

# GUIDANCE NOTE FOR PARTIES INVOLVED IN PHARMACY MARKET ENTRY APPEALS

#### 1 Introduction

This Guidance Note is for general information purposes only. It is not exhaustive but does cover the essential elements needed for parties involved with pharmacy appeals.

#### 2 Who are we?

NHS Resolution, amongst other things, deals with appeals against local decisions about the provision of Pharmaceutical and Dispensing Services.

Although the relevant Regulations refer to the Secretary of State, these matters were delegated to NHS Resolution. The Primary Care Appeals service discharges these functions (for NHS Resolution).

# 3 What regulations are applicable?

The relevant procedures for the determination of appeals are currently contained in the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations").

#### 4 Is legal representation permitted?

Parties can be represented or assisted by whoever they wish although representatives who are not bound by The Law Society's Code of Conduct should provide an 'authority to act' letter from their client.

# 5 What information should I provide?

An appeal should include:

- the full names and contact details of the applicant and local decision maker;
- a statement containing your ground(s) of appeal;
- any supporting documentation (generally there will not be any further opportunity to submit new information)

Persons appealing pharmacy applications are encouraged to use the online form for pharmacy application appeals available on-line. Completion of the online form is entirely discretionary.

NHS Resolution notes the difficulties for appellants if the Commissioner has not provided reasons for any aspect of the original decision. In such circumstances, NHS Resolution will accept as a valid notice of appeal (subject to appeal rights and compliance with applicable time limits) comments which indicate that a person wishes to appeal and which sets out the appellant's reasons why a determination should have been made in their favour on that aspect (or does so by reference to earlier submissions). NHS Resolution will then consider whether the grounds of appeal are valid and reasonable in accordance with the Regulations.

# 6 What is the procedure?

The Commissioner is asked to supply all application paperwork (which should include any additional circulations and responses, any site visit reports and relevant local information, and the decisions reached).

NHS Resolution will first consider whether it has jurisdiction to hear the appeal including whether the appellant has a right of appeal against the original decision.

NHS Resolution will then consider whether the appellant has provided a concise and reasoned statement of the grounds of appeal. It will then consider if the grounds of appeal are valid and reasonable.

If satisfied, NHS Resolution will invite representations from the parties **who provided** substantive submissions to the Commissioner.

We will correspond with parties, not their representatives, unless we have had prior notification that the representative is acting for the party and a letter of authority has been provided. Where an appeal is against a grant and we only have the representative details for the applicant, we will approach the representative directly.

At this stage, the parties should provide all evidence which they wish NHS Resolution to consider and not assume it has been provided to NHS Resolution by other parties. This includes copies of, and reference to, previous representations made to the Commissioner. In the absence of such, NHS Resolution will not take this material into account. Please note that this will be the only opportunity for consulted parties to submit new material. Anything new raised after this stage may have little or no weight placed upon it. Any representations received will be circulated for final observations before the appeal is determined. For the appellant, who should have provided all supporting information with the appeal and is not entitled to make representations, anything new raised at this stage will have little or no weight placed upon it unless it can be demonstrated that it is adduced by way of rebuttal of the representations received from parties.

There are some limited circumstances where we will invite additional comments from parties with the specific purpose of ascertaining or clarifying a relevant factual matter. Those circumstances would not include providing additional opportunities to strengthen arguments.

No document may be provided on a 'confidential basis'. In general, all information received which has a bearing on the determination of the appeal will be disclosed to the other parties and reference may be made to it in NHS Resolution's determination.

In light of the General Data Protection Regulation, parties wishing to provide evidence containing personal data of third parties (such as, but not limited to, petitions and questionnaires) have an obligation, when collecting such evidence, to inform third parties that their data might be submitted or is being submitted to NHS Resolution, and to direct them to NHS Resolution's on-line privacy notice.

NHS Resolution determines appeals by way of confirmation of the original decision, redetermination of an application (or substitution of a decision) or remission to the original decision maker. It does not conduct a 'review' of the original decision or

decision making process. As a result, it <u>must</u> consider any new information provided by parties which was not available to the Commissioner at the time it took its decision.

# 7 Who will take the decision on the appeal?

Decisions are taken by the Pharmacy Appeals Committee appointed by NHS Resolution to determine cases on the papers or at an oral hearing. Its Terms of Reference are available on-line.

## 8 How will NHS Resolution approach the information it receives?

NHS Resolution will consider the application afresh and will seek to give full reasons for its decision (including the relevant regulations, but also explaining how they have been applied).

Where the parties agree on a relevant fact, NHS Resolution will proceed on the basis of that fact having been proven for the purposes of the appeal.

Where a party has provided evidence of a relevant fact which has not been disputed, NHS Resolution will usually proceed on the basis that the fact has been proven unless NHS Resolution considers it reasonable to determine otherwise in which case NHS Resolution will set out its reasons for doing so.

Where any issue of fact is in dispute, and that issue of fact would be material to NHS Resolution's decision, NHS Resolution will set out its finding on the point and give its reasons for that finding.

Where NHS Resolution has concluded that the issue is not material to its consideration of the appeal, it may elect not to discuss it specifically in its decision.

NHS Resolution will not treat submissions as evidence but, where submissions are made in relation to a disputed issue of fact, NHS Resolution will take any submissions into account when weighing up its finding.

# 9 What are the powers of NHS Resolution?

If NHS Resolution is not in a position to confirm the decision of the Commissioner, it is generally empowered to quash the decision and either to redetermine the application or to substitute its own decision for that of the Commissioner.

In some circumstances, it may also remit the matter back to the Commissioner for it to determine.

# 10 How will NHS Resolution exercise its powers of redetermination or remission under the 2013 Regulations?

NHS Resolution may (on quashing an appeal) redetermine the application. In doing so, NHS Resolution will consider whether it has sufficient information on which it may properly do so.

If it has not, and it is not open to NHS Resolution to remit the matter (or the conditions for remission are not met), it will require such information from the parties as is necessary for it to determine the appeal.

# 11 Why might there be an Oral Hearing?

The majority of cases are decided on the basis of the written appeal and written representations made to NHS Resolution, together with any other documentation available when the original decision was made. Occasionally, and usually as a result of conflicts of evidence provided by parties, which are difficult to resolve when considering the appeal, it may be necessary to hold an Oral Hearing.

# 12 Who will conduct the Oral Hearing?

The constitution of those conducting the hearing varies but each individual will either be an officer of NHS Resolution or a person appointed by NHS Resolution for the purpose of determining pharmaceutical appeals.

## 13 Who will be invited to attend the Oral Hearing?

Your attention is drawn to the provisions of Paragraph 8 of Schedule 3 to the Regulations which sets out those persons who will be permitted to attend any oral hearing that may be convened. A failure to comply with these provisions will result in you not being invited and thus not allowed to make oral representations.

# 14 What papers will the parties receive?

If you have indicated your intention to attend the hearing, you (and all other parties attending) will receive a set of papers which will usually include:

- the papers available when the original decision was made, including any map (together with the decision)
- NHS Resolution's 'Brief' (which summarises the appeal and any representations made).

# What happens if I want to produce new or additional material?

Parties should refer to NHS Resolution's publication titled "Requirement of Parties attending Pharmacy Oral Hearings", available on line.

# 16 Will there be an inspection of the local area?

Prior to the hearing, those conducting the hearing will visit the area and may visit the proposed premises and other pharmacies in the vicinity of the application site in order to better understand the evidence of the parties.

The Committee will take into account what has been said by the parties in their written representations. Any information relating to a disputed matter, which is raised by a party at the hearing for the first time, may therefore be treated as less persuasive.

# 17 What procedure will be followed at the Oral Hearing?

The procedure to be followed will be outlined at the beginning of the hearing.

In general terms, each party (usually starting with the applicant) will be allowed to expand (not repeat) on their written evidence and will have the opportunity to comment on any matters raised at the hearing. NHS Resolution's publication titled "Requirement of Parties attending Pharmacy Oral Hearings" provides more information in this regard.

#### 18 Are witnesses allowed?

Witnesses may be brought to support your case although, you should notify in advance and, where possible, provide NHS Resolution with a brief outline of their evidence, as stated in NHS Resolution publication titled "Requirements of Parties attending Pharmacy Oral Hearings".

# 19 How long will the hearing last?

Hearings usually last about two or three hours but this depends on the number of people who wish to speak.

# 20 What happens after the hearing?

NHS Resolution will notify all parties of the decision of any Committee (which has itself conducted the hearing); normally within 4 weeks of the hearing.

## 21 Parties with special and other needs

NHS Resolution is committed to ensuring that adequate facilities and equipment is provided at oral hearing venues to assist parties with disabilities.

Please notify NHS Resolution in advance if any particular assistance is required, providing as much notice as possible.

# 22 Considering two or more appeals together?

NHS Resolution may decide that it intends to consider two or more appeals together at any time in the process. It may decide this at the outset, e.g. if two appeals relating to the same location are received at the same time or later on, e.g. if one appeal is received and circulated for representations and then a further appeal is received. NHS Resolution will notify the parties when it intends to deal with appeals together and in relation to each other.

#### 23 Choosing between applications

The Regulations allow some flexibility in terms of how to choose between applications. It should be noted that judicial guidance [Rushport LLP v NHS LA re Bidford] suggests that, when considering applications together, the applicants' ability to deliver services is likely to be a relevant factor. Where this is relevant, the decision maker may consider related factors such as the availability of premises [including the ownership of premises]. A range of other factors may also be considered by the decision maker, for example, the geographical advantage of the proposed location and the services to be provided.

# 24 Dealing with different application types

On some occasions, NHS Resolution may receive appeals regarding Regulation 18 and Regulation 24 applications for the same or similar location. In general, the Committee will deal with the relocation application first.

# 25 How will any question of a reserved location be dealt with?

When considering an appeal which requires determination of whether or not an area should be a Reserved Location, NHS Resolution will need to consider whether the number of individuals residing in the area and on a patient list *at the time of the application* was equal to or greater than 2750.

In Chapter 14 of Regulations under the Health and Social Care Act 2012: Market entry by means of Pharmaceutical Needs Assessments – Information for NHS England (provision of pharmaceutical services in controlled localities), the Department of Health and Social Care gives the following guidance which NHS Resolution will take into account:

- "60. Calculation of the relevant population should be done by postcode using the last three digits. NHS England may find it helpful to work from large scale Ordnance Survey maps with the radius distance clearly marked. All postcodes linked to streets or roads within the circle would then count.
- 61. Whilst this may not yield 100% accuracy, this should usually provide adequate information on which to base a calculation.
- 62. A manual count may then be necessary where the population is on the borderline of 2,750 in which case NHS England should ascertain the streets/locations on the edge of the circle. NHS England may wish to adopt the same procedures here that it has for notifying patients when they can no longer use the services of their dispensing doctor after a new pharmacy opens."

NHS Resolution will therefore be looking for evidence that the Commissioner:

- has compiled a list of postcodes which were included within the calculation for the relevant area, together with the number of individuals resident within each postcode who were noted as appearing on a patient list;
- can demonstrate that, for any postcode which straddled the border of the relevant area, the postcode was subject to a manual count to ensure that irrelevant individuals were excluded from the calculation.

In the absence of such evidence, NHS Resolution will consider whether there is other information from which it can be satisfied as to the position as it was at the date of the application.

# 26 How long will the process take?

It may take up to 15 weeks for NHS Resolution to determine appeals on the papers and up to 25 weeks for oral hearing cases. NHS Resolution appreciates that parties may wish for faster decisions - on average papers decisions are usually taken within 13 weeks. Regrettably some cases may take longer than either 15 or 25 weeks.

## What happens if the appeal is withdrawn?

It has been drawn to the attention of NHS Resolution that, in cases where a party withdraws an appeal, it is not always clear when the final decision runs from – is it the date of the original decision (by the Commissioner), or the date the appeal is withdrawn? To avoid confusion, NHS Resolution's policy will be to refuse all appeals that have been withdrawn as soon as practicable after receipt. NHS Resolution will send a letter confirming this decision as soon as practicable after the date it is made. The Committee's decision will be the final decision in relation to the application, and any timescales dependent on a final decision will run from the date of that decision.

#### 27 To whom can I appeal to after a decision has been reached?

Decisions of NHS Resolution can only be set aside by the High Court. Independent legal advice should be sought on this.

# To whom can I write to if I am dissatisfied with the conduct of Appeals staff or Panel Members?

You can write to:

Deputy Director of Corporate and Information Governance NHS Resolution 10 South Colonnade Canary Wharf London E14 4PU

Please note that Challenges to NHS Resolution's interpretation of the regulations, procedures during the process and to final decisions are outside the scope of the Complaints Policy.

# 29 Is there any other information available?

NHS Resolution publishes previous appeal decisions, statistical information and other material on its website at https://resolution.nhs.uk.

Alternatively you can email nhsr.appeals@nhs.net

Please note however that we do not provide advice.

## **Document Control - Change Record**

Date	Author	Version	Reason for Change
19	Technical Case	28	Amended to reflect how the Appeals
Decembe	Manager, Primary		service considers the validity of appeals.
r 2024	Care Appeals		