fixed for the hearing *(regulation 29(16))*.

3.181 Although the regulations do not require this, the practice is that the Appeal Unit will construct a paginated bundle of documents including:

- (a) all the papers considered by the Primary Care Trust when it made its original decision;
- (b) the decision itself; and
- (c) Any representations made following the notice of appeal.

3.182 Unsolicited submissions (e.g. a local petition) will be held in a separate bundle by the Chair of the hearing, and may be read by the parties attending the hearing.

3.183 The Chair of the hearing will also have been provided with relevant dispensing figures by the Primary Care Trust. The panel may consider this information. The figures may be disclosed to the other parties, but only with their mutual consent. If consent is not forthcoming, the panel may consider the information so long as it tells the parties that that is what it is going to do.

3.184 Any information which is supplied by one of the parties, which is commercially confidential, should only be disclosed to the parties – and

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then only on a confidential basis – with the consent of the party submitting it. If such consent is not forthcoming, then since the other parties would not have an opportunity to comment on it, the hearing panel should not use the data either.

- 3.185 Where a party seeks to introduce further documentation at the hearing stage, this can be permitted, as long as all the parties are given time to read and digest its contents. Care should be taken, however, that such a document does not introduce a new ground of appeal; if it does, the hearing should only proceed with the consent of all the parties. If necessary, an adjournment can be granted.
- 3.186 The appellant and any other person whom notice of the hearing was sent may attend the hearing and be heard in person, or by counsel, solicitor or other representative. The Primary Care Trust who took the decision may also be heard by any duly authorised officer, or member, or by counsel or solicitor (*regulation 29(17)*).
- 3.187 Once the hearing is finished, the panel shall report its findings to the Appeal Unit. The final decision is actually taken by the Pharmacy Appeals Unit. It shall either allow the appeal, or confirm the decision of the Primary Care Trust (*regulation 29(18)*).

### **Notification of the decision**

- 3.188 As soon as is practicable thereafter, the Appeal Unit shall send a written notice of its decision to the appellant and to any other person who was sent a copy of the notice of appeal *and* who made a written representation prior to the appeal hearing (*regulation 29(19)*).
- 3.189 The decision letter must also contain a statement of the findings of fact material to the decision and a statement of the reasons for the decision.

### **Times when pharmaceutical services will be provided**

- 3.190 Applicants for inclusion in a pharmaceutical list have to supply details of the hours in which they will provide pharmaceutical services. The arrangements for dealing with pharmacy opening hours are set out in Part 3 *Hours of Opening of Schedule 1 Terms of Service of Pharmacists* to the regulations. The arrangements for dealing with opening hours for appliance contractors are set out in paragraphs 10 - 12 of Schedule 3 *Terms of Service of Suppliers of Appliances* to the regulations. More information on hours is in the guidance on the contractual framework.
- 3.191 However, Primary Care Trusts will wish to note that all the new arrangements for dealing with opening hours applied as from 1st April 2005 – both to existing contractors and new applicants.

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- 3.192 The core contractual hours are 40 hours per week for pharmacies and 30 hours per week for appliance contractors - unless fewer or more hours are agreed with/directed by the Primary Care Trust, or on appeal by the Appeal Unit. Primary Care Trusts should note that under SI 2006/3373, the previous wording of “not less than 40 hours” for pharmacy contractors has changed and now only refers to “40 hours”. These ‘core’ hours should be notified to the Primary Care Trust along with ‘supplementary hours’ that make up the total hours during which the pharmacy will provide pharmaceutical services. Note this does not apply to a pharmacy granted an exemption for intending to open for at least 100 hours per week, as it is a condition of its being included in the list that it is open for at least 100 hours per week or more – and that condition cannot be varied or removed. Such a pharmacy will identify the 100 hours which are ‘core’, together with any supplementary hours above this that make up the total hours during which the pharmacy normally will provide pharmaceutical services.
- 3.193 For the purposes of calculating the number of hours that a pharmacy or appliance contractor is open during a week, they are deemed to be open as normal on Good Friday, Christmas Day and bank holidays. This means that pharmacies do not have to open on these days, unless they wish to do so. The PSNC has agreed that it would be helpful if pharmacies gave three months’ notice to their Primary Care Trust of whether they are intending to open on a bank holiday to allow local planning. Primary Care Trusts may commission additional hours to meet local needs or, in the absence of agreement, Primary Care Trusts may however direct pharmacy or appliance contractors to open specifically on these days, subject to being satisfied that the pharmacy will receive reasonable remuneration and the normal rights to make representations and of appeal. Where they do so, Primary Care Trusts need to allow at least three month’s notice of issuing any such direction to allow for any appeals to be dealt with. So it can be helpful for Primary Care Trusts to begin planning for Christmas and Easter cover well in advance, for example, during the early summer.

### **Temporary failure**

- 3.194 Where a contractor is unable to comply with his obligations to provide pharmaceutical services, either because of illness or for other reasonable cause beyond his control, he is required, where it is practicable, to make arrangements with other contractors whose premises are situated in the neighbourhood for them to provide those services. It may only make these arrangements with an LPS chemist where these are of a similar description and extent to the pharmaceutical services that the contractor normally provides.
- 3.195 In any case where there is a temporary suspension of services, the contractor must notify the Primary Care Trust as soon as is practicable and must use all reasonable endeavours to resume the provision of

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pharmaceutical services as soon as is practicable (*Schedule 1 Part 3 paragraph 22 (9)*).

- 3.196 Planned refurbishment of a pharmacy is expressly excluded from what could be considered a reasonable cause or a reason beyond the control of a pharmacist for a temporary suspension. Contractors will need to ensure that planned refurbishment takes place in a way that does not disrupt continuity of service provision. (*Schedule 1 Part 3 paragraph 22 (10)*) However, Primary Care Trusts may, in appropriate circumstances, agree a temporary suspension of services for a set period where it has received three months' notice of the proposed suspension (*Schedule 1 Part 3 paragraph 22 (1)*).

## 4. Exemptions to the reformed regulatory test

### Introduction

- 4.1 Four categories of pharmacy applications are exempted from the reformed control of entry test. They are:

- **Pharmacies based in approved retail areas over 15,000 square metres gross floor space away from town centres. A list of these is on the Department of Health website.**
- **Pharmacies that intend to open for at least 100 hours per week**
- **Consortia establishing new One Stop Primary Care Centres**
- **Wholly mail-order or internet based pharmacy services**

- 4.2 It is not possible to make a single application which combines one type of exemption with another (e.g. an internet pharmacy and a 100 hours per week pharmacy). Applicants must identify the particular exemption category applied for. All such applications are still subject to such pharmacies providing a full and prescribed range of services, appropriate to local needs, determined by the Primary Care Trust. All exempted pharmacies must provide the full range of essential services under the new contractual framework (see Schedule 1: Part 2 to the Regulations). Primary Care Trusts may specify additional directed services for the first three categories of exemption. The four exemptions apply in both controlled and non-controlled localities. **However, where an application is received for premises within a controlled locality, the “prejudice test” will continue to apply (see Chapter 5 for more information on “prejudice”) unless the Primary Care Trust determines the locality of the premises relating to the application is a reserved location.** This is to meet the Government commitment to ensure no detrimental effect on services for those in rural areas.
- 4.3 Primary Care Trusts should note that these exemptions do not apply to applications in a neighbourhood in which local pharmaceutical services are (or are to be) provided (*regulation 13(1)*). Where this is the case, there must either be local pharmaceutical services being provided or definite plans for such provision – for example, proposals are at an advanced stage and the area for the provision of local pharmaceutical services has been designated.
- 4.4 The possibility that local pharmaceutical services (for example, the Primary Care Trust is considering inviting expressions of interest to set up a Local Pharmaceutical Services contract) may be provided at some stage in the future is insufficient for the exemption not to apply. However, it will apply where a pharmacy is already operating or is

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about to open as a Local Pharmaceutical Services contractor.. . Where a Primary Care Trust has designated an area under the LPS regulations, it may defer consideration of all applications, including exempt applications, until such time as the designation is withdrawn.

- 4.5 The proposed exempt premises must also be in the same neighbourhood in which designated local pharmaceutical services are or are to be provided. The local pharmaceutical contractor(s) do not have to have premises in the same neighbourhood but are providing services to that neighbourhood. If the proposed exempt premises are, then it is open to the applicant accordingly to withdraw his application or to amend it so that it is then considered under the reformed control of entry test. Primary Care Trusts may have established local pharmaceutical services across their entire area. In such cases, an exempt application cannot at present succeed. For more information on this, see the Cleveleys appeal case (number 13223, October 2006) on the FHSAA website at [www.fhsaa.nhs.uk](http://www.fhsaa.nhs.uk)

### Pharmacies based in large retail shopping areas over 15,000 sq m or more leasehold gross floor space away from town centres

#### Key points (*regulation 15*)

- Must be leasehold retail premises with 15,000 sq metres or more retail leasehold gross floor space
- Can apply to shopping centres, single retail premises or retail parks
- Must be away from a city, metropolitan or town centre primary shopping area – or a district centre which performs the function of a town, city or metropolitan centre
- Must not be on the edge of such centres (i.e. it must not have functional links to the primary retail area in those centres)
- Must be on a list of approved areas compiled by the Office of the Deputy Prime Minister and/or approved for inclusion by the Secretary of State
- Any party is able to request the inclusion or exclusion of a retail area on the approved list.

- 4.6 Changes in lifestyles, work and shopping patterns mean that many patients and consumers choose to visit larger shopping developments. They may find there is no or only one NHS pharmacy contractor available within such a development. If a development provides relatively self-contained facilities (i.e. shoppers visit retail outlets in that development but tend not to venture into adjacent neighbourhoods), access to pharmaceutical services by people choosing to visit the development may be restricted or there may be none available at all.

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- 4.7 Therefore, pharmacies wishing to provide services in shopping developments where the gross retail leasehold floor space is 15,000 sq. metres or more do not have to meet the requirements of the reformed regulatory test. The floor space minimum area requirement includes vacant retail premises and sales areas but does not include common areas such as pedestrian areas, corridors, stairs or car parks.
- 4.8 Provided they undertake to provide the full and prescribed range of services the Primary Care Trust requires of such exempted pharmacies (and provided other conditions are met – e.g. the contractor meets the “fitness to practise” requirements and other legal requirements for operating a pharmacy), the contractor shall be admitted to the Primary Care Trust list for the premises specified. There is no limit on the number of contractors who can apply in any such exempted retail area.
- 4.9 Such developments which are away from town centre sites include major regional shopping centres, retail warehouse parks and factory outlet centres. Most if not all such developments can be expected to have a number of retail outlets though it can include single outlet developments.
- 4.10 Developments of 15,000 sq metres or more retail leasehold gross floor space are likely to contain retail facilities which consumers from a wide catchment area visit purposefully and where they would find it convenient to have improved access to pharmaceutical services. Applicants who wish to set up in smaller developments will still be able to make use of other exemptions such as opening at least 100 hours a week or satisfying the reformed control of entry test.
- 4.11 The then Office of the Deputy Prime Minister<sup>19</sup> in collaboration with Government Offices for the Regions compiled a database of approved retail areas. The database included all current schemes and schemes under construction or due to open. A list of such shopping developments as approved by the Secretary of State for Health is available on the Department of Health website. This has been subject to further inclusions since April 2005. (*regulation 15(4)*).

### **Criteria for determining whether a development is exempted or not**

- 4.12 The overall criteria for determining whether a development is or is not within the terms of the exemption are in regulation 15. It must be:
- which comprises or is planned to comprise a discrete site or building which will be a shopping centre, retail park or retail premises
  - an area where the leasehold retail premises exceeds or will exceed 15,000 square metres or more leasehold gross floor space, and in

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<sup>19</sup> Now the Department for Communities and Local Government

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the case of retail parks, adjacent retail areas can also be taken into consideration

- not in a city, metropolitan or town centre or on the edge of such centres
- not in a district centre or on the edge of such a centre which performs the role of a city, metropolitan or town centre.

*(regulation 15(2) and (3))*

### **What is a development?**

- 4.13 For the purposes of this exemption, a development is a defined area, which can be self-contained and which can comprise one or more units/outlets within it that share common facilities such as car parks, communication links or pedestrian areas.

### **Type of retail development**

- 4.14 A retail development is a development within the “A” Use Class of the Town and Country Planning (Use Classes) Order 1987.

### **Location of the development**

- 4.15 The development must be out of town. It must not be within a town or similar centre or be closely linked to a town or similar centre (where reference is made to town centres below, the reference to similar centres should be taken as implicit). The reason for this is that consumers are likely to leave town centre shopping developments to shop elsewhere in the town centre. It would not be appropriate to treat pharmacies in town centre retail developments differently to those immediately adjacent to such developments or in the rest of the primary retail area or other parts of the town centre.

### **Determining whether a development included in or excluded from the list held by the Secretary of State is within a town centre or not**

- 4.16 Whether a development is within or close to a town centre is a matter of fact and particular local circumstances which are for the Secretary of State to determine based on advice received. The Department has worked with NHS Estates to determine an independent procedure for deciding whether a shopping development should be included – or should remain – on the list. Details of the procedure are on the Department’s website. Primary Care Trusts may be approached for help with the determination. It is difficult to lay down hard and fast rules to cover every eventuality but Primary Care Trusts may be asked for information along the lines of:
- Does the local authority development documents/local plans and planning applications identify a list of centres in its area (Primary

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Care Trusts should note this is not guaranteed)?

- Does the local authority development documents/plans and planning applications show the town centre and primary shopping area for the designated town centre?
  - How far is the shopping development from the edge of town centre or the edge of the primary shopping area? Does it form a functional part of that town centre? For example, are the two well-connected and integrated with, for example, common transport and communication links, such as car parks or pedestrian areas?
- 4.17 Primary Care Trusts should bear in mind that precise distances cannot be set down, as much will depend on local factors such as geographic and communication links which are matters of fact. However, as a guide, it is unlikely (though not impossible) that a retail development within 300 metres of the primary shopping area or a town centre would be included on the exempt list.
- 4.18 Whilst there is no standard definition of a "town", the term "town centre" as used here is as defined in national planning guidance. Further information on these terms is available at Annex F which contains extracts of policy guidance from the then Office of the Deputy Prime Minister (now the Department for Communities and Local Government).
- 4.19 The list of shopping developments has altered since April 2005 and may be subject to further change. In the event of any dispute as to whether a development should be included or not within the list, a party should first take this up with the Department of Health. The Department will then commission a report (unless this shopping development has already been reviewed and there are no material changes since the last review). Decisions by the Secretary of State as to whether a development is or is not exempted are reviewable by the Courts and therefore it is important that the Department of Health has a factual basis for the determination as with any other type of pharmacy application determination.
- 4.20 Where a Primary Care Trust receives an application for a shopping development which is on the approved retail area list, it should deal with the application as laid out below i.e. notifying interested parties, allowing 45 days for representations.
- 4.21 Where a Primary Care Trust receives an application concerning a development which is not on the approved list – or believes there may be reasons for a development already listed not to be exempt, they should notify Gillian Farnfield at the Department of Health immediately. The current telephone number is: 0207 972 2700, e-mail: [gillian.farnfield@dh.gsi.gov.uk](mailto:gillian.farnfield@dh.gsi.gov.uk). Similarly, applicants can request the Department review the status of the retail area prior to submitting an

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application. The Department will review the facts and may commission a report on the development before coming to a decision. The Department aims to complete this within 4 – 6 weeks of receiving the request.

- 4.22 Primary Care Trusts should note that they cannot grant any application under this exemption, unless the retail area is approved by the Secretary of State.
- 4.23 The Department will amend the list of exempted developments as necessary (generally when a new approved area is added to the list).

### *Applications*

- 4.24 Any number of pharmacies can be permitted to apply to open in such exempted developments. However, they will have to provide the full and prescribed range of services, appropriate to local needs which has been determined and specified by the Primary Care Trust.
- 4.25 Applicants can apply to the Primary Care Trust at any time after planning permission has been given. However, Primary Care Trusts should bear in mind that there might be planning law restrictions, or restrictive covenants between the retail site developer and retail companies, which limit the number of particular types of retailer which may open in such developments.
- 4.26 Such restrictions lie outside the scope of the Regulations and the reforms being introduced here. Provided all legal and professional conditions are met as to the services to be provided, the Primary Care Trust may nonetheless grant the applicant the right to provide services even though there is no immediate prospect that services will be available because of these other restrictions. The reason for this is that circumstances may change over time and such restrictions removed or amended.
- 4.27 For this and other reasons, Primary Care Trusts should not issue a notice to such an exempted pharmacy requiring them to commence provision of pharmaceutical services within a given period. However, the situation can arise where a pharmacy declares they are about to or have commenced provision of services and the Primary Care Trust includes them on the pharmaceutical list. If the pharmacy then remains unopened for six months, the Primary Care Trust has a discretion to remove him from the list under the procedure set out in regulation 45. More is explained about this process in Chapter 7.

## Pharmacies that intend to open for at least 100 hours per week

### Key points

- Typically 08.00 am to 22.30 pm Monday to Sunday
- Must meet the requirements of the Sunday Trading Act 1986 – but this has an exemption for pharmacies
- Primary Care Trusts may remove from the list if the pharmacy repeatedly fails to meet the terms of the exemption without good cause, or if a serious breach led to patient safety being put at serious risk (*regulation 13(2)(b)*).

- 4.28 Patients and consumers who, for whatever reason, are unable to access services during normal shopping hours may benefit particularly from pharmacies which intend to open for at least 100 hours per week. For example, people who work long or irregular hours, shift workers, or those who work in locations away from shopping areas where most pharmacies are found, may find it difficult to access pharmacy services during conventional shopping hours. Those pharmacies prepared to open longer hours and extend service provision should therefore be able to do so unencumbered by control of entry.
- 4.29 It is up to the applicant (not the Primary Care Trust) to specify the hours that they will provide pharmaceutical services. Typically, this could be 0800 – 2230 hours Monday to Sunday or it could be 1830 – 0900 Monday evening to Friday morning and all weekend from 1830 Friday to 0900 Monday. It is a condition of this exemption that the total contractual hours during which pharmaceutical services will be available are not less than 100. The usual 40 hours minimum does not apply.
- 4.30 Pharmacies which are part of larger stores (in excess of 280 square metres) will need to ensure that they comply with the requirements of the Sunday Trading Act 1986. Further details of this are on the Department of Trade and Industry website at [www.dti.gov.uk](http://www.dti.gov.uk) but in summary, unless the pharmacy can be accessed separately from the rest of the store, such stores can only open for a six-hour period on Sundays between 1000 and 1800 hours. If the pharmacy can be accessed separately to the rest of the store and is only available for the sale of pharmaceutical products, it can open outside these hours.
- 4.31 As with pharmacies in out of town shopping developments, the Primary Care Trust will be able to specify the full and prescribed range of services such pharmacies are to provide. Such pharmacies must fully meet all other legal and professional requirements, including ensuring a

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pharmacist is normally available for the hours at which the pharmacy is open.

### **Removal of such an exempted pharmacy from the list** (*regulation 13(2)(b)*)

- 4.32 It will be up to applicants when they apply to set out how they will provide information about their opening hours to enable monitoring and audit of service provision. This is because the Regulations include provision for a pharmacy to be removed from the pharmaceutical list and thereby lose the right to dispense NHS prescriptions where it fails, without good cause, to provide services consistently for at least 100 hours per week, or where there is a serious breach that puts patient safety at serious risk.
- 4.33 Under regulations 45(8) and 13(2)(b), Primary Care Trusts shall remove a chemist for breach of the 100 hours requirement where the chemist has repeatedly breached the condition. They shall also remove them if they are likely to breach the condition repeatedly without good cause or the breach is in all the circumstances a serious breach and consequently, the safety of a patient is at serious risk. Such decisions are appealable.
- 4.34 Determining what constitutes “good cause” will vary according to the facts of a given case. Primary Care Trusts have discretion here. However, it is important that Primary Care Trusts follow the same requirements as to “bias” and “fairness” as set out in Chapter 3 above. In particular, Primary Care Trusts should follow good administrative practice and provide documented evidence and reasoning for their decisions.
- 4.35 For example, it may be unreasonable to remove or threaten to remove a contractor from the list if the contractor fails to staff a pharmacy for at least 100 hours one week in the first three months of trading owing to pharmacist recruitment problems but undertakes to have this dealt with within a set period which is reasonable in the circumstances.
- 4.36 Equally, it may be unreasonable or unjust to remove or to threaten removal of the contractor or premises from the list if the pharmacy has failed to meet the terms of the exemption because of circumstances beyond its control (e.g. fire, condemned premises). However, in these circumstances, it would be reasonable for the Primary Care Trust to require the contractor to recommence provision of services at the premises within a given period and as agreed between the Primary Care Trust and the contractor or the pharmacy will then face the possibility of removal.
- 4.37 The procedure to be followed is set out in regulation 45 of the Regulations. The Primary Care Trust will need to give the contractor 28 days notice of its intention and the contractor has a right to make representations. The Primary Care Trust must also consult the Local

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Pharmaceutical Committee and if a decision is taken to remove, there are rights of appeal.

- 4.38 In all these circumstances, it is essential that Primary Care Trusts have adequate documentary evidence that the contractor is not providing services within the terms of the exemption. That is why the model application form at Annex D asks applicants how they will verify to the Primary Care Trust the information as to their actual opening hours. It is up to the Primary Care Trust to be satisfied these meet their requirements. Primary Care Trusts can ask such contractors to notify them monthly or at other periods of the actual times the pharmacy has been open. Primary Care Trusts have this power under paragraph 37(3)(b) of Schedule 1 to the regulations. The Primary Care Trust can also consider any patient complaints about the availability of services, or evidence from other local bodies such as Patient Forums and the Local Pharmaceutical Committee concerned.

### **Consortia wishing to establish new One Stop Primary Care Centres**

#### **Definition of a One Stop Primary Care Centre for the purposes of this exemption (*regulation 16*)**

A discrete site or building

- at which the services of a broad range of health care professionals is or will be regularly and frequently provided, together where appropriate with other health or social services ( for these purposes, a "health care professional" means essentially the professions that are subject to statutory regulations: nurses, including community nurses such as district nurses; midwives; dentists, physiotherapists, pharmacists, optometrists, etc)
- at which there is or will be one or more provider(s) of primary medical services with a patient list which comprises or which together comprise of at least 18,000 patients
- which is under the management or control of a consortium.

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### Key points (*regulation 16*)

- Must be part of the Primary Care Trust's Strategic Service Development Plan (SSDP) or written equivalent and included for the first time **on or after 1 April 2005** (*regulation 16(1)*)
- Such centres bring together a range of facilities for primary and community services and can include social services (*regulation 16(1) (a) and (b)*)
- Must provide a broad range of services to a primary medical services list or lists of 18,000 patients or more (*regulation 16(2)(a) and (b)*)
- Does not apply to centres agreed and included on the SSDP or written equivalent before 1 April 2005, unless there is substantial new development or redevelopment after 1 April 2005
- Pharmacies do not have to be part of the consortium but the centre must be under the control or management of a consortium (for a definition of consortium see regulation 16(2)(e)) – 4.49 below.
- The consortium must have agreed articles of association (*regulation 16(2)(c)*)
- This definition of a consortium used in this context is not to be confused with a consortium of pharmacists getting together to provide, for example, services to a health centre on a rota basis.

4.39 One stop primary care centres bring together on the same site a range of facilities for primary and community services (and where desired, social services) to provide more convenient patient access, integrated service delivery and hence better healthcare provision.

4.40 Exempting applications from consortia wishing to provide pharmacy services as part of a one stop primary care centre will remove an additional hurdle from the development process. Such consortia will therefore be freed from the uncertainty of knowing whether an application is likely to be successful or not. As with other exempted applications, conditions attach to the exemption and Primary Care Trusts will retain the ability to influence local pharmacy provision and the services provided by pharmacies within such centres.

4.41 Further information about the types of one-stop primary care centres is at Annex A.

### Criteria for the exemption

4.42 In order to be exempted from the reformed control of entry test, applications using this exemption will need to demonstrate that the (proposed) one stop primary care centre:

- was included in the Primary Care Trust's SSDP or written equivalent on or after 1 April 2005 (*regulation 16(1)*);

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- meets the requirements to be treated as such a centre – i.e. it provides or proposes to provide a regular and broad range of services of health care professionals. This may include GP and related practice team services, together with services provided by NHS trusts in the community and other primary care practitioner services such as dentistry, optometry, podiatry, physiotherapy as well as a pharmacy service. The proposed centre may also comprise other community based health or social services. Services must be provided for the first time on or after 1 April 2005, whether at a new or redeveloped centre (*regulation 16(3)*);
  - offers these services to a substantial patient list (at which there is or will be a provider or providers of primary medical services of at least 18,000 patients at the centre when it opens or is granted the exemption whichever is sooner). Where there is a subsequent fall in the number of patients listed after the pharmacy has opened, the pharmacy should not be removed automatically from the pharmaceutical list (*regulation 16(2)*);
  - provides such services on a frequent, regular and continuous basis.
- 4.43 The centre does not have to be on a single site and can include “campus” site arrangements where facilities are spread over a defined area.
- 4.44 What constitutes a broad range of service provision at such centres will be a question of fact and degree according to prevailing local circumstances. *It should not comprise a few ad hoc services provided on an irregular or occasional basis.* However, it should not preclude a range of providers who offer services on an infrequent or part-time basis that collectively amounts to a broad range of services, regularly and frequently provided. In summary, the range of services provided should be of a variety and extent considerably above that a patient would expect of a usual GP surgery.
- 4.45 If the one stop primary care centre in question has been identified or named in an SSDP prior to 1 April 2005 then this exemption cannot apply. This was to protect existing centres and NHS LIFT schemes which had been agreed prior to that date. However, where an SSDP only identified a need for such a centre generally, or said there were plans for such a centre, prior to 1 April 2005, without specifying its location then the exemption can continue to apply.
- 4.46 The question of what hours an exempted pharmacy is normally open is for the Primary Care Trust and the applicant to agree within the requirements set out in the Regulations, i.e. normally 40 contracted hours, unless the Primary Care Trust agrees to fewer or directs more. The Primary Care Trust will wish to ensure that patients who use the primary care centre have adequate access to the pharmaceutical services the Primary Care Trust requires the pharmacy to provide at

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times patients are likely to need. That may mean the pharmacy is open earlier or later as needs dictate.

### *Minor relocations and this exemption*

- 4.47 Where a Primary Care Trust receives applications for example from neighbouring chemists within 500 metres of the one stop primary care centre to move to these premises under the automatic minor relocation provisions, the Primary Care Trust should grant these applications provided they meet the criteria for such a minor relocation. If the applicant does not secure premises in the new one stop centre then the grant of the minor relocation will lapse after six months (or nine months if granted a further extension of three months)..

### **Duties of the Primary Care Trust in relation to NHS LIFT schemes**

- 4.48 In considering such applications which relate to local NHS LIFT schemes, Primary Care Trusts will need to ensure they act with utmost probity where they are party to a consortium which applies for the exemption or a PCTMS provider and ensure there is no undue influence or bias in determining such applications. The Primary Care Trust's responsibilities in terms of the local NHS LIFT scheme they are a party to will be set out in that agreement.

### **Consortia**

- 4.49 The Regulations state that the definition of consortium is **“an association of persons or undertakings carrying on a business together with a single management and equity structure and agreed written articles of association which commit them to running a one stop primary care centre”** (*regulation 16(2)(c)*).
- 4.50 In this instance, a consortium may involve a range of parties, including the NHS, other local health care providers, or finance or venture capital companies.
- 4.51 The members of a consortium do not have to include a pharmacy contractor but can do so. The applicant does not have to be a pharmacy contractor, but will have to comply with the requirements regarding the Medicines Act 1968 (see Chapter 3 above). Therefore, the consortium will need to engage a body corporate pharmacy contractor or group of pharmacists who are able to meet the legal and professional requirements for running a pharmacy. So it is sensible for such consortia to have determined which contractor or contractors are to provide pharmaceutical services at the centre before making the application. The preferred pharmacy partner then makes the application on behalf of the consortium.
- 4.52 Equally, pharmacies can also establish their own consortium to promote a new centre but there is no automatic right for such groupings

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to have “first refusal” as to who is to be contracted to provide a pharmacy service.

- 4.53 For a consortium setting up a new one stop centre, the grouping is likely to be of a permanent or long-standing nature (but allowing parties to leave or join) and, by way of formal association or agreement, to set out the specific responsibilities of the parties to the consortium, such as the provision of finance or services or distribution of equity, and have suitable governance arrangements. To protect ongoing provision of NHS services, a consortium could not be deemed such by way of an informal or oral agreement between the parties. It has to be defined and the terms and conditions of the association clearly spelt out. Primary Care Trusts should assure themselves that consortia making applications have their terms of association clearly defined and accepted by all parties to the consortia.

### Range of services to be provided

- 4.54 For

- pharmacies based in leasehold premises in large shopping developments away from town or similar centres with more than 15,000 sq. metres or more retail leasehold gross floor space;
- pharmacies providing services of at least 100 hours per week; and
- consortia set up to establish new one stop primary care centres

these exemptions from the reformed test will only be available where such pharmacies provide a full and prescribed range of services, appropriate to local needs as determined by the Primary Care Trust. In addition, such pharmacies must be prepared to offer these services from the day they are admitted to the pharmaceutical list. There is no “transitional” period as applies to existing contractors.

- 4.55 Primary Care Trusts will therefore need to be able to determine – and publicise - which services are to be provided over and above essential services. Primary Care Trusts will most probably use their **pharmaceutical needs assessments** to draw on the range of advanced and local enhanced services in the new contractual framework in order to determine which services are to be provided. Both local enhanced and advanced services are directed services within the Regulations. It is therefore open to Primary Care Trusts to specify either or both in their service requirements (*regulation 13(3)*).
- 4.56 Primary Care Trusts should note that if they have not established in advance of receiving an application the services required of such an exempted pharmacy, then the applicant need only undertake to provide the essential services specified under the new framework, to be admitted to the pharmaceutical list.

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- 4.57 In determining the services to be provided, Primary Care Trusts should act fairly and objectively. The needs assessment will help provide the factual basis for the services which are required. Primary Care Trusts have considerable discretion as to what services are to be provided but they must at all times act reasonably. For example, it may be unreasonable to require an out of town shopping development pharmacy to provide substance misuse services if the patients concerned are unlikely to make use of such a facility. However, it may be reasonable for such a pharmacy to provide access to emergency hormonal contraception services.
- 4.58 Whilst Primary Care Trusts can designate different services to be provided by different types of exempted pharmacy, Primary Care Trusts should be cautious in differentiating the services pharmacies which use the same exemption are to provide. Therefore, it should be expected that a pharmacy opening at least 100 hours a week in one locality will be required to provide the same services as a pharmacy opening at least 100 hours a week in a different locality within the Primary Care Trust area. Primary Care Trusts are, however, at liberty to specify – as long as this remains reasonable and evidence-based – the total range of directed services pharmacies using the same exemption are to provide but not commission some of these until such time as the Primary Care Trust judges that the need for such services within the area the pharmacy is located is sufficient.
- 4.59 For example, a Primary Care Trust's pharmaceutical needs assessment may have determined that pharmacies in three shopping developments over 15,000 sq metres or more retail leasehold gross floor space within its area should provide an emergency hormonal contraception service. However, it does not wish to commission this service yet in respect of one out of the three shopping developments as the needs assessment has only identified a requirement for such a service at the other two developments.
- 4.60 Primary Care Trusts can, and probably will, wish to amend the services exempted pharmacies are to provide in the light of experience and changing patient need. However, they may only add additional directed services where this is at the request of the pharmacy or under the normal commissioning arrangements for directed services. Pharmacies which have set up already using one of the exemptions can not be required to provide these revised services but it is open to the contractor and the Primary Care Trust to agree which ones it will provide (and any the Primary Care Trust and the contractor wish to drop) as a consequence of the revision.
- 4.61 The Regulations state that a contractor can only apply for a variation after three years have elapsed or he has not been required to provide the directed services originally required of him by the Primary Care Trust (*regulation 14*). Primary Care Trusts should determine such applications within 60 days, and can confirm the same, different or no

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directed services (*regulation 14(3)*). Where it specifies different or no directed services it must consult the Local Pharmaceutical Committee first. As with conventional applications the Primary Care Trust should notify the reasons for its decision to the contractor where it refuses or only partially grants the application. Decisions are appealable and similar procedures apply as for conventional appeals.

### Change in circumstances for an exemption

- 4.62 Primary Care Trusts should note the provisions for removing a pharmacy which fails to meet the requirements of the exemptions below. If circumstances change – for example a shopping development no longer meets the criteria for the exemption – prior decisions about granting applications remain valid. However, future applications would have to be dealt with under the reformed control of entry test and not as an exempt application.

### Wholly mail order or internet based (distance-selling) pharmacy services (*regulation 13(1)(d)*)

#### Key points

- Must provide the full range of NHS pharmacy services determined nationally
- Must be registered with Royal Pharmaceutical Society of Great Britain
- Must have premises within the Primary Care Trust area
- Must not provide “face to face” NHS services (but can do so privately)

- 4.63 The reason for this exemption from control of entry is that a wholly mail order or internet-based pharmacy can face obstacles in meeting the “adequacy” test. Previously, businesses providing such services did so from established premises. A new applicant for such a pharmacy would face difficulty in proving a need for a purely postal (in the case of mail order) or remote delivery (in the case of internet-based) pharmacy service by reference to the immediate vicinity in which it proposed to locate. Demand would likely be very small. Patients drawn from a much wider catchment area, however, may well value such a service offering both improved convenience and choice.
- 4.64 The Regulations define such a pharmacy as “premises at which essential services are to be provided but the means of providing those services are such that all persons receiving them do so otherwise than at those premises (“distance selling premises”)” (*regulation 13(1)(d)*).
- 4.65 Otherwise, there is no definition of an “internet pharmacy” in law. In effect, an internet-based pharmacy is a registered pharmacy business that operates like any mail-order company in that it receives and fulfils

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orders for medicines “remotely” from a patient or customer rather than face to face as in a traditional pharmacy.

- 4.66 Thus, to qualify for this exemption, a wholly mail order or internet-based pharmacy must not provide NHS services direct to patients or customers on the premises. It may, however, sell or supply goods which are not NHS-related.
- 4.67 The Regulations also provide that Primary Care Trusts shall refuse applications if the premises to which the application relates are on the same site or in the same building as a provider of primary medical services with a patient list. This is one of the safeguards promised in connection with this exemption to avoid circumstances arising where patients inadvertently might present prescriptions for dispensing if such facilities were available (*regulation 17*).
- 4.68 As with traditional retail pharmacies, wholly mail order or internet based pharmacies must have premises which are registered with the Royal Pharmaceutical Society of Great Britain (RPSGB). All pharmacies, whether or not they provide online services, are subject to the same statutory requirements. The current edition of the Royal Pharmaceutical Society of Great Britain’s Code of Ethics and Standards<sup>20</sup> sets out further professional standards regarding remote delivery and on-line pharmacy services. These cover issues such as safe and secure transportation and delivery, confidentiality, provision of advice and record keeping.
- 4.69 All such pharmacies must be admitted to the pharmaceutical list of the Primary Care Trust in which the premises are located to provide NHS services.
- 4.70 All such pharmacies will also need to provide the complete range of essential services as set out in the new NHS contractual framework. However, the means of delivery of such services may vary from traditional shop-front pharmacies. Such pharmacies must be available for the 40 core contractual hours though many may be available for longer.
- 4.71 Therefore, as with pharmacies open for at least 100 hours a week, it will be the responsibility of the applicant to set out how they will provide all the essential services. Primary Care Trusts should also set up adequate arrangements for ensuring such pharmacies are not providing traditional NHS services in addition from shop-front premises.
- 4.72 It is open to the Primary Care Trust to contract with such pharmacies for the provision of directed pharmaceutical services which can be provided face-to-face.

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<sup>20</sup> See Section 2 Part 3 of *Medicines, Ethics and Practice – Number 30, July 2006* - Royal Pharmaceutical Society of Great Britain, London. This Code is updated annually.

## **Dealing with applications for exemptions**

- 4.73 As with non-exempted applications, the Medicines Act 1968 restricts the ownership of pharmacies to pharmacists, partnerships of pharmacists and bodies corporate. Primary Care Trusts should reject forthwith any applications to run wholly mail order or internet-based pharmacies from individuals who are:
- not pharmacists;
  - from partnerships which do not consist wholly of pharmacists;
  - bodies corporate which do not meet the requirements of the Medicines Act; or
  - consortia in one stop primary care centres that do not fall under the proper definition (see above).
- 4.74 Those wishing to apply for any of the four exemptions should provide the relevant information set out in Schedule 4 of the Regulations.
- 4.75 Primary Care Trusts should **notify** the same organisations and people of applications for an exemption as set out in paragraph 3.92 above and give 45 days for any representations. This is to enable sufficient time to check and verify the details of the application against the relevant criteria for the exemption. If applicants demonstrate that they are intending to provide the full and prescribed range of services and sign the relevant declarations, and satisfactorily meet other requirements regarding “fitness to practise”, Primary Care Trusts shall grant the application. For the wholly mail order and internet based pharmacy applications, it is sufficient to notify the usual organisations and people within the Primary Care Trust area and nearest neighbouring Primary Care Trust as well as the other organisations listed in Chapter 3.
- 4.76 Applicants should inform Primary Care Trusts as soon as possible of their trading address if this is not already known and before any commencement of services.
- 4.77 For pharmacy applications in large retail developments of 15,000 sq m or more retail leasehold gross floor space, Primary Care Trusts should assure themselves that the development is an exempted development as described above and included in the list held by the Secretary of State.
- 4.78 Primary Care Trusts should notify the Local Medical and Local Pharmaceutical Committees and other interested bodies of the granting of applications for all such exempted pharmacies. The list is the same as in paragraph 3.145 above. It is open to, for example, Local Pharmaceutical Committees to circulate details of internet applications more widely if they wish to do so, though those circulated may not have rights of representation.

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- 4.79 Primary Care Trusts should notify exempted applicants of their decision within four months as with a normal application. This period may be extended where there is good cause – for example, the Primary Care Trust has requested details of the consortia applying in respect of a one stop primary care centre and this information is not immediately available or the application is for a large shopping development not on the list held by Secretary of State.
- 4.80 Successful applicants for inclusion in a pharmaceutical list have six months from the date of the notification of the decision on the full application or the date of notification of an appeal decision in their favour in which to begin the provision of pharmaceutical services. The Primary Care Trust may extend the period which in total may not exceed a further three months (exclusive of the six months) if the applicants can show good cause why they should do so (for example substantial rebuilding or renovation) (*regulation 39(2)*). In cases where a shopping development or one stop primary care centre is not yet available, or where the premises are available but the applicant has not commenced provision of services, the application will lapse at the end of nine months. The applicant may submit a further application.
- 4.81 Applicants have a right to appeal under regulation 29 against a Primary Care Trust's decision not to grant an application which uses one of the exemptions. If an exemption application is rejected by the Primary Care Trust because it does not meet the criteria for the exemption, applicants can still apply under the "reformed control of entry" test as outlined in Chapter 3. Alternatively Primary Care Trusts will wish to note that where there is no direct right of appeal against their decision (for example, including a one stop primary care centre in a Strategic Service Development Plan), the other remedy available is to seek a judicial review of the Trust's determination. Primary Care Trusts should therefore ensure as much information as possible is included in the determination as to the facts, reasons and subsequent decision.
- 4.82 Where an exempt applicant is successful, there is a 30-day waiting period from the day following the date of grant before the provision of services can begin, to allow for any appeals. However, here only the applicant has a right of appeal. Under an amendment to regulation 39 effective from 19 January 2007, this 30-day period can be reduced by the Primary Care Trust where there is good cause. An example of where this might be applied is where the exempt applicant confirms to the Primary Care Trust they will not appeal and wish to begin providing services sooner.
- 4.83 Otherwise, the procedures for an appeal are the same as for a conventional application – see Chapter 3 above.

## Circumstances under which Primary Care Trusts can remove an exempted pharmacy

- 4.84 Once a chemist is accepted onto the pharmaceutical list, the Primary Care Trust has defined powers to remove persons from the list. These are outlined in Chapter 7.
- 4.85 If a chemist has been accepted onto a pharmaceutical list through an exemption, Primary Care Trusts can remove from the pharmaceutical list for failure to comply with the terms of the exemption, where that case can be brought as an efficiency case or an unsuitability case. In addition, Primary Care Trusts shall remove a pharmacy from a list under regulation 45 (8) for the following reasons:
- the pharmacy has repeatedly failed, without good cause, to provide services consistently for at least 100 hours per week;
  - pharmacies who have applied under the wholly mail order internet-based pharmacy services exemption are also providing NHS pharmaceutical services “face to face” or over the counter.

## Procedure for removing an exempted pharmacy from the list.

- 4.86 Where a Primary Care Trust determines to remove an exempted chemist from the list under regulation 45, it
- must first give 28 days’ notice of this intention to the chemist and provide reasons;
  - must give the chemist the opportunity to make representations in writing, or at his/her option, orally; and
  - must consult the Local Pharmaceutical Committee and may consult other local representative groups
- 4.87 This regulation does not mean that the pharmacist will automatically come off the list after the 28-day period has expired. This event will only occur if, in the exercise of its discretion after the 28-day period is over, the Primary Care Trust decides to remove his/her name.
- 4.88 Any decision under the above is to be notified in writing to the chemist. The chemist will remain on the list until the expiry of the 30-day period for appeal, or, if an appeal is made, until the final determination of the appeal.

## Appeal (*regulation 29*)

- 4.89 A chemist so notified has a right of appeal to the Appeal Unit. The appeal must be in writing and set out the grounds of appeal and be

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lodged within 30 days. If the appeal is allowed, the chemist may not be removed from the list.

- 4.90 The mere fact that a chemist has been taken off the list is not to prejudice his/her right to be included again in the list. There are specific additional safeguards in regulation 45 (16) where a chemist is undertaking "relevant service" for example as a member of the armed forces.

## 5. Entry onto a pharmaceutical list: special provisions – controlled localities

### Introduction

- 5.1 There are two separate issues which relate to “controlled localities”. The first is whether a particular area is, in fact, within a controlled locality. The second relates to special provisions for applying for entry to the pharmaceutical list which operate in relation to controlled localities.
- 5.2 The overall objective of defining rural areas as controlled localities under the Regulations is to help Primary Care Trusts ensure that patients in rural areas have access to pharmaceutical services which are no less adequate than would be the case in non-controlled localities.

### Main changes in relation to rurality and the application of the control of entry test in rural areas

- 5.3 Whilst the underlying principles relating to rural areas remained unaltered, a number of measures were introduced from 1 April 2005 to the previous regulatory system to reform the rules governing NHS rural dispensing. These are listed below:

#### Summary of changes:

- To provide that Primary Care Trusts should notify pharmacists and doctors (and not just Local Representative Committees) of rural applications and give them a right of appeal.
- To regularise the rules so that pharmacy contractors already on the Primary Care Trust’s pharmaceutical list must also satisfy the “prejudice test” as would any new applicants.
- To regularise the rules so that all applications from dispensing GPs must satisfy the “prejudice test” (see Chapter 6).
- To introduce a new concept of “reserved location” i.e. where the number of patients on medical lists within the designated area is less than 2,750. If a pharmacy decided to open, it would not have the usual protection that patients of dispensing doctors within 1.6 km of the new pharmacy would no longer be able to receive dispensing services from those doctors. This allows those patients who wish to continue to receive dispensing services from their doctor to continue to do so.

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- To introduce a new concept of “premises approval” in addition to outline consent so that a Primary Care Trust approves the particular premises from which a doctor is permitted to dispense (see Chapter 6)
- A GP’s application for outline consent (and any premises approval) to dispense is to be refused if the doctor’s premises are within 1.6 km of an existing pharmacy - see Chapter 6. This includes cases where a doctor applies for outline consent and premises approval in a new location and the Primary Care Trust grants provisional approval pending outstanding pharmacy applications in that area (this gives an existing pharmacy operating close to the existing premises an opportunity to move with the GPs). However, this only applies to pharmacy applications received by the Primary Care Trust by the day before outline consent is granted.
- To improve the way the regulations work regarding the arrangements for the grant of preliminary consent in rural areas.
- To amend the regulations so that if doctors want to change the premises from which they dispense, or to dispense from new premises, the “prejudice test” applies unless the move is a relocation of less than 500 metres, there is otherwise no significant change in arrangements for pharmaceutical or dispensing services, or there are exceptional circumstances which lead the Primary Care Trust to conclude that the GPs should be permitted temporarily to dispense in order to secure the adequate provision of pharmaceutical services (see Chapter 6).
- From 19 January 2007, the need to consider, when determining applications, whether the issue of “reserved location” arises, only applies to applications from chemists.
- To amend the regulations so that if a non-dispensing doctor amalgamates or, since 19 January 2007, has amalgamated his or her practice with that of a dispensing doctor, a fresh application for outline consent needs to be made, applying the “prejudice test” (see Chapter 6).

### Background

- 5.4 The Advisory Group on the Reform of the NHS (Pharmaceutical Services) Regulations 1992 was asked to consider work already developed to reform and implement the rules governing rural dispensing in the light of the Government’s response to the Office of Fair Trading and Health Select Committee’s 5th report. This came from an agreement between the Pharmaceutical Services Negotiating Committee (PSNC), the General Practitioners Committee of the British

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Medical Association (GPC) and the Dispensing Doctors' Association (DDA) originally concluded in 2001.

- 5.5 The representative bodies re-examined their pre-existing joint proposals taking into account the commitment to introduce more competition and choice to the regulatory system as a whole and presented their findings to the Advisory Group. The Group's recommendations regarding these proposals are in Chapter 5 of their full report available at <http://www.dh.gov.uk/assetRoot/04/10/62/91/04106291.pdf>
- 5.6 The over-riding principle with these amendments is to improve access to and the quality of pharmaceutical services for patients in rural areas by encouraging new services, whilst retaining the existing choice of patients to receive medicines from their GPs. It is hoped they will improve inter-professional relationships and resolve a number of administrative difficulties within the present system as it applies in rural areas.

### Determination of rurality

#### Definition of a "controlled locality"

- 5.7 A "controlled locality" is an area which has been determined, either by a Primary Care Trust or on appeal by the Appeal Unit, to be "rural in character". Special rules relate to the provision of pharmaceutical services in such areas.

#### Deciding whether an area is a controlled locality (*regulation 31*)

- 5.8 In many cases, this should not be a problem. Primary Care Trusts are required to have maps with areas which have been determined as rural in character clearly delineated on them (*regulation 31(7)(b)*). This carried forward a commitment under the previous 1992 Regulations. If there has been no substantial change of circumstances, such maps will show which areas have been determined as rural and therefore controlled localities. It is important that the boundaries of such areas should be clearly marked, using appropriate geographical markers, not simply the squared off grid markings overprinted on Ordnance Survey maps. They should also be at a sufficient level of detail to enable any enquirer to tell whether any particular location falls within a controlled locality or not. Other areas are, by definition, not rural areas until they have been determined as such.
- 5.9 Primary Care Trusts should publish maps of their controlled localities (*regulation 31(7)(b)*).
- 5.10 In addition, changes can occur to the appropriate designation of an area, particularly where an urban area is expanding into the surrounding countryside, or where there has been a substantial

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development permitted in what has hitherto been a controlled locality. The reverse is much rarer but can happen for example where an industrial area in the country (e.g. mining) ceases. When determining questions of rurality, **it is essential** that Primary Care Trusts undertake site visits.

- 5.11 If there are no maps showing defined controlled localities available or there is doubt that an area is rural, the Primary Care Trust will have to follow the procedures set out below. Where that applies, they should not take any further action on an application until those notified who wish to make representations have had the opportunity to do so or the Appeal Unit has decided an appeal.

### What makes an area rural?

- 5.12 The factors that might be considered include, for example:
- environmental – the balance between different types of land use;
  - employment patterns (bearing in mind that those who live in rural areas may not work there);
  - the size of the community and distance between settlements;
  - the overall population density;
  - transportation – the availability or otherwise of public transport and the frequency of such provision including access to services such as shopping facilities;
  - the provision of other facilities, such as recreational and entertainment facilities. A rural area is normally characterised by a limited range of local services.
- 5.13 None of the above will automatically determine the matter. For example, the expansion of housing provision may also be an indication that the status of the area should be reconsidered, but of itself will not necessarily change that status. That will remain a question of judgement.
- 5.14 Therefore, rurality is not something which can be subject to rules such as density or distribution of population or the number of trees – it is essentially a matter of common sense. However, experience has shown that photographs and documents are an unreliable basis for determining rural questions. Judgment will need to depend on local knowledge of the area. A rural area need not have a high level of agricultural employment; many residents may commute to jobs in local towns.
- 5.15 Primary Care Trusts should be aware of misconceptions about rurality. The fact that an area is not classified as controlled, or that a decision is taken to remove such a classification, does not necessarily mean that it is urban.

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- 5.16 A Primary Care Trust can consider and determine the question of whether an area is a controlled locality at any time, on its own initiative (*regulation 31(2)*).
- 5.17 The question of whether an area is a controlled locality may also be raised at any time by a Local Pharmaceutical Committee or a Local Medical Committee. Either of these bodies may apply in writing to the Primary Care Trust, asking it to consider and determine whether the area specified in the application or any part of it is rural in character (*regulation 31(3)*).
- 5.18 However, once taken, a decision on the rurality of an area cannot be reconsidered in relation to that area or any part of it for five years from the date of the determination unless the Primary Care Trust is satisfied that there has been a **substantial change of circumstances** to the area in question, or the relevant part thereof, since the question was last decided (*regulation 31(11)*).
- 5.19 Before making any determination, the Primary Care Trust is required by the Regulations to give written notice to:
- (a) the Local Pharmaceutical Committee
  - (b) the Local Medical Committee
- plus
- (c) any provider of primary medical services; and
  - (d) any chemist or LPS chemist
- who the Primary Care Trust decides may be affected by the determination.
- The notice must state that they may make written representations within 30 days from the date on which the notice was sent (*regulation 31(5)*).
- 5.20 The regulations also, logically, provide that any area forming part of an area referred to in an application which is determined not to be rural in character, shall not be a controlled locality. Similarly, if part of an area mentioned in an application was once rural in character but the decision is that it no longer has that character, it shall cease to be a controlled locality.
- 5.21 Areas that are not already delineated as controlled, or have not been referred to in an application and thus not subject to a formal determination, however, are not controlled localities until the Primary Care Trust decides they are. Such areas may meet the criteria for being considered as rural but are not a controlled locality until so determined by the Primary Care Trust.

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- 5.22 Even though a decision on the rurality of an area may have been taken, the Primary Care Trust should not take any steps in relation to that decision during the period for bringing an appeal against that decision, or, where an appeal is made, pending the determination of the appeal (*regulation 31(9)*). Appellants have 30 days in which to appeal.
- 5.23 The Regulations provide that the Primary Care Trust must notify, in writing the outcome of its decision, provide a statement of reasons for the decision and their rights of appeal (*regulation 31(12)*) to:
- (a) the Local Pharmaceutical Committee
  - (b) the Local Medical Committee
- plus
- (c) any provider of primary medical services; and
  - (d) any chemist or LPS chemist

who the Primary Care Trust decides may be affected by the determination.

### **Appeals**

- 5.24 All those notified of the determination have the right to appeal a decision on rurality, or a refusal to decide the question, or a decision to postpone (or not, as the case may be) the making or determination of arrangements (*regulation 32(1)*).
- 5.25 The Appeal Unit handles such appeals on behalf of the Secretary of State and the procedures are broadly the same as apply to the system set out in Chapter 3. A notice of appeal is to be sent to the Appeal Unit within 30 days of the date on which the Primary Care Trust decision was sent. The notice must state, concisely, the grounds for appeal (*regulation 32(2)*).
- 5.26 The Appeal Unit must, at once, send a copy of the notice of appeal to the Primary Care Trust that made the original decision, and to all the other parties to whom notice of the original decision was sent (*regulation 32(3)*).
- 5.27 Before reaching a decision, the Appeal Unit may require an oral hearing to be held. Where this is to happen, one or more persons are appointed to hear the appeal and report to the Appeal Unit. The procedure for the hearing is to be determined by the person(s) so appointed (*regulation 32(5)-(7)*).
- 5.28 Any oral hearing will take place where and when the Appeal Unit directs. Notice of the hearing is to be sent to the appellant and any person to whom a copy of the notice of appeal was sent not less than fourteen days before the date fixed for the hearing (*regulation 32(8)*).

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- 5.29 The appellant and any other person to whom notice of the hearing was sent may attend the hearing and be heard in person, or by counsel, solicitor or representative. The Primary Care Trust that made the decision may also be represented by any duly authorised officer or member, or by counsel or solicitor (*regulation 32(9)*).
- 5.30 Whether or not there has been an oral hearing, the Appeal Unit must clearly reach its own decision.
- 5.31 If the Appeal Unit decides to allow an appeal against a refusal to consider a question on whether an area is rural in character within the normal five year period, it must also itself determine the substantive question on the rurality of the area in question (*regulation 32(10)*).
- 5.32 Once a decision has been reached by the Appeal Unit, it must send written notice of that decision, together with its reasons for it, to all the parties to whom the notice of appeal was initially sent (*regulation 32(11)*).

### **Applications for inclusion in a pharmaceutical list in respect of controlled localities**

#### **Initial procedures**

- 5.33 Applications for inclusion in the pharmaceutical list in respect of controlled localities must be made in a similar manner to non-controlled localities (see model application form in Annex D). On receipt of these applications, Primary Care Trusts should check whether the application relates to a rural controlled locality. Similarly, Primary Care Trusts should check whether applications which are for premises in a non-controlled area are within 1.6km of a controlled locality or check with their neighbouring Primary Care Trust if boundaries are close to the location of the proposed premises.
- 5.34 Where an applicant is seeking only to change within the controlled locality the premises at which he provides pharmaceutical services; and the Primary Care Trust is of the view that the granting of the arrangement would not result in a significant change in the arrangements for the provision of pharmaceutical services in any part of the controlled locality, the application must be treated as if it was not an application within a controlled locality (*regulation 22(1) and (2)(b)*). If it is an application for a minor relocation, it should be dealt with in accordance with regulation 6 or 7 as appropriate.
- 5.35 What will or will not amount to a significant change is a judgmental issue for decision-makers to determine. By way of guidance, the kinds of question that might be taken into account in deciding the issue are:

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- what would be the impact of the proposed change on the population served under the present arrangements?
  - are the new premises as accessible for those who wish to use them as the original ones were? (if so, there may be no significant change)
  - will there be a serious deterioration in accessibility? (If so, there may well be a significant change.)
- 5.36 The question of accessibility should not be measured solely in terms of distance, but also by taking factors such as the availability of public and other modes of transport into account as well.
- 5.37 If an application for a pharmacy is in a controlled locality, the Primary Care Trust must decline to consider it as an application within a controlled locality to the extent that:
- the application is for preliminary or, since 19 January 2007, for full consent and the location of the premises applied for is within a locality in respect of which any provider of primary medical services has finally been granted outline consent in the five years prior to the date of the application (*regulation 34(1)(b)(i) as amended*).
  - the application is for preliminary, or since 19 January 2007, for full consent and the location of the premises applied for is within 1.6 km of the location specified in any application for a pharmacy which has been finally refused in the five years prior to the date of the application (*regulation 34(1)(b)(ii) as amended*).
  - the chemist requests a determination as to whether the location of the premises applied are in a reserved location where the Primary Care Trust has refused to grant the application in relation to the premises in the previous five years on the basis that to grant it would prejudice (*regulation 18ZA*) the proper provision of primary medical services, dispensing services or local pharmaceutical services in the locality. (*regulation 34(1)(c)*).
- 5.38 Again, if the Primary Care Trust is of the view that there has been a substantial change in circumstances affecting the controlled locality, it can consider such an application (*regulation 34(2)*).

### Notification requirements

- 5.39 The regulations provide that the Primary Care Trust must notify, in writing and send a copy of the application to:
- the Local Pharmaceutical Committee;
  - the Local Medical Committee;
  - any provider of primary medical services, and any chemist including any LPS chemist who in the opinion of the Primary Care Trust may be significantly affected by a grant of the application;

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- any other Primary Care Trust or Local Health Board (if the application is close to the border with Wales) any part of whose area is within 2 km of the premises specified in the application;
- any Patient's Forum serving the Primary Care Trust area;
- any other patient, consumer or community groups in the area of the Primary Care Trust that it considers has an interest in the provision of pharmaceutical services in the neighbourhood;
- any other Primary Care Trust, part of whose area is or might form part of a reserved location; and
- where the application concerns a new grant of outline consent (*regulation 61*), any other Primary Care Trust or Local Health Board (if the application is close to the border with Wales) any part of whose area is within 1.6 km of the premises from which the doctor wishes to dispense (Primary Care Trusts should note this is less than the 2 km rule above).

(*regulation 33(2)*)

5.40 Where another Primary Care Trust or Local Health Board has been notified of the application, it shall, as soon as practicable, send a copy of the application to:

- the Local Pharmaceutical Committee for its own area;
- the Local Medical Committee for its own area;
- any provider of primary medical services, and any chemist including any local pharmaceutical services chemist who in the opinion of the Primary Care Trust may be significantly affected if the application is granted;
- any Patient's Forum serving the Primary Care Trust area; and
- any other patient, consumer or community groups in the area of the Primary Care Trust that it considers has an interest in the provision of pharmaceutical services in the neighbourhood.

(*regulation 33(3)*)

5.41 Any person who is sent a copy of the application in 5.39 and 5.40 above has 45 days from the date on which the copy was sent to make representations in writing to the Primary Care Trust to which the application was made (*regulation 33(4)*). If they were sent a copy of the application prior to 5 July 2005, the time limit was 30 days.

5.42 In some circumstances where e.g. local groups who are not notified by the Primary Care Trust may not become aware of an application for some time, the regulations specifically provide that any other person who considers that he may be affected by the decision on the application may, within **such reasonable period** as the Primary Care Trust to which the application was made may allow, make written representations to it (*regulation 33(5)*). This is because people or local groups who wish to make representations about applications related to rural areas may meet less frequently or want to undertake their own

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site visits to inspect. Primary Care Trusts should therefore allow such time as they consider reasonable provided this does not lead to undue delay in dealing with the application. It may be that 45 days as with normal applications is sufficient but some may require longer to respond.

- 5.43 See paragraphs 5.52 - 5.55 for more information on determining applications in controlled localities.

### **Pharmaceutical services in reserved locations** (*regulation 35*)

**Reserved locations in controlled localities are where:**

- **The patient population (on all of the patient lists) within 1.6 km of the proposed location or the actual premises is less than 2,750** (*regulation 35(2)(a)*).

**If a Primary Care determines that an area is a reserved location, the effect is that:**

- **The “prejudice” test** (*regulation 18ZA*) **does not apply**
- **A pharmacy will not have the usual 1.6 km protection that patients within that area should cease receiving dispensing services and instead use the pharmacy’s services**
- **Patients will continue to be able to exercise a choice as to whether to continue to receive dispensing from their dispensing doctor or from the pharmacy**

**Primary Care Trusts can remove (or not apply) reserved location status under two specific circumstances:**

1. **If the patient list population exceeds 2,750.**
2. **If that population is still below 2,750 but nonetheless the needs of the patient population in that reserved location are such that they are similar to those areas with a larger population** (*regulation 35(3)*).

**Where either of these events occur, the “prejudice” test will re-engage.**

- 5.44 Primary Care Trusts should, on receipt of an application for a controlled locality, consider whether the application relates to premises in a reserved location.

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- 5.45 A reserved location is an area within 1.6 km of the proposed location of the premises (applicants should specify the location as precisely as possible) where the patient population is less than 2,750. This means the total patients on all the lists. **It does not matter whether all the area within 1.6 km of the proposed location is a controlled locality or not.** However, temporary patients, such as students, are not included for these purposes. Calculation of the relevant population should be done by postcode using the last three digits. Primary Care Trusts may find it helpful to work from large scale Ordnance Survey maps with the radius distance clearly marked. All post codes linked to streets or roads within the circle would then count. Whilst this may not yield 100% accuracy, this should usually provide adequate information on which to base a calculation. A manual count may then be necessary where the population is on the borderline of 2,750 in which case Primary Care Trusts should ascertain the streets/locations on the edge of the circle. Primary Care Trusts may wish to adopt the same procedures here that they already do so when notifying patients within 1.6 km of a new pharmacy opening up that they can no longer use the services of their dispensing doctor.
- 5.46 The reason the figure of 2,750 has been chosen is that this is the figure below which pharmacy viability becomes questionable. There is, however, a provision that allows a Primary Care Trust to remove reserved location status where the population is below 2,750 but there is likely to be unmet patient needs for pharmaceutical services which will not be catered for without a pharmacy and the circumstances are such as to be likely to support the pharmacy's continued viability, These include but are not limited to factors of age or degree of infirmity (*regulation 35(3)*). It is open to applicants to provide evidence to support the removal of reserved location status although this is not expected to happen frequently. Before this decision is reached, Primary Care Trusts should invite and consider representations from those persons notified in 5.39 and 5.40 above (*regulation 35(4)*). Regulation 35(1) says Primary Care Trusts shall determine reserved location once they have received representations from those notified of the application. But regulation 35(4) requires the Primary Care Trust then to invite and consider representations on this matter before coming to an opinion. In practice therefore, it is sensible, before inviting such representations, for the Primary Care Trust to have examined the area in question and come to a preliminary view on whether or not "reserved location" status will, or will continue to, apply or not as the case may be. The Primary Care Trust then seeks views on this issue alongside views on the application itself. This avoids asking the same people to consider the issues of the application and reserved location separately.
- 5.47 Where an applicant for proposed premises within a reserved location has applied, for example, for preliminary consent because they do not know the precise location of the premises and reserved location status is granted, the applicant can ask the Primary Care Trust to make a

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fresh determination once the details of the premises are known. An applicant does so by making a further application in writing to the Primary Care Trust to determine whether reserved location status is still applicable on the date the request is made (*regulation 35(5)*).

- 5.48 If, when making a further determination for reserved location status, the Primary Care Trust determines that the premises are not in a reserved location, or an appeal against a determination of reserved location is upheld, the “prejudice” test re-engages. In this instance:
- the Primary Care Trust shall determine that the premises are to be treated as if they were in a reserved location where it is of the opinion that not to do so would prejudice the proper provision of primary medical services (other than by the Primary Care Trust itself), dispensing services or pharmaceutical services in any area or
  - if the Primary Care Trust considers that the provision of primary medical services by a provider of primary medical services (other than by the Primary Care Trust itself) or pharmaceutical services by a chemist is likely to be adversely affected by a determination that the premises are not in a reserved location, it could determine that the area is not in a reserved location, but impose conditions (i.e. “gradualisation” – see below). (*regulation 35(6)*)
- 5.49 Where a reserved location status is removed and there is deemed to be no “prejudice” to the proper provision of primary medical services, the dispensing practice will lose the right to dispense to patients living within 1.6 km of the pharmacy. However, they can continue to dispense to patients that live in the controlled locality at a greater distance from the pharmacy.
- 5.50 There is a right of appeal where a Primary Care Trust determines that the premises are or are not in a reserved location. Where the appeal determines that they are not, the Primary Care Trust shall re-determine the application (*regulation 35(8)*). This is because at the time of the appeal, the population or circumstances may have changed.
- 5.51 If the Primary Care Trust determines that an area is a reserved location, it should delineate this area on a map. It should also publish the map (*regulation 35(9)*).

## Determination of applications in respect of controlled localities (*regulation 36*)

There are two matters concerning pharmacy applications for premises in controlled localities:

“Prejudice Test”

“Necessary or Desirable Test”

As mentioned above, if the Primary Care Trust has determined that the premises will be in a reserved location, the application should only be considered under the “Necessary or Desirable” test.

5.52 When considering an application for a pharmacy in a controlled locality (which is not determined to be a reserved location), the Primary Care Trust will notify the overall determination but this has two distinct stages. These should be considered in the order set out below, but it may be convenient, and help to avoid delay, to consider them separately, but at different sessions of the same meeting:

- (a) whether to grant it would prejudice the proper provision of primary medical services, dispensing services, local pharmaceutical services or pharmaceutical services in any area (see Annex C for further information on “prejudice”) (*regulation 18ZA(2)(a)*). **Primary Care Trusts should note that the prejudice test applies to applications made under regulation 13 in respect of the four exemptions from the “control of entry” test where the application is for a shopping centre, one stop primary care centre etc in a controlled locality.**

and if there is no prejudice, the Primary Care Trust then determines:

- (b) whether it is necessary or desirable to grant the application in order to secure in the neighbourhood the adequate provision of pharmaceutical services or some of the services specified in the application.

5.53 As mentioned above, for applications where the Primary Care Trust has determined that the area is a “reserved location”, the “prejudice test” does not apply. This also applies where a Primary Care Trust has determined reserved location status applies to an exempt pharmacy application under regulation 13. They should only be considered under the criteria relevant to the appropriate exemption in regulation 13 and not the prejudice test.

5.54 **Primary Care Trusts should note that it is only the overall determination which is appealable under regulation 38 – not the**

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**individual stages of the separate questions of “prejudice” and “necessary or desirable”.** It should also be noted that when considering the question of whether the application is “necessary or desirable”, the Primary Care Trust should only be concerned with the provision of services by persons **on the pharmaceutical list** and not with any pharmaceutical services provided by primary medical services. The Primary Care Trust does not have to have particular regard to representations made by doctors in relation to the “necessary or desirable” test. Nor can they take part in the process in any way should there be an oral hearing. Appeal rights in respect of determinations within controlled localities are clarified in new regulation 38 (1A-1D). From 19 January 2007, doctors do not have the right to appeal “necessary or desirable” decisions on pharmacy applications (which they did not have either under the previous 1992 regulations) but still continue to have the right to appeal on grounds of “prejudice”.

- 5.55 The rights of appeal are exercisable within 30 days of the notification of the decision (*regulation 38*).

### **Adverse effects/ “gradualisation”**

- 5.56 In some situations, the Primary Care Trust will need to consider whether to impose conditions with the aim of reducing adverse consequences arising from a decision taken by the Primary Care Trust (*regulations 36(2), 60(7) and 20(2)*). This means in effect that the Primary Care Trust may decide to postpone, for such period as it thinks fit, the making or termination of arrangements for the provision by a doctor of pharmaceutical services to his patients. The situations in which the need to consider such action (known as “gradualisation”) are:

- a decision that a locality should cease to be classified as “controlled”
- a decision to grant an application for a new pharmacy (excluding a minor relocation or a change of ownership)
- a grant of outline consent to a primary medical services provider to dispense – it may be desirable to control the rate of acceptance of dispensing patients
- a decision to classify as “rural” or “controlled” a locality which has previously been unclassified
- a decision to grant an application for inclusion in a pharmaceutical list where the premises specified, while not in a controlled locality, fall within 1.6 km of any part of a controlled locality in which patients for whom a primary medical services provider has authority to dispense are residing.

In all these cases, reasonable notice of the basic decision will be needed. Normally this might be three months. The arrangements to implement gradualisation may need to be for a longer period. Very often, this can extend to a year and in some cases, a longer period may be reasonable. What is reasonable in all the circumstances is for

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the Primary Care Trust to determine. It is good practice to specify the reasons behind any decision on gradualisation.

### Procedure for determining applications

- 5.57 As with applications in non-controlled localities, the Primary Care Trust has, under the regulations, a broad discretion as to the procedure to be adopted. The Primary Care Trust may make a decision on an application “in such manner as it thinks fit”. In particular, it may decide the application without hearing any oral representations, if it considers oral representations are unnecessary (*regulation 36(1)*).
- 5.58 If the Primary Care Trust decides that a hearing is to be held, the regulations provide that not less than fourteen days’ notice must be given both to the applicant and any person from whom it has received representations, of the time and place at which the representations are to be heard (*regulation 36(4)*). In addition, it is specifically stated that the Primary Care Trust may invite any other person to give evidence, as it thinks fit (*regulation 36(5)*).
- 5.59 The applicant and any other person who has made written representations may be assisted at any hearing in the presentation of his/her oral representations by some other person. However, as with oral hearings for applications in “non-controlled localities”, no person is entitled to be heard in the capacity of counsel or solicitor (*regulation 36(6)*).
- 5.60 The procedure to be adopted at the hearing is to be such as the Primary Care Trust in question may determine (*regulation 36(7)*).
- 5.61 As with all hearings of this nature, the fundamental principles of administrative law – fairness and lack of bias – must be observed (see Chapter 3). As with the procedure for determining applications for “non-controlled” localities, no person who provides *or assists in providing* primary medical services, local pharmaceutical services or pharmaceutical services under Part II of the National Health Service Act 1977 can take part in any decision under this regulation. **Thus, all doctors, chemists and their staff are excluded from taking part in any decision, irrespective of where they practise in the UK** (*regulation 36(8)*).
- 5.62 As with the procedure for determining applications for “non-controlled” localities, the Primary Care Trust may “consolidate” two or more applications together, and determine them together (*regulation 36(9)*).

### Notification of decision in respect of applications in controlled localities (*regulation 37*)

- 5.63 Once the Primary Care Trust has determined the application, it is under a duty, as soon as practicable after making the determination

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and in any event within four months beginning with the date of receipt of the application (unless the Primary Care Trust has good cause to require a longer period), give notice in writing of its decision to:

- the applicant
- the Local Pharmaceutical Committee
- the Local Medical Committee
- any person who is included in a pharmaceutical list, is an LPS chemist or is a provider of primary medical services within the area of the Primary Care Trust or whose name is included in the dispensing doctor list of the Primary Care Trust and whose interests might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted
- any other Primary Care Trust or Local Health Board to which notice was sent
- any other person who has made representations.

Where the application involves a change of ownership, the time limit for notification of the decision is 30 days rather than the usual four months.

5.64 The Primary Care Trust should also send a statement of rights of appeal. As noted above, appeal rights in respect of determinations within controlled localities have been clarified by amending regulation 37 and setting out the rights in new regulation 38 (1A-1D). So from 19 January 2007, doctors do not have the right to appeal decisions on the basis of the “necessary or desirable” criteria. In short, the appeal rights now follow the same rights set out in Chapter 3.

5.65 Any Primary Care Trust or Local Health Board which is notified of the decision shall, as soon as is practicable, give notice in writing to:

- the Local Pharmaceutical Committee for its area
- the Local Medical Committee for its area
- any person who is included in its pharmaceutical list, is an LPS chemist or is a provider of primary medical services within the area of the Primary Care Trust or Local Health Board or whose name is included in the dispensing doctor list of the Primary Care Trust or Local Health Board and whose interests might, in the opinion of the Primary Care Trust or Local Health Board, be significantly affected if the application were granted

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### Appeals against “controlled locality” decisions (*regulation 38*)

5.66 An appeal against a decision on an application relating to a “controlled locality” may be made to the Appeal Unit in the following circumstances:

- where the Primary Care Trust has determined an application relating to a controlled locality or a question raised by such an application (for example, a decision not to consider the issue of a reserved location under regulation 35)
- where the Primary Care Trust has refused to consider an application relating to a controlled locality because it is not satisfied that there has been a substantial change of circumstances affecting the controlled locality
- where the Primary Care Trust has decided that it should (or should not) postpone the making or termination of arrangements for dispensing doctors or pharmaceutical services by chemists
- where the Primary Care Trust has refused to consider an application for preliminary consent

and in relation to other types of appeal for dispensing doctor applications (see Chapter 6)

- where the Primary Care Trust has determined that the provisional date for outline consent shall be extended, or outline consent is refused or has lapsed
- where the Primary Care Trust has determined an application for new or additional premises approval
- where the Primary Care Trust has determined an application relating to a practice amalgamation
- where the Primary Care Trust has refused to grant temporary premises approval
- where the Primary Care Trust has determined whether or not to grant premises approval under transitional arrangements

(*regulation 38(2)*)

5.67 The people who may appeal depend on the type of application. Where the appeal is against a decision on an application relating to a “controlled locality”, the applicant can appeal as of right, and any person whose name is either on the pharmaceutical list of the Primary Care Trust (or any other Primary Care Trust to which a copy of the original application had been sent) or who is a provider of local pharmaceutical services may also appeal. However they must have submitted prior evidence in connection with the application (*regulation 38(3)(a)*). From 19 January 2007, doctors do not have the right to appeal “necessary or desirable” decisions on pharmacy applications (which they did not have either under the previous 1992 regulations) but still continue to have the right to appeal on grounds of “prejudice”..

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- 5.68 Exceptions to this are appeals against the Primary Care Trust's decision to refuse to consider an application relating to a controlled locality because it is not satisfied there has been a substantial change of circumstances affecting the controlled locality. In this case, only the applicant may appeal.
- 5.69 Only the applicant may appeal where the appeal concerns:
- a determination by the Primary Care Trust that the provisional date for outline consent should be extended/refused or shall lapse;
  - has determined an application for premises approval for new premises; or
  - has refused to grant temporary premises approval
- (regulation 38(3)(b))*
- 5.70 In a case where a Primary Care Trust has considered applications together, any of the applicants and any of the persons mentioned in paragraph 5.67 may appeal, and where appeals are received against two or more of the determinations considered together by the Primary Care Trust, the appeals must be considered together by the Appeal Unit *(regulation 38(4))*.
- 5.71 Any appeal must be in writing. It must contain a concise statement of the grounds of appeal. It must be submitted within 30 days from the date on which notice of the decision was sent to the appellant. *(regulation 38(5))*. On receipt, the Appeal Unit is to consider the appeal.
- 5.72 If the Appeal Unit is of the opinion that the appeal discloses no grounds of appeal, or that the appeal is otherwise vexatious or frivolous, the NHSLA can determine the appeal by dismissing it *(regulation 38(6))*.
- 5.73 If the Appeal Unit is not of such an opinion, then it should send a copy of the notice of appeal to the Primary Care Trust whose determination is appealed against as well as the persons entitled to appeal as above as well as to any Local Medical Committee and Local Pharmaceutical Committee that received notice of the application *(regulation 38(7))*.
- 5.74 Any person to whom a copy of the notice of appeal has been sent has 30 days from the date on which the notice was sent in which to make written representations to the Appeal Unit, the period to run from the date on which the copy of the notice was sent *(regulation 38(8))*.
- 5.75 Before reaching a decision, the Appeal Unit may require an oral hearing to be held. Where this is to happen, one or more persons are

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to be appointed to hear the appeal and report to the Appeal Unit. The procedure for the hearing is to be determined by the person(s) so appointed (*regulation 38(9)-(11)*).

- 5.76 The regulations set down that if an oral hearing will take place the Appeal Unit will direct the time and place. Notice of the hearing must be sent not less than fourteen days before the date fixed for the hearing to:
- the appellant
  - the Primary Care Trust
  - the Local Pharmaceutical Committee
  - the Local Medical Committee
  - any one else who made representations to the Primary Care Trust in connection with the application

*(regulation 38(12))*

- 5.77 The appellant and any other person to whom notice of the hearing was sent may attend the hearing and be heard in person, or by counsel, solicitor or other representative. The Primary Care Trust which took the decision may also be represented by any duly authorised officer or member, or by counsel or solicitor (*regulations 38(13)*).

- 5.78 Once the hearing is finished, the panel shall report its findings to the Appeal Unit. Then the Appeal Unit may either:
- allow the appeal
  - where the Primary Care Trust considered whether to impose conditions relating to the provision of pharmaceutical services by a provider of primary medical services may itself impose such conditions
  - where that question was not considered, must remit the matter to the Primary Care Trust for determination  
or
  - may dismiss the appeal.

*(regulation 38(14))*

- 5.79 As soon as practicable, the decision of the Appeal Unit must be given in writing, together with a statement of reasons and findings of fact, and be sent to those listed above (*regulation 38(15)*).

### **Effect of grant of application**

- 5.80 Once an application is granted (or an appeal decided), the same time periods apply as set out in Chapter 3 (see paragraphs 3.154 – 3.156 above).

## 6. Entry onto a dispensing list: special provisions - pharmaceutical services by GPs

### Introduction

New regulations are as follows:

- If a doctor moves his premises outside the 1.6 km radius of a pharmacy, full outline consent is not granted for 12 months to give any local pharmacy/ies time to relocate nearer those premises if it/they wish.
- The concept of a minor relocation is introduced for doctors authorised to dispense.
- Where two practices amalgamate (or have amalgamated) and one is currently or was a non-dispensing practice, a fresh application for outline consent is needed so that consideration can be given as to whether doctors in the non-dispensing practice can dispense. If the merger does not go ahead, the dispensing practice can continue to dispense.
- “Reserved location” status does not apply to these applications from 19 January 2007
- Premises from which doctors were dispensing as at 1 April 2005 or had outline consent granted needed to have been given premises approval by the local Primary Care Trust by 1 July 2005.
- Primary Care Trusts should not consider applications for outline consent or premises approval where they have been refused by the operation of regulation 18 (2) (which includes applications not in reserved locations where the premises are within 1.6 km of a pharmacy) unless there has been a substantial change of circumstances affecting the controlled locality.

### Request by a patient

- 6.1 A doctor may be granted a general permission to supply drugs to a particular patient. However, there are preconditions to be satisfied before a doctor can be granted such permission. A patient must:

**either** satisfy a Primary Care Trust that he would have *serious difficulty* in obtaining any necessary drugs or appliances from a pharmacy by reason of distance or inadequacy of communication (see Annex C for further information on serious difficulty)(*regulation 60(1)(a)*);

**or** that patient must be resident in a controlled locality, at a distance of more than 1.6 km from any pharmacy or from any pharmacy within 1.6 km which has been determined to be in a reserved location, and in either case, one of the conditions set out in paragraph 6.3 below is

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satisfied. (*regulation 60(1)(b) and (c)*). A patient can also receive these services if they are living as a member of the household, other than as a temporary resident, of someone who either has serious difficulty getting to a pharmacy or lives more than 1.6 km from a pharmacy in a controlled locality (*regulation 60(1)(d)*).

- 6.2 In either case, the patient may request in writing that a doctor on whose list he is included provide him or her with pharmaceutical services (*regulation 60(1)*).
- 6.3 The conditions mentioned in 6.1 above are that:
- There is in effect an outline consent granted to that doctor providing primary medical services and any conditions imposed in connection with the grant will permit arrangements to be made for the provision of pharmaceutical services by that doctor to the patient; or
  - immediately before 1 April 2005, arrangements were in place under the 1992 Regulations for that doctor to provide drugs or appliances to patients. These are known as “historic rights”. In this situation, there is the further requirement that the patient has either not previously been included in a patient list, or has changed his address from that last notified to the Primary Care Trust, or received pharmaceutical services from another doctor prior to being a patient of the new doctor (*regulation 60(3)(b)*).
  - in both cases, there must also be premises approval in effect in relation to the premises from which the doctor will dispense to that patient (*regulation 60(3)(a)(ii) and (b)(iii)*).
- 6.4 Where a doctor has been requested to provide pharmaceutical services by a patient, the regulations require that the doctor must himself or herself then apply to the Primary Care Trust to provide such services. The patient’s written request must accompany the application (*regulation 60(4)*).
- 6.5 On receipt of such an application, the Primary Care Trust shall make arrangements for the provision of pharmaceutical services by the doctor (*regulation 60(4)(a)*).
- 6.6 If the doctor fails to put in the request within 30 days of receipt of the request from the patient, the Primary Care Trust may require the doctor to undertake to provide pharmaceutical services and shall give him notice to that effect. (*regulation 60(4)(b)*).
- 6.7 In a situation where the Primary Care Trust requires a doctor to provide pharmaceutical services to any person, then it shall give reasonable notice to that effect to the doctor (*regulation 60(7)(a)*)

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- 6.8 Similarly, where a patient no longer satisfies the conditions set out in 6.1 above, the Primary Care Trust shall give reasonable notice that the provision of pharmaceutical services shall be discontinued (*regulation 60(7)(b)*)
- 6.9 In a situation where a drug or appliance is one for which the doctor is entitled to an additional payment if he provides it, the doctor may, with the consent of the patient, not supply it directly, but instead issue a prescription to the patient, to enable it to be acquired from some other source (*regulation 60(9)*), in accordance with the doctor's contractual terms.
- 6.10 Any arrangement or requirement in effect on the date on which the current regulations came into force, made under earlier regulations is to continue in effect, notwithstanding the fact that neither of the conditions set out in paragraph 6.3 was satisfied at the time the original arrangements were made (*regulation 60(10)*).

### **Temporary residents**

- 6.11 Once a doctor has been authorised to provide pharmaceutical services to some or all of his/her patients under these provisions, the authorisation also extends to any other person accepted by the doctor as a temporary resident (*regulation 60(11)*).

### **Appeals**

- 6.12 Any appeal against a requirement by the Primary Care Trust that the doctor provides pharmaceutical services from listed premises is to be made in writing within 30 days from the date on which the decision was sent to the doctor, and must contain a concise statement of the grounds of appeal (*regulation 60(12)*).
- 6.13 On receipt of the notice of appeal, the Appeal Unit, which carries out this function on behalf of the Secretary of State, must send a copy to the Primary Care Trust which made the decision, and to the relevant doctor providing primary medical services. The doctor then has 30 days from the date on which such copy was sent to make written representations (*regulation 60(13)*).
- 6.14 The Appeal Unit may determine such an appeal "in such manner as it thinks fit" (*regulation 60(14)*).
- 6.15 Having determined the appeal, the Appeal Unit must give written notice of the decision to the doctor, the Primary Care Trust and the relevant provider of primary medical services, together with a statement of the reasons for it (*regulation 60(15)*)

## Outline Consent and premises approval: applications by doctors

- 6.16 The next step is for the doctor to apply in writing to the Primary Care Trust to provide pharmaceutical services. This has to be triggered by the request from a patient or patients, under regulation 60 for the doctors to provide these services. The doctor applies for outline consent to provide pharmaceutical services to patients in a certain area and in addition for approval of any premises from which he wishes to dispense (*regulation 61(1)(a) and (b)*). Whilst outline consent existed under the 1992 Regulations, premises approval is the new concept introduced by the 2005 Regulations.
- 6.17 When applying for approval to dispense in respect of particular premises, a doctor must specify the premises for which he wishes to be granted premises approval. He must also specify whether these are listed premises in relation to a different area (*regulation 61(1)(b)(i)*) and whether the application arises because there has been or will be a practice amalgamation and, if so, the names of the doctors or contractors participating in the amalgamation (*regulation 61(1)(b)(ii)*).
- 6.18 Up to 18 January 2007, the first step was for the Primary Care Trust to consider whether the premises were going to be within a reserved location (see Chapter 5 for more information on this). If they were then a doctor could be granted outline consent even though the proposed premises would be within 1.6 km of a pharmacy unless that grant would fail the “prejudice” test. However, from 19 January 2007, this step does not apply to applications from doctors for outline consent. The reason for this is that it was never the intention that reserved location status could be applied for in an area where there was already an alternative pharmaceutical service in place. Primary Care Trusts should, however, remember that where a minor relocation or relocation of a dispensing practice which does not significantly change pharmaceutical provision is involved, there is no change in a doctor’s continuing rights to dispense to eligible patients. The issue of reserved location also no longer applies where there is no chemist already in the area, since the question of reserved location need only ever be determined if and when a chemist’s application is received. This avoids unnecessary additional work for the Primary Care Trust and those notified of the application. There are additional circumstances under which a Primary Care Trust must or may refuse an application. A Primary Care Trust must refuse the application if it is within 1.6 km of a pharmacy or would otherwise prejudice the proper provision of primary medical services, dispensing services, pharmaceutical services or local pharmaceutical services (*regulation 18(2)*). There are exceptions to this rule for minor relocations of premises (see paragraphs 6.23 – 6.35 below). It must also not consider the application if, within the past five years, a previous application has been refused (either by the Primary Care Trust or on appeal)(*regulation 34(1)(a)*). It may refuse an

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application in respect of some of the premises for which approval is sought. This happens where the number of applications for premises approval are such, or the circumstances in which they are made are such, that to grant all or some of them would prejudice the proper provision of primary medical services, dispensing services, local pharmaceutical services or pharmaceutical services in any area (*regulation 61(3)*).

- 6.19 Applications for outline consent are dealt with on the same basis as applications by pharmacists in controlled localities (though there is of course no “necessary or desirable” test) (*regulation 62*).
- 6.20 The outline consent is effective from the date of its final grant **unless** there are outstanding applications from pharmacists in relation to premises with 1.6 km of the premises in respect of which the doctor is applying (*regulation 62(2)(a) and (5)*). If there are outstanding pharmacy applications (on the day before the date outline consent is granted or the pharmacy application has either not been decided or has been granted but the pharmacy has not begun to provide services) outline consent will not be determined until after the outstanding applications have been disposed of. Instead, the Primary Care Trust grants outline consent from a provisional date. This is in effect a date one year on (either from the date of the Primary Care Trust decision or determination of any appeal). This can be extended by up to three months. Primary Care Trusts should advise the doctor of the details of the outstanding applications and the earliest date that the doctor can apply to the Primary Care Trust to determine that outline consent should come into effect. Primary Care Trusts should keep doctors informed of any developments in this interim period (for example, withdrawal of applications or time extension). Premises approval is effective when the relating outline consent takes effect (*regulation 62(16)*). However, if an outstanding pharmacy application is granted and the provision of pharmaceutical services has begun before the provisional date, then the grant of outline consent lapses. (*regulation 62(10)*).
- 6.21 Where a Primary Care Trust determines that the provisional date is to be extended, or the application for outline consent is refused or the outline consent lapses, the applicant has a right of appeal under regulation 38(5) (*regulation 62(15)(c)*).
- 6.22 Outline consent also lapses in the following circumstances:
- where no arrangement is made under regulation 60 within 12 months from its taking effect;
  - when more than 12 months has elapsed since the last provision of drugs and appliances; or

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- where there is a practice amalgamation and following the amalgamation there are no practice premises which have premises approval or outline consent (*regulation 63(1)(a)-(c) and 63(3)*). Premises approval lapses when outline consent lapses, and additionally when the practice premises cease to be used for dispensing (*regulation 63(3)*).

### Change of premises and minor relocations for dispensing practices

- 6.23 Where a doctor who is authorised to dispense wants to change the premises from which he wishes to dispense either before outline consent is effective or the provisional date mentioned above, he should apply to the Primary Care Trust in writing for approval for the new premises (*regulation 64(1)*).
- 6.24 The Primary Care Trust may grant the application if it is satisfied that the change of premises is a minor relocation (e.g. under 500 metres – see paragraph 6.26 onwards). If it is not satisfied, it must refuse the application (*regulation 64(2)*). The doctor has a right of appeal under regulation 38 (*regulation 64(4)*).
- 6.25 If a doctor who has been granted outline consent and premises approval wishes to be granted premises approval in relation to additional premises, he should apply in writing to the Primary Care Trust/s concerned (*regulation 65(1)*). The application can be refused in the same way as an application for outline consent (see for example paragraph 6.18 above) (*regulation 65(1)(ii)*).
- 6.26 The reforms to the Regulations now include a provision for practices with existing dispensing rights to relocate if it is a relocation of less than 500 metres or, if greater than 500 metres, the Primary Care Trust is satisfied that to grant it would not result in a significant change to pharmaceutical services or dispensing services which are provided to any part of the controlled locality. “Significant change” for these purposes can be seen as a change in the dispensing list size which would be prejudicial to chemists’ or doctors’ services. This is similar, but different, to the existing provisions for chemists. Such dispensing practices may need to relocate if the practice outgrows its premises or the premises become unsafe. If such a practice were not able to satisfy the requirement for relocation, it would lose all dispensing rights if the new premises were within 1.6 km of any pharmacy. So this is a special exception allowing relocations even it means dispensing premises move even closer to a pharmacy. The procedures to be followed are set out in *regulation 65*.
- 6.27 If a doctor, who has been granted outline consent or has historic dispensing rights and premises approval. wishes to relocate those existing premises, he should apply for premises approval in relation to

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new premises (i.e. instead of his existing premises) in writing to the Primary Care Trust(s) concerned (*regulation 65(3)*).

- 6.28 If the relevant Primary Care Trust considers that the application meets one of the relevant criteria, then it should grant the application. To recap, these criteria are that:
- the distance to the new premises is less than 500 metres by the most practicable route on foot from the existing listed premises; or
  - where the distance is greater but the Primary Care Trust is satisfied that there would not be any significant change in the arrangements for the provision of pharmaceutical services or dispensing services to any part of a controlled locality.

(*regulation 65(4)(a)*)

- 6.29 Primary Care Trusts should note that applications do not have to meet both of these criteria. One is sufficient. The onus is on the practice to show that there would be no significant change in consequence of the relocation of premises.
- 6.30 The Primary Care Trust has a duty to notify its determination **but not consult** all those referred to in regulation 33(2) and (3)(*regulation 65(5)*). Any person notified, other than the Local Pharmaceutical Committee or the Local Medical Committee has a right to appeal the determination (*regulation 65(6)*).
- 6.31 Once granted, no further applications for such new premises are to be granted for a period of 12 months (as is the case with chemists). The 12 months' period starts from the date on which the doctor started providing services from the new premises. Primary Care Trusts can override this where there is good cause (*regulation 65(4)(a)*). What constitutes good cause is similar to the circumstances described in Chapter 3 for chemists.
- 6.32 If the relevant Primary Care Trust does not consider that the application meets one of the criteria identified in paragraph 6.28 above (for example, it disagrees about the most practicable route to the new premises being less than 500 metres), the application shall be determined as if it were one for additional premises.
- 6.33 The relevant Primary Care Trust may grant temporary premises approval to a doctor who has outline consent and premises approval in relation to additional or new premises where it considers it desirable to do so to secure the adequate provision of pharmaceutical services in the area served by the premises (*regulation 65(9)*). Temporary premises approval may be granted for a period not exceeding 12 months, and may be renewed for a further period not exceeding three

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months.

- 6.34 Regardless of whether a dispensing practice remains at its present location, or following a proposed move of premises, **any application to extend the area of outline consent is to be treated as a new application for outline consent.** It therefore follows that doctors with historic rights to dispense may not extend the area in which they are authorised to provide dispensing services unless they apply for a fresh outline consent for the new area in question.

### Practice amalgamations

- 6.35 A practice amalgamation occurs when two or more providers of primary medical services merge or a GMS, PMS, APMS contractor or a doctor who provides primary medical services for a PCTMS practice is employed or engaged another such contractor or provider as a result of which two or more patient lists are combined (*regulation 66(1)*).
- 6.36 If following a practice amalgamation, all the practice premises of the new practice are premises which had approval immediately before the practice amalgamated, then outline consent and premises approval shall continue to have effect (*regulation 66(2)*). If none or not all of the practice premises of the new practice had premises approval immediately before the amalgamation, then the doctor who has been granted outline consent and premises approval previously, may make an application for premises approval as outlined in 6.23 - 6.31 above (*regulation 66(3)*).
- 6.37 When the practice amalgamation takes effect, the doctors shall notify all Primary Care Trusts in whose area the amalgamated practice is situated that the amalgamation has taken place (*regulation 66(5)*).
- 6.38 Any grant of premises approval due to an amalgamation will lapse if the practice amalgamation has not taken place before the end of a period of one year beginning with the date that premises approval was granted (*regulation 66(7)*).
- 6.39 If the application for premises approval following a practice amalgamation is refused, doctors who had premises approval prior to the amalgamation shall have residual premises approval (*regulation 66(8)*). In other words, this means that they can continue to dispense to the patients they were dispensing to prior to the failed application and only those patients.

### Transitional provisions from 1 April 2005

- 6.40 Special transitional arrangements were in place under regulation 67 for doctors who either had been granted outline consent or who had historic rights to dispense under the 1992 Regulations. Such doctors

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needed to register their premises with their local Primary Care Trust. Primary Care Trusts should have written out to all such doctors within 30 days of 1 April 2005. A standard letter setting out the conditions and reply form for doctors to use was placed on the Department's website at [www.dh.gov.uk](http://www.dh.gov.uk).

- 6.41 In this context "relevant premises" meant premises (which can include additional or substitute premises) from which the doctor was or intended as at 31 March 2005 to provide primary medical services
- 6.42 The doctor was able to make written representations to the Primary Care Trust in relation to the determination. The doctor normally had 30 days to reply but where there was good cause (e.g. because of holiday or illness) the Primary Care Trust could extend this period. The Primary Care Trust should also have notified the Local Medical Committee and the Local Pharmaceutical Committee. They too were able to make written representations to the same timescale.
- 6.43 The Primary Care Trust then considered any representations received and determined whether or not to grant premises approval. The Primary Care Trust then notified its decision to the doctor and the Local Representative Committee along with any person providing pharmaceutical services or dispensing services in the Primary Care Trust's area whose interests might, in the opinion of the Primary Care Trust, be affected if the application was granted. It also notified all Patients' Forums in that area.
- 6.44 Primary Care Trusts were **obliged** to grant premises approval where they were satisfied that either the premises were as at 31 March 2005 being routinely used to provide dispensing services or outline consent had been granted under the 1992 Regulations after 31st March 2004 in respect of the relevant premises.
- 6.45 The fact that the premises may have been within 1.6 kilometres of any pharmacy were **not** grounds for refusal.
- 6.46 The Primary Care Trust's determination was appealable to the Appeal Unit by any person except the Local Representative Committees.
- 6.47 Until the matter had been finally decided a doctor was deemed to have been granted premises approval. However, in this particular instance he was prevented from making an application to change his premises under regulation 64 or apply for additional or new premises under regulation 65 until the matter was finally resolved.

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## **Dispensing doctor lists**

- 6.48 Primary Care Trusts must prepare, maintain and publish a list of the names of those doctors authorised or required by the Primary Care Trust to provide pharmaceutical services to their patients and who are actually doing so (*regulation 68(1)*).
- 6.49 The dispensing doctor list shall indicate the name and address of the relevant provider of primary medical services from whose premises the dispensing doctor provides primary medical services (*regulation 68(2)*). Where the doctor whose name is included in the dispensing doctor list provides primary medical services within a PCTMS practice, the list should give the name and address of the Primary Care Trust (*regulation 68(3)*).
- 6.50 The dispensing doctor list should also include:
- the premises where the doctor has premises approval
  - whether the premises approval is granted, temporary or residual
  - the date on which premises approval took effect or where it has not taken effect, the date when it was finally granted
  - the area where the doctor has outline consent and premises approval (premises where the doctor has outstanding applications for premises approval should be included and identified separately).

*(regulation 68(4))*

- 6.51 A Primary Care Trust shall remove the name of a doctor from its dispensing doctor list if it determines that:
- the doctor has died
  - the doctor is no longer performing primary medical services within the area of the Primary Care Trust
  - more than 12 months have elapsed since the doctor last provided drugs or appliances
  - the doctor has been removed from the medical performers list.

*(regulation 69)*

## 7. Removal from a pharmaceutical list

- 7.1. Once a chemist is accepted onto the pharmaceutical list, the Primary Care Trust has defined powers to remove such persons from the list.

### Death

- 7.2. Where a Primary Care Trust decides that a chemist has died, it may remove that person's name from the list, unless the business is being carried on by a personal representative, in accordance with the provisions of the Medicines Act 1968<sup>21</sup> and such representative has agreed to be bound by the National Health Service terms of service (*regulation 45(2)(a)*).

### Chemist "no longer a chemist"

- 7.3. The Primary Care Trust must also remove a chemist's name from the list where it has determined that a chemist is no longer a chemist. This provision would apply where the Primary Care Trust becomes aware that a pharmacist has resigned from the Register of Pharmaceutical Chemists maintained by the Royal Pharmaceutical Society of Great Britain (RPSGB) or has had his name removed from the Register in accordance with a direction of the Statutory Committee of the RPSGB. In the case of a body corporate, this would apply where the company had been removed from the Companies' Register or is no longer the person listed in the Register maintained by the RPSGB of retail pharmacy premises (*regulation 45(2)(b)*).
- 7.4. Similar provisions also apply for chemists removed from Primary Care Trust's pharmaceutical lists on fitness to practise grounds. Guidance on this is available at [http://www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/NHSPPharmaceuticalRegulations/NHSPPharmaceuticalRegulationsArticle/fs/en?CONTENT\\_ID=4134713&chk=76sF%2Bt](http://www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/NHSPPharmaceuticalRegulations/NHSPPharmaceuticalRegulationsArticle/fs/en?CONTENT_ID=4134713&chk=76sF%2Bt)

### Those not providing pharmaceutical services (*regulation 45(7)*)

- 7.5. In addition, the Primary Care Trust has the power to remove from the list any chemist who was for the preceding six months on the list, but whom the Primary Care Trust has determined did not for that period of six months provide pharmaceutical services.
- 7.6. If the Primary Care Trust is minded to use this provision, the regulations say that:

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<sup>21</sup> Section 72 provides that a pharmaceutical business may be carried on by a personal representative under the personal control of a pharmacist for a period of five years from the date of death.

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- it must first give 28 days' notice of this intention to the chemist
- it must give the chemist the opportunity to make representations in writing, or at his/her option, orally; and
- it must consult the Local Pharmaceutical Committee

*(regulation 45(10))*

- 7.7. This regulation does **not** mean that the pharmacist will automatically come off the list after the 28 day period has expired. This event will only occur if, in the exercise of its discretion after the 28 day period is over, the Primary Care Trust decides to remove his/her name.
- 7.8. Any decision under the above is to be notified in writing to the chemist. The chemist will remain on the list until the expiry of the 30 day period for appeal, or, if an appeal is made, until the final determination of the appeal.

### **Appeal** *(regulation 45(12))*

- 7.9. A chemist so notified has a right of appeal to the Appeal Unit. The appeal must be in writing and set out the grounds of appeal and be lodged within 30 days. If the appeal is allowed, the chemist may not be removed from the list.
- 7.10. The mere fact that a chemist has been taken off the list is not to prejudice his/her right to be included again in the list. Further safeguards exist in relation to periods of "relevant service" under *regulation 45(16)*.