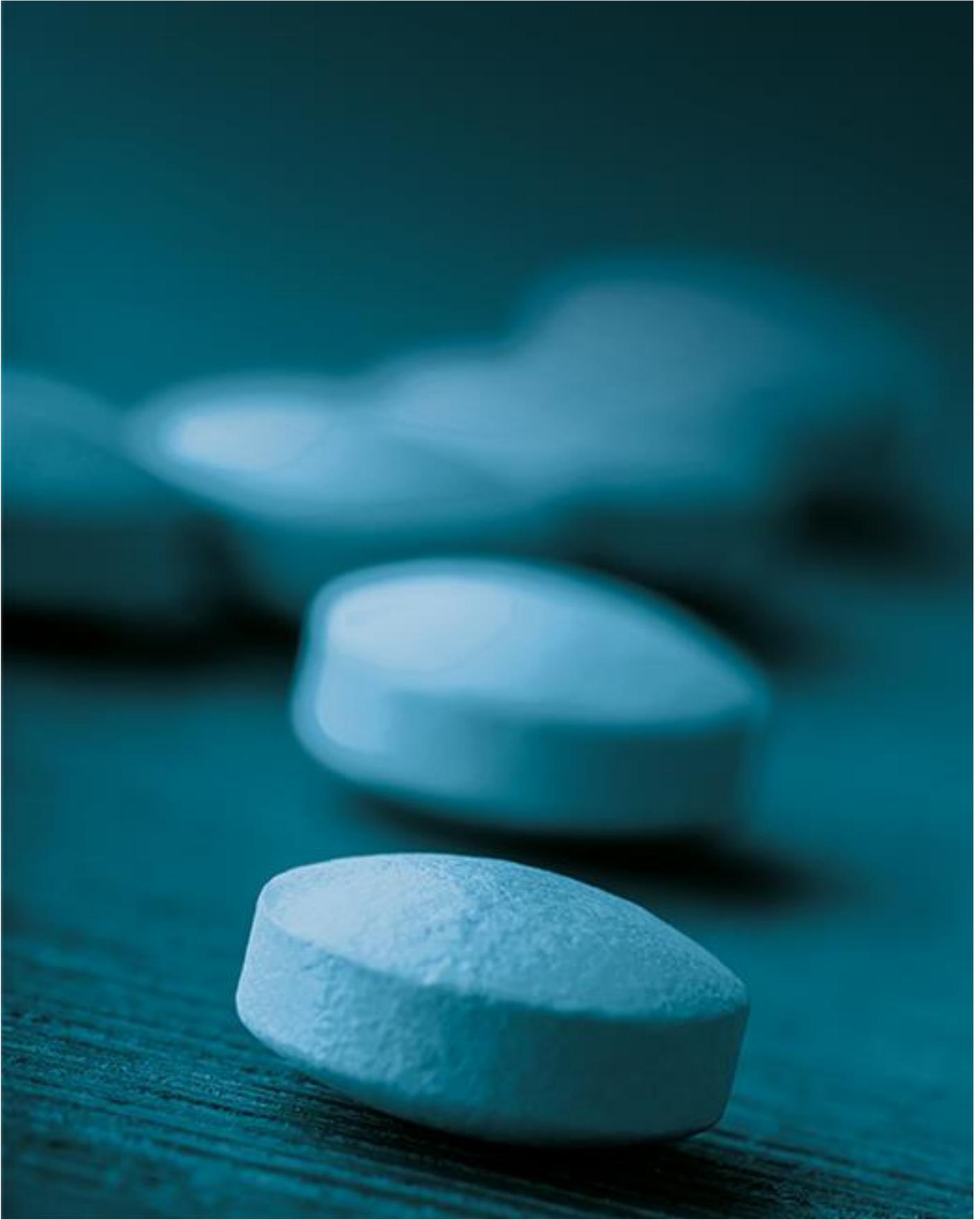

**A guide to market entry applications
for NHS pharmacy contracts in
England**



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Introduction

NHS contracts are valuable because they are hard to come by. Equally, if a new contract is granted, it can have devastating consequences for existing pharmacy businesses.



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Obtaining a pharmacy contract or opposing an application that would impact on an existing pharmacy business is not a straightforward process. The regulations and the law are complicated. What is more, rights can easily be lost if specific requirements are not met, such as the right to appeal or the right to attend a hearing.

We act for both applicants and objectors, and have been involved in key developments and changes in the law for some 30 years, and continue to lead the way with up-to-the-minute expertise and our active participation in the Users Group of the Family Health Services Appeal Unit.

As a law firm regulated by the Solicitors Regulation Authority, we provide our clients with:

- The highest professional standards
- Unrivalled experience
- Unique legal expertise
- Clear advice without legalese or jargon
- The confidence that we will act in our client's best interests
- Site visits
- Representation and advocacy at hearings
- Fee estimates (and we are also happy to discuss fixed fee arrangements)

Charles Russell Speechlys is the UK's only law firm specialising in providing a full range of legal services to the community pharmacy sector. We have advised and represented pharmacists and pharmacy owners for over 50 years; and we have been involved in market entry cases since controls were introduced in 1987.

This guide is intended as an overview of market entry applications. It deals with the most common questions that our clients ask us when they are considering making an application or have received notification of an application in their local area.

Starting out

What is market entry and what is an NHS pharmacy contract?

NHS England is required to maintain lists for every Health and Wellbeing Board (HWB) area. These lists contain the names and addresses of companies and pharmacists who provide NHS services.

Only someone who is on the pharmaceutical list can provide NHS pharmaceutical services

Only someone who is in a pharmaceutical list can provide pharmaceutical services under the NHS and be paid for doing so.

Being included in a pharmaceutical list is often referred to as having an NHS contract.

The term “market entry” refers to being entered in a pharmaceutical list. The term “control of entry” is sometimes used to mean the same thing.

Pharmaceutical Needs Assessments

Every HWB must publish a Pharmaceutical Needs Assessment (PNA) for its area. Health and Wellbeing Boards (or HWBs) cover local authority areas

What is a “PNA”?

The PNA will list the services available throughout the area and refer to any need that has been identified for additional services that are needed now, or will be needed in the future.

PNA's tend to take an overview of local authority wards or significant towns. They usually do not look at particular needs in smaller localities.

The PNA should be the starting point for anyone who is thinking of making an application for a new pharmacy contract or anyone who wants to object to an application being granted.

We can review the relevant PNA and advise you on the best type of application to make.

Getting it right from the start

What types of application can be made?

The main types of application are:

To meet a current need

To meet a future need

**To secure improvements or better access to services
(unforeseen benefits)**

**For distance selling applications (these are sometimes called
mail order or internet pharmacies)**

To relocate a pharmacy that already has an NHS contract

Change of ownership

Merging pharmacies

We can provide you with the relevant application form

There are standard application forms that must be used for each type of application. It is important to use the right application form from the beginning because the type of application being made cannot be changed once the form has been sent in to NHS England. We can provide you with the relevant application form.

Applicants do not have to own premises when they make an application. If they cannot put a specific address in their new contract application form, they must give their best estimate of where their premises would be. However, applications should not be made for premises which are already listed.

There is a fee for making an application payable to NHS England ranging from £150 to £3,000. We can advise on the appropriate fee.

New contracts

Current and future needs applications

If the PNA identifies any current or future need for a pharmacy, then an application can be made to meet this need. An application that meets a need identified in the PNA will usually be granted.

It is rare for a PNA to identify a need for a new pharmacy. When a need is identified, it typically relates to:

- A need for out-of-hours or weekend services
- A town where there is no existing pharmacy
- A significant new housing development

Unforeseen benefits applications

If a PNA does not identify a current or future need for a new pharmacy, an application can be made to secure improvements or better access to services. This is called an “unforeseen benefits” application.

The applicant will need to show that:

- Granting the application would secure improvements or better access to services
- Granting the application would confer significant benefits on people in the HWB area

Choice is the most important factor in our experience

Three things are taken into account when deciding whether an application should be granted:

- The desirability of having a reasonable choice regarding obtaining services in the area
- Whether people with a protected characteristic (like age or infirmity) who require access to a specific pharmaceutical service have difficulty accessing that service
- Innovative approaches to providing services.

Choice is the most important of these factors, in our experience.

What other information should an applicant put in a form and what should an objector look for?

Apart from the contents of the local PNA, other relevant information may include:

- The local population size, and whether it is growing
- Local demographics
- The locations of existing GPs (and any recent or future changes)
- The location and accessibility of existing pharmacies
- The appointment times of GPs and the opening times of existing pharmacies
- The provision of services by existing pharmacies

Why might an unforeseen benefits application be turned down?

If an applicant does not demonstrate that improvements or better access would be secured, and that significant benefits would be conferred on local people, the application will be turned down.

An application will also be refused if granting it would cause significant detriment to:

- proper planning of pharmaceutical service provision
- the current arrangements in place for the provision of services

These factors may involve consideration of any plans NHS England has in relation to health services; and whether an existing pharmacy would lose so many prescriptions that it could close, leaving a gap in services that the new pharmacy would not fill.

Distance selling applications

Distance selling contracts cannot be located at the site of a GP practice.

Essential pharmacy services cannot be provided to patients who are present on premises that have a distance selling contract. Applicants for one of these contracts must satisfy NHS England that there would be safe and effective provision of essential services without face to face contact with patients or carers.

Services cannot be limited to a locality and must be available on a nationwide basis.

We have a lot of experience of reviewing SOPs

In order to demonstrate that services would be provided safely and effectively, applicants often send SOPs with their application forms. These will be scrutinised rigorously, for example to see if they might involve patients receiving services at the premises, and to make sure that there will be satisfactory arrangements for dealing with controlled drugs and fridge lines.

SOPs should be tailored to the proposed distance selling pharmacy.

We have a lot of experience of reviewing SOPs when acting for both applicants and objectors. We can provide detailed guidance on the contents of SOPs, and can take a look at draft SOPs and advise on changes that will help to secure a grant. For objectors, we can review the SOPs provided by the applicant and spot areas of weakness to help secure a refusal.

Determining new applications and appeals

Applications are decided by NHS England.

If NHS England turns down an application, the applicant will have a right of appeal to the Family Health Services Appeal Unit (FHS AU). You might hear the FHS AU be referred to as the NHSLA or the NHS Litigation Authority.

There is a right of appeal against most decisions of NHS England

If NHS England grants an application, objectors may have a right of appeal to the FHS AU. They will only have this right if they made written representations to NHS England and if their representations were relevant. Our many years of experience enable us to identify the relevant issues to ensure that appeal rights are preserved.

If the applicant did not specify an address in its application form, a grant will be conditional, and the applicant must notify NHS England of a specific address within 6 months of NHS England's decision.

Changes to existing pharmacies

As well as including new pharmacies in the pharmaceutical list, NHS England can make changes to pharmacies which are already listed.

NHS England can make changes to pharmacies which are already listed

Relocations

Applicants who want to relocate an existing pharmacy contract must show that the new premises will not be significantly less accessible for the patient groups who use the existing pharmacy. They must also show that granting an application would not result in a significant change in arrangements for the provision of services in the local area and would not cause significant detriment to proper planning for services in the area.

A pharmacy can only be relocated within a HWB area or to a neighbouring HWB area.

Relocation applications are often highly contentious, and the question of what is a patient group has proved to be complicated and has involved arguments in the High Court.

Change of ownership

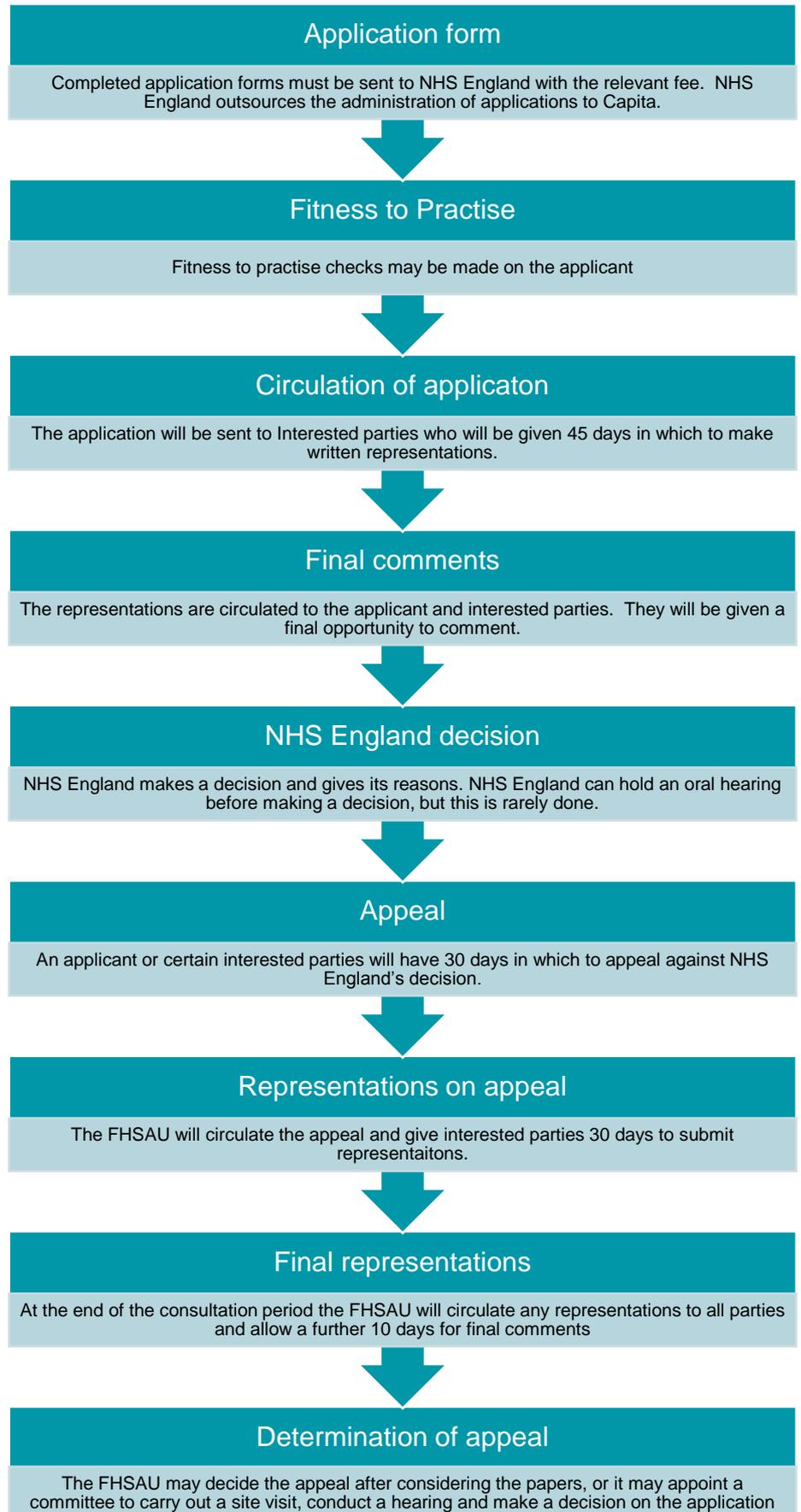
Change of ownership applications are needed when pharmacies are sold. Applications are generally straightforward and must be dealt with by NHS England within 30 days. Because applicants do not have control over the precise date when NHS England will put a buyer's name in the pharmaceutical list, the buyer and seller might need a separate contract (known as a Management Agreement) to allow the buyer to run the business on behalf of the seller from the date the purchase is completed.

We can advise you on Management Agreements.

Merging pharmacies

Pharmacies that are close together may apply to consolidate onto a single site. The pharmacies that merge together may have a single owner, or may have different owners before the merger takes place. Following a merger, the same services must be provided. Once a merger has been approved, NHS England cannot grant an application by someone else for a pharmacy contract on the basis that the closure of a one of the merged pharmacies has left a gap in service provision.

What is the procedure for applications?



Applications may take up to a year to be finally determined

How long does it take?

NHS England should make its decision within 4 months of receiving the application although it does not always meet this time limit.

If there is an appeal, it typically takes 15 weeks to receive a decision from the FHSU, or 25 weeks if there is an oral hearing.

What happens after an application has been granted?

Within 6 months of an application being granted, the applicant must send a form to NHS England, giving notice of the date on which services will commence. If the applicant has submitted a “best estimate” location for a new contract application, within 6 months of the grant it must notify NHS England of the actual address of the new pharmacy and then has 6 months to give notice of commencement.

If there was an appeal, the 6 months will run from the date of the appeal decision.

It may be possible to obtain an extension of up to 3 months before services commence if the applicant can show “good cause”

There is no right of appeal against a decision of the FHSU

What if you are unhappy with an appeal decision?

There is no right of appeal against a decision of the FHSU.

If the FHSU has got the law wrong or was unfair in some way, it may be possible to apply to the High Court to overturn the decision (a process known as “judicial review”). It is essential to act quickly or you may lose your rights. We have a lot of experience of challenges to FHSU decisions.

How can we help?

Since 1987 we have dealt with hundreds of cases and have many satisfied clients – applicants for whom we have secured valuable contracts, and objectors who credit us with having saved their businesses.

"They are leaders in acting for pharmacies, with great familiarity with the industry and relevant regulations."

Chambers UK 2016, Healthcare

Ask to be added to our free quarterly *Pharmacy Brief* in which we give examples of our recent cases, as well as other issues that are important to community pharmacy.

We will tailor our services to meet your needs and resources. These services can include:

- Site visits
- Assessing and advising you on your chances of success.
- Completing application forms
- Reviewing Standard Operating Procedures in applications for distance selling contracts
- Reviewing application forms before submission to NHS England
- Drafting objections to applications
- Drafting responses to objections
- Drafting appeals against NHS England decisions
- Making written representations to the Family Health Services Appeal Unit (FHSU)
- Advocacy at NHS England and FHSU hearings
- Advice on whether FHSU decisions can be overturned
- Bringing or defending judicial review cases

"Charles Russell Speechlys are legal specialists in the area of pharmacy regulation."

Chambers UK 2016, Healthcare

Our fees

We provide a cost effective service by tailoring our approach to meet your individual needs

We provide a cost effective service by adapting our approach to meet your individual needs. We recognise the importance of achieving a successful outcome and can tailor the cost to suit your resources, depending on which of the listed services you want.

We understand that every client is different. We are happy to work with you, providing as much or as little support as you need. We can offer a full service from start to finish, but some clients choose to instruct us later in the application process. This means that we can provide a service that meets your individual needs.

We are happy to visit the local area if you would like, although our experience means that we are able to carry out virtual site visits, using online resources. This helps keep costs down for clients.

Most of our clients choose a fee structure that means we only charge for the work that we do. We will always provide you with a fee estimate before starting work to help you budget.

Other clients prefer the certainty of a fixed fee structure, and we are happy to discuss these.

For clients that are looking to build their pharmacy group through multiple applications, we are happy to discuss fee discounts based on work volume, with a regular payment plan to help spread the cost.

What if you need help with anything else?

As a full service law firm, we can also advise on other areas of law

The regulation of community pharmacy is complicated. We can advise you on a wide range of issues to avoid problems with NHS England and other regulators like the GPhC. These issues may include extensions of time, or relate to hours of opening or the terms of service that apply to everyone with an NHS contract.

As a full service law firm, we can also advise on other areas of law, including buying and selling a pharmacy business, property law, employment, business and company law, wills and trusts and family law.

We have a broad range of skills and experience across the full spectrum of business and personal needs. This gives us a wide perspective, clear insight and a strongly commercial long-term view. We use this approach to secure the growth of our clients as they move confidently into the future.

This guide relates to applications in England. Different regulations apply in Wales, Scotland and Northern Ireland. We are also able to advise on applications in those countries.

Our team



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"Noel Wardle is often retained by pharmacists to advise on disciplinary proceedings and judicial reviews. Peers praise his 'excellent judgement and his 'detailed knowledge of the practice area'."

Chambers UK 2015, Healthcare



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"David Reissner is respected by market commentators as 'a senior figure in the profession of regulatory work'. He is an expert in healthcare and pharmacy law."

Chambers UK 2016, Professional Discipline



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"Rachel Warren has 'impeccable judgement and is worth listening to in terms of judgement. She is a delight to work with'."

Chambers UK 2014, Professional Discipline



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"Susan Hunneyball 'has such good knowledge of pharmacy law that it makes it easier for us to make technical decisions'."

Chambers UK 2014, Professional Discipline

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