

7 February 2019

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APPEAL AGAINST NHS COMMISSIONING BOARD ("NHS ENGLAND") DECISION TO REFUSE AN APPLICATION BY BOOTS UK LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST OFFERING IDENTIFIED IMPROVEMENTS OR BETTER ACCESS UNDER REGULATION 17 AT 35 MARKET PLACE, PICKERING, NORTH YORKSHIRE, YO18 7AE

1 Outcome

- 1.1 The Pharmacy Appeals Committee ("Committee"), appointed by NHS Resolution, quashes the decision of NHS England and redetermines the application.
- 1.2 The Committee determined that the application should be refused.

Advise / Resolve / Learn

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1 The Application

By application dated 23 November 2017, Boots UK Ltd ("the Applicant") applied to NHS Commissioning Board ("NHS England") for inclusion in the pharmaceutical list offering identified improvements or better access under Regulation 17 at 35 Market Place, Pickering, North Yorkshire, YO18 7AE. In support of the application it was stated:

This application should not be refused pursuant to Regulation 31 for the following reasons:

- 1.1 There are no other pharmacies adjacent to, or in close proximity, therefore Regulation 31 should not be engaged.
- 1.2 The Applicant currently has a Boots store at this address, but there is no NHS pharmacy within it.

Information in support of the application

- 1.3 In making this application I/we am/are seeking to secure the improvements or better access identified on page 90 of the HWB's pharmaceutical needs assessment.

Please insert the identified improvement or better access you are offering to secure here.

- 1.4 The Applicant believes that the 5 year rule has now ended and therefore the Applicant is submitting this application.

Pickering Town Centre

- 1.5 The proposed location is at the Applicant's current non-contract store in Pickering Town Centre which is a destination in its own right, attracting customers from a wide area. It is a tourist destination, seeing visitors all

throughout the year, many attracted because of its connection with the North Yorkshire Moor Railway.

Improvements & better access

- 1.6 The PNA states under Areas for improvement or Better Access the following;
- 1.7 *"Access to pharmaceutical services on week day evening, Saturday evening and Sundays could be improved for Ryedale residents. This would also provide improved access to respond to planned housing developments .. "*
- 1.8 The Applicant's pharmacy in Pickering town centre would provide improved access to pharmaceutical provision. The Applicant is proposing to offer core hours every evening Monday to Saturday and core hours on a Sunday when there is currently only pharmacy provision for an hour in the middle of the day. The Applicant will also offer services on all Bank Holidays.
- 1.9 The late night opening on a Tuesday will accommodate the late night GP surgery, where an appointment can be made until 7.30pm. This will allow patients to access a pharmacy immediately after should they require to do so. The existing pharmacy closes at 6.30pm.
- 1.10 The Applicant currently operates a non-contract store at these premises. Therefore the Applicant already has premises and should its application be approved, the Applicant will be offering pharmacy services without delay.
- 1.11 Staff within the Applicant's store have received requests for pharmaceutical services to be provided on a daily basis. This shows a clear demand for pharmaceutical provision at this location.

In the box below please explain how you intend to secure the identified improvement or better access either in whole or in part.

- 1.12 As detailed above, the Applicant's pharmacy will be open seven days a week including bank holidays. The Applicant will offer a late night to cover the surgery opening hours and core hours on a Sunday.
- 1.13 The Applicant will provide all Essential, Advanced and local Enhanced Services that may be commissioned.
- 1.14 The Applicant's Pharmacy is DDA Compliant and will have a Consultation room for provision of services.

2 **The recirculation of the application by NHS England**

- 2.1 NHS England re-circulated the application to parties on 24 July 2018 requesting representations. The letter to parties also stated that according to NHS England's records the number of registered patients living within 1.6 kilometres of **35 Market Place, Pickering, North Yorkshire, YO18 7AE** is **7150**.

3 **The Decision**

NHS England considered and decided to refuse the application. The decision letter dated 2 November 2018 states:

- 3.1 NHS England has considered the above application and is writing to inform the Applicant that it has not been approved for the following reasons:
- 3.2 The current PNA has not identified a need for additional pharmacy services in the Pickering area.
- 3.3 The current PNA states:-
- 3.4 In the Ryedale district, there is adequate service provision during Monday to Sunday.

4 **The Appeal**

In a letter dated 20 November 2018 addressed to NHS Resolution Boots UK Ltd (the Applicant) appealed against NHS England's decision. The grounds of appeal are:

- 4.1 Boots UK Limited (the Applicant) wishes to appeal against NHS England to refuse this application.
- 4.2 The Applicant believes that the grounds for appeal are as follows;
- 4.3 When NHS Resolution quashed the decision of NHS England and referred it back to the area team to re-determine, within their report they directed NHS England to;
 - 4.3.1 "6.27 The Committee therefore directed NHS England to:
 - 4.3.2 6.27.1 Re-determine the application in accordance with paragraph 19;
 - 4.3.3 6.27 .2 Ensure it is clear in communications with parties notified of the application why the matter is being re-determined and including in such communications a copy of this determination;
 - 4.3.4 6.27.3 Ensure the parties notified of the application are given an explanation of Regulation 22 and the opportunity to comment on Regulation 22 and the contents of the revised PNA;
 - 4.3.5 6.27.4 After circulating comments for observations in the usual way, determine the application ensuring that such determination includes its determination of the application of Regulation 22;
 - 4.3.6 6.27.5 Provide to the parties that NHS England is required to notify about the outcome of the application full reasons for that outcome."
- 4.4 The decision (which is enclosed for your information) contained very little reasoning and detail and they have failed to meet the criteria as set out by NHS Resolution, particularly with regard to point 6.27.4 and 6.27.5.
- 4.5 Furthermore, within the decision letter, NHS England have quoted the PNA incorrectly.
- 4.6 Chapter 22 is as follows and the Applicant believes that 22 2 (a) is relevant. The Applicant submits that NHS England have not made it clear as to whether has been considered.

- 4.7 Refusal of routine applications that are based on neither a pharmaceutical needs assessment nor unforeseen benefits
- 4.8 22.----(1) If the NHSCB receives a routine application to which regulation 19(6) does not apply, the NHSCB must refuse it unless granting it, or granting it in respect of some only of the services specified in it, would-
- 4.9 (a) meet a current or future need for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB that has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 2 of Schedule 1; or
- 4.10 (b) secure (including in the future) improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB that have or has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 4 of Schedule 1.
- 4.11 (2) For the purposes of paragraph (1), the relevant pharmaceutical needs assessment is—
- 4.12 (a) the pharmaceutical needs assessment of the relevant HWB that is current at the time that the NHSCB takes its decision to grant or refuse the application, unless in the opinion of the NHSCB (or on appeal the Secretary of State) the only way to determine the application justly is with regard to an earlier pharmaceutical needs assessment, in which case the relevant pharmaceutical needs assessment is that earlier assessment; or (b) if the relevant HWB has not published a pharmaceutical needs assessment, the pharmaceutical needs assessment of a Primary Care Trust (as extended by regulation 7(1)) that relates to the locality in which the location or premises to which the application relates is or are situated.

Timeline

- 4.13 The Pickering locality was subject to the five year rule after a previous application for unforeseen benefits was refused. This period of five years ended November 2017.
- 4.14 Boots UK Limited submitted the application under Regulation 17 (Improvements or Better Access Identified in the Pharmaceutical Needs Assessment) of the NHS Pharmaceutical Services Regulations 2014 on 23 November 2017.
- 4.15 The Pharmaceutical Needs Assessment (PNA) which was the current PNA at the time of making the application was the North Yorkshire Pharmaceutical Needs Assessment 2015-2018.
- 4.16 It states within this PNA that:
- 4.17 Areas for Improvement or Better Access
- 4.18 Access to pharmaceutical services on week day evenings, Saturday evenings and Sundays could be improved for Ryedale residents. This would also provide improved access to respond to planned housing developments, outlined above. (page 90).

- 4.19 When the application was determined by NHS England, the PNA that was current at the time of the decision was the PNA 2015-2018 and the one of which the Applicant took into account when making its application. The Applicant submits that they were incorrect to then determine this application under the 2018-2021 PNA. The 2018-2021 was not published until April after being approved by the Health and wellbeing board on the 23 March 2018.
- 4.20 The Applicant believes that Pickering Pharmacy, who appealed the original decision, whilst they have increased their supplementary hours, they have not fully fulfilled the need that was identified within the 2015-2018 PNA.
- 4.21 To conclude:
- 4.22 Boots UK applied in good faith under the PNA that was relevant at the time which was the 2015-2018 PNA. NHS England determined it correctly in accordance with the relevant PNA.
- 4.23 All matters above considered the Applicant believes the decision to be unjust.
- 4.24 For the reasons stated within this letter, the Applicant respectfully asks that this appeal is upheld and that the application be approved. .
- 4.25 Please be aware that Boots UK Ltd would wish to attend any Oral Hearing that may be required in connection with this appeal.

5 **Summary of Representations**

This is a summary of representations received on the appeal.

5.1 COMMUNITY PHARMACY NORTH YORKSHIRE (CPNY)

5.1.1 In respect of the above application, CPNY would like to make the following comments:

5.1.2 It is CPNY's position that the appeal should be determined based on the North Yorkshire Health and Wellbeing Board Pharmaceutical Needs Assessment 2018-2021. This is the current and most up to date assessment of pharmacy provision within the location. If the previous PNA is to be used the appeal will be decided on out of date information.

5.1.3 The data from patient surveys within the 2018-2021 PNA indicate that patients can access a pharmacy when needed and that they prefer to do this close to home. The reality of allowing an additional pharmacy to open in Pickering would be that it would simply serve the immediate local population. Pickering is already well served by the existing pharmacy which indicated that it is willing to extend their opening hours and has done so.

5.1.4 The proposed site of the pharmacy is under one mile from.....

5.1.4.1 Less than 100 metres from Pickering Pharmacy [Please see map –available to Committee]

- 5.1.5 The current 2018-2021 PNA states, around 98% of the population of North Yorkshire lives within five miles (as the crow flies of a pharmacy); with around 63% of the population living within a 20 minutes' walk of a pharmacy.
- 5.1.6 The current 2018-2021 PNA states: There is adequate service provision during throughout the week in Ryedale.
- 5.1.7 Areas for improvement or better access: None identified.
- 5.1.8 The LPC would be grateful if [Primary Care Appeals] would take these comments into consideration as part of the determination of the application.

5.2 CHARLES RUSSELL SPEECHLYS LLP REPRESENTING YORCARE LTD OF PICKERING PHARMACY

- 5.2.1 Charles Russell Speechlys LLP act for Yorcare Ltd of Pickering Pharmacy, 22 Market Place, Pickering, North Yorkshire, YO18 7 AE. Yorcare Ltd representative has seen a copy of your letter dated 5 December 2018 and note that NHS Resolution has received an appeal dated 20 November 2018 from Boots UK Ltd against the decision of the NHS Commissioning Board ("NHS England") to refuse its application for inclusion in the pharmaceutical list for premises at 35 Market Place, Pickering, North Yorkshire, YO18 7AE. This application was made pursuant to Regulation 17 of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations"). NHS England's decision was communicated to interested parties under cover of a letter dated 5 November 2018.
- 5.2.2 Yorcare Ltd's representative writes to make the following representations in relation to the appeal:

Representations

NHS England's decision

- 5.2.3 As NHS Resolution will be aware, it has previously considered an appeal by Boots against NHS England's decision to refuse its application. In its decision dated 21 June 2018 (SHA/19880) NHS Resolution remitted the application to NHS England to be re-determined and in so doing directed NHS England to:
 - 5.2.3.1 Re-determine the application in accordance with paragraph 19 (of the Regulations);
 - 5.2.3.2 Ensure it is clear in communications with parties notified of the application why the matter is being re-determined and including such communications a copy of this determination.
 - 5.2.3.3 Ensure the parties notified of the application are given an explanation of Regulation 22 and the opportunity to comment on Regulation 22 and the contents of the revised PNA;

- 5.2.3.4 After circulating comments for observations in the usual way, determine the application ensuring that such determination includes its determination of the application of Regulation 22;
- 5.2.3.5 Provide to the parties that NHS England is required to notify about the outcome of the application full reasons for that outcome.
- 5.2.4 In accordance with this direction, NHS England wrote to interested parties on 24 July 2018. In this letter, NHS England explained why the matter was being re-determined, and invited written representations.
- 5.2.5 Additionally, the wording of Regulation 22 was reproduced for the benefit of the parties. Consequently, parties specifically were given the opportunity to comment on the content of the current PNA; this being the reason for NHS Resolution remitting the application to NHS England to be re-determined (paragraph 6.21 SHA/19880).
- 5.2.6 NHS England subsequently notified interested parties of its decision by way of its letter dated 5 November 2018. Under cover of this letter it provided a copy of the letter dated 2 November 2018, which NHS England had sent to Capita. In this NHS England confirmed the reasons for refusing the application, namely that the current PNA had not identified a need for additional pharmacy services in the Pickering area. The relevant section of the PNA was reproduced, which reads "In the Ryedale district, there is adequate service provision during Monday to Sunday". Given that at the date on which NHS England made its decision:
- 5.2.6.1 The current PNA had been in force for seven months;
- 5.2.6.2 As such, it provides the most up to date assessment of pharmaceutical services and needs in the area of the relevant Health and Wellbeing Board,
- 5.2.6.3 The PNA also states at Page 69 "There is adequate service provision during throughout the week in Ryedale. Areas for improvement or better access: None identified".
- 5.2.7 It was logical for NHS England to conclude that the 2018 PNA is the relevant PNA for the purposes of Regulation 22. As a result, NHS England was correct in refusing this application.

The application does not meet the statutory test

- 5.2.8 The statutory test as set out in Regulation 17 has not been met for the following reasons:
- 5.2.8.1 Boots states that applying the current PNA would be unjust because it was not in force when the application was prepared in November 2017. However, it has not explained why it considers that, for the purposes of determining this application on appeal in early 2019, the relevant PNA should be one which

was published almost four years ago, and which is no longer in force.

5.2.8.2 The relevant PNA for the purposes of determining this appeal must be the current PNA which was published in April 2018. This PNA has now been in force for eight months and represents the most up to date assessment of pharmaceutical needs in the area of the relevant Health and Wellbeing Board. To apply the 2015 PNA, which was published almost four years ago, and which was superseded eight months ago, to the determination of this application on appeal would be irrational and unjust.

5.2.8.3 The current PNA clearly states the provision of pharmaceutical services in Ryedale (in which the proposed pharmacy is located), is adequate. Therefore, this application does not satisfy Regulation 17(1) which requires the improvements or better access which it says it will secure to be included in the relevant PNA. Consequently, the application must fail.

5.2.9 Even if the 2015 PNA was the relevant PNA for the purposes of determining this appeal (and for the reasons set out above, Yorcare Ltd does not accept that can be the case), this application should be refused because:

5.2.9.1 After the publication of the 2015 PNA Yorcare Ltd increased its hours. As a result, it secured any perceived improvements or better access to pharmaceutical services identified in the former PNA (which is why the 2018 PNA does not identify any such improvements or better access) (Regulation 17(2)(f)).

5.2.9.2 Any improvements or better access mentioned in the previous PNA was in relation to hours; not essential services. Opening hours do not fall within the list of essential services (Part 2 of Schedule 4 to the Regulations). Granting this application for a new pharmacy located so close to an existing pharmacy would result in additional essential services being provided in Pickering, where no need has been identified, and which would not result in any additional benefit to either patients or the NHS. This would result in an undesirable increase in the availability of essential services in the area of the relevant HWB (Regulation 17(2)(g)).

5.2.10 For all the reasons set out above, this application does not meet the relevant statutory test and so must be refused on appeal.

Other matters

5.2.11 From information previously provided by NHS England it appears that the proposed location is situated within a controlled locality. When determining this application, NHS Resolution should consider whether granting it would prejudice the proper provision of relevant NHS services in the area in accordance with Regulation 44.

5.2.12 Should NHS Resolution hold an oral hearing before determining this appeal, Yorcare Ltd would wish to attend the hearing and make representations.

Conclusion

5.2.13 For the reasons set out in this letter, this application does not meet the relevant statutory test. Yorcare Ltd, therefore, invites NHS Resolution to uphold NHS England's decision and to refuse this appeal.

6 Summary of Observations

No observations were received by NHS Resolution in response to the representations received on appeal.

7 Late Observations

7.1 PICKERING TOWN COUNCIL

7.1.1 The council considered [NHS Resolution's] letter of 11 January at their ordinary meeting this week. The council also listened to a representation from one of the doctors from Pickering Medical Practice who is in support of an additional pharmacy in the town.

7.1.2 The council felt that there is a significant requirement for an additional pharmacy in Pickering and decided that the application by Boots UK Ltd should be supported. Pickering has a growing population and it is uncommon for a town the size of Pickering to only have one pharmacy. The council feels that additional pharmacy services would benefit residents of the town both now and in the future.

8 Consideration

8.1 The Pharmacy Appeals Committee ("Committee") appointed by NHS Resolution had before it the papers considered by NHS England, together with a plan of the area showing existing pharmacies and doctors' surgeries and the location of the proposed pharmacy.

8.2 It also had before it the responses to NHS Resolution's own statutory consultations.

8.3 The Committee had before it a copy of the North Yorkshire PNA dated 2015 to 2018 and prepared by North Yorkshire Health and Wellbeing Board. It also had a copy of the North Yorkshire PNA dated 2018 to 2021 and prepared by North Yorkshire Health and Wellbeing Board, which had been provided by NHS England.

8.4 On the basis of this information, the Committee considered it was not necessary to hold an Oral Hearing.

8.5 The Committee dealt with the appeal by way of reconsideration of the application.

8.6 The Committee had regard to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations").

- 8.7 The Committee considered that the correct course was to first consider if the application must be refused pursuant to Regulation 31. The Committee will then consider if the application must be refused pursuant to Regulation 40. If the Committee is not so required to refuse the application, it will consider the issue of reserved location pursuant to Regulation 41. The Committee will then consider the application under Regulation 17. If the Committee has determined that the Applicant is seeking the listing of pharmacy premises which are in a part of a controlled locality that is not in a reserved location, it will consider the issue of prejudice under Regulation 44 last. The reason for this staged approach and in particular for dealing with prejudice last is that if the application does not meet the requirements of Regulation 17 the Committee is required to refuse it and prejudice cannot arise. The potential for prejudice only arises if the Committee has concluded that the application meets the requirements of Regulation 17 and may be granted.

Regulation 31

- 8.8 The Committee first considered Regulation 31 of the regulations which states:

(1) A routine or excepted application must be refused where paragraph (2) applies

(2) This paragraph applies where -

(a) a person on the pharmaceutical list (which may or may not be the applicant) is providing or has undertaken to provide pharmaceutical services ("the existing services") from -

(i) the premises to which the application relates, or

(ii) adjacent premises; and

(b) the NHSCB is satisfied that it is reasonable to treat the services that the applicant proposes to provide as part of the same service as the existing services (and so the premises to which the application relates and the existing listed chemist premises should be treated as the same site).

- 8.9 The Applicant states in its application that "there are no other pharmacies adjacent to, or in close proximity, therefore Regulation 31 should not be engaged. The Applicant currently has a Boots store at this address, but there is no NHS pharmacy within it." The Committee noted that NHS England had not addressed Regulation 31 in its decision and also that Boots comments had not been disputed by parties. Therefore, based upon the information before it, the Committee was of the view that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 40

- 8.10 Pickering is in a controlled locality and the application is based on securing improvements or better access to pharmaceutical services in that controlled locality.

8.11 In those circumstances, the application (which is made under Regulation 17 of the Regulations) must be assessed against the provisions of Part 7 of the Regulations and, in particular Regulation 40 which reads:

(1) This paragraph applies to all routine applications—

(a) for inclusion in a pharmaceutical list as an NHS pharmacist; or

(b) from an NHS pharmacist included in such a list—

(i) to relocate to different pharmacy premises in the area of the relevant HWB, or

(ii) to open, within the area of the relevant HWB, additional pharmacy premises from which to provide pharmaceutical services,

where the applicant is seeking the listing of pharmacy premises which are in a controlled locality.

(2) If the NHSCB receives an application (A1) to which paragraph (1) applies, it must refuse A1 (without needing to make any notification of that application under Part 3 of Schedule 2), where the applicant is seeking the listing of premises at a location which is—

(a) in an area in relation to which outline consent has been granted under these Regulations, the 2012 Regulations or under the 2005 Regulations within the 5 year period—

(i) starting on the date on which the proceedings relating to the grant of outline consent reached their final outcome, and

(ii) ending on the date on which A1 is made; or

(b) within 1.6 kilometres of the location of proposed pharmacy premises (other than proposed distance selling premises), in respect of which—

(i) a routine application under these Regulations or the 2012 Regulations, or

(ii) an application to which regulation 22(1) or (3) of the 2005 Regulations (relevant procedures for applications) applied,

was refused within the 5 year period starting on the date on which the proceedings relating to the refusal reached their final outcome and ending on the date on which A1 is made,

unless the NHSCB is satisfied that since the date on which the 5 year period started, there has been a substantial and relevant change of circumstances affecting the controlled locality.

(3) For the purposes of paragraphs (1) and (2), if no particular premises are proposed for listing in A1, the applicant is to be treated as seeking the listing of pharmacy premises at the location which is the best estimate that the

NHSCB is able to make of where the proposed listed pharmacy premises would be, having regard to the best estimate given by the applicant under paragraph 1(7)(a)(ii) of Schedule 2.

[(4) Paragraph (2)(b) does not apply where the NHSCB is satisfied that there are reasonable grounds for believing the person making the refused application was motivated (wholly or partly) by a desire for that application to be refused.

(5) The refusal of an application pursuant to paragraph (2)(b), or regulation 40(2)(b) of the 2012 Regulations (applications for new pharmacy premises in controlled localities: refusals because of preliminary matters), is to be ignored for the purposes of the calculation of a 5 year period pursuant to paragraph (2)(b).]

- 8.12 The Applicant, in its application states that it believes that the five year rule has ended and so submitted its application. The Committee noted that there was no information to suggest that the instant application was in respect of a location where outline consent had been granted or there had been a refusal for a previous application within the last five years.

Regulation 41

- 8.13 Based on its conclusion above, the Committee went on to consider the application in light of the remainder of Part 7 of the Regulations and, in particular, regulation 41 which reads:

(1) This paragraph applies to any routine application—

(a) for inclusion in a pharmaceutical list as an NHS pharmacist; or

(b) from an NHS pharmacist included in such a list—

(i) to relocate to different pharmacy premises in the area of the relevant HWB, or

(ii) to open, within the area of the relevant HWB, additional pharmacy premises from which to provide pharmaceutical services,

where the applicant is seeking the listing of pharmacy premises which are in a controlled locality and the NHSCB is required to notify the application under Part 3 of Schedule 2.

(2) If paragraph (1) applies to an application (referred to in this regulation and regulation 42 as “A1”), subject to paragraph (5), the NHSCB must determine whether or not the “relevant location”, that is—

(a) the location of the premises for which the applicant is seeking the listing; or

(b) if no particular premises are proposed for listing in A1, the location which is the best estimate that the NHSCB is able to make of where the proposed pharmacy premises would be, having regard to the best

estimate given by the applicant under paragraph 1(7)(a)(ii) of Schedule 2,

is, on basis of the circumstances that pertained on the day on which A1 was received by the NHSCB, in a reserved location.

(3) Subject to regulation 43(2), the area within a 1.6 kilometre radius of a relevant location is a “reserved location” if—

(a) the number of individuals residing in that area who are on a patient list (which may be an aggregate number of patients on more than one patient list) is less than 2,750; and

(b) the NHSCB is not satisfied that if pharmaceutical services were provided at the relevant location, the use of those services would be similar to, or greater than, the use that might be expected if the number of individuals residing in that area who are on a patient list were 2,750 or more.

(4) Before making a determination under paragraph (2) (referred to in this regulation and regulation 42 as “D1”), the NHSCB must—

(a) notify the persons notified under Part 3 of Schedule 2 about A1 that the NHSCB is required to make D1 (and it may make this notification at the same time as it notifies those persons about A1); and

(b) invite them, within a specified period of not less than 30 days, to make representations to the NHSCB with regard to D1 (and the period specified must end no earlier than the date by which the person notified needs to make any representations that they have with regard to A1).

(5) The NHSCB must not make a determination under paragraph (2) in respect of A1 in circumstances where an earlier application which was in respect of the relevant premises and to which paragraph (1), regulation 44 of the 2012 Regulations (prejudice test in respect of routine applications for new pharmacy premises in a part of a controlled locality that is not a reserved location) or regulation 18ZA of the 2005 Regulations (refusal: premises which are in a controlled locality but not a reserved location) applied was refused—

(a) for the reasons relating to prejudice in—

(i) regulation 44(3),

(ii) regulation 44(3) of the 2012 Regulations, or

(iii) regulation 18ZA(2) of the 2005 Regulations; and

(b) within the 5 year period starting on the date on which the proceedings relating to the refusal reached their final outcome and ending on the date on which A1 is made,

unless the NHSCB is satisfied that since the date on which the 5 year period started, there has been a substantial and relevant change of circumstances affecting the controlled locality.

(6) For the purposes of paragraph (5), the “relevant premises” are—

(a) *the premises which are proposed for listing; or*

(b) *if no particular premises are proposed for listing in A1, premises at the location which is the best estimate that the NHSCB is able to make of where the proposed listed pharmacy premises would be, having regard to the best estimate given by the applicant under paragraph 1(7)(a)(ii) of Schedule 2.*

8.14 The Committee considered the issue of reserved location for premises described in the application.

8.15 The Committee noted that NHS England, when it re-circulated the application on 24 July 2018, had informed interested parties that:

8.15.1 *“According to our records the number of registered patients living within 1.6 kilometres of 35 Market Place, Pickering, North Yorkshire, YO18 7AE is 7,150.”*

8.16 The Committee noted that this figure has not been disputed by parties. The Committee was mindful that Regulation 41(2) is mandatory: it requires NHS England to make a determination regarding reserved location status in circumstances such as these. However NHS England’s decision dated 2 November 2018 did not refer to regulation 41. The Committee concluded that as there is no dispute about the number of patients within a 1.6 kilometre radius of the proposed site and that this figure is above the threshold figure of 2,750, the Committee was satisfied that the site of the application is not a reserved location.

8.17 The Committee was aware that, depending on its view on reserved location, it may then need to deal with prejudice. However, the Committee considered that prejudice could only arise if the application meets the requirements of Regulation 17 and may therefore be granted. It therefore next considered whether the application met the requirements of Regulation 17.

Regulation 17

8.18 The application (which was to be determined in accordance with the procedures in Schedule 2 to the Regulations) was submitted by the Applicant based on providing improvements, or better access, identified in the pharmaceutical needs assessment (pursuant to Regulation 17).

8.19 The Committee considered whether purported improvements or better access, on which the Applicant based its application, satisfied the elements of Regulation 17(1) which reads as follows:

“(1) If -

(a) *the NHSCB receives a routine application and is required to determine whether granting it, or granting it in respect of some*

only of the services specified in it, would secure improvements, or better access to pharmaceutical services of a specified type, in the area of the relevant HWB: and

(b) the improvements or better access that would be secured have or has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 4(a) of Schedule 1,

in determining whether it is satisfied as mentioned in section 129(2A) of the 2006 Act (regulations as to pharmaceutical services), the NHSCB must have regard to the matters set out in paragraph (2).

8.20 Paragraph 4(a) of Schedule 1, reads as follows:

"A statement of the pharmaceutical services that the HWB has identified (if it has) as services that are not provided in the area of the HWB but which the HWB is satisfied—

(a) would, if they were provided (whether or not they were located in the area of the HWB), secure improvements to, or better access to, pharmaceutical services, or pharmaceutical services of a specified type, in its area.

8.21 The Committee noted in the application form, that the Applicant has focused on page 90 of the 2015 to 2018 PNA, where the improvements or better access which the Applicant seeks to address, have been identified.

8.22 The Committee was mindful of its previous determination at paragraph 6.27 to 6.27.5, dated 21 June 2018 which stated:

8.23 *"The Committee therefore directed NHS England to:*

8.23.1 Re-determine the application in accordance with paragraph 19;

8.23.2 Ensure it is clear in communications with parties notified of the application why the matter is being re-determined and including in such communications a copy of this determination;

8.23.3 Ensure the parties notified of the application are given an explanation of Regulation 22 and the opportunity to comment on Regulation 22 and the contents of the revised PNA;

8.23.4 After circulating comments for observations in the usual way, determine the application ensuring that such determination includes its determination of the application of Regulation 22;

8.23.5 Provide to the parties that NHS England is required to notify about the outcome of the application full reasons for that outcome."

8.24 The Committee noted that NHS England invited parties to comment on Regulation 22. The Committee noted that this has not been disputed by parties.

8.25 Regulation 22 states:

"(1) If the NHSCB receives a routine application to which regulation 19(6) does not apply, the NHSCB must refuse it unless granting it, or granting it in respect of some only of the services specified in it, would—

(a) meet a current or future need for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB that has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 2 of Schedule 1; or

(b) secure (including in the future) improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB that have or has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 4 of Schedule 1.

(2) For the purposes of paragraph (1), the relevant pharmaceutical needs assessment is—

(a) the pharmaceutical needs assessment of the relevant HWB that is current at the time that the NHSCB takes its decision to grant or refuse the application, unless in the opinion of the NHSCB (or on appeal the Secretary of State) the only way to determine the application justly is with regard to an earlier pharmaceutical needs assessment, in which case the relevant pharmaceutical needs assessment is that earlier assessment; or

(b) if the relevant HWB has not published a pharmaceutical needs assessment, the pharmaceutical needs assessment of a Primary Care Trust (as extended by regulation 7(1)) that relates to the locality in which the location or premises to which the application relates is or are situated."

8.26 The Committee noted the timeline of the application as described by the Applicant in its appeal. The Committee is also mindful that it must consider which is the relevant PNA, that is current, at the time that the decision is taken unless the only way to determine the application justly is with regard to an earlier PNA. The Committee noted that the Applicant had stated that when the application was determined previously, the 2015 PNA was relevant as the 2018 PNA had not yet been published. However the Committee was mindful that since the application was made the deadline in the Regulations for publishing a revised PNA had passed and the 2018 PNA had been published and a subsequent appeal was submitted.

8.27 The Committee was of the view that the starting point as set out in Regulation 22 was that the relevant PNA was the PNA of the relevant HWB that is current at the time that the decision is taken. There is no dispute that the 2018 PNA is now the current PNA. However, the Committee was mindful that Regulation 22 goes on to say that if, in the opinion of the decision maker the only way to determine the application justly is with regard to an earlier PNA, then the relevant PNA is the earlier PNA.

8.28 The Committee considered whether in this case it should have regard to an earlier PNA.

- 8.29 The Committee noted that in representations to Primary Care Appeals both Community Pharmacy North Yorkshire and Yorcare Ltd consider the 2018 - 2021 PNA is the current and most up to date PNA. Community Pharmacy North Yorkshire state that consideration of the previous (2015) PNA would be based on out of date information. Yorcare Ltd's representative states that the 2018 PNA has now been in force for seven months and provides the most up to date assessment of pharmaceutical services and needs in the area of the relevant Health and Wellbeing Board. The Applicant considered NHS England's decision (of 2 November 2018) to be unjust because it believes that the pharmacy that increased its supplementary hours, (as recorded in the 2018 PNA), has not, in the opinion of the Applicant, fully fulfilled the gap which the Applicant has identified within the 2015 PNA.
- 8.30 The Committee noted the reasons provided by the Applicant as to why it was just to consider the 2015 PNA as the relevant PNA. These reasons are:
- 8.30.1 that it submitted its application in November 2017 and that the PNA which was current at the time of making the application was the North Yorkshire PNA 2015 to 2018;
- 8.30.2 that when the application was determined [by NHS England] the PNA which was current at the time of the decision was the 2015 to 2018 PNA as the 2018 to 2021 PNA was not approved until 23 March 2018 and not published until April 2018;
- 8.30.3 that the pharmacy who appealed the original decision whilst increasing their supplementary hours, have not fully fulfilled the need as identified by the Applicant in the 2015 to 2018 PNA.
- 8.31 The Committee considered the time line as provided by the Applicant in its appeal In particular noting that the original decision on the application had been determined by NHS England on 7 March 2018 whilst the 2015 to 2018 PNA was current and appealed against on 4 April 2018 by which time the 2018 to 2021 PNA had been published.
- 8.32 The Committee considered that the Applicant was potentially relying in part on the argument that the 2018 PNA was incorrect in its assessment of the provision of pharmaceutical services and the gaps thereof. The Committee considered that this amounted to a challenge to the legality or reasonableness of the 2018 PNA or alternatively a challenge to the fairness of the process by which the HWB undertook the assessment of pharmaceutical services provision which is evidenced in the 2018 PNA. Notwithstanding the restrictions as set out in paragraph 2 of Schedule 3 (misconceived appeals) as to the remit of matters to be considered on appeal, the Committee noted that there was no reference in this regard to any services identified in the PNA, which would fall within the description set out in paragraph 4(b) of Schedule 1 to the Regulations.
- 8.33 The Committee was of the view therefore that the 2018 PNA would reflect upon the needs from the former 2015 PNA and take this into consideration when assessing the existing pharmaceutical services currently provided and the pharmaceutical need for the coming years as the former PNA would have done so in 2015. The Committee does not have the powers to challenge the findings of the current PNA.

- 8.34 The Committee was of the view that it would be unjustifiable to rely upon a document that was now out of date in order to decide whether or not there are gaps in the existing pharmaceutical services. The Committee concluded that it was more prudent to rely upon an up to date document which had considered the present existing situation in order to determine if there were improvements or better access identified in the PNA.
- 8.35 The Committee considered the wording of the 2018-2021 PNA.
- 8.36 The Committee noted that page 5 of the 2018 – 2021 PNA states:
- 8.36.1 *“In the Ryedale district, there is adequate service provision during Monday to Sunday.”*
- 8.37 The Committee noted that page 69 of the 2018 – 2021 PNA states:
- 8.37.1 *“During Monday to Saturdays there is good provision of pharmaceutical services. On Sunday one pharmacy in Pickering opens for one hour in response to recommendations in the previous PNA.”*
- 8.38 And further:
- 8.38.1 *“There is adequate service provision during throughout the week in Ryedale. [sic]*
- 8.38.2 *Areas for improvement or better access: None identified.”*
- 8.39 The Committee noted that the Applicant neither in its application nor on appeal had made reference to the 2018 to 2021 PNA in respect of how it would meet the test in Regulation 17(1).
- 8.40 The Committee did not consider, from the information before it that the 2018 - 2021 PNA indicated there was a need identified which would secure improvements or better access to pharmaceutical services in the area of the relevant HWB.
- 8.41 The Committee was of the view that such improvements or better access had not been identified in accordance with paragraph 4(a) of Schedule 1 of the regulations and as such the provisions of Regulation 17(1) were not met.

Regulation 44 - Prejudice

- 8.42 Having considered the matter of reserved location and, having considered the application under Regulation 17, the Committee next considered the question of prejudice under Regulation 44.
- 8.43 The Committee has already indicated that if the application does not meet the requirements of Regulation 17 then the Committee is required to refuse it and prejudice cannot arise. The potential for prejudice only arises if the Committee has concluded that the application meets the requirements of Regulation 17 and may be granted. As indicated above, the Committee has determined that the application does not meet the requirements of Regulation 17 and therefore the Committee considered that consideration of prejudice was not required.

Summary

- 8.44 The Committee was not required to refuse the application under the provisions of Regulation 31.
- 8.45 The Committee found no reference in the PNA to services which would fall within the description set out in paragraph 4(a) of Schedule 1 to the Regulations.
- 8.46 The Committee determined that, in the absence of specified circumstances in which the provision of services would secure improvements, or better access to, pharmaceutical services, the provisions of Regulation 17(1) were not met.
- 8.47 Pursuant to paragraph 9(1)(a) of Schedule 3 to the Regulations, the Committee may:
- 8.47.1 confirm NHS England's decision;
 - 8.47.2 quash NHS England's decision and redetermine the application;
 - 8.47.3 quash NHS England's decision and, if it considers that there should be a further notification to the parties to make representations, remit the matter to NHS England.
- 8.48 As NHS England had not made a determination regarding Regulations 22, 31, 40 or 41 in its decision, the Committee determined that the decision of NHS England must be quashed.
- 8.49 The Committee went on to consider whether there should be a further notification to the parties detailed at paragraph 19 of Schedule 2 of the Regulations to allow them to make representations if they so wished (in which case it would be appropriate to remit the matter to NHS England) or whether it was preferable for the Committee to redetermine the application.
- 8.50 The Committee noted that representations on Regulation 17 had already been made by parties to NHS England, and these had been circulated and seen by all parties who made representations on the application, as part of the processing of the application by NHS England. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 17.
- 8.51 The Committee concluded that further notification under paragraph 19 of Schedule 2 would not be helpful in this case.

9 Decision

- 9.1 The Committee quashes the decision of NHS England, for the reasons given above, and redetermines the application.
- 9.2 The Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.
- 9.3 The Committee concluded that Pickering is in a controlled locality and that the site of the application is not in a reserved location.

- 9.4 The Committee has determined that the application should be refused for the following reasons:
- 9.4.1 The PNA does not specify any circumstances in which the provision of specified services will secure improvements to, or better access to, pharmaceutical services in Pickering
- 9.5 Having determined that the application should be refused, it was unnecessary for the Committee to make a decision upon whether granting the application would prejudice the proper provision of relevant NHS services in the area of (a) the relevant HWB; or (b) a neighbouring HWB of the relevant HWB.

Alison

Alison McCafferty
Case Manager
Primary Care Appeals

A copy of this decision is being sent to:

Boots UK Ltd
NHS England
Charles Russell Speechlys LLP representing Yorcare Ltd
Community Pharmacy North Yorkshire