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16 January 2025

REF: SHA/26365

APPEAL AGAINST HUMBER AND NORTH YORKSHIRE ICB DECISION TO REFUSE AN APPLICATION BY TENNYSON HEALTHCARE LIMITED FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 58 – 60 BECK BANK, COTTINGHAM, HU16 4LH WITH REGARD TO CURRENT NEED UNDER REGULATION 13

1 **Outcome**

1.1 The Pharmacy Appeals Committee ("Committee"), appointed by NHS Resolution, quashes the decision of the Commissioner and redetermines the application.

1.2 The Committee determined that the application should be granted.

A copy of this decision is being sent to:

Gordons Partnership on behalf of Tennyson Healthcare Ltd
Community Pharmacy Humber
PCSE on behalf of Humber and North Yorkshire ICB

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1 The Application

By application dated 30 May 2024, Tennyson Healthcare Ltd ("the Applicant") applied to Humber and North Yorkshire ICB ("the Commissioner") for inclusion in the pharmaceutical list at 58 – 60 Beck Bank, Cottingham, HU16 4LH with regard to Current Need under Regulation 13. If these premises are no longer available, the best estimate of the location of the pharmacy would be within 0.5km radius of the same postcode, HU16 4LH (location Map 1) [see Appendix A]. In support of the application it was stated:

1.1 The Applicant did not provide a response as to why the application should not be refused pursuant to Regulation 31.

1.2 Opening hours

1.2.1 Proposed core opening hours

Monday	08:00 – 12:00 13:00 – 17:00
Tuesday	09:00 – 12:00 13:00 – 17:00
Wednesday	09:00 – 12:00 13:00 – 17:00
Thursday	09:00 – 12:00 13:00 – 17:00
Friday	09:00 – 12:00 13:00 – 17:00
Saturday	
Sunday	09:00 – 13:00
Total	40:00

1.2.2 Total proposed opening hours

Monday	08:00 – 12:00 12:00 – 13:00 13:00 – 17:00
Tuesday	08:00 – 09:00 09:00 – 12:00 12:00 – 13:00 13:00 – 17:00
Wednesday	08:00 – 09:00

	09:00 – 12:00 12:00 – 13:00 13:00 – 17:00
Thursday	08:00 – 09:00 09:00 – 12:00 12:00 – 13:00 13:00 – 17:00
Friday	08:00 – 09:00 09:00 – 12:00 12:00 – 13:00 13:00 – 17:00
Saturday	08:00 – 17:00
Sunday	09:00 – 13:00
Total	58:00

Information in support of the application

1.3 In making this application I/we am/are seeking to meet the current need identified on page

1.3.1 “East Riding PNA 2022 - 2025:

1.3.2 Cottingham North Ward - page 60

1.3.3 Cottingham South Ward - page 62

1.1.1 Supplementary Statement 18 - 31st March 2024 of the HWB's pharmaceutical needs assessment - https://eastridingjsna.com/wpcontent/uploads/2024/04/18.-Supplementary-Statement-closure-Boots-Pharmacy.pdf”

Please insert the identified current need you are offering to meet here.

1.2 “Supplementary Statement 18 to East Riding PNA states:

1.3 'this closure does create a significant change to the East Riding PNA 2022-2025 that are of a [sic] it does create a gap in the need for pharmaceutical services within the Cottingham North and South Wards'.

1.4 Specific details regarding the gap in provision have not been disclosed by the HWB, however this proposed pharmacy would plan to deliver all essential services as well as both nationally and locally commissioned advanced and enhanced services where appropriate and when there is a local need identified e.g. EOI process.

Background

1.5 The location of the proposed pharmacy is within a retail unit on a commuter route, less than 0.5 miles from Cottingham train station and on a bus connection. Unemployment rates in Cottingham South are in line with the East Riding average levels and are lower in Cottingham North so there are many commuters travelling in and out of the area.

1.6 Cottingham village centre previously had three pharmacies, two Boots pharmacies and a Lloyds Pharmacy. It is understood that one of the Boots pharmacies (FRN54, 156 Hallgate, Cottingham, HU16 4BD) closed in November 2023 and the Lloydspharmacy

(FTC54, Unit 1, Kings Parade, Hallgate, Cottingham, HU16 5QQ) is now operated by Jhoots (the change of ownership having taken place in late 2023).

1.7 The change of ownership of the Lloydspharmacy has caused access issues to pharmaceutical services for patients. There have been several occasions where the pharmacy has failed to open, particularly during out of hours periods, such as weekends, meaning that patients have lacked choice in accessing services. This has also caused increased pressure on healthcare services like 111 or GP Out of Hours services, which is avoidable where there is sufficient service pharmaceutical provision and choice for patients in the Cottingham area.

1.8 The applicant proposes to replace the pharmaceutical services provided by the Boots pharmacy and more generally the reduction in the provision of pharmaceutical services across Cottingham and according provide a significant benefit to the community.

Reg 6(3) – PNA

1.9 The improvements and better access that would be secured were not included in the original Pharmaceutical Needs Assessment (PNA) 2022-2025 as the PNA does not cover the closure and loss of service of the Boots pharmacy nor other pharmacies in the area. The Supplementary Statement 18 (issued on 31st March 2024) confirms that the closure of the Boots on Hallgate does create a significant gap in pharmaceutical services, hence this application, in the area, the proposed pharmacy would preserve the status quo and ensure that access to pharmaceutical services is consistent and reliable.

1.10 The proposed location, within the Cottingham South Ward falls within an area that has a mixed profile of deprivation at LSOA level. Four out of six LSOAs in this Ward are ranked in the middle and least deprived quintiles of England (the other two falling into the second most deprived quintile).

1.11 This has an impact on the transport options to which the population have access and how they get to the pharmacies they use.

1.12 It also has an impact on health needs discussed below.

1.13 Currently, the nearest pharmacy to the proposed location is the Boots pharmacy at 42 – 44 King Street, Cottingham, Hull, HU16 5QE. This pharmacy is 0.3km away. There are only 2 pharmacies within a kilometre of the proposed location, and neither offer Sunday opening.

1.14 Nearest pharmacies to the proposed site:

1.14.1 Boots, 42 – 44 King Street, Cottingham, Hull, HU16 5QE, Mon-Fri: 9am-6pm, Sat: 9am-5pm, Sun: Closed

1.14.2 Lloyds Pharmacy (Jhoots), Unit 1 Kings Parade, King Street, Cottingham, East Riding of Yorkshire, HU16 5QQ, Mon-Fri: 9am-6pm, Sat: 9am-12.45pm, Sun: Closed

1.15 The proposed pharmacy will offer early morning and Sunday opening and consequently will be accessible at times when existing pharmacies are not offering services.

In the box below please explain how you intend to meet the identified current need either in whole or in part.

1.16 (Please see above as well for information)

1.17 Importantly the applicant pharmacy will match the morning opening hours of the local surgeries.

1.18 There two GP practices within a kilometre of the proposed location:

1.18.1 Cottingham Medical Centre (Greengates Medical Group), 17-19 South Street, Cottingham, HU16 4AJ, Mon-Fri: 8am-6pm, Sat & Sun: Closed

1.18.2 Kings Street Medical Centre, 168 King Street, Cottingham, HU16 5QJ, Mon-Fri: 8am-6pm, Sat & Sun: Closed

1.19 As of November 2023, the list sizes of Greengates Medical Group was 23,045 and King Street Medical Centre was 7,462. This is a total of 30,507 patients registered at either practice that require adequate provision of pharmaceutical services. (Taken from https://www.nhsbsa.nhs.uk/prescription-data/organisation-data/practice-list-size-andgp-count-each-practice).

1.20 Chestnuts Surgery merged with Hallgate Surgery again contributing to a lack of choice of where patients can go to access healthcare services. The merger of these two practices resulted in the formation of King Street Medical Practice.

1.21 Kings Street Medical Centre has been rated as good by less than 70% of patients (according to GP Patient Survey Results from 2023). This poor rating emphasises the importance of accessible pharmacy services. As pharmacies are increasingly seeing more clinical services being commissioned e.g. Pharmacy First, being able to increase the choice of pharmacies patients can offer would contribute to easing demand on other services e.g. general practices, as well as urgent and emergency care providers.

1.22 Residents living in the East of Cottingham (e.g., Endyke Lane, Inglemire Lane, Snuff Mill Lane, Hull Road, Bricknell Avenue, Golf Links Road, Thwaite Street, and the surrounding areas) would no longer have to travel more than a mile to access a pharmacy, as is currently the case. Many of the people who live around Cottingham are reliant on having access to a pharmacy to which they can walk. Pictorial representation available, but unfortunately cannot upload to online market entry application.

1.23 Locating the pharmacy in close proximity to the train station and on a bus route also facilitates access to residents travelling to and from work (into and out of the area) and commuters who work in Cottingham.

1.24 Estimated premises would be 58-60 Beck Bank, a retail unit with parking immediately at the front door, on a commuter route to the train station and on a bus route. This is subject to the property remaining available for rent. Failure to secure these premises the pharmacy premises would be within 0.5 kilometre radius from the HU16 4LH postcode (see below screenshot for pictorial representation – See Appendix A). With the population of Cottingham having low unemployment rates, the working population would have increased access to pharmaceutical services upon the approval on this application.

1.25 If approved, a prescription ATM (e.g. MedPoint or Pharmaself) would be installed at the premises (subject to planning permission approval and landlord approval) to facilitate 24/7 access to prescription collection. Consideration would also be given to an additional solution with the capability for patients to purchase medicines (OTC) via an ATM to promote and encourage self-care and improve access to medicines in out

of hours periods, reducing burden on UEC providers who patients may choose to present to if they feel this is the only way to access treatment in an out of hours period.

1.26 Currently there is a choice of two pharmacies to the population of Cottingham which continues to increase due to several recent housing developments. The documents below detail the planned/newly built housing developments in Cottingham total an additional 1,070 dwellings being built, and as most are family homes, can estimate an increase in population of 3,000+ to Cottingham, all of which are entitled to appropriate access to pharmaceutical services. Copies of the Cottingham Neighbourhood Plan documents available, but unfortunately no functionality to attach to this online market entry application.

1.27 There have been several complaints made to councillors regarding the lack of choice of community pharmacies in Cottingham, as well as the issues with demand on existing services stretched beyond capacity including anecdotal evidence from patients of long queues at both pharmacies, and repeated trips back to the pharmacies in order to pick up medicines and/or access other services e.g. Minor Ailments Scheme, etc.

1.28 In a time where the Primary Care Access Recovery Plan and NHS Long Term Plan calls for the greater use of community pharmacy services, Cottingham residents would receive a limited service from existing contractors due to capacity issues of both workforce, time and estates. The approval of a new contractor would contribute significantly to easing this burden.

Reg 6(2)(b) – people who share a protected characteristic having access to services that meet specific needs for pharmaceutical services that, in the area of the relevant HWB, are difficult for them to access.

1.29 Providing services at the proposed location would have a significant benefit for patients, particularly those who may have difficulty in accessing services in other localities, such as the elderly or disabled.

1.30 As stated in the current PNA:

"the East Riding already has a higher-than average older population and a lower-than average younger population. The proportion of people aged over 65 is expected to increase at a much higher rate than national and regional averages".

1.31 The East Riding overall has fewer pharmacies per 100,000 population than both the Yorkshire and Humber and England averages. However because of the very rural nature of large parts of the East Riding where dispensing GP practices provide the dispensing service this is not considered to be an issue to address.

1.32 Poor health is related to both advancing age and material deprivation. The least healthy are likely to be the greatest users of pharmaceutical services.

1.33 So, we know that:

1.33.1 East Riding has a higher than average older (and ageing) population

1.33.2 East Riding already has fewer pharmacies to service an increasing population (e.g. increased burden on existing providers)

1.33.3 Poorer health is associated with advancing age

1.34 These are three significant and interlinked points to signal that an additional pharmacy in the Cottingham boundary would enhance pharmaceutical provision and support the surrounding population with improving their health.

1.35 Neither of the two pharmacies are registered to deliver the Pharmacy Contraception Service and only the Lloydspharmacy (Jhoots) is registered to offer the Smoking Cessation Service. Both of these are nationally commissioned services that have the potential to relieve some of the burden on other healthcare services e.g. stop smoking providers, sexual health providers and general practices to enable them to focus on more complex cases and work collaboratively to address health inequalities and improve overally health. [sic]

1.36 Where the pharmacies are registered to provide services they are not in fact providing them:

1.37 As an example, SHAPE Atlas includes data from the BSA for the Hypertension Case-Finding Service. From the data, both pharmacies: Lloydspharmacy (aka Jhoots) and Boots currently has no activity data for the service.

1.38 They also do not return on a search to 'Find a pharmacy for a BP check' via: https://www.nhs.uk/nhs-services/prescriptions-and-pharmacies/find-a-pharmacy-thatoffers-free-blood-pressure-checks/ How can the Health & Wellbeing Board be assured that individuals with potentially undiagnosed hypertension (and therefore increased risk of cardiovascular disease) when the two pharmacies servicing the population of Cottingham are not delivering this meaningful and beneficial service?

1.39 Additionally, while 95.2% of the Cottingham population identify as 'white' (https://www.citypopulation.de/en/uk/yorkshireandthehumber/admin/east_riding_of_yorkshire/E04000509__cottingham/), the remaining 4.8% are rightly entitled to parity and the assurance that when they do require pharmaceutical services they are not disadvantaged due to their ethnicity or any other protected characteristic e.g. religion, sexual orientation, maternity, etc. If approved, the pharmacy would seek to understand the genuine needs of those with protected characteristics and look to adapt how pharmaceutical services if needed to ensure these populations are not disadvantaged.

1.40 As an example, there is a large traveller community in Cottingham, based on Woodhill Way, which are known to be 'hard to reach' when it comes to offering healthcare services (https://www.cqc.org.uk/sites/default/files/20160505%20CQC_EOLC_Gypsies_FINAL_2.pdf). The pharmacy, if approved, would seek to engage with support workers and community representatives in order to ensure their needs are best met, meeting the Accessible Information Standard (AIS) and using health literacy tools where appropriate e.g. picture labels.

1.41 In summary, this application offers a combination of replacement of an important provider of services, and improved services, and will provide choice and accessibility to pharmaceutical services where both are currently limited and are likely to be increasingly so in the future. The applicant will accordingly provide overall improvements and better access to pharmaceutical services in the HWB area."

2 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 27 September 2024 states:

2.1 “Humber and North Yorkshire ICB has considered the above application and I am writing to confirm that it has been refused. Please see the enclosed report for the full reasoning.”

Extract from the decision report

2.2 “NHS England has considered the above application, and I am writing to inform you that it has been rejected for the following reasons:

2.3 The committee [of NHS England] did not support this application as the applicant has not demonstrated a current need as required by Regulation 13 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

2.4 13(1)(a) for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB – none identified.

2.5 13(1)(b) that has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 2(a) of Schedule - none identified.

2.6 13(2)(a)-(c) there are no other applications offering to meet the current need nor any appeals in relation to a current need application - none.

2.7 13(2)(d), Humber & North Yorkshire Integrated Care Board (ICB) are satisfied that since the publication of the PNA there have been no changes in pharmaceutical needs for the HWB that are such that refusing the application is essential to prevent significant detriment to the provision of pharmaceutical services.

2.8 13(2)(e) granting of the application would not meet the current need (as there has been none identified) either in part or fully.

2.9 13(2)(f) granting of the application would not meet the current need (as there has been none identified) either in part or fully.

2.10 13(2)(g) granting of the application would not meet the current need (as there has been none identified) either in part or fully.

2.11 13(2)(h) granting of the application would not meet the current need (as there has been none identified)

2.12 Appeal rights have been granted to the applicant.”

3 The Appeal

In a letter dated 25 October 2024, Gordons Partnership Solicitors on behalf of the Applicant appealed against the Commissioner’s decision. The grounds of appeal are:

3.1 “We act for Tennyson Healthcare Limited. We are instructed by our client to appeal against the refusal of its application offering to meet an identified current need at 58-60 Beck Bank, Cottingham, HU16 4LH.

3.2 The application is made under regulation 13 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (“the Regulations”).

The Decision

3.3 Humber and North Yorkshire ICB refused the application on the overall basis that our client had not demonstrated a current need as required by Regulation 13 of the Regulations. They said as follows:

3.3.1 [see paragraphs 2.4 to 2.11 above.]

The Appeal

3.4 The ground of the appeal is that the ICB misdirected itself in its interpretation of the effect of the Supplementary Statement to the East Riding of Yorkshire Council Pharmaceutical Needs Assessment (PNA) dated 31 March 2024. There is no appeal on its conclusion on 13(2)(d).

3.5 It may be helpful for Primary Care Appeals to understand the context of the application. Our client initially made an application under Regulation 18 against a background of closure of the Boots Pharmacy, at 156 Hallgate, Cottingham, HU16 4BD which closed in November 2023 and evidence of failures in the service provided by the remaining pharmacies as evidenced by an independent Healthwatch survey. There is also an increase in population from local housing developments. There is an indication that the current need is continuing from a letter of support received today [see Appendix B] from the local GP surgery, Greengates Medical Group.

3.6 Following the circulation of the original application, the East Yorkshire Health and Wellbeing board issued a supplementary statement indicating that the closure of the Boots Pharmacy in Cottingham had created a gap in the provision of pharmaceutical services in Cottingham. This statement was considered in the determination of the Regulation 18 application on appeal on 23 October under reference SHA/26268. The application was refused on the basis that the Committee determined that the improvements or better access set out in the unforeseen benefits application were included in the PNA and consequently Regulation 18(1)(b) was not satisfied.

3.7 It was concluded at paragraph 7.33 of the decision that "*The Committee consequently considered that a supplementary statement may refer only to the availability of pharmaceutical services but, if considered appropriate by the HWB, is also able to identify a gap. As noted above, a supplementary statement then forms part of the PNA*."

3.8 The decision then goes on to say "*The Committee considered that it was clear that the gap could potentially be filled by an application submitted pursuant to Regulations 13, 15 or 17*"

3.9 Our client's case is that the gap would be filled by his application under regulation 13. The comment on the gap or need for services is preceded in the supplementary statement by a statement about the closure of the Boots Pharmacy. The wording of the supplementary statement is

"Boots Pharmacy at 115 Hallgate, HU16 4BD in the Cottingham North Ward closed on the 11/11/2023.

This closure does create a significant change to the East Riding PNA 2022-2025 that are of a [sic] it does create a gap in the need for pharmaceutical services within the Cottingham North and South Wards."

3.10 When taking the statement as a whole it is clear the gap is the services no longer provided by the Boots Pharmacy. Our client is offering to replace those services at the same or adjacent location and will offer the same opening times and services as the closed Boots.

3.11 It is also clear that this is a current as opposed to future need; the closure has occurred and the need for the services that were provided by Boots Pharmacy is clearly articulated by the supplementary statement.

Dealing with the decision made by the ICB

3.12 13(1)(a) - would granting the application meet a current need for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB? The services were identified in the supplementary statement as being those replacing the services offered by Boots Pharmacy.

3.13 13(1)(b) – has the current need been included in the relevant pharmaceutical needs assessment in accordance with paragraph 2(a) of Schedule? Regulation 6(3) of the regulations confirms that the supplementary statement becomes part of the PNA and accordingly a gap in services is identified in the PNA.

3.14 13(2)(e) -that whether the application will only meet part of the current need is not relevant to the consideration as our client's application will provide all services offered by the closed pharmacy.

3.15 13(2)(f) is not relevant as the application includes all essential services.

3.16 13(2)(g) is not relevant as the application does not offer services other than essential services.

3.17 13(2)(h) is not relevant as there have been no grants at this location.

3.18 In summary, the application will meet the current need identified in the supplementary statement dated 31 March 2024 and we ask NHS Resolution to allow our client's appeal and to quash the decision by NHS England and redetermine and grant our client's application. If an oral hearing is arranged our client would want to attend and be represented."

4 Summary of Representations

This is a summary of representations received on the appeal. A summary of those representations made to the Commissioner are only included insofar as they are relevant and add to those received on the appeal.

4.1 THE COMMISSIONER

4.1.1 "Thank you for your letter dated 7th November 2024.

4.1.2 The response will focus on the supplementary statement and draw on the determination of NHS Resolution in relation to the applicant's appeal SHA/26268 which was for an Unforeseen Benefits application under Regulation 18.

4.1.3 For context, the applicant had initially submitted an Unforeseen Benefits application under Regulation 18 due to the closure of a Boots Pharmacy in November 2023 at 156 Hallgate, Cottingham, HU16 4BD. Within the application, they proposed to replace the services provided by Boots and more generally the reduction in the provision of pharmaceutical services across Cottingham. This application was refused by the Humber & North Yorkshire (HNY) Integrated Care board (ICB) Pharmacy Services Regulations Committee (PSRC). This decision was appealed by the applicant. The

determination made by NHS Resolution in relation to this appeal quashed HNY ICBs decision but still refused the application on the basis that the improvements or better access set out in the unforeseen benefits application were included in the Pharmacy Needs Assessment (PNA) due to the publication of a supplementary statement which identified there was a gap, and consequently Regulation 18(1)(b) was not satisfied meaning the application should not have been submitted as an unforeseen benefits application.

Supplementary Statement

4.1.4 Following the closure of the Boots Pharmacy in November 2023, East Riding Council Health & Wellbeing Board published a Supplementary Statement on 31st March 2024 which stated "This closure does create a significant change to the East Riding PNA 2022-2025 that are of a [sic] it does create a gap in the need for pharmaceutical services within the Cottingham North and South Wards".

4.1.5 It went on to state that "it is the view of the East Riding Council Health and Wellbeing Board that this change to the availability of pharmaceutical services is relevant to the granting of applications referred in Section 129(2)(c)(i) or (ii) of the 2006 Act and is satisfied that a revised PNA would be a disproportionate response".

4.1.6 On page 63 of chapter 8 of the DHSC PNA information pack for local authority health and wellbeing boards, the guidance supports this:

A supplementary statement is to be published to explain changes to the availability of pharmaceutical services where:

(a) the changes are relevant to the granting of an application or applications for inclusion in the pharmaceutical list for the area of the health and wellbeing board's area; and

(b) the health and wellbeing board is satisfied that producing a new pharmaceutical needs assessment would be a disproportionate response to those changes or it is already producing its next pharmaceutical needs assessment but is satisfied that it needs to immediately modify the existing document in order to prevent significant detriment to the provision of pharmaceutical services

4.1.7 At the bottom of page 63, the guidance states "Supplementary statements are statements of fact; they do not make any assessment of the impact the change may have on the need for pharmaceutical services. Effectively, they are an update of what the pharmaceutical needs assessment says about the availability of pharmaceutical services. They are not a vehicle for updating what the pharmaceutical needs assessment says about the need for pharmaceutical services". It then goes on to say "Once published the supplementary statement becomes part of the pharmaceutical needs assessment and will therefore be referred to by NHS England and NHS Improvement when it determines applications for inclusion in a pharmaceutical list. It will also be referred to by NHS Resolution when it determines an appeal. Supplementary statements are therefore to be published alongside the pharmaceutical needs assessment".

4.1.8 Within the decision letter for appeal SHA/26268, in paragraph 7.43 it stated that "as the Commissioner had disregarded the supplementary statement, the

Committee determined that the decision of the Commissioner must be quashed".

4.1.9 Reflecting on the outcome of the appeal SHA/26268 and looking again at the DHSC PNA information pack for local authority health and wellbeing boards, the wording contradicts itself and therefore it is difficult to ascertain the role of the supplementary statement.

4.1.10 As a result of this it is also then difficult to ascertain which application type would be applicable under the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013."

4.2 COMMUNITY PHARMACY HUMBER

4.2.1 "The LPC will leave the questions raised around the application of the regulations to the appeals unit to consider. However we do note that even if the decision by PSRC is quashed NHS resolution does have the remit to redetermine the decision to the same outcome, we would support that same outcome. The LPC continues to not support this application.

4.2.2 We will however provide local clarification and comment on the matters of 'context' and claims made in the appeal. This will necessitate the use of extracts from the appeal letter presented in italics and those from the appellants previous appeal SHA/26268 underlined.

Context

4.2.3 *It may be helpful for Primary Care Appeals to understand the context of the application. Our client initially made an application under Regulation 18 against a background of closure of the Boots Pharmacy, at 156 Hallgate, Cottingham, HU16 4BD which closed in November 2023 and evidence of failures in the service provided by the remaining pharmacies as evidenced by an independent HealthWatch survey*.

4.2.4 Service failures need evidence, and no reliable evidence has been supplied to support the claims throughout the previous application and this appeal.

4.2.5 The HealthWatch summary of themes showed temporary issues related to customer service that could be addressed by the existing contractors or via ICS/NHSE's contract management and are outside the decision processes within these regulations. Even with Healthwatch's sample size of 172, 0.98% from a population of 17,543 in the PNA, there are numerous examples within the comments showing little issue with accessing dispensing services out with Cottingham. Taken within the context of the upheaval at the time this data would have been gathered, the closed Hallgate shop was mentioned by some as though still in operation, this does colour the views seen within the true context of the time. The cause of much of the historical issues is well evidenced within the SHA/26268 determination.

4.2.6 *There is also an increase in population from local housing developments. There is an indication that the current need is continuing from a letter of support received today from the local GP surgery, Greengates Medical Group.*

4.2.7 Housing developments are noted in the PNA, and therefore foreseen in planning terms. The PNA talks of a 2019-2029 plan and as the current PNA covers 2022-2025 housing is well accounted for. Planned construction does

not equal built, sold and inhabited homes. The points raised in the Greengates letter are addressed later.

4.2.8 *Following the circulation of the original application, the East Yorkshire Health and Wellbeing board issued a supplementary statement indicating that the closure of the Boots Pharmacy in Cottingham had created a gap in the provision of pharmaceutical services in Cottingham. This statement was considered in the determination of the Regulation 18 application on appeal on 23 October under reference SHA/26268. The application was refused on the basis that the Committee determined that the improvements or better access set out in the unforeseen benefits application were included in the PNA and consequently Regulation 18(1)(b) was not satisfied*.

4.2.9 The status of the supplementary statement and what it says was a point of in-depth consideration in the previous appeal. There is a regulatory basis to query any declared gap in the supplementary statement and whether the gap actually demonstrates any unmet need that would require a contract.

4.2.10 Regulation 6(3) states that a supplementary statement may be published by a HWB explaining changes to the availability of pharmaceutical services since the publication of its PNA where:

4.2.11 <u>The changes are relevant to the granting of applications referred to in section 129(2)(c)(i) or (ii) of the NHS Act 2006 (i.e. routine applications);</u>

<u>and</u>

4.2.12 <u>The HWB is: Satisfied that producing a new PNA is a disproportionate response to the changes, or Is in the process of producing a new PNA and is satisfied that immediate modification of its PNA is essential in order to prevent significant detriment to the provision of pharmaceutical services in its area.</u>

4.2.13 Supplementary statements, therefore, simply explain changes to the availability of services e.g. a pharmacy has closed/opened/relocated. They are not intended to go on to identify a gap etc.

4.2.14 Where the HWB identifies changes to the need for pharmaceutical services in its area, which are of a significant extent, then regulation 6(2) says that it is to produce a new PNA.

4.2.15 It's not, therefore, simply the case that a supplementary statement is issued when a pharmacy closes. The rest of regulation 6(3) must be satisfied too.

4.2.16 When determining the application, therefore, NHSR should have regard to the PNA and note that a supplementary statement has been issued confirming the closure of a pharmacy, if it chooses to factor in the supplementary statement at all.

4.2.17 Setting aside the fact a supplementary statement is not intended to identify gaps, needs, improvements or better access, the supplementary statement that was issued wouldn't meet the requirements of either paragraph 2 or 4, Schedule 1 in any case.

4.2.18 The HWB has not stated which pharmaceutical services are not being provided in its area but which either:

4.2.18.1 need to be in order to meet a current or future need (as well as specifying the future circumstances) for, or

4.2.18.2 would, if they were provided, secure current or future improvements, or better access, to pharmaceutical services or pharmaceutical services of a specified type.

4.2.19 It is therefore our understanding that within the PNA it isn't sufficient to simply say there is a gap – the HWB has to go further and say what the gap is and what is required to fill it, i.e. what services, where and when they are to be provided, and what the specified future circumstances are that would trigger the need/improvements/better access if relevant. If it fails to do so in our opinion, as in this case, [emphasis added by Community Pharmacy Humber] then there is no gap to fill and nothing to consider. The decision in SHA/26268 did consider that the supplementary statement did create a gap but did not describe any current need.

4.2.20 It is worth noting that Cottingham, while it often refers to itself as Cottingham village, is not a rural location and is very much attached to the conurbation of Hull, actually coterminous, and its surroundings with the access and facilities that implies. People are mobile within and without Cottingham and into Hull as well as the East Riding.

4.2.21 *It was concluded at paragraph 7.33 of the decision that* "The Committee consequently considered that a supplementary statement may refer only to the availability of pharmaceutical services but, if considered appropriate by the HWB, is also able to identify a gap. As noted above, a supplementary statement then forms part of the PNA."

4.2.22 In the previous decision it also says:

4.2.23 7.36 The Committee noted that, regardless of the clear error in the drafting, the surrounding wording in the supplementary statement is very specific, it said the closure "does" create a gap in service provision. However, the Committee also and as argued by Gordons Partnership, that **the supplementary statement did not overtly state that the closures have created a current or future need.** [sic] [emphasis added by Community Pharmacy Humber]

4.2.24 Therefore even if the supplementary statement as written does indicate a gap it does not describe any current or future unmet need ascribed to it. Hence no basis for an application.

4.2.25 *The decision then goes on to say* "The Committee considered that it was clear that the gap could potentially be filled by an application submitted pursuant to Regulations 13, 15 or 17".

4.2.26 The pertinent sections in full here are:

4.2.27 7.37 The Committee therefore considered if, on one hand, this indicated a level of certainty in relation to a gap that could potentially be filled by an application submitted pursuant to Regulations 13, 15 or 17 (and so prevent the application of Regulation 18(1)(b) to the application) or if, on the other hand, the level of ambiguity was such as to enable the Committee to determine that the improvements or better access that the Applicant is seeking to secure were not or was not included in the PNA.

4.2.28 7.38 The Committee considered that it was clear that the gap could potentially be filled by an application submitted pursuant to Regulations 13, 15 or 17 and so prevent the application of Regulation 18(1)(b) to the application, even if it was not entirely clear to the Committee which one it was. The Committee noted that parties to this appeal had not been expected to provide comments on which type of application (Regulation 13, 15 or 17) could fill the gap, but the Committee concluded it was not necessary in this determination to do so.

4.2.29 When taken together the extracts are not so certain about the regulation 13 avenue. Very much a potential route and not a definite one.

4.2.30 *Our client's case is that the gap would be filled by his application under regulation 13. The comment on the gap or need for services is preceded in the supplementary statement by a statement about the closure of the Boots Pharmacy. The wording of the supplementary statement is* "Boots Pharmacy at 115 Hallgate, HU16 4BD in the Cottingham North Ward closed on the 11/11/2023. This closure does create a significant change to the East Riding PNA 2022-2025 that are of a it does create a gap in the need for pharmaceutical services within the Cottingham North and South Wards."

4.2.31 *When taking the statement as a whole it is clear the gap is the services no longer provided by the Boots Pharmacy. Our client is offering to replace those services at the same or adjacent location and will offer the same opening times and services as the closed Boots*.

4.2.32 The previous judgement says: "7.36… the closure "does" create a gap in service provision. However…the supplementary statement did not overtly state that the closures have created a current or future need"

4.2.33 The statement only says 'a gap in the need for pharmaceutical services' and does not say which services. It is a significant assumption to equate any gap stated, even though there are no 'needs' identified, to match the entirety of the closed contracts offer which happily matches the appellants offering. A gap is not a defined need let alone a direct copy. It is just as likely that should there be any unmet need it could not be as expansive as would require a full contract; it could just as easily be an enhancement of a specific service that the existing contractors could address. However nothing is so described. This is a gap without a defined need, necessary to access it with, let alone a need for an entire new contract.

4.2.34 *It is also clear that this is a current as opposed to future need; the closure has occurred and the need for the services that were provided by Boots Pharmacy is clearly articulated by the supplementary statement.*

4.2.35 The previous decision, 7.36 above, is clear that there is no stated need, just a gap and nothing to indicate it is current either.

4.2.36 It is established fact that a closure of a contract does not automatically mean that a gap has been created, or that a perceived gap equals unmet need. The remaining contractors can, and do, adjust to meet the new demand without the need for another contract. This would come under the contract management remit of the ICS.

4.2.37 The NHSR appeal letter specifically requests information around regulations 31 & 13 in particular, I shall deal with each in turn.

Reg 31:

4.2.38 We can confirm that there are no pharmacy premises within the geographical footprint described in the application that would bring Regulation 31 into effect. However, there are very few business units within that area also. The area is primarily residential, and we are unaware of any premises in discussion or having been secured, pictures are shared to best illustrate the locale in question [see Appendix C].

4.2.39 The only 'units' on Beck Bank and Station Road junction.

4.2.40 We do wonder exactly where the appellant is planning to locate a pharmacy.

Reg 13:

4.2.41 *13(1)(a) - would granting the application meet a current need for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB? The services were identified in the supplementary statement as being those replacing the services offered by Boots Pharmacy*.

4.2.42 We would be interested in seeing where the wording referred to above exists as the version of the supplementary statement circulated and published does not actually say anything about any specific service needs let alone reference to what Boots offered.

4.2.43 "This closure does create a significant change to the East Riding PNA 2022-2025 that are of a it does create a gap in the need for pharmaceutical services"

4.2.44 No specific services are described at all, let alone replicating all of those from the closed Boots. Defining them is important within the regulations and not something to assume.

4.2.45 *13(1)(b) – has the current need been included in the relevant pharmaceutical needs assessment in accordance with paragraph 2(a) of Schedule? Regulation 6(3) of the regulations confirms that the supplementary statement becomes part of the PNA and accordingly a gap in services is identified in the PNA*.

4.2.46 Even if this gap does transfer to the PNA it still doesn't specify need, and need is required to gauge when the need has been addressed and what steps are required to do so, everything from more engagement from the existing contractors to a new contract, but neither is specified.

4.2.47 *13(2)(e) -that whether the application will only meet part of the current need is not relevant to the consideration as our client's application will provide all services offered by the closed pharmacy*.

4.2.48 As the need is not specified, whatsoever, you cannot claim to meet it fully, partially or not at all. This also applies to others below.

4.2.49 *13(2)(f) is not relevant as the application includes all essential services*.

4.2.50 *13(2)(g) is not relevant as the application does not offer services other than essential services*.

4.2.51 1*3(2)(h) is not relevant as there have been no grants at this location*.

4.2.52 *In summary, the application will meet the current need identified in the supplementary statement dated 31 March 2024 and we ask NHS Resolution to allow our client's appeal and to quash the decision by NHS England and redetermine and grant our client's application. If an oral hearing is arranged our client would want to attend and be represented*.

4.2.53 Again, the appellant is trying to conflate a gap with an unmet need and also self-describing that need. No need is identified.

4.2.54 We also need to address the evidence presented to support a claim of current need:

"Greengates Medical Group – We fully support an application for a new pharmacy in Cottingham as our patients registered at that site find it extremely difficult to obtain their prescriptions and kept waiting up to a week as the current provision in that area cannot cope with demand."

4.2.55 This is entirely Anecdotal and comes with no further evidence of changes in any metrics. For regularly ordered medicines in this locale a week to allow for ordering and then supply is not uncommon due to local policies on Rx ordering. If there were to be an issue about current dispensing capacity this would fall within the contract management auspices of the ICS/NHSE and has no bearing on this application.

"Our patients are constantly having to travel further and further to obtain same day prescriptions as the queues are so long and would welcome you favourably considering this appeal."

4.2.56 Again this comment would fall within the contract management capacity of the ICS/NHSE, and no data is supplied to back the claim up.

4.2.57 Patients in Cottingham are already used to travelling as they are part of the greater Hull conurbation and the PNA shows 80% car ownership.

4.2.58 It is worth remembering that there are 10 community pharmacies within 2 miles, 5 within 1.2 miles and 2 current Cottingham contractors within 0.3 miles of the appellants described area. 2 contracts alone constitute choice and provide the option to increase capacity to provide any unmet service needs if they are so defined.

4.2.59 Cottingham has 2 GP surgeries, and those surgeries provide prescriptions that are dispensed at 150 and 97 different community pharmacies respectively (SHAPE data).

4.2.60 The table below shows the dispensed items data for just the 6 pharmacies within 1.5 miles of the proposed location, to show how the items from the closed contract have been absorbed in the locality around Cottingham.

4.2.61 2 have had changes of ownership which render their data incomparable. However the remaining 4 do clearly show that they have all increased their dispensing volume significantly and well beyond the average increase for the Humber LPC area. The 4, when comparing the 6 months prior to Boots Hallgate closing, then compared to 5 months of 2024 afterwards, show an average increase of 17% compared to the LPC average of 3.3%. These items have to come from somewhere and note the Cottingham GPs prescriptions are split across up to 150 pharmacies.

Contract	Average monthly items Apr-Sep 23	Average monthly items Jan-May 24	Variance items	Variance %	Comments
Boots King St Cottingham	10922	13267	2345	21.47%	
Jhoots King St Cottingham	3946	3908	-38	-0.96%	COO impact from Lloyds
Boots Endike Lane	7513	9035	1522	20.265	
Keiths Bricknell Ave	7678	7633	-45	-0.59%	COO Impact from Whitworths
Keiths Cottingham Rd	6713	7680	967	14.40%	
Boots Orchard Park	15905	17848	1943	12.22%	
			6694		
Boots Hallgate Cottingham	5031	n/a			The closed pharmacy
Humber LPC	1765376	1823820	58444	3.31%	

+17% average for the 4 CPs unaffected by COO compared to +3.31% LPC Average

4.2.62 Boots Hallgate was dispensing roughly 5000 items monthly before the closures impact, the 4 comparable community pharmacies shown here alone have seen a collective increase above that amount, before remembering the other 146 contractors processing the Cottingham prescriptions.

4.2.63 Solid evidence of unmet need at any specific times, or indeed evidence of failure to meet core contractual responsibilities, is not present.

Summary:

4.2.64 In general there is a lack of information to reinforce the various statements made about the current contractors and situation in Cottingham.

4.2.65 The supplementary statements impact on gaps, and needs, has already been well discussed in the previous appeal SHA/26268 which decided that while the statement may say there's a gap it does not say there is a need. It made no attempt to define such a need in services terms or the exact location to be applied. The appellant has taken leaps of faith and optimism to equate its offering with any non-defined non-existent need.

4.2.66 We ask NHS Resolution to consider our clarification of the appellants 'context' and refuse this appeal.

4.2.67 The LPC appreciates being kept informed of the progress of the application and would request to be invited to any oral hearing, should one be required."

5 Summary of Observations

This is summary of observations received.

5.1 GORDONS PARTNERSHIP ON BEHALF OF THE APPLICANT

5.1.1 “Thank you for your letter of 12 December 2024 with enclosures. We note that we have the opportunity to make comments in rebuttal on the enclosed representations. Our client’s comments are as follows:

Community Pharmacy Humber – 6 December 2024

5.1.2 Context

5.1.3 Community Pharmacy Humber provide comments at great length, not all of which are relevant to the determination of the current needs application. Much of the letter is a recitation of comments made by [Mr M] in relation to our client’s previous application for unforeseen benefits. A reliance on these points misses the issue that by operation of the supplementary statement, a gap has been identified in relation to the provision of pharmaceutical services in the Cottingham area. It is not the function of a current needs application to provide evidence of need but to set out the way an applicant can meet the identified need. The fact that Community Pharmacy Humber /[Mr M] take issue with that finding does not mean that he is entitled to revise the PNA through his response to this application.

5.1.4 Notwithstanding the above, errors are made in the summary and we need to challenge some obvious misstatements within the letter from Community Pharmacy Humber:-

5.1.5 The HealthWatch assessment was an independent assessment within Cottingham and to suggest the sample size is a low percentage by reference to the entire population of the PNA is to fundamentally misunderstand the exercise that Healthwatch were engaged in, which was to look at pharmaceutical services in Cottingham. It is worth noting that HealthWatch was set up to understand the needs, experiences and concerns of service users by The Health and Social Care Act 2012. It has statutory powers to provide NHS England with information and advice on the views of people who use health care services on their needs for and experiences of health services; and also on the views of Healthwatch and individuals on the standard of health services. It is concerning to see its findings dismissed by Community Pharmacy Humber in the way that they do in their response.

5.1.6 It is also not correct to say that the evidence of need is a snapshot in time. We have provided evidence from a concerned GP surgery that show that patients’ struggles to obtain pharmaceutical services continue and there is a need for alternative provision. For [Mr M] to dismiss this as “anecdotal” when it comes from a representative of healthcare professionals is also concerning.

5.1.7 In relation to car ownership, it is noted that [Mr M] refers again to “patients who are used to travelling” and references car ownership. There is no reference to the 20% of households without access to a car or van which means that for some of the population driving to local pharmacies is not possible.

5.1.8 In relation to the new developments: [Mr M] says “Planned construction does not equal built, sold and inhabited homes.” this is of course the case but in our previous correspondence to NHS Resolution over six months ago we identified that many of the new developments were either advertising their properties for sale or they were already occupied.

5.1.8.1 The Harland Gardens development has 87 built properties, and these are being advertised for sale.

5.1.8.2 The Vines – 57 homes which again are already being marketed for sale.

5.1.8.3 Poppy Fields – 350 homes were all phase one homes are been [sic] occupied and phase two homes have been reserved.

5.1.9 It can be inferred that occupancy has increased since that date.

5.1.10 In relation to data relating to use of pharmacies: [Mr M]'s presentation of the data fails to recognise that part of the increase in pharmacy usage in the local area is due to the new developments and increase in population. He attributes any increase solely to the closure of the Boots pharmacy. He also fails to acknowledge that the two pharmacies within Cottingham show either a failure to cater for the increase at all (Jhoots) or a very significant and unsustainable increase of 25% which clearly gives rise to the complaints and failures in the provision of pharmaceutical services that have been picked up by HealthWatch and the local surgery.

5.1.11 It is said that these are service provisions that should be managed by NHS England. However the capacity of pharmacies to take on new patients is not unlimited. If the failings identified are due, not to management issues, but capacity issues, then this is dealt with through the HWB and regulatory processes governing market entry. These processes clearly include identifying through the PNA where there is a gap in provision so that applications for new pharmacies can be made to increase capacity in the local area. This is the purpose of the current application.

Regulation 13 of the NHS (Pharmaceutical and Local Pharmaceutical services) Regulations 2013 (the Regulations).

5.1.12 The starting point for consideration of this application is that the HWB has identified a gap in provision which means that a section of the population in Cottingham are not receiving the pharmaceutical services they need. The fact that a gap was identified was endorsed by the NHS Resolution in decision reference SHA/26268 already quoted in the appeal letter. Bearing in mind NHS England's obligations to secure the provision of pharmaceutical services under the 2006 NHS Act, any uncertainly in interpretation should be resolved in a way that would ensure the gap in the provision of pharmaceutical services is filled.

5.1.13 Taking the regulatory issues raised by Community Pharmacy Humber in turn:

5.1.14 Effect of the supplementary statement

5.1.15 Community Pharmacy Humber say "Supplementary statements, therefore, simply explain changes to the availability of services e.g. a pharmacy has closed/opened/relocated. They are not intended to go on to identify a gap etc."

5.1.16 Regulation 6(2) and (3) state:

"6(2) Each HWB that has published a pharmaceutical needs assessment] must make a revised assessment as soon as is reasonably practicable after identifying changes since the previous assessment, which are of a significant extent, to the need for pharmaceutical services in its area, having regard in particular to changes to—

(a)the number of people in its area who require pharmaceutical services;

(b)the demography of its area; and

(c)the risks to the health or well-being of people in its area, unless it is satisfied that making a revised assessment would be a disproportionate response to those changes.

(3) Pending the publication of a statement of a revised assessment, a HWB may publish a supplementary statement explaining changes to the availability of pharmaceutical services since the publication of its or a Primary Care Trust's pharmaceutical needs assessment (and any such supplementary statement becomes part of that assessment), where—

(a)the changes are relevant to the granting of applications referred to in section 129(2)(c)(i) or (ii) of the 2006 Act; and

(b)the HWB—

(i)is satisfied that making its first or a revised assessment would be a disproportionate response to those changes, or

(ii)is in the course of making its first or a revised assessment and is satisfied that immediate modification of its pharmaceutical needs assessment is essential in order to prevent significant detriment to the provision of pharmaceutical services in its area."

5.1.17 It is agreed that Regulation 6(2) relates to the issuing of a revised full PNA covering changes unless the revised assessment is a "*disproportionate response*". It appears agreed that there is no requirement in this case for a full revised PNA. However [Mr M]'s analysis of the effect of Regulation 6(3) is not accepted.

5.1.18 My client's position is that both limbs of Regulation 6(3) are met; the changes are relevant to the "granting of applications" and that the HWB "is satisfied that making a revised assessment would be a disproportion response to the changes" . The Regulation also refers to immediate modification being essential in order to prevent significant detriment to the provisional pharmaceutical services in its area. The supplementary statement has been issued appropriately. It highlights the changes are significant changes that are relevant to the granting of applications and also states that there is a gap.

5.1.19 It is not accepted that the supplementary statement is no more than a statement of changes as suggested by [Mr M]. Regulation 6(3) allows the HWB to regulate the pharmaceutical needs between iterations of the full PNA. It is hard to see how the issue of the supplementary statement could be interpreted as a neutral act that does not give rise to an indication that there is a need for pharmaceutical services in the area.

5.1.20 If [Mr M]'s analysis is correct either there would be no need for supplementary statements or all opening and closing of pharmacies would simply be recorded within a supplemental statement. However, neither of these of the case [sic]. The legislation has specifically identified circumstances and a mechanism in

which the HWB is able to take action between PNA cycles where there is a change that is relevant to the granting of applications.

Meeting the requirements of Regulation 13 and Schedule 1

5.1.21 Mr. M further argues that the supplemental statement produced would not meet the requirements of either paragraph 2 or 4 of Schedule 1 of the regulations. This is not accepted.

5.1.22 It may be correct that if the application had been made under Regulation 15 as an application for future needs there would need to be some specification ie; of the trigger event. However, the need for pharmacy services in Cottingham is immediate and not a future need so an application under this regulation was not thought appropriate. Similarly, an application made under Regulation 17 was not considered to be the appropriate application in this case as the applicant wished to provide the full current need identified.

5.1.23 The supplementary statement identified the gap as a result of the loss of the Boots Pharmacy in Hallgate and therefore the services previously offered. Accordingly, the identified current need is for a replacement of all services offered by the closed Boots pharmacy. Given the supplementary statement becomes part of the PNA, a correct interpretation of the regulations does not require the listing all the services and hours of provision that were previously offered by the Boots Pharmacy in Hallgate in the Supplementary Statement. This is because they are already listed in the PNA as the pharmacy was included in the original 2022 version of the PNA; the services provided were listed at Appendix 15 and the hours services were provided at Appendix 13.

5.1.24 In addition, the original market entry guidance available on the government website “Regulations under the Health and Social Care Act 2012: Market entry by means of Pharmaceutical Needs Assessments. Information for NHS England Chapter 5 - Current needs” gives an example of a current need application as follows “A community is served by one poorly situated pharmacy and the HWB identifies a current need for a better-situated pharmacy in its PNA. A routine application is submitted to meet that current need.” This confirms the position that it is not mandatory to do more than specifying a need for a pharmacy.

5.1.25 More generally, it is clear what is meant by pharmaceutical services. Regulation 13 provision states:

“13.—[F2(1) If—

> *(a)[F1NHS England] 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 meet a current need for pharmaceutical services, or pharmaceutical services of a specified type,”*

5.1.26 NHS Resolution will be aware that “pharmaceutical services” are already defined within NHS legislation and in particular the regulations. The guidance to the Regulations emphasised these definitions and said at paragraphs 10 and 11 of the preamble “Information for NHS England Executive Summary and Chapters 1-4”

"10. The 2006 Act allows for arrangements to be made for the provision of three types of pharmaceutical services, depending on the type of contractor providing the services:

> *• essential services, other mandatory arrangements, advanced services and enhanced services provided by pharmacy contractors*
>
> *• services set out in Schedule 5 and advanced services as provided by dispensing appliance contractors; and*
>
> *• dispensing services provided by dispensing GPs as set out in Schedule 6.*

11. Within the 2013 Regulations, the definition of pharmaceutical services differs between the Parts and Schedules:

> *Part 2 and Schedule 1 – provisions regarding PNAs – as per the definition in paragraph 10 above, plus local pharmaceutical services (LPS)*
>
> *Parts 7 and 8 and Schedule 6 – provisions regarding controlled localities, reserved locations and dispensing doctors, and the terms of service for dispensing doctors – in the context of service provision by services provided by dispensing doctors, pharmaceutical services means the dispensing services provided by dispensing GPs as set out in Schedule 6. In the context of service provision by pharmacy contractors or appliance contractors, it means the services mentioned in relation to those types of contractor in paragraph 10 above, but not LPS; and*
>
> *Parts 3 to 6 and 9 to 13 – as per the definition in paragraph 10 above, although in practice, services provided by dispensing GPs will generally not be relevant where pharmaceutical services is used in these Parts, as these Parts relate almost exclusively to market entry and performance sanctions for pharmacy and dispensing appliance contractors."*

5.1.27 Accordingly, it is clear that it was expected that when the term "pharmaceutical services" was used within the regulations it would be understood in the context of the regulatory definitions without further elaboration.

5.1.28 It is relevant that there is a differentiation between "pharmaceutical services and pharmaceutical services of a specified type." Given the applicant's case that what is meant by pharmaceutical services is already clear from the legislation, only a gap in relation to "pharmaceutical services of a specified type" would be required to be fully particularised as there would be a need to clarify the identity of the specified type of pharmaceutical services within the already defined "pharmaceutical services".

5.1.29 It is our position that the supplementary statement goes far enough in identifying a current need by specifying the identity and address of the relevant pharmacy which closed and therefore the requirements of regulation 13 and schedule 1 are satisfied. There can be no confusion about the services and hours of provision that are required to fill that gap or what should go into an application to meet the current need.

Gap or need

5.1.30 [Mr M] also discusses the use of the word “Gap” and suggests that does not equate to an unmet need.

5.1.31 It is agreed that the closure of a pharmacy does not always equate to a gap in provision. However here the HWB have identified that the closure of this pharmacy does “create a gap in the need for pharmaceutical services within the Cottingham North and South Wards.”

5.1.32 This equates to a current need. The use of the word “gap” has become used as shorthand in PNAs across the country and this is derived from usage of the word within the Regulations. Schedule 1, paragraph 2 of the regulations deals with current needs and says;

“Necessary services: gaps in provision

2. 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)need to be provided (whether or not they are located in the area of the HWB) in order to meet a current need for pharmaceutical services, or pharmaceutical services of a specified type, in its area;

(b)will, in specified future circumstances, need to be provided (whether or not they are located in the area of the HWB) in order to meet a future need for pharmaceutical services, or pharmaceutical services of a specified type, in its area.” (emphasis added).

5.1.33 It can be seen that the provision that requires the HWB to identify areas where there is a current need for services is equated to gap in provision in the heading of the regulation. It was not necessary for the HWB to fully quote the Regulation and say expressly “these are services that are not provided in the area of the HWB but which the HWB is satisfied, need to be provided in order to meet a current need for pharmaceutical services” when they could just say there is a gap in provision. Unfortunately, this drafting shortcut appears to have created confusion but it is my client’s contention that when reviewed against Schedule 1, paragraph 2, the meaning is clear.

Current need

5.1.34 Finally, it should also be noted that, not only is there evidence that the need is continuing, as mentioned above, but the supplementary statement identifying the gap has not been withdrawn so it still current.

Humber & North Yorkshire (HNY) Integrated Care board (ICB) – letter dated 21 November 2024

5.1.35 The ICB reiterates sections from the DHSC guidance pack that were not accepted in SHA/26268 and concludes that it is difficult to ascertain which application would be applicable. My client relies on the points made in the original application, appeal and above which make it clear that the application under Regulation 13 is the application that should be made.

5.1.36 Importantly, it should be noted that the ICB does not suggest that there is no need for a pharmacy at the location, merely that they are not sure which regulatory route would be correct.

5.1.37 In all the circumstances, we would ask you to allow our client's appeal and grant the application."

6 Consideration

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

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

6.3 The Committee had before it a copy of the East Riding Health and Wellbeing Board (HWB) PNA 2022 – 2025 which was published on 1 October 2022 and prepared by East Riding of Yorkshire Council. The Commissioner advised that there had been Supplementary Statements to the PNA and that "Supplementary Statement 18", which had been published on 31 March 2024, was relevant to this application.

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

6.5 The Committee dealt with the appeal by way of consideration of all the issues.

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

Regulation 31

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

(1) A routine or excepted application, other than a consolidation 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) NHS England 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).

6.8 The Committee noted that the Applicant had not provided any information in the application form on this point but the Committee noted that the wording of the application form only required the Applicant to include information in the relevant

section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. On the basis of the information available, the Committee determined that it was not required to refuse the application under the provisions of Regulation 31.

6.9 The Committee noted that, if the application were granted, the successful applicant would - in due course - have to notify the Commissioner of the precise location of its premises (in accordance with paragraph 31 of Schedule 2). Such a notification would be invalid (and the applicant would not be able to commence provision of services) if the location then provided would (had it been known now) have led to the application being refused under Regulation 31.

Regulation 13

6.10 The Committee noted the reference by parties to a previous decision (SHA/26268) in which the Applicant had made an application under the provisions of Regulation 18 for inclusion in the pharmaceutical list at 58-60 Beck Bank, Cottingham, HU16 4LH, which is the same site as in the instant application. The Committee in the previous decision had, on consideration of the PNA and "Supplementary Statement 18", concluded "*that it was clear that the gap could potentially be identified by an application submitted pursuant to Regulations 13, 15 or 17 …"* The Committee noted that in the previous decision it had determined "*the improvements or better access were or was included in the PNA and the Committee therefore had to determine that Regulation 18(1)(b) was not satisfied."*

6.11 The Committee noted that in the previous appeal (SHA/26268) parties had not been expected to provide comments on which type of application (Regulation 13, 15 or 17) could fill the gap and the Committee in that decision had concluded that it was not necessary in that determination to do so.

6.12 This instant application (which was to be determined in accordance with the procedures in Schedule 2) was submitted by the Applicant based on addressing a current need for pharmaceutical services.

6.13 The Committee considered whether the need on which the Applicant based its application satisfied the elements of Regulation 13(1) which reads as follows:

"(1) If - —

(a) NHS England 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 meet a current need for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB; and

(b) the current need has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 2(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), NHS England must have regard to the matters set out in paragraph (2). "

6.14 Paragraph 2(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) need to be provided (whether or not they are located in the area of the HWB) in order to meet a current need for pharmaceutical services, or pharmaceutical services of a specified type, in its area"*

6.15 The Committee noted that, in its application, the Applicant had identified that the current need that it was offering to meet was contained within "Supplementary Statement 18".

6.16 The Committee considered the PNA prepared by East Riding of Yorkshire Council, conscious that the document provides an analysis of the situation as it was assessed at the date of publication. The Committee noted that, under Regulation 6(2), the body responsible for the PNA must make a revised assessment as soon as reasonably practicable, after identifying changes that have occurred that are relevant to the granting of applications, unless to do so appears to be a disproportionate response to those changes. Where it appears disproportionate, the responsible body may, but is not obliged to, issue a supplementary statement under Regulation 6(3). Such a statement then forms part of the PNA.

6.17 The Committee noted that a supplementary statement may refer only to the availability of pharmaceutical services but, if considered appropriate by the HWB, is also able to identify a gap. The Committee was of the view that the Regulations clearly envisage that a supplementary statement will contain a statement relevant to the need for pharmaceutical services that forms part of the PNA. The Committee therefore reviewed the PNA dated 1 October 2022 and the various Supplementary Statements that had been issued.

6.18 The Committee reviewed the East Riding of Yorkshire Council PNA which had been published on 1 October 2022 as well as "Supplementary Statement 18" which had been published on 31 March 2024. The Committee noted that the Supplementary Statement had been quoted verbatim by the Applicant in its application and subsequent appeal. "Supplementary Statement 18" states:

Supplementary Statement to the East Riding of Yorkshire Council
Pharmaceutical Needs Assessment (PNA)

Date of Publication of Pharmaceutical Needs Assessment	*01/10/2022*
Date of Supplementary Statement	*31/13/2024*
Supplementary Statement Number	*18*

Pharmacy Closure

Boots Pharmacy, Hallgate, Cottingham

Boots Pharmacy at 115 Hallgate, HU16 4BD in the Cottingham North Ward closed on the 11/11/2023.

This closure does create a significant change to the East Riding PNA 2022-2025 that are of a it does create a gap in the need for pharmaceutical services within the Cottingham North and South Wards. [sic]

It is the view of the East Riding Council Health and Wellbeing Board that this change to the availability of pharmaceutical services is relevant to the granting of applications referred to in Section 129(2)(c)(i) or (ii) of the 2006 Act and is satisfied that a revised PNA would be a disproportionate response.	*Yes*	✓
	No	

This Supplementary Statement to the East Riding Council Pharmaceutical Needs Assessment is issued in accordance with Paragraph (3) in Part 2 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

Statement issued by:	*[AK]*
Post:	*Director of Public Health*
Date:	*31/03/2024*

6.19 The Committee noted that the Supplementary Statement, as well as providing a factual update on the closure of Boots Pharmacy, goes on to indicate, by the positive response to the question as set out in the Supplementary Statement that services are not provided in the area of the HWB but which the HWB is satisfied would, if they were provided meet a need for pharmaceutical services, or pharmaceutical services of a specified type, in Cottingham North and South Wards.

6.20 The Committee noted that the Applicant was proposing to meet this need in full by opening a new pharmacy in the vicinity of the location of the pharmacy that has now closed. The Committee further noted that based on the original application form submitted by the Applicant they were proposing to offer the same services and hours which would fill the "*gap in need for pharmaceutical services within the Cottingham North and South Wards*".

6.21 The Committee was mindful of the previous decision (SHA/26268) and its considerations and conclusion that there was a gap, however the Committee noted that the Supplementary Statement gave no indication as to whether the need that would be met was a need under Regulations 13, 15 or 17.

6.22 The Committee went on to consider the wording of the Regulations and consider which application was the relevant application to meet the need that had been identified.

6.23 The Committee noted that the Applicant had sought to apply under the provisions of Regulation 13 "Current Needs". The Committee considered if the application had been made under the appropriate regulation.

6.24 The Committee was of the view that the gap was not a need under Regulation 15 "Future Needs" as there was no indication in the Supplementary Statement that there was an event at some point in advance of the date of the Supplementary Statement which would create a need which this application could secure. The Committee was of the view that it was the closure of the Boots Pharmacy, a past event, which has created the need.

6.25 The Committee went on to consider if the need as described in the Supplementary Statement could be fulfilled by an application made under Regulation 17 "Improvements or better access to the current service". The Committee noted that the Supplementary Statement had not identified pharmaceutical services currently not provided, which if they were provided would secure better access to pharmaceutical services. The Committee was of the view that the reference to the gap did not fall within the requirements set out in paragraph 4(a) of Schedule 1 to the Regulations and

therefore the application should not be considered as an application for “Improvements or better access” as envisaged in Regulation 17(1).

6.26 The Committee therefore went on to consider the wording of Regulation 13 “Current Needs” as outline above. The Committee was of the view that, following the closure of the Boots Pharmacy, the need was ‘current’ based on the usual meaning of the word. The Committee was of the view that the need for pharmaceutical services was a present, ongoing need following the closure of the Boots Pharmacy and therefore a “Current Needs” application under the provisions of Regulation 13 was the appropriate application in this instance.

6.27 Based on all of the information before it, the Committee determined that Supplementary Statement 18 forms part of the 2022 – 2025 PNA and that the need in question was therefore included in the PNA in accordance with paragraph 2(a) of Schedule 1.

6.28 In this case, the provisions of Regulation 13(1) were met.

6.29 The Committee therefore proceeded to consider the application having regard to those matters set out at 13(2), which states:

(a) whether it is satisfied that it would be desirable to consider, at the same time as the applicant's application, applications from other persons offering to meet the current need mentioned in paragraph (1) that the applicant is offering to meet;

(b) whether it is satisfied that another application offering to meet the current need mentioned in paragraph (1) has been submitted to it, and it would be desirable to consider, at the same time as the applicant's application, that other application;

(c) whether it is satisfied that an appeal relating to another application offering to meet the current need mentioned in paragraph (1) is pending, and it would be desirable to await the outcome of that appeal before considering the applicant's application;

(d) whether it is satisfied that, since the publication of the relevant pharmaceutical needs assessment, there have been changes to the needs for pharmaceutical services in the area of the relevant HWB that are such that refusing the application is essential in order to prevent significant detriment to the provision of pharmaceutical services in its area;

(e) whether it is satisfied that—

(i) granting the application would only meet the current need mentioned in paragraph (1) in part, and

(ii) if the application were granted, it would be unlikely, in the reasonably foreseeable future, that the remainder of that need would be met;

(f) whether—

(i) it is satisfied that granting the application would only meet the current need mentioned in paragraph (1) in part, but

(ii) it considers that, if the application were granted, it would not be unlikely, in the reasonably foreseeable future, that the remainder of that need would be met;

(g) whether it is satisfied that—

(i) the current need mentioned in paragraph (1) was for services other than essential services, and

(ii) granting the application would result in an increase in the availability of essential services in the area of the HWB;

(h) whether it is satisfied that, since the publication of the relevant pharmaceutical needs assessment, the current need mentioned in paragraph (1) has been met by another person who is providing, or is due to be met by another person who has undertaken to provide, either in the area of the relevant HWB or in the area of another HWB, NHS services;

(i) whether the application needs to be deferred or refused by virtue of any provision of Part 5 to 7.

13(2)(a) and 13(2)(b)

6.30 The Committee noted that there are no applications from other persons offering to meet the current need mentioned in paragraph (1) that the Applicant is offering to meet which should be considered at the same time as the instant application.

13(2)(c)

6.31 The Committee was satisfied that there is no appeal relating to another application offering to meet the current need mentioned in paragraph (1) pending and it would be desirable to await the outcome of that appeal before considering the Applicant's application.

13(2)(d)

6.32 The Committee noted that the Commissioner was satisfied that since the publication of the PNA there have been no changes in pharmaceutical needs for the HWB that are such that refusing the application is essential to prevent significant detriment to the provision of pharmaceutical services. The Committee noted that this had not been disputed by any party.

6.33 Based on the information before it, the Committee was therefore satisfied that, since the publication of the relevant PNA, there have not been changes to the needs for pharmaceutical services in the area of the relevant HWB that are such that refusing the application is essential in order to prevent significant detriment to the provision of pharmaceutical services in its area.

13(2)(e) and (f)

6.34 The Committee was satisfied from the information provided to it that granting the application would meet the current need included in the PNA in full.

13(2)(g)

6.35 The Committee was satisfied that:

6.35.1 the current need included in the PNA was for services other than essential services, and

6.35.2 granting the application would result in an increase in the availability of essential services in the area of the HWB.

13(2)(h)

6.36 The Committee had no information to show that, since the publication of the PNA and Supplementary Statement 18, the current need included in the PNA has been met by another person who is providing, or is due to be met by another person who has undertaken to provide, either in the area of the relevant HWB or in the area of another HWB, NHS services. The Committee was therefore not satisfied that the need had been or was due to be met.

13(2)(i)

6.37 The Committee noted that no information had been provided to indicate that the application needed to be deferred or refused by virtue of any provision of Part 5 to 7. The Committee was therefore satisfied that it was not required to defer or refuse the application under Regulation 13(2)(i).

Additional Considerations

6.38 The Committee noted the information and comments from Community Pharmacy Humber in response to the application and subsequent appeal.

6.39 The Committee was of the view that a current need application is assessed against the criteria in Regulation 13 in order to determine if the application meets such a need. The location and availability of the proposed premises or other premises in the area of the best estimate was not a relevant matter. Further, the Committee was of the view that the location and dispensing of other pharmacies in the area, as well as access to those pharmacies and whether those wishing to access pharmaceutical services could do so from other pharmacies located in the area was also not a relevant matter.

6.40 The Committee noted the comments from the Applicant that they were meeting the need in full as set out in Supplementary Statement 18 and that in addition to providing core opening hours to match those previously offered by Boots Pharmacy they were also offering to provide all services as commissioned locally which had been offered previously by Boots Pharmacy.

Regulation 21(A)

6.41 The Committee noted that Regulation 21A of the Regulations has been in effect since 1 January 2022. Regulation 21A states:

> *(1) Paragraph (2) applies where NHS England receives a routine application which is in respect of premises not already listed, where—*
>
> *(a) the applicant's stated intention (in accordance with paragraph 7(1)(a) of Schedule 2) is to meet a need, or secure improvements or better access, identified in the relevant pharmaceutical needs assessment (whether current or future gaps in provision); and*
>
> *(b) the need is, or the improvements are or the better access is, in respect of the days on which or the times at which essential services are provided in the area of the relevant HWB.*
>
> *(2) In determining whether or not it is satisfied as mentioned in section 129(2A) of the 2006 Act (regulations as to pharmaceutical services), NHS England must have regard to whether granting the application would result in an undesirable increase in the availability of essential services in the area of the relevant HWB.*

(3) If NHS England is satisfied that granting the application would result in the undesirable increase in availability mentioned in paragraph (2), it must refuse the application.

6.42 The Committee considered that, in relation to Regulation 21A(1)(a), the Applicant's stated intention is to meet a need identified in the PNA. Regulation 21A(1)(b) states that the need is in respect of the days on which or the times at which essential services are provided in the area of the relevant HWB. The Committee considered that this means that Regulation 21A applies where the need refers to certain days on which and times at which essential services have been identified as needing to be provided.

6.43 The PNA had not specified the days on which or times at which pharmaceutical services were to be provided, just that there is a "*need for pharmaceutical services within the Cottingham North and South Wards".* The Committee is mindful that no party has sought to argue that granting the application creates an undesirable increase in essential services and the Committee noted that no party had specifically commented on the application of Regulation 21A. The Committee determined that granting the application would not result in an undesirable increase in the availability of essential services in the area of the relevant HWB.

6.44 Pursuant to paragraph 9(1)(a) of Schedule 3 to the Regulations, the Committee may:

6.44.1 confirm the Commissioner's decision;

6.44.2 quash the Commissioner's decision and redetermine the application;

6.44.3 quash the Commissioner's decision and, if it considers that there should be a further notification to the parties to make representations, remit the matter to the Commissioner.

6.45 In those circumstances, given that the Committee has reached a different outcome from the Commissioner for the reasons set out above, the Committee determined that the decision of the Commissioner must be quashed.

6.46 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 the Commissioner) or whether it was preferable for the Committee to redetermine the application.

6.47 The Committee noted that representations on Regulation 13 had already been made by parties to the Commissioner, and these had been circulated and seen by all parties as part of the processing of the application by the Commissioner. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 13.

6.48 The Committee concluded that further notification under paragraph 19 of Schedule 2 would not be helpful in this case.

7 Decision

7.1 The Pharmacy Appeals Committee ("Committee"), appointed by NHS Resolution, quashes the decision of the Commissioner, for the reasons given above, and redetermines the application.

7.2 The Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.

7.3 The Committee has determined that the application should be granted for the following reason:

7.3.1 The PNA has identified a current need which this application can meet.

7.4 Accordingly, the application is granted.

Case Manager
Primary Care Appeals