Regulations under the Health Act 2009: Market entry by means of Pharmaceutical Needs Assessments

Information for Primary Care Trusts
Transitional provisions

July 2012

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Transitional provisions

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First published July 2012

Published to DH website, in electronic PDF format only.
http://www.dh.gov.uk/publications

DH INFORMATION READER BOX	
Policy	Estates
HR / Workforce	Commissioning
Management	IM & T
Planning /	Finance
Clinical	Social Care / Partnership Working

Document Purpose	Best Practice Guidance
Gateway Reference	17812
Title	Market entry by means of PNAs : information for PCTs - transitional guidance
Author	Department of Health - Medicines and Pharmacy
Publication Date	July 2102
Target Audience	PCT CEs, SHA CEs, Directors of PH, Pharmacy organisations, Primary Care Trust Commissioning, Patient groups
Circulation List	
Description	Guidance on the NHS (Pharmaceutical Services) Regulations 2012 - transitional guidance
Cross Ref	The NHS (Pharmaceutical Services) Regulations 2012 and accompanying documents
Superseded Docs	The NHS (Pharmaceutical Services) Regulations 2005
Action Required	
Timing	**n/a**
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For Recipient's Use	

Executive summary

- **Schedule 7** to the NHS (Pharmaceutical Services) Regulations 2012 (the "2012 Regulations") sets out the provisions for matters, which are not finally determined on the "appointed day". For the purposes the 2012 Regulations, the "appointed day" is 1 September 2012 when the 2012 Regulations come into force.

- The primary purpose of this document is to help all those working in PCTs with the task of determining applications relating to the provision of pharmaceutical services in England in the period of transition after the NHS (Pharmaceutical Services) Regulations 2005, as amended ("the 2005 Regulations") have been repealed but during which some applications still fall to be determined under those Regulations rather than the 2012 Regulations. This guidance is also intended to be of assistance to all others who are affected by such decisions.

- In summary and in general, applications which do not have an equal provision in the 2012 Regulations are treated as void if the period for submitting comments ends on or after 1 September 2012. Any fees paid should be refunded. The only exception to this is where the PCT has decided to defer consideration of an application (but not because the application was incomplete). PCTs will therefore wish to review all current applications which:

  - have been sent out for notification but the period for submitting comments does not expire until on or after 1 September 2012; or
  - which have not yet been notified to interested parties,

  and inform applicants accordingly as soon as is practicable. It is good practice to copy the Local Pharmaceutical Committee (LPC) into the letter and to advise unsuccessful applicants that there is no right of appeal against the PCT's decision to treat such applications as void.

- Applications which have been notified and where the period for receiving comments ended on 1 September 2012 or earlier should continue to be determined under the 2005 Regulations.

- Applications which have an equivalent in the new 2012 Regulations are not affected and continue to be determined under the 2005 Regulations, including the procedures for notification, consideration of comments received, determination, communicating the decision and appeal rights.

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Introduction

1. **Schedule 7** to the NHS (Pharmaceutical Services) Regulations 2012 (the "2012 Regulations") sets out the provisions for matters, which have not been finally determined under the NHS (Pharmaceutical Services) Regulations 2005, as amended (the "2005 Regulations") on the "appointed day". For the purposes of the 2012 Regulations, the "appointed day" is 1 September 2012 when the 2012 Regulations come into force.

2. Although this guidance contains reference to most of the paragraphs in Schedule 7, the primary purpose of this document is to help all those working in PCTs with the task of determining[1] applications relating to the provision of pharmaceutical services in England in the period of transition after the 2005 Regulations have been repealed but during which some applications still fall to be determined under those Regulations rather than the 2012 Regulations. This guidance is also intended to be of assistance to all others who are affected by such decisions.

3. Although this guidance contains reference to the legal provisions, the rules themselves are not, in the main, set out word for word 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.

4. This document's legal status is that it is non-statutory guidance, designed to assist PCTs 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 based on the analysis and advice contained in this guidance (or indeed any other commentary on the law).

5. Furthermore, although it is hoped that PCTs will find this guidance helpful, the Department's view is that PCTs are not obliged to take this guidance into consideration when formulating their decisions. Their own understanding of the law is fundamentally a matter for them[2] and where they are in doubt, they should seek legal advice.

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[1] Reference is made in the Regulations to the determination of applications. Effectively, this means making a decision on an application i.e. approval, refusal or deferral.

[2] It should be noted that in a Court of Appeal decision, Lord Justice Lawrence Collins stated that '*if the Secretary of State issues non-statutory guidance for decision-makers, and there is a radical departure from the guidance, then, although not relevant to the construction of the relevant provisions, the guidance may be relevant to a challenge because the decision-maker may be under an obligation to take it into account and to explain why he has taken that radically different approach*. Assura Pharmacy Ltd and NHS Litigation Authority (Family Health Services Appeal Unit) and E Moss Ltd (trading as Alliance Pharmacy) December 2008 - http://www.bailii.org/ew/cases/EWCA/Civ/2008/1356.html.

Transitional provisions – Pharmaceutical needs assessments and listing matters: introduction

1. The tables below outline most of the transitional provisions in Schedule 7 to the 2012 Regulations. The tables indicate, where relevant, how PCTs should deal with certain applications received under the 2005 Regulations before 1 September 2012 and how those provisions under the 2005 Regulations, such as current pharmaceutical needs assessments (PNAs) and listing of premises which will continue under the 2012 Regulations, should be dealt with.

2. The tables are divided between three issues:

    - pharmaceutical needs assessments (PNAs);
    - applications for market entry and in rural areas; and
    - other continuing matters.

Applications for inclusion in a pharmaceutical list

3. There are two different categories of application for inclusion in a pharmaceutical list that have been made under the 2005 Regulations and which are outstanding on 1 September 2012:

    - applications for which there is an equivalent type of application under the 2012 Regulations, i.e. applications for distance-selling premises, change of ownership applications, minor relocations, applications relating to rural dispensing including determining controlled localities, reserved location re-determinations and applications for inclusion in a dispensing doctor list; and

    - applications for which there is no equivalent under the 2012 Regulations, i.e. applications under the “necessary or expedient test” and applications for three of the four exemption applications.

In the light of this, the Department has sought to make its own view clear that decision-makers are not bound to take this particular example of non-statutory guidance into account. However, as Lord Justice Sedley notes in his judgment in Assura, it is currently unresolved at appellate level how an independent tribunal should treat departmental guidance given otherwise than under statutory authority, and reserves his view on the matter to a case where the issue is pivotal. This issue may therefore be subject to further judicial consideration in the future.

Applications for which there is an equivalent type of application under the 2012 Regulations

4. Applications for which there is an equivalent type of application under the 2012 Regulations are preserved[3] and will continue to be dealt with in accordance with the 2005 Regulations until finally determined[4]. For example, a change of ownership application is received prior to 1 September 2012 under the 2005 Regulations. This would be dealt with under the 2005 Regulations until it is finally determined. There is one matter to note with regard to distance-selling premises – regulation 64(d) and (e) of the 2012 Regulations (conditions relating to pharmacy procedures and communications matters) do not apply to pharmacy contractors already on a PCT's pharmaceutical list on 1 September 2012 until 1 March 2013 (six months after the appointed day). See Chapter 11 of the market entry guidance for more details.

Applications for which there is no equivalent type of application under the 2012 Regulations

5. Applications for which there is no equivalent under the 2012 Regulations are **not** preserved unless the period for which they have to be notified by the applicant's PCT has come to an end, or is treated as having come, to an end. For example, an application is deferred for a period of at least 14 days but not because the application was incomplete. Applications are also preserved if they are an application for full consent based on an earlier successful application for preliminary consent. These applications will continue to be dealt with in accordance with the 2005 Regulations until finally determined.

6. If an application is not preserved by the transitional provisions because its notification period has not (or is not treated as having) come to an end, **the application is void** and the PCT must return any fee charged in relation to that application. PCTs should notify the applicant accordingly. There is no right of appeal against this notification.

3 "Preserved" is a term used in this document to mean that the application continues to be dealt with under the 2005 Regulations and not the 2012 Regulations

4 An application is not 'finally determined' or "finally granted" until the end of the period for bringing an appeal or until the determination of any such appeal, whichever is the later.

Title	Stage in process	Transitional provision
A1 Pharmaceutical Needs Assessments	**B1(1)** PCT has published its first or a revised PNA (and subsequent supplementary statements) before 1 September 2012.	**C1(1)** The PNA continues to have effect under the 2012 Regulations until it is replaced by a revised assessment (the maximum gap between assessments remains three years). (**paragraph 1(1) of Schedule 7**)
	B1(2) PCT is consulting on a revised PNA as required by regulation 3F of the 2005 Regulations immediately before 1 September 2012.	**C1(2)** If the consultation on the PNA is valid under the 2005 Regulations, it remains so under the 2012 Regulations despite any differences between the 2005 and the 2012 Regulations. For example, equalities issues are treated differently in the two sets of Regulations (a shift of emphasis to allow reliance on pre-existing equalities duties rather than creating new ones). However, the transitional provisions will not validate a consultation exercise that is invalid for some other reason, for example, because a draft PNA has been consulted on for less than the required minimum period of 60 days. (**paragraph 1(2) of Schedule 7**)

<table>
<tr><th colspan="3">Listing applications: NHS chemists</th></tr>
<tr><td rowspan="3">A2 Applications made for preliminary consent ((40(1) of the 2005 Regulations) or full consent (5(1) of the 2005 Regulations) which do not have regard to regulations 6-10, 13(1)(d) or 54 of the 2005 Regulations.

The types of applications that fall into this provision are those determined in accordance with the “necessary or expedient test”; 100 hours per week pharmacies, one stop primary care centre pharmacies and pharmacies in approved retail areas (paragraph 2(1), (4) and (5) of Schedule 7)[5].</td><td>B2(1) Application has been notified under the 2005 Regulations and the period for making representations has elapsed before 1 September 2012 (paragraph 2(1) of Schedule 7).</td><td>C2(1) Determine the application and notify appeal rights referring to the 2005 Regulations. Any appeal is made under the 2005 Regulations.</td></tr>
<tr><td>B2(2) Application has been deferred for at least 14 days, but:
(i) the deferment was not simply because the application was incomplete; and
(ii) had the application been notified on the date on which it was deferred, the relevant notification period would have elapsed before 1 September 2012 (paragraph 2(2) of Schedule 7).

Deferral could have been on fitness grounds or due to an LPS designation.</td><td>C2(2) Determine the application and notify appeal rights referring to the 2005 Regulations. Any appeal is made under the 2005 Regulations.</td></tr>
<tr><td>B2(3) Application is for full consent and follows an application for preliminary consent that was finally granted before 1 September 2012 (please note, the full</td><td>C2(3) Determine the application and notify appeal rights referring to the 2005 Regulations. Any appeal is made under the 2005 Regulations.</td></tr>
</table>

[5] Where PCTs undertake fitness to practise checks on applicants not already included on their pharmaceutical list to satisfy themselves that the applicant is suitable for inclusion in the pharmaceutical list prior to beginning to process an application, PCTs should ensure that they are still meeting the regulatory obligation to determine applications within four months or 30 days for receipt. At the appointed day, a PCT may therefore find it has an application, which it has not yet started to process – the PCT will therefore need to work out whether the notification period for the application would have ended by the appointed day if they had instead run the fitness to practise checks in tandem with the notification of the application. When in doubt, PCTs are advised to seek legal advice.

	consent application does not have to have been submitted before 1 September 2012. However, it must have been submitted in line with the requirements of regulation 41 of the 2005 Regulations) (**paragraph 2(4) of Schedule 7)**.	
	B2(4) Application is for full consent and follows a successful application for preliminary consent which was made before 1 September 2012 but determined on or after 1 September 2012 under the 2005 Regulations in accordance with the transitional provisions (**paragraph 2(5) of Schedule 7**).	**C2(4)** Determine the application and notify appeal rights referring to the 2005 Regulations. Any appeal is made under the 2005 Regulations.
	B2(5) Application requires notification under the 2005 Regulations but on 1 September 2012 has not reached the point where the period for making such representations has elapsed and cannot be determined by virtue of the transitional provisions set out in Schedule 7 of the 2012 Regulations.	**C(2)(5)** The application is void. The application is not deemed to be refused. There are no appeal rights and such applications should not be taken into account for the purposes of regulation 40(2) of the 2012 Regulations. Any fee paid should be refunded back to the applicant (**paragraph 2(8) of Schedule 7**).

A3 Applications made for preliminary consent ((40(1) of the 2005 Regulations) or full consent (5(1)) of the 2005 Regulations which have regard to regulations 6-10, 13(1)(d) or 54 of the 2005 Regulations. The types of applications that fall within this provision are distance-selling applications, minor relocations, change of ownership, applications arising out of suspensions or declared emergencies and LPS chemists exercising a right of return (**paragraph 2(3) and (5) of Schedule 7**).	**B3(1)** A preliminary or full application is submitted for one of these types of application, but has not been determined by 1 September 2012.	**C3(1)** Determine the application and notify appeal rights referring to the 2005 Regulations. Any appeal is made under the 2005 Regulations.
	B3(2) A preliminary application submitted for one of these types of application is determined on or after 1 September 2012, and subsequently the full application is submitted in line with regulation 41 of the 2005 Regulations.	**C3(2)** Determine the application and notify appeal rights referring to the 2005 Regulations. Any appeal is made under the 2005 Regulations.
Approved retail areas **A4** Application made under regulation 5(1) of 2005 Regulations for premises within an approved retail area (having regard to regulation 13(1)(a) of the 2005 Regulations).	**B4(1)** The transitional provisions (**paragraph 4 of Schedule 7**) only apply if the application is to be determined under the 2005 Regulations. In order to determine if that is the case, see A2, B2 and C2 above.	**C4(1)** If the application is to be determined in accordance with the 2005 Regulations, for the purposes of that determination an area is an approved retail area if immediately before 1 September 2012, it is included in the Secretary of State's approved retail areas list.

	B4(2). A retail area is newly included on the Secretary of State's approved retail areas list before 1 September 2012 and a related application requires notification under the 2005 Regulations but has not reached the point where the period for making such representations has elapsed before 1 September 2012 and cannot be determined by virtue of the transitional provisions set out in Schedule 7 of the 2012 Regulations.	**C4(2)**The application is void. The application is not deemed to be refused. There are no appeal rights and such applications should not be taken into account for the purposes of regulation 40(2) of the 2012 Regulations. Any fee paid should be refunded back to the applicant (**paragraph 2(8) of Schedule 7**).
Listing applications: dispensing doctors		
A5 Application under Part 5 of the 2005 Regulations for outline consent and premises approval including temporary premises approval.	**B5** Application made under 2005 Regulations has not been finally determined before 1 September 2012 (including applications under appeal).	**C5** Determine the application and notify appeal rights referring to the 2005 Regulations. Any appeal is made under the 2005 Regulations (**paragraph 3(1) and (2) of Schedule 7**).
A6 PCT requires a doctor to provide pharmaceutical services under regulation 60(4)(a) of 2005 Regulations.	**B6** Doctor has appealed against decision before 1 September 2012/or the time limit for bringing an appeal against the decision in regulation 60(12) of the 2005 Regulations has not elapsed before 1 September 2012.	**C6** Appeal processed and determined under 2005 Regulations (**paragraph 3(3) of Schedule 7**).

Controlled localities		
A7 Controlled localities determined before 1 September 2012.	**B7** Areas that are, or are part of, controlled localities on 1 September 2012.	**C7** These controlled localities continue under the 2012 Regulations. PCTs must delineate the boundary of the controlled locality/part of controlled locality on the map published alongside or as part of the PNA (**paragraph 5(1) of Schedule 7**).
A8 Determining whether or not an area is or is not a *controlled locality* or part of one whether by instigation of PCT or a Local Pharmaceutical Committee or a Local Medical Committee but not in connection with an application to be included in a pharmaceutical list in a rural area.	**B8** In the process of determining whether or not an area is or is not a *controlled locality* before 1 September 2012.	**C8** Determine the matter and notify appeal rights referring to the 2005 Regulations. Any appeal is made under the 2005 Regulations. (**paragraph 5(2)(a) of Schedule 7**). When the matter is finally determined the PCT will need to ensure its maps are updated accordingly (**paragraph 5(3) of Schedule 7**).
A9 Determining an application to be included in a pharmaceutical list, in the course of which the question arises, or has already arisen, as to whether or not there needs to be a *controlled locality* determination.	**B9** The transitional provision (**paragraph 5(2)(a) of Schedule 7**) only applies if the application is to be determined under the 2005 Regulations. In order to determine if that is the case, see A2 and 5, B2 and 5 and A5 and C5 above.	**C9** If the related application is to be determined under the 2005 Regulations, the *controlled locality* determination must also be determined under the 2005 Regulations, whether or not the process for that has started before 1 September 2012 (**paragraph 5(2)(b) of Schedule 7**). When the matter is finally determined the PCT will need to ensure its maps are updated accordingly (**paragraph 5(3) of Schedule 7**).

Other rural dispensing matters		
Reserved locations **A10** Applications for inclusion in a pharmaceutical list by NHS chemists which fall to be determined in accordance with the "necessary or expedient test" and the premises or relevant location from which the applicant wishes to provide pharmaceutical services is or may be in a reserved location.	**B10(1)** The application is to be determined in accordance with the 2005 Regulations by virtue of the transitional provisions, and has not been finally determined before 1 September 2012.	**C10(1)** Classification of area as reserved location is determined under 2005 Regulations (if a further determination is required of the same area after application is finally determined, it should be re-determined under the 2005 Regulations) (**paragraph 6(1) of Schedule 7**). If, or when, a determination takes effect, the reserved location must be included on the PCT's map published alongside or as part of the PNA (**paragraph 6(3) of Schedule 7**).
	B10(2) Determination of whether or not an area is a reserved location has been made before 1 September 2012, and either the determination has been appealed or the time limit for bringing an appeal has not elapsed before 1 September 2012.	**C10(2)** Arrangements for bringing an appeal and determination of it (if valid) should be made under the 2005 Regulations (**paragraph 6(2) of Schedule 7**). If, or when, a determination takes effect, the reserved location must be included on the PCT's map published alongside or as part of the PNA (**paragraph 6(3) of Schedule 7**).

Gradual discontinuation of provision of pharmaceutical services by doctors (gradualisation) **A11** Circumstances where PCT is required to terminate any arrangements with relevant dispensing doctors and consider "gradualisation".	**B11(1)** Before 1 September 2012, PCT has made a decision (in circumstances where gradualisation is possible) to terminate arrangements or to postpone the termination of such arrangements and the decision has been appealed or the time limit for an appeal has not elapsed before 1 September 2012.	**C11(1)** Arrangements for bringing an appeal and the determination of it (if valid) should be made under the 2005 Regulations (**paragraph 7(2) of Schedule 7**).
	B11(2) Before 1 September 2012, the PCT is considering terminating or postponing the termination of such arrangements under the 2005 Regulations in circumstances where gradualisation is possible, but the PCT has not yet taken a decision in relation to it.	**C11(2)** The consideration, decision and any appeal are made under the 2005 Regulations (**paragraph 7(3) of Schedule 7**).
	B11(3) On or after 1 September 2012, a pharmacy application is granted under the 2005 Regulations by virtue of the transitional provisions, and as a consequence, the PCT has to make a decision to terminate arrangements with dispensing doctors or postpone termination of such arrangements.	**C11(3)** Any decisions and appeals are to be made under 2005 Regulations (**paragraph 7(1) and (2) of Schedule 7**).
	B11(4) Gradualisation conditions are imposed on dispensing doctors under the 2005 Regulations, postponing the termination of arrangements, whether	**C(11)(4)** The conditions continue to have effect under the 2012 Regulations (**paragraph 7(4) of Schedule 7).**

	before 1 September 2012 or by virtue of the transitional provisions.	
Gradual introduction of provision of pharmaceutical services by doctors **A12** Circumstances where PCT is required to consider postponing introduction of pharmaceutical services by doctors, which impacts on pharmaceutical services provided by pharmacy contractors.	**B12(1)** Before 1st August 2012, the PCT has made a decision to postpone the introduction of such arrangements and the decision has been appealed or the time limit for an appeal has elapsed before 1 September 2012.	**C12(1)** Arrangements for bringing an appeal and determination of it should be made under the 2005 Regulations (**paragraph 8(2)(b) of Schedule 7**).
	B12(2) Before 1 September 2012, the PCT is considering postponing the introduction of such arrangements under the 2005 Regulations in circumstances where gradualisation is possible but the PCT has not yet taken a decision in relation to it.	**C12(2)** The consideration, decision and any appeal are made under the 2005 Regulations (**paragraph 8(3) of Schedule 7**).
	B12(3) On or after 1 September 2012, an application is granted under the 2005 Regulations by virtue of these transitional provisions, and as a consequence, the PCT has to make a decision under regulation 20(2) of those Regulations to postpone the introduction of arrangements with a dispensing doctor.	**C12(3)** Any decisions and appeals are to be made under 2005 Regulations (**paragraphs 8(1) and (2)(a) of Schedule 7)**.

	B12(4) Gradualisation conditions are imposed on dispensing doctors under the 2005 Regulations, postponing the introduction of arrangements, whether before 1 September 2012 or by virtue of these transitional provisions.	**C12(4)** The conditions continue to have effect under the 2012 Regulations (**paragraph 8(4) of Schedule 7**).
Lists		
Giving effect to listing decisions taken under 2005 Regulations **A13** Before 1 September 2012 or under the transitional arrangements, an application for inclusion in a pharmaceutical or dispensing doctor list is granted.	**B13** A person is entitled to be included in a PCT's pharmaceutical or dispensing doctor list or to have their listing changed before 1 September 2012.	**C13** PCTs should follow the listing arrangements set out in the 2005 Regulations (**paragraph 9 of Schedule 7**).

Dispensing contractor lists **A14** GP contractors are, or have applied to be, included in a PCT's dispensing contractors' list under the GMS or PMS Regulations to provide dispensing services. These lists are different to the dispensing doctor lists provided for in the 2005 and 2012 Regulations, and PCTs may well not have one.	**B14** The dispensing contractor list system is being abolished. Therefore, any existing arrangements or applications to enter into arrangements that either are or are going to become ongoing dispensing arrangements, must be incorporated into the dispensing doctor list system.	**C14** Dispensing contractor lists and dispensing doctor lists merge on 1 September 2012, unless there are outstanding fitness to practise issues in relation to a dispensing contractor, in which case, their PCT's dispensing contractor list continues in being until the outstanding issues are resolved. Any outstanding applications are processed under the dispensing contractor list system. However, successful applications are included in the PCT's dispensing doctor list rather than the dispensing contractor list (**paragraph 10 of Schedule 7**).
Terms of service		
Terms of service for distance selling pharmacies **A15** Persons and premises included in a pharmaceutical list immediately before 1 September 2012 on the basis of an application to which regulation 13(4) of the 2005 Regulations applied.	**B15** Pharmacy contractor whose application was granted on the basis of regulation 13(4) of the 2005 Regulations and has been included in the PCT's pharmaceutical list before 1 September 2012.	**C15** Regulation 64(3)(d) and (e) of the 2012 Regulations do not apply to these listed chemist premises until the mid-March February 2013 (six months after the appointed day) (**paragraph 16 of Schedule 7**). These are conditions relating to pharmacy procedures and communications matters.

Other continuing matters

Title	Explanation
Continuing matters: periods of time	**Paragraph 11 of Schedule 7** allows for the continuity of periods of time between the two sets of Regulations. For example, if a contractor is obliged to provide fitness to practise information under the 2005 Regulations, the timetable for providing that information does not automatically restart on 1 September 2012. Similarly, if a contractor is facing removal from a pharmaceutical list because they have not been providing services, the clock for that cessation period does not restart when the 2012 Regulations come into force.
Other continuing matters: NHS chemists	**Paragraph 12(1) of Schedule 7** confirms that PCTs' pharmaceutical and electronic prescription service (EPS) lists as at 1 September 2012 continue. **Paragraph 12(2) of Schedule 7** addresses what happens to contractors in the case of issues arising before 1 September 2012 that could lead to action being taken under the NHS (Service Committees and Tribunal) Regulations 1992, as amended (the SCAT Regulations) in relation to concerns relating to non-compliance with terms of service. Matters arising before 1 September 2012 continue to be dealt with under the SCAT Regulations and the 2005 Regulations, as appropriate. **Paragraph 12(3)-(5) of Schedule 7** address what happens to contractors who are facing any fitness to practise action. Proceedings that are commenced before 1 September 2012 continue in accordance with the relevant

	provisions of the 2005 Regulations. However, proceedings commenced on or after 1 September 2012, even if they deal with matters arising before 1 September 2012, use the new system. The exception is reviews of decisions under the old system which are requested by contractors on or after 1 September 2012 – these reviews are dealt with under the 2012 Regulations. In relation to decisions with regard to remuneration of suspended chemists, if the chemist was suspended before 1 September 2012, these are to be made in accordance with the arrangements in force before 1 September 2012. **Paragraph 12(6) of Schedule 7** confirms that any direction or approval relating to a pharmacy or dispensing appliance contractor's (DAC) terms of service under the 2005 Regulations continues under the 2012 Regulations, for example, where a PCT has directed a pharmacy to open at certain times.
Fees for applications	By virtue of the transitional provisions set out in **Schedule 7**, PCTs may need to make further decisions on applications that were or are (under the transitional arrangements) submitted under the 2005 Regulations. The fee to be paid by the applicant in these cases, where relevant, is the fee relating to the Pharmaceutical Services Fees for Applications Directions 2008 as amended.