

Briefing 001/24: Market Entry

For applicants in the market entry process

Background

Community Pharmacy England has been increasingly aware of delays in the market entry process, which includes change of ownership applications. The process is administered by Primary Care Support England (PCSE) with decisions being made by integrated care boards (ICBs).

The delays appear to be due to a number of factors and issues including:

- increased pharmacy sales, for example, the sale of hundreds of pharmacies by Lloyds, which has substantially increased the volume of applications and notifications being submitted,
- delays due to applicants not providing all the required information (particularly fitness information) or referees not responding to reference requests,
- delays due to PCSE's capacity to process the high number of applications, and
- delays at the ICB decision-making stage of the process.

This briefing should help to identify and explain the main issues that cause delays.

If you're making an application, you should read the guidance available from PCSE and NHS England (see below) to help you complete the relevant forms and navigate the process. There are many different types of applications and different requirements apply to each.

While many of these delays are outside your control there are steps that you can take to help reduce delays.

The Market Entry Process

The process that applications for inclusion in a pharmaceutical list follow is set out in considerable detail in [NHS England's pharmacy manual](#); an overview can be found in Annex 1.



There isn't one pharmaceutical list for England; there are over 150 of them as pharmaceutical lists are prepared and maintained for each health and wellbeing board's (HWB) area. Where the applicant is applying to be included in a particular pharmaceutical list for the first time, the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the 2013 regulations), state that a decision has to first be made as to whether they are a fit and proper person to be included in that list. This is irrespective of whether the applicant is included in another pharmaceutical list elsewhere in England.

All applicants are required to provide the fitness information set out in [paragraph 3](#) and [paragraph 4](#), Schedule 2 of the 2013 regulations. By 'applicant' we mean the entity that wishes to open the pharmacy so that could be an individual pharmacist, a partnership of pharmacists, or a body corporate with a superintendent. If the applicant has previously provided the required information to an ICB, NHS England or, before 1 April 2013 to their "home primary care trust"¹ then they do not have to provide it again as long as there have been no changes since it was provided. (If you cannot remember if you have provided the information, it is better to complete the fitness information forms in full, to avoid delays.)

If the applicant is not already included in the pharmaceutical list for the HWB in whose area the proposed premises will be located, then the ICB must first assure itself that the applicant is a 'fit and proper person'. Applications may be refused on fitness grounds and appeal rights are given to the applicant who can then appeal within 28 days to the [First-tier Tribunal](#), part of HM Courts & Tribunals Service. (These appeals are rare because it is usually easier to make a revised application.)

Once the ICB is satisfied that the applicant is a 'fit and proper' person it will then consider the market entry element of the application. For example, is the change of ownership to be granted, or has the applicant demonstrated that granting their application would confer significant benefits that were not foreseen when the pharmaceutical needs assessment was written.

ICBs are required to determine applications for inclusion in a pharmaceutical list within:

¹ "Home primary care trusts" were the primary care trust in whose area the body corporate's registered office was located.

- 30 days for applications that are not notified to interested parties, for example, changes of ownership, or
- four months for applications that are notified to interested parties, for example, unforeseen benefits applications.

The clock starts ticking on the day the application is received by PCSE. It then stops if missing information, documentation or undertakings are requested, and restarts when (or if) it is or they are provided. If an application is deferred in line with the regulations, for example, to undertake a controlled locality determination, then this stops the clock as well.

The regulations allow an ICB to take longer than these timescales where it has “good cause”. While there is no definition of what may constitute “good cause” in the regulations, the pharmacy manual gives an example of delays in references being received.

All communications regarding the progress of an application are between PCSE and the applicant or their nominated agent (on occasion the ICB may contact the applicant directly). In relation to change of ownership applications, neither PCSE nor the ICBs can update the seller of the pharmacy. Sellers will therefore need to liaise with the buyer/applicant for updates on progress.

From discussions with NHS England and PCSE, it is understood that the most common reason for a delay in the determination of an application is the ICB needing to decide whether the applicant is a ‘fit and proper person’.

Fitness Information

As noted above, fitness information must be provided as part of an application for inclusion in a particular pharmaceutical list for the first time, unless it has previously been provided by the applicant and nothing has changed since.

If anything has changed then the applicant must confirm what fitness information has already been provided and provide the new information. This could, for example, include:

- additional pharmaceutical qualifications that have been obtained since the fitness information was originally provided,

- personal work history for the period since the fitness information was originally provided, or
- different referees as the previously nominated referees are no longer able to provide a reference in respect of a recent post as a pharmacist that lasted at least three months without a significant break, or they are no longer willing to provide a reference.

The fitness information must be provided as follows.

- Sole traders – by the pharmacist
- Partnerships – by each partner who is a pharmacist
- Bodies corporate – by each director and the superintendent
- Limited liability partnerships – by each member and the superintendent.

For the purposes of this briefing use of the word 'applicant' includes all of these people.

NHS England has produced template forms which can be completed on [PCSE's online portal or by submitting the relevant paper version](#).

The fitness information covers a range of matters and includes the following.

- Convictions and cautions – it is recommended that legal or professional advice is sought if you are in any doubt as to whether or not a particular conviction or caution should be declared. These could relate to any aspect of your personal or professional life.
- Any current or previous investigation or proceedings into the applicant's fitness to practise by a licensing body.
- Any current or previous investigation or proceedings into the applicant's professional conduct by an employer.
- Where the applicant is a pharmacist, details of their pharmaceutical qualifications and their personal work history for the seven years ending on the date on which the application is submitted².

² Previously applicants were required to provide a full work history, starting with when they completed their pre-registration training post, now called the pharmacist foundation training scheme. This was amended with effect from 25 May 2023, and the work history is now for the previous seven years.

- A declaration that the personal work history is a complete and accurate account, that the applicant has not been dismissed in that time (or if they have, details are provided on any dismissal), that there has been no break of more than six months during that time (or if there has, details are provided on such a break or breaks), and confirmation that the applicant has complied with the requirements of [paragraph 31, Schedule 4](#) of the 2013 regulations (this relates to the notification of fitness matters to the relevant ICB or ICBs).
- Where the applicant is a pharmacist, the names and addresses of two referees who are willing to provide references in respect of two recent posts (which may include any current post) as a pharmacist which lasted at least three months without a significant break (generally only certain people may provide a reference – see later in this briefing).

NB. ICBs assess whether the applicant is a fit and proper person *to be included in a particular pharmaceutical list*.

If you make only occasional applications, it is likely to be better to provide all the required fitness information at the start of the application, rather than rely on relevant information that may have been provided before. If you have not made an application recently, you will not have provided the required declaration (point 5 above).

Delays Due to Applicants

Our understanding is that the most common causes of delays in fitness decisions, which are within the control of applicants, are as follows:

1. **Applicants fail to provide the required fitness information at the same time as their market entry application form.** If you have not previously provided the required fitness information, then it must be submitted at the same time. Otherwise, it will be treated as missing information, and this will delay the overall determination of the application. Information provided more than seven years ago will need to be updated. Also, your personal work history declaration for the last seven years may not have been provided previously or may need to be updated.

NHS England's pharmacy manual states that where there is missing fitness information in relation to an application then the applicant is to be given ten working days to provide it. If the information is not submitted by the specified date the application will be treated as

withdrawn i.e. nothing further will be done with it and the case will be closed. The application would therefore need to be resubmitted, and the required application fee paid again.

- 2. Applicants stating they have previously provided the required fitness information, but this was in relation to a different legal entity.** It is not uncommon for people to be a director and/or superintendent of more than one company, for example, or for a sole trader to establish a company and become the sole director and also the superintendent. However, applicants sometimes think that they have already provided the required fitness information and don't provide it again in relation to an application made by a different entity.

Example

Mr Counter is the director and superintendent of Village Drugs Ltd and successfully applied to open a pharmacy in the Midshire Health and Wellbeing Board's area in 2022. He establishes Town Drugs Ltd and submits a change of ownership application in relation to another pharmacy in Midshire. He is the only director of Town Drugs Ltd and is the superintendent.

In the change of ownership application, he states that he provided the required fitness information to the ICB in 2022 in relation to Village Drugs Ltd's application.

The 2013 regulations require the entity that wishes to operate a pharmacy to provide the required fitness information. In the example above, Town Drugs Ltd is required to provide fitness information on its director and superintendent. Even though Mr Counter previously provided that as the director/superintendent of Village Drugs Ltd in 2022, it needs to be provided again by Town Drugs Ltd, as a different legal entity, as part of its change of ownership application.

- 3. Applicants failing to advise their referees that they will be contacted by PCSE.** This is a particular issue when the fitness information was provided some time ago (and the referee agreed to provide a reference some time ago) as the referee may no longer be

willing to be contacted or their contact details may have changed in the meantime. If you are relying on previously provided fitness information, we advise you to:

- check in your records who you nominated as a referee on that occasion,
- check that the referees still meet the requirements of the regulations and NHS England,
- check with your referees that their contact details haven't changed, and
- confirm that they are still willing to provide a reference.

Your referees will be contacted once it has been confirmed with you that there is either no missing information in the application or once the receipt of any missing information has been confirmed by PCSE. PCSE will email your referees and give them ten working days to provide a reference. If no response is received, they will email the referee again. If no response is received then PCSE will contact you. If any references are not received, your application will likely be refused on fitness grounds. It is therefore important that your referees respond.

4. *The nominated referees do not meet the requirements of the 2013 regulations.*

Regulatory requirements in relation to referees

Paragraph 1(8), Schedule 2 of the 2013 regulations states that referees:

- must be willing to provide references,
- the references must be in respect of two recent posts as a pharmacist, which may be a current post, which lasted at least three months without a significant break.

If referees do not meet these requirements, then you must provide the names and addresses of alternative referees who are acceptable to the ICB.

If your referees are not from two recent posts, then you must acknowledge this on the fitness information form and explain why not. If your referees do not satisfy the requirements of the 2013 regulations this will be treated as missing information, you will be asked to nominate alternative referees, and there will be a delay to your application.

5. *The nominated referees do not meet the requirements of NHS England's pharmacy manual.* The requirements are listed in the fitness information form but are included here for completeness. Please note these are as listed in the 10 February 2023 version of the pharmacy manual.

NHS England's requirements for referees

ICBs should **not**, without good reason, accept references from:

- family members (and this includes family members of a partner, directors or the superintendent giving references in relation to other partners, directors or the superintendent)
- business partners providing references for each other
- any person with a financial interest in the application
- persons with significant control of the body corporate (and where that person is another body corporate, any director or superintendent of, or person with significant control of, that (second) body corporate)
- trainee pharmacists/pre-registration trainees
- the applicant's (and this includes partners, directors and superintendents) designated supervisor/pre-registration trainer.

If you nominate a referee who falls within one of these categories they are unlikely to be accepted and you will be asked to nominate another person. This will be treated as missing information and delay your application.

The pharmacy manual says that referees 'should' be a pharmacist rather than 'must' be a pharmacist. This provides ICBs with the flexibility to accept another registered healthcare

professional as a referee as long as that person can comment on the applicant's work as a pharmacist.

6. ***PCSE's unique reference number not being included in all communications.*** PCSE allocates each case a unique reference number which starts 'CAS'. Applications that require a fitness decision to be made will have two reference numbers, one for the fitness element and one for the market entry element. It is important that all communications sent to PCSE include the correct CAS reference number in the email subject header and/or letter. This enables PCSE to quickly link each piece of correspondence with the correct case, thereby helping reduce delays.

Delays Due to PCSE

Possibly the biggest challenge that PCSE has had has been to increase the size of the team dealing with market entry applications to deal with the substantial increase in volume of applications and to get new members of the team up to speed as quickly as possible. The regulations set out certain steps that must be followed when processing applications for inclusion in a pharmaceutical list, and the pharmacy manual expands upon the process. However, neither can fully encompass all the variations and issues that may be encountered as an application is processed.

PCSE has increased the size of its pharmacy market administration services team and has indicated that it will continue to monitor its capacity and the length of time applications take to be determined.

Delays at the ICB Stage

While the commissioning of pharmaceutical services, and therefore the determination of applications for inclusion in a pharmaceutical list, has been delegated by NHS England to ICBs it is believed that on the whole the NHS England staff that previously dealt with these applications have been transferred to the ICBs.

ICBs manage this workload in different ways. This may be done by the ICB itself, or by one ICB hosting the former NHS England team which continues to provide services across a number of ICBs.



Previously each NHS England region had a committee called a 'pharmaceutical services regulations committee' or PSRC which, amongst other things, was responsible for determining applications for inclusion in a pharmaceutical list. Each ICB is required to have a committee which determines these applications and while it is free to call it by a different name, it is understood that most, if not all, have decided to still call it the PSRC. Many ICBs have decided to establish a PSRC that covers more than one ICB.

Chapter 2 of the pharmacy manual sets out who are the decision-makers in relation to the commissioning of pharmaceutical services.

- the PSRC,
- the pharmacy contract manager or equivalent person within an ICB,
- the performers list decision panel (although it should be noted that since 1 April 2023, the NHS England performers list decision panels are no longer responsible for fitness decisions relating to pharmacy applicants or contractors), and
- officers nominated by the PSRC to determine whether or not an applicant is a fit and proper person to be included in a particular pharmaceutical list, where no concerns are identified in the checks or references.

In relation to applications for inclusion in a pharmaceutical list, the following types are determined by the PSRC:

- current or future needs,
- current or future improvements or better access,
- unforeseen benefits,
- no significant change relocations,
- distance selling premises
- consolidations, and
- combined change of ownership and no significant change relocations.



The following three types of application can be determined by the pharmacy contract manager or equivalent ICB post:

- changes of ownership,
- right of return applications, and
- temporary arrangements during emergencies or because of circumstances beyond the control of the contractor.

This means that they can be determined much more quickly. However, it is understood that in a number of ICBs, pharmacy contract managers or those with equivalent ICB posts do not decide these applications and they wait for a PRSC meeting for a determination.

While PCSE will review applications for missing information it is for the ICB to confirm if there is any. As can be seen from the overview of the market entry process in Annex 1, this review takes place shortly after the ICB has received the application. Missing information is requested and once provided the application progresses. If this occurs this is likely to cause a delay.

Similarly, to assist decision-making, a report of the application is prepared. Initially, PCSE prepares the report and sends this to the relevant ICB. At this stage, a member of staff (usually a person with more experience of market entry applications) will review and complete the committee report which is then submitted to the PSRC or relevant officer for a decision. It is possible that this more experienced member of staff who, for fitness cases, is likely to be a clinical advisor, may identify something that was missed earlier on in the process, or an issue with a referee. This may then lead to a further request for missing information which then delays the determination of the application.

As this is also the first time that the ICB will have seen the references, it is possible that an issue or issues may be identified with them. For example, if a referee has answered 'No' against one of the questions in the reference form but has not expanded upon this. Or a referee has failed to answer one of the questions. This may then lead to a delay as the referee is contacted.

Information to Support Applicants

There is a range of documents that can support applicants in the submission of their application and how it will be processed.

- The [2013 regulations](#) are available on the legislation.gov.uk website.
- PCSE provides [user guides](#) on its website for applicants, and applications may be made [via PCSE Online or by hard copy](#).
- NHS England's pharmacy manual – each type of application has its own chapter in Part 2 <https://www.england.nhs.uk/primary-care/pharmacy/pharmacy-manual/> .
- [Information](#) on the changes that were made to the fitness information that is to be provided as part of an application in May 2023 has been published by NHS England.

Information is also available on [our website](#).

To contact PCSE to enquire about an application or resolve any issues, you may:

- use the [online enquiry form](#)
- telephone the customer support centre on 0333 014 2884 (Monday to Friday, 08.00 to 17.00), or
- write to PCSE at PO Box 350, Darlington, DL1 9QN (there is a different address for couriering documents to PCSE).

Please remember to include the relevant CAS reference number in all communications with PCSE.

Should you be unable to resolve any issues and wish to raise a complaint, it is to be emailed to pcse.complaints@nhs.net, again including the relevant CAS reference number.

Finally, if applicants are struggling to resolve issues with PCSE and the delays are lengthy, please contact Gordon Hockey, Director Legal or Katrina Worthington, Regulations Officer at Community Pharmacy England, quoting the CAS reference number and the issues, including any relevant correspondence with PCSE. Preferably contact us by e-mail at regulations.team@cpe.org.uk.



Annex 1 – Overview of the Market Entry Process

1. The applicant chooses the type of application, completes the relevant form (or forms) and submits it (them) to PCSE.
2. PCSE opens a case for the market entry element of the application and a separate case for the fitness element of the application if applicable. Two CAS reference numbers are allocated.
3. PCSE undertakes an initial check of each form completed, collates the list of those who are to be notified of the application and/or the decision on it (the “interested parties”), and sends the form or forms to the relevant ICB.

From this point onwards the fitness and market entry elements of the application are progressed simultaneously. If missing information on either element isn't provided the whole application is treated as withdrawn.

A decision on the applicant's fitness must be made before the application is determined. For applications that aren't notified to interested parties, for example, changes of ownership, the market entry element will be put on hold until that decision is made.

4. The ICB reviews the form or forms, identifies if there is any missing information/documentation/undertakings, and reviews and amends as required the list of interested parties.
5. Where there is missing information/documentation/undertakings, this is requested by PCSE. If there is no missing information/documentation/undertakings the applicant is advised of this.
6. Once/if any missing information/documentation/undertakings are received they are passed to the relevant ICB to review and confirm whether or not the application can be progressed. If it can, the applicant is advised accordingly. If the missing information/documentation/undertakings are not received the application is treated as



withdrawn, the applicant is notified, and the application is closed (both the fitness and market entry elements).

7. Once the application can proceed, if the market entry element of it is to be notified to interested parties (not changes of ownership), this is undertaken by PCSE. At the end of the 45-day (30 days for consolidation applications) notification period, PCSE will circulate any representations that have been received to the applicant and those who submitted representations.
8. If a fitness decision is required, PCSE will undertake the required checks with the General Pharmaceutical Council, NHS Resolution and the NHS Counter Fraud Authority, and references are taken up while the market entry element of the application is being processed. If referees do not respond within ten working days, they are written to again. If they fail to respond within the second ten-working day period, the applicant will be asked to follow up.
9. Once all the required fitness checks are completed and references received, a committee report will be prepared by PCSE and sent to the relevant ICB. An officer will review the report and supporting documents and it is possible that missing information may be identified at this stage, or issues identified with the referees or references. If so, a further missing information request will be sent to the applicant and the case will not proceed until a response is received.
10. If the application is refused on fitness grounds the applicant will be advised of the reasons and their right of appeal to the First-tier Tribunal. Nothing further will be done with the market entry element of the application until the fitness decision is known. If the application is refused, on appeal, on fitness grounds then the market entry element will be closed. If the First-tier Tribunal determines that the application is not to be refused on fitness grounds, the ICB will go on to determine the market entry element of it.
11. It is possible that the application may be deferred by the ICB on fitness grounds, for example, due to a General Pharmaceutical Council investigation into the superintendent which, if the outcome was adverse, would lead the ICB to remove the body corporate



from the relevant pharmaceutical list if it was already included. In that instance both elements of the application will be deferred until such time as the outcome is known, or the investigation comes to an end.

12. Once it is confirmed that the application is not to be refused or deferred on fitness grounds, PCSE will prepare the committee report for the market entry element of the application and send it to the relevant ICB. An officer will review the report and supporting documents and it is possible that missing information may be identified at this stage. If so, a further missing information request will be sent to the applicant and the application will not proceed until a response is received. Depending on the nature of the missing information, the application may need to be notified to interested parties for a second time.
13. The committee or officer will then determine the application and document the decision and reasons for it. A decision will also be made as to whether anyone is to be given a right of appeal against the decision.
14. In due course the decision is sent to PCSE who will then notify the applicant and interested parties. Anyone with a right of appeal against the decision has 30 days to appeal to NHS Resolution.