

28 April 2023

REF: SHA/25847

APPEAL AGAINST NHS ENGLAND (NORTH EAST AND YORKSHIRE AREA TEAM) DECISION TO REFUSE AN APPLICATION BY MANUEL MESTRE VALDÉS FOR INCLUSION IN THE PHARMACEUTICAL LIST OFFERING UNFORESEEN BENEFITS UNDER REGULATION 18 AT WILLAND PRIMARY CARE CENTRE, LOWFIELD ROAD, ANLABY, HU10 7JR

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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.

A copy of this decision is being sent to:

Mr Manuel Mestre Valdés,
NHS England,
Community Pharmacy Humber,
Boots UK Ltd

Advise / Resolve / Learn

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1 The Application

By application dated 30 June 2022, Manuel Mestre Valdés (“the Applicant”) applied to NHS England for inclusion in the pharmaceutical list offering unforeseen benefits under Regulation 18 at Willand Primary Care Centre, Lowfield Road, Anlaby, HU10 7JR. In support of the application it was stated:

- 1.1 In response to why the application should not be refused pursuant to Regulation 31, the Applicant had left this section blank.

Information in support of the application:

- 1.2 The Applicant would like to offer the Application [sic] Use Review and Stoma Appliance Customisation services to the population in the East Riding of Yorkshire and area of influence. It’s a service rarely provided from Community Pharmacy and the Applicant has noticed there is a need for patients with stoma for more help and advice face to face. The Applicant has discussed the issue with the Stoma Care nurses in Castle Hill hospital and they agreed that a link with a Community Pharmacy would help the patients. The Applicant has also spoken with local GP’s who saw this a great opportunity for a pharmacist involvement as often they see patients with worsening condition that could have been avoided with some proactive measures. It was also mentioned by the GP’s how there was a problem with over-prescribing.
- 1.3 The pharmacy will be located in the same building as the new relocated GP surgery. This surgery had 2 surgeries in different villages, which are now amalgamated in this new building. This will create an increase of pharmaceutical services in the area. Also there are plans to increase the number of dwellings in the area by 2028/29 as round [sic] 3550, with potentially more than 9000 people in the area.
- 1.4 To strength [sic] the relationship with the PCN and the local GP’s to develop new pharmacy services and promote the collaboration between Community Pharmacy and General Practice.
- 1.5 The Applicant has done the CPPE course “Lower GI: stoma management”, and the Clinimed Securicare “An introduction to Stoma Care” e-learning. The Applicant is in contact with the Stoma Care nurses at Castle Hill Hospital for further training, and also the Applicant has developed links with the local Ileostomy Association. The Applicant will help the patients with the ordering of only the required items and offer free delivery.
- 1.6 Being located within the surgery the pharmacy will have parking spaces and disabled access in place.
- 1.7 The Applicant is the current Community Pharmacy PCN Lead in the area (Harthill PCN) and also a Humber LPC member, which has allowed the Applicant to discuss the

collaboration of CP/GP's at different levels and the Applicant could take this forward in the new premises.

2 The Decision

NHS England considered and decided to refuse the application. The decision letter dated 4 January 2023 states:

2.1 NHS England have considered the above application and [I] am writing to confirm that it has been refused. Please see the enclosed report for the full reasoning.

NHS England decision report

2.2 NHS England has considered the above application and [I] am writing to inform you that it has been refused for the following reasons:

2.3 Regulation 18 and 19 – unforeseen benefits: additional matters and consequences – Regulation not met – no evidence of a gap in the market identified by the PNA, no evidence of innovation or improvement, no additional hours being provided that are not already being covered by existing contractors.

2.4 Regulation 31 – refusal: same or adjacent premises. Regulation not applicable.

2.5 Regulation 32 – deferral arising out of LPS designations. Regulation not applicable.

2.6 Regulation 40 to 44 – applications in a controlled locality. Regulation not applicable.

2.7 Regulation 50 – gradualisation for doctors. Regulation not applicable.

2.8 Regulation 65 – core opening hours conditions. Regulation not met.

2.9 Paragraph 31, schedule 2 – conditional grant of applications where the address of the premises is unknown – Regulation not applicable.

2.10 DHSC market entry guidance chapter 8 – Regulation not met.

2.11 Appeal rights are granted to the Applicant – Manuel Mestre Valdés.

3 The Appeal

Under cover of an email dated 27 January 2023 and using the “Online form for pharmacy application appeals” dated the same day, the Applicant appealed against NHS England's decision. The grounds of appeal are:

3.1 The decision report refused the application for the following reasons:

3.1.1 Regulation 18 and 19 – unforeseen benefits: additional matters and consequences – Regulation not met – no evidence of a gap in the market identified by the PNA, no evidence of innovation or improvement, no additional hours being provided that are not already being covered by existing contractors.

3.2 The key point in the Applicant's application is that, as recognised on the PNA, AUR and SAC are services that will provide “Improvements and Better Access to Discretionary Services”.

3.3 The PNA also specifies that “the numbers of pharmacies providing appliance review/customisation services is very low because Stoma Appliance Customisation

and Appliance Use Review services are generally provided via outsourced prescriptions to specialised appliance contractors outside of the East Riding area.”

- 3.4 This identifies a gap in the market in the PNA, and also is clearly an innovation as no one is providing this service at the moment.
- 3.5 The definition of an AUR in the NHSBSA website says that: “An appliance use review (AUR) is a planned face to face consultation between a pharmacist or appliance contractor and a patient to discuss the appliance or device that the patient is currently using.” [emphasis added by the Applicant]
- 3.6 Face to face consultations are not provided in the area. The NHS is asking pharmacists to help patients on the use of their appliances. It’s a discrimination against this group of patients as they can’t access this service anywhere.
- 3.7 The Applicant has been suggested that it should provide evidence based data, and the Applicant does not have the resources to conduct a nationwide survey of the need of this service, but the Applicant does have first-hand overwhelming evidence that patients on appliances are not receiving the help they need, and local GPs are asking for Community Pharmacy to help this patients are we supposed to do it [sic] and, furthermore, allowed to do it, although no one is choosing to provide this help.
- 3.8 It’s your decision to consider this an “unforeseen benefit” that should grant a new Market entry or not, but all the Applicant can do is ask you to talk to a number of appliances, specially [sic] elderly, and see what they have to say. Also GPs opinions about it are valuable.
- 3.9 Regulation 65 – core opening hours conditions. Regulation not met.
 - 3.9.1 The opening hours the Applicant entered on the application cover the Core Opening Hours requirement (40+), so the Applicant does not understand why this regulation has not been met. If the Applicant had to open more hours the Applicant could do it, as it’s the intention on the supplementary hours.
- 3.10 DHSC market entry guidance chapter 8 – Regulation not met.
 - 3.10.1 This chapter is about Market entry by means of PNAs, and refers to unforeseen benefits. The Applicant considers it has covered this previously.

4 **Summary of Representations**

This is a summary of representations received on the appeal.

4.1 NHS ENGLAND

- 4.1.1 In response to this appeal, both regulation 18(1) and regulation 31 have been considered.

Regulation 18

- 4.1.2 The 2018 – 2023 Pharmacy Needs Assessment (PNA) identified a gap in improvements and better access in none of their electoral wards (page 14, PNA 2018 – 2021 [sic]). This was the same in the 2022 – 2025 PNA. As a result of this NHS England have not sought to commission any additional services from existing providers of pharmaceutical services in the East Riding.

- 4.1.3 Potential new provision of commissioned services was identified in twenty-four wards, one of which was Tranby which is the ward in which the Willand Health Centre sits. The table below (page 23, PNA 2018 – 2021 [sic]) indicates

potential new commissioned services, one of which is stoma appliance customisation (where needed) and will only be explored subject to funding and need (page 17, PNA 2018 – 2021 [sic]).

Electoral Ward	Improvement and Better Access: Commissioned Services	Potential Future local Public Health Commissioned Services	Other Potential Future Commissioned Services
Tranby	None identified	<ul style="list-style-type: none"> • Chlamydia screening & treatment • Access to free pregnancy testing 	<ul style="list-style-type: none"> • Dementia screening services • Pharmaceutical care services to older people in residential homes • Stoma Appliance Customisation where needed • Social prescribing

- 4.1.4 In relation to need, although there is no dispensing appliance contractor (DAC) included on the NHS England pharmaceutical list with the ER Health & Well Being Board (HWBB) area, paragraph 2.57 (page 37, PNA 2018 – 21) has “considered and assessed the provision of pharmaceutical services to its population by dispensing appliance contractors that are not on the pharmaceutical list. Less than 1% of the total prescription volume is dispensed by dispensing appliance contractors not on the East Riding’s pharmaceutical list. The HWBB therefore considers that the dispensing of prescriptions by dispensing appliance contractors not on the pharmaceutical list has no significant impact on the provision of pharmaceutical services across the East Riding”.
- 4.1.5 This was supported by the representations made by the Local Pharmaceutical Committee (LPC) who in their comments considered the following:
- 4.1.6 The data shows very little, or no, activity with SAC/AIR services that is common nationally.
- 4.1.6.1 That patients do receive these services, just not from a community pharmacy. It’s the committee experience that patients are serviced by specialist stoma equipment suppliers with direct referral from their practice stoma nurses.
- 4.1.6.2 The LPC committee saw no evidence provided to show any unmet need in the locality for the service.
- 4.1.6.3 The plans submitted for the proposed site and queried their suitability for a service predicated on AUR/SAC services.
- 4.1.6.4 Nothing in the application described innovation or improvement from that existing approach for patients with protected or other characteristics.

4.1.7 On page 103 of the 2018 – 2021 PNA, the potential future commissioned services are highlighted again with clarification that there are no improvements and better access: gaps in provision related to commissioned services that could not be met by existing contractors.

Improvements and Better Access: gaps in provision related to Market Entry and Exit Regulations	None
Improvements and Better Access: gaps in provision related to Commissioned Services that could be met by existing contractors.	None identified
Potential new Commissioned Services	<ul style="list-style-type: none"> • Chlamydia screening and treatment • Access to Free Pregnancy Testing • Dementia Screening Services • Pharmaceutical Care Services to older people residing in care homes • Stoma Appliance Customisation where needed • Social Prescribing

4.1.8 The LPC took the same view as the PNA that there are no service gaps in this locale requiring a new pharmacy contract. Additionally, they felt that with the many existing pharmacy contracts close by, and by consulting local mapping in effect surrounding the new builds, that the likely nature of a full contract at this health centre location could be detrimental to the existing contractors delivering existing services.

Regulation 31:

4.1.9 This regulation is not applicable as there is currently no pharmacy at the Health Centre.

4.2 COMMUNITY PHARMACY HUMBER

4.2.1 The LPC wishes to make it clear that the Applicant is a committee member of this LPC and took no part in the deliberations and its response to this appeal. The matter was discussed in closed business following the Applicant's departure.

4.2.2 The Boots LPC member present declared an interest and the matter was discussed and voted on by the unconflicted members.

4.2.3 The appeal was considered against the criteria for an unforeseen application, the points in the appeal and the LPC's original submission. The [sic] considered both old & new can be summarised as:

4.2.4 While data shows very little, or no, activity with SAC/AUR services that is common nationally, the LPC was of the view that patients do receive these services, just not from a community pharmacy. It's the LPC's experience that patients are serviced by specialist stoma equipment suppliers with direct referral from their practice stoma nurses. Nothing in the application described

innovation or improvement from that existing approach for patients with protected or other characteristics.

- 4.2.5 The LPC did consult the PNA in place at the time of the application, and the one in place at the time of consideration. Both PNAs did make mention of the housing developments, making them seen and duly considered.
 - 4.2.6 The LPC saw no evidence provided to show any unmet need in the locality for the service in the application or appeal. The LPC also note that it is for the Applicant to provide information to prove their argument and not for others to research it on their behalf, especially if the Applicant believes they have 'overwhelming' (first hand) evidence that has not been provided.
 - 4.2.7 The LPC also considered the plans submitted for the proposed site and queried their suitability for a service predicated on AUR/SAC services.
 - 4.2.8 The LPC also felt that, along with the housing development being accounted for within the PNA, not all of the planned houses are due to be built at the pharmacy site and that planned houses do not always turn into built or occupied homes.
 - 4.2.9 The LPC took the same view as the PNA that there are no service gaps in this locale requiring a new pharmacy contract.
 - 4.2.10 Additionally the LPC felt that with the many existing pharmacy contracts close by, and by consulting local mapping in effect surrounding the new builds, that the likely nature of a full contract at this health centre location could be detrimental to the existing contractors delivering existing services.
 - 4.2.11 Due consideration was given to whether granting the contract would significantly improve access to these services for those with protected, or other, characteristics. With knowledge of how these supplies are normally supplied, by existing numerous contracts, along with the lack of evidence from the Applicant to show that there are any unmet needs, or difficulties with accessing supply of these products, or delivery of AURs/SAC currently, the LPC has therefore considered the appeal and those able to vote duly voted unanimously not to support this appeal.
 - 4.2.12 The LPC appreciates being kept informed of the progress of the appeal and would request to be invited to any oral hearing, should one be required.
- 4.3 **BOOTS UK LTD**
- 4.3.1 Boots include a copy of its response as Boots stand by the comments made with regards to the original application. Boots do not believe that there is a need for a further pharmacy in this locality and therefore respectfully ask NHS Resolution to dismiss this appeal and uphold the original decision made by NHS England to refuse the application.
 - 4.3.2 Boots fail to understand what unforeseen benefit this application is proposing to secure. The appeal seems to be based, as was the original application, on the Applicant proposing to offer to provide an appliance review/customisation service and this would support innovation. Whilst there may be no provider in the locality, there are providers nationally, therefore how can this be deemed as innovation? This service is not new and would offer nothing by means of innovation in its proposed delivery.
 - 4.3.3 The Pharmaceutical Needs Assessment (PNA) produced by East Riding of Yorkshire Wellbeing board 2025, clearly states in its executive summary page 14;

- 4.3.3.1 Nationally, the numbers of pharmacies providing appliance review/customisation services is very low because Stoma Appliance Customisation and Appliance Use Review services are generally provided via outsource prescriptions to specialised appliance contractors outside of the East Riding area which have the advantage of holding the full range of products.
- 4.3.4 As the PNA recognises that patients have access to providers, it is clear that this need has been recognised, considered and then concluded that no gap identified. Therefore, how can such a need be classed as “unforeseen”?
- 4.3.5 The Applicant has failed to provide evidence that the current pharmacy provision is not adequate and that there is a requirement for additional pharmaceutical needs in the area. The PNA, which has now been adopted, has clearly covered off both the current and future needs for this locality. It also specifically details that there are no gaps, now or in the future, in Hull and the surrounding areas.
- 4.3.6 There is already adequate choice of pharmacy provider in the area, offering a range of services and opening hours.
- 4.3.7 Boots have no further comments with regards to this appeal but respectfully ask that NHS Resolution inform us of the decision in due course and would wish to attend an oral hearing should it be deemed necessary to hold one.

Letter to NHS England dated 7 November 2022

- 4.3.8 Whilst Boots accept that the application is based on benefits not foreseen when drafting the Pharmaceutical Needs Assessment (PNA), it is unclear from the information provided what elements of this application were ‘unforeseen’ during the preparation of the East Riding of Yorkshire PNA. Both the current PNA and the previous 2018 PNA (which would have been in place at the time of application) do not believe that there are any gaps in provision both now or in the lifetime of the PNA.
- 4.3.9 The Applicant has numbered the sections within section 6 of their application so Boots will address each one in turn.
- 4.3.10 The basis of this application appears to be unclear and on initial reading, it looks like it was an application for a Dispensing Appliance contract. The Applicant is proposing to offer Appliance Use Reviews and Stoma Appliance Customisation Services. They state that these are rarely offered within community pharmacy and that there is more of a need for face to face advice and support.
- 4.3.11 The Pharmaceutical Needs Assessment (PNA) produced by East Riding of Yorkshire Wellbeing Board 2025, clearly states in its executive summary page 14;
- 4.3.11.1 Nationally, the number of pharmacies providing appliance review/customisation services is very low because Stoma Appliance Customisation and Appliance Use Review services are generally provided via outsourced prescriptions to specialised appliance contractors outside of the East Riding area which have the advantage of holding the full range of products.
- 4.3.12 It is note that the PNA goes on to say;

- 4.3.12.1 Existing pharmacies can apply to provide these discretionary NHS Advanced Services if they are competent and where there is a local need.
- 4.3.13 This suggests that such a service has been considered during the production of the PNA, but no need has been identified. The Applicant may feel that after discussions with local GPs and nurses that there is an opportunity to offer this service, but there is no gap identified. Patients are clearly being supported by specialist contractors nationwide. The statement above, highlights that should an EXISTING pharmacy wish to provide these advanced services where this is local need, they can apply to do so. This does not suggest a new contract should be granted based on this offering, but the existing provision can be utilised.
- 4.3.14 The NHS commission services relevant to the needs of the patient within their locality. Should any patient need any help or advice that needs to be provided face to face rather than via a phone or on-line, this is available to them by speaking to their usual pharmacist who would support the same way they do with any patient query. Patients can be signposted to the most appropriate place or person if relevant. Whilst any patient may find it convenient for a pharmacy to offer all services they may wish to access, it is unlikely that all pharmacies would be able to do so and to do this would also soon become financially unviable.
- 4.3.15 The statement about GPs mentioning a problem of over prescribing is not relevant to this application.
- 4.3.16 The new relocated GP surgery has been operating for some time, opening in May 2022. Boots are not aware of any complaints made to NHS [sic] or itself where patients have been unable to access pharmacy services or experiencing and difficulty in obtaining prescriptions and/or advice.
- 4.3.17 The Applicant refers to plans to increase the number of dwellings in the area by 2028/29, a total of 3350 between 2012 and 2029. These planned houses, many of which have been built and occupied already, are proposed across a large area, not just in the vicinity of the Applicants proposed location. This includes Hessle and Cottingham and 1200 of these homes will be in Anlaby, Willerby and Kirk Ella. The population will increase (and already has) but will not be concentrated in just the Anlaby area. The residents have access to existing pharmacies and GP surgeries offering services to them. There are currently pharmacies in Anlaby, Hessle, Willerby and towards Hull centre. NHS Choices state that there are 4 pharmacies within a mile of the proposed location and a further 9 within 2 miles. Some of these will be closer to patients' homes as you cannot assume all patients will be patients of or visiting the Willand Primary Care Centre. Many patients will be registered at surgeries across the locality situated in Anlaby, Hessle, Calvert Lane or Hull centre. There are a further 9 GP surgeries within 2 miles of the Willand Primary Care Centre.
- 4.3.18 The Applicant hasn't provided any evidence to suggest that the existing pharmacies in the area are not meeting current demands for pharmaceutical services or that these pharmacies will be unable to meet any future increase in demand arising from any planned new developments.
- 4.3.19 The Willand Primary Care Centre is a 10 minute, straightforward walk from the Boots pharmacy in Anlaby. The pavement is well maintained and well lit should any patient choose to walk this route. There is parking outside the Boots pharmacy and a Sainsbury car park a few metres away for those who choose this method of transport. Boots are located in the central hub on Anlaby where many people visit to carry out their day to day activities. A supermarket, bakery,

fruit shop as well as a gift shop and other well established shops can be found here.

- 4.3.20 Patients are likely to already have their preferred pharmacy. With EPS (Electronic Prescription Service) many patients will choose their prescriptions sent directly to their current chosen provider to collect at a time convenient to them. Not all patients visit a pharmacy as a result of a visit to the GP and with EPS well established there is no longer a demand for a collocated pharmacy.
- 4.3.21 The Applicant suggests by approving a new pharmacy contract at the surgery, it will strengthen relationships with the PCN and local GPs. The Applicant states that they are a PCN Lead and that they sit on the Humber LPC. Boots do not believe that this should be given any weight to this application. Many pharmacists and colleagues working within the area are also members of supporting organisations, including the local LPC's.
- 4.3.22 Boots can confirm that relationships are good between Boots and local GPs in the area and there is no suggestion that Boots do not already work collaboratively. Should NHS England wish to discuss any additional services or opening hours with us, Boots are happy to do so. Should there be any need for additional services, Boots are also more than happy to discuss this.
- 4.3.23 Boots notes that the Applicant is not offering any opening hours over and above those already offered, in fact, Boots in Anlaby opens until 5.30pm on a Saturday whereas the Applicant is proposing to close at lunchtime.
- 4.3.24 Boots believes that patients have already access to providers and choice in the area and do not believe that the Applicant is offering to secure any innovation by way of services or delivery.
- 4.3.25 For these reasons Boots respectfully urge NHS England to refuse this application.
- 4.3.26 Please be aware that Boots may wish to make further representations at a later stage and attend any oral hearing that may be held in relation to the application. Boots would therefore be most grateful if you could keep us informed of the progress of this application.

5 Observations

5.1 THE APPLICANT

- 5.1.1 The Applicant is writing this letter to appeal the decision that the service of appliance use reviews can be conducted remotely, rather than face to face in the pharmacy itself. As a professional in the industry, the Applicant strongly believes that providing this service in person is crucial for the wellbeing of its customers.
- 5.1.2 For starters, providing an appliance use review in person allows for better communication between the pharmacy staff and the customer. When the reviews takes place face to face, customers are able to ask questions and receive immediate answers that are tailored to their situation. This means that any concerns are addressed right away, and customers are properly educated on how to use their appliances safely and effectively. A remote review simply can't provide the same level of personalisation and attentiveness to the customers' needs as an in-person review.
- 5.1.3 Moreover, face-to-face appliance use reviews provide the opportunity for the pharmacists to support customers in a more holistic manner. By reviewing and demonstrating proper use of appliances in person, pharmacists can better

identify potential issues that may not have been communicated by the customer. The pharmacist can then advise and recommend other products or services that are not only useful for the customer but may also provide a significant rural income to the pharmacy.

5.1.4 Additionally, there is a level of trust that is developed between the pharmacist and the customer in a face-to-face meeting. It shows the customer that the pharmacist and pharmacy staff are sincere in their effort to help. This improves customer loyalty, which is important in the long run for the pharmacy's reputation and financial growth.

5.1.5 In conclusion, the Applicant strongly believes that face-to-face appliance use reviews are an essential service that pharmacies should continue to provide. It is not only beneficial for the customers, but it also promotes good customer relations and helps boost the financial performance of the pharmacy. The Applicant hopes NHS Resolution reconsiders the decision and prioritise the provision of this service in person.

6 Consideration

6.1 The Pharmacy Appeals Committee ("the 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.

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

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

6.4 Since 1 April 2023, Integrated Care Boards have taken on delegated responsibility for the commissioning of pharmaceutical services. NHS Resolution will issue this decision to NHS England and it is for NHS England to inform the relevant Integrated Care Board.

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

Regulation 31

6.6 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) 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).

- 6.7 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.
- 6.8 The Committee noted that NHS England, in its decision letter, determined that the application was not required to be refused with regard to Regulation 31 and that this had not been disputed by any party. The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 18

- 6.9 The Committee noted that this was an application for “unforeseen benefits” and fell to be considered under the provisions of Regulation 18 which states:

“(1) If—

- (a) the NHSCB receives a routine application and is required to determine whether it is satisfied that granting the application, or granting it in respect of some only of the services specified in it, would secure improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB; and*
- (b) the improvements or better access that would be secured were or was not included in the relevant pharmaceutical needs assessment in accordance with paragraph 4 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).

(2) Those matters are—

- (a) whether it is satisfied that granting the application would cause significant detriment to—*
 - (i) proper planning in respect of the provision of pharmaceutical services in the area of the relevant HWB, or*
 - (ii) the arrangements the NHSCB has in place for the provision of pharmaceutical services in that area;*
- (b) whether, notwithstanding that the improvements or better access were not included in the relevant pharmaceutical needs assessment, it is satisfied that, having regard in particular to the desirability of—*
 - (i) there being a reasonable choice with regard to obtaining pharmaceutical services in the area of the relevant HWB (taking into account also the NHSCB’s duties under sections 13I and 13P of the 2006 Act (duty as to patient choice and duty as respects variation in provision of health services)),*

- (ii) *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 (taking into account also the NHSCB's duties under section 13G of the 2006 Act (duty as to reducing inequalities)), or*
- (iii) *there being innovative approaches taken with regard to the delivery of pharmaceutical services (taking into account also the NHSCB's duties under section 13K of the 2006 Act (duty to promote innovation)),*

granting the application would confer significant benefits on persons in the area of the relevant HWB which were not foreseen when the relevant pharmaceutical needs assessment was published;

- (c) *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 secure the improvements or better access that the applicant is offering to secure;*
 - (d) *whether it is satisfied that another application offering to secure the improvements or better access has been submitted to it, and it would be desirable to consider, at the same time as the applicant's application, that other application;*
 - (e) *whether it is satisfied that an appeal relating to another application offering to secure the improvements or better access is pending, and it would be desirable to await the outcome of that appeal before considering the applicant's application;*
 - (f) *whether the application needs to be deferred or refused by virtue of any provision of Part 5 to 7.*
 - (g) *whether it is satisfied that the application presupposes that a gap in pharmaceutical services provision has been or is to be created—*
 - (i) *by the removal of chemist premises from a pharmaceutical list as a consequence of the grant of a consolidation application, and*
 - (ii) *since the last revision of the relevant HWB's pharmaceutical needs assessment other than by way of a supplementary statement.*
- (3) *The NHSCB need only consider whether it is satisfied in accordance with paragraphs (2)(c) to (e) if it has reached at least a preliminary view (although this may change) that it is satisfied in accordance with paragraph (2)(b)."*

6.10 The Committee considered that Regulation 18(1)(a) was satisfied in that it was required to determine whether it was satisfied that granting the application, or granting it in respect of some only of the services specified in it, would secure improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB.

6.11 The Committee went on to consider whether Regulation 18(1)(b) was satisfied, i.e. whether the improvements or better access that would be secured if the application was granted were or was included in the PNA in accordance with paragraph 4 of Schedule 1 of the Regulations.

- 6.12 Paragraph 4 of Schedule 1 requires the PNA to include: “a *statement of the pharmaceutical services that the HWB had 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....secure improvements or better access, to pharmaceutical services... (b) **would** if in specified future circumstances they were provided...secure future improvements or better access to pharmaceutical services...*” (emphasis added).
- 6.13 The Committee noted that the Applicant referenced the PNA in its appeal however did not confirm whether this was in relation to the current 2022 – 2025 PNA or the previous 2018 – 2021 PNA. The Committee further noted that NHS England had referred to the 2018 – 2021 PNA in its subsequent representations. The Committee noted that the HWB had, on 1 October 2022, issued a new version of the PNA for 2022 to 2025 (the “2022 PNA”).
- 6.14 The Committee considered that there were two related issues that it needed to determine in relation to the PNA. It needed to determine which PNA was the relevant PNA for the purposes of Regulation 22 and whether the relevant PNA had identified the improvements or better access that the application was looking to secure.
- 6.15 In considering these issues, the Committee had regard to any comments made by the parties.
- 6.16 The Committee considered 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 2022 PNA is the current PNA.
- 6.17 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 bears in mind 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. The Committee noted that the PNA was dated 2022 – 2025 and that no supplementary statements had been issued.
- 6.18 The 2022 PNA states on page 13:
- 6.18.1 *“As required by the Regulations, East Riding of Yorkshire Council Health and Wellbeing Board publicly consulted on this PNA for a period of 60 days. The consultation commenced on 11 July 2022 and closed on 9 September 2022.*
- Gaps in Necessary service provision in zero Electoral Wards;*
- Gaps in improvements and better access in zero Electoral Wards.”*
- 6.19 The Committee noted that the PNA, on page 14, as stated by the Applicant says:
- 6.19.1 *“Nationally, the numbers of pharmacies providing appliance review/customisation services is very low because Stoma Appliance Customisation and Appliance Use Review services are generally provided via outsourced prescriptions to specialised appliance contractors outside of the East Riding area which have the advantage of holding the full range of products... Existing pharmacies can apply to provide these discretionary NHS Advanced services if they are competent and where there is a local need.”*
- 6.20 And further, on page 32:

6.20.1 *"Dispensing appliance contractors are unable to supply medicines. Most specialise in supply stoma appliances. NHS England has **no** dispensing appliance contractors (DAC) included on the Pharmaceutical List for the ERYC HWBB area."* [Emphasis included in the PNA.]

6.21 The Committee had regard to Regulation 22 and considered whether in this case it should have regard to an earlier PNA. The Committee was of the view that no need had been identified for a pharmacy at this site in either the 2018 or 2022 PNA. The Committee considered that whichever PNA it had regard to it would not materially affect its decision.

6.22 The Committee noted that the Applicant seeks to provide unforeseen benefits to the patients of Anlaby. The Committee noted that the improvements or better access that the Applicant was claiming would be secured by its application were not included in the relevant PNA in accordance with paragraph 4 of Schedule 1.

6.23 In order to be satisfied in accordance with Regulation 18(1), regard is to be had to those matters set out at Regulation 18(2). The Committee's consideration of the issues is set out below.

Regulation 18(2)(a)(i)

6.24 The Committee had regard to

"(a) whether it is satisfied that granting the application would cause significant detriment to—

(i) proper planning in respect of the provision of pharmaceutical services in the area of the relevant HWB"

6.25 The Committee noted that NHS England, in its decision, had not referenced Regulation 18(2)(a)(i) and that no party had sought to argue or provide any information which would produce a finding that significant detriment would be caused if the application was granted.

6.26 The Committee was therefore not satisfied that significant detriment to the proper planning of pharmaceutical services would result from a grant of the application.

Regulation 18(2)(a)(ii)

6.27 The Committee had regard to

"(a) whether it is satisfied that granting the application would cause significant detriment to— ...

(ii) the arrangements the NHSCB has in place for the provision of pharmaceutical services in that area"

6.28 The Committee noted that NHS England, in its decision, had not referenced Regulation 18(2)(a)(ii). The Committee noted that the LPC, in its representations, had expressed concerns that an additional pharmacy contract could be detrimental to the existing providers in an area that already has a high presence of pharmacy contractors. The Committee was of the view that this may be a pressing concern however no information had been provided by the LPC to show that the provision of pharmaceutical services in the area would experience significant detriment in the event of this application being granted.

6.29 The Committee was therefore not satisfied that significant detriment to the arrangements currently in place for the provision of pharmaceutical services would result from a grant of the application.

- 6.30 In the absence of any significant detriment as described in Regulation 18(2)(a), the Committee was not obliged to refuse the application and went on to consider Regulation 18(2)(b).

Regulation 18(2)(b)

- 6.31 The Committee had regard to

"(b) whether, notwithstanding that the improvements or better access were not included in the relevant pharmaceutical needs assessment, it is satisfied that, having regard in particular to the desirability of—

(i) there being a reasonable choice with regard to obtaining pharmaceutical services in the area of the relevant HWB (taking into account also the NHSCB's duties under sections 13I and 13P of the 2006 Act (duty as to patient choice and duty as respects variation in provision of health services)),

(ii) 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 (taking into account also the NHSCB's duties under section 13G of the 2006 Act (duty as to reducing inequalities)), or

(iii) there being innovative approaches taken with regard to the delivery of pharmaceutical services (taking into account also the NHSCB's duties under section 13K of the 2006 Act (duty to promote innovation)),

granting the application would confer significant benefits on persons in the area of the relevant HWB which were not foreseen when the relevant pharmaceutical needs assessment was published"

Regulation 18(2)(b)(i) to (iii)

- 6.32 The Committee noted that the Applicant had referred to the proposed developments that would increase the number of houses in the area by 3550 by 2028/29 and inferred that the Applicant was suggesting that there would be an increased demand for pharmaceutical services including appliance reviews. With respect to planned housing developments, the Committee noted that the PNA states:

6.32.1 *"Over the 2012-2029 period, 3,550 new housing are proposed across the Major Haltemprice Settlements (which also includes Hessle and Cottingham). Of these, approximately 1,200 are proposed to be in Anlaby, Willerby and Kirk Ella."*

- 6.33 The Committee noted that both the LPC and Boots had provided information to show that the planned developments were not to be concentrated across the Anlaby area, but spread over a larger area including, but not limited to, the ward where the proposed pharmacy would be located. This had not been disputed by the Applicant. In any event, the Committee considered that the Applicant was speculative that increased developments would automatically equate to an increased demand for the services referenced in the application.

- 6.34 The Committee had regard to the location of the existing pharmacies and GP surgeries as provided on the map by NHS England, which had not been disputed by any party. The Committee noted the comments by Boots that the proposed location, co-located at the Willand Primary Care Centre, is a ten minute "*straight forward*" walk from its store in Anlaby. The Committee noted that this information had not been disputed by the Applicant. The Committee had no additional information, from the Applicant, regarding the terrain or other factors to support a finding that for those willing and able to walk,

they would find difficulty in this regard. The Committee is mindful that distance, or time spent walking, does not of itself indicate that there is difficulty in respect of there being a reasonable choice with regard to obtaining pharmaceutical services in the area of the relevant HWB. The Committee was mindful that there would be some residents who would be unwilling or unable to walk and so went on to consider ease of access to pharmaceutical services by private or public transport.

- 6.35 The Committee noted that in the application, the Applicant states that the pharmacy would benefit from the parking spaces and disabled access that currently exists at the Willand Primary Care Centre where it proposes to be located. The Committee further notes the comments by Boots regarding the parking outside its store in Anlaby and that there is a supermarket car park a 'few metres away' for those who choose this method of transport. This had not been disputed by the Applicant. The Committee has not been provided with any information from the Applicant to suggest that patients are having difficulty accessing car parking facilities at any of the existing pharmaceutical contractors. The Committee was therefore not persuaded that the Applicant had demonstrated that for those who did choose to access services by private transport were experiencing any difficulties in accessing the existing pharmaceutical provision.
- 6.36 The Committee noted that no information had been provided by the Applicant regarding public transportation. The Committee noted the finding in the PNA that, of the 98 patients who responded, only 3.06% (3 respondents) accessed pharmaceutical services by bus or public transport. In the absence of any information from the Applicant, the Committee was unable to take a view that patients are having difficulty accessing the existing pharmaceutical provision via public transport.
- 6.37 The Committee noted that the Applicant is of the view that having a pharmacy within the locality that offers face-to-face consultations and Appliance Use Reviews would provide a significant benefit for those that require the service. However, the Committee noted the comments by parties that these services can be accessed nationally from a centralised base who can deliver services to patients across the country. The existing DACs do not limit their services by local geography. The Committee noted that whilst there is no DAC in the relevant HWB no information had been provided by the Applicant to show that patients are experiencing difficulties accessing these services from DACs in other HWBs. The Committee was also not persuaded by the Applicant's arguments that there is an increased need for face to face consultations.
- 6.38 Therefore the Committee was not satisfied that, having regard to there being a reasonable choice with regard to obtaining services, granting the application would confer significant benefits by way of physical access on persons.
- 6.39 The Committee was of the view that there is already reasonable choice with regard to obtaining pharmaceutical services in the area of the relevant HWB, such that it was not satisfied that, having regard to the desirability of there being a reasonable choice with regard to obtaining services, granting the application would confer significant benefits on persons.
- 6.40 In considering Regulation 18(2)(b)(ii) the Committee reminded itself that it was required to address itself to people who share a protected characteristic under the Equality Act 2010 (age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, sexual orientation) having access to services that meet specific needs for pharmaceutical services that, in the relevant area, are difficult for them to access. In considering 18(2)(b)(ii), the Committee noted the Applicant stated "*The NHS is asking pharmacists to help patients on the use of their appliances. It's a discrimination against this group of patients as they can't access this service anywhere... the Applicant does not have the resources to conduct a nationwide survey of the need of this service, but the Applicant does have first-hand overwhelming evidence that patients on appliances are not receiving the help they need, and local*

GPs are asking for Community Pharmacy to help this patients are we supposed to do it [sic] and, furthermore, allowed to do it, although no one is choosing to provide this help”.

- 6.41 The Committee noted that no information had been provided to demonstrate the ‘first-hand overwhelming evidence’ that patients are experiencing difficulty in relation to accessing Stoma Appliance Customisation or Appliance Use Review services. It was noted that the Applicant had invited the Committee to investigate with patients and GPs if the current service provision in relation to appliances is inaccessible however the Committee considers it the responsibility of the Applicant to provide evidence to support its application.
- 6.42 The Committee noted that the PNA states, in relation to the Tranby ward where the proposed pharmacy would be located:
- 6.42.1 *“NHS England will seek to commission a Hepatitis C testing service, an Appliance Use Review service, a Stoma Customisation service, and/or a palliative care service from existing local pharmacies, if needed. These services are available in the Beverley area, but this may involve a drive time of more than 20 minutes.”*
- 6.43 The Committee noted that NHS England had the ability to commission a local pharmacy to provide the appliance services as referenced in the application and that, the failure of NHS England to do so would suggest that the demand for this service in the Anlaby area was not present. With regard to pharmaceutical services more generally, whilst the Committee had not been provided with any information with regard to car ownership levels in the area, the PNA notes that *“the level of deprivation in this Ward is generally low”*. On the basis of the lack of information provided, the Committee was unable to reach the conclusion that persons with specific needs for pharmaceutical services are having difficulty accessing those services.
- 6.44 The Committee was therefore not satisfied that, having regard to the desirability of people who share a protected characteristic having access to services that meet specific needs for pharmaceutical services that are difficult for them to access, granting the application would confer significant benefits on persons.
- 6.45 In considering Regulation 18(2)(b)(iii) the Committee had regard to the desirability of innovative approaches to the delivery of pharmaceutical services. In doing so, the Committee would consider whether there was something more over and above the usual delivery of pharmaceutical services that might be expected from all pharmacies, some ‘added value’ on offer at the location.
- 6.46 The Committee noted that the Applicant asserted that the application was innovative due to the services proposed, namely Stoma Appliance Customisation and Appliance Use Reviews, not being provided in the locality at the current time. The Committee further noted comments by parties that the application did not suggest any new or innovative approaches and that, as the services are currently offered by providers nationally it was, by its nature, unable to be deemed as innovation.
- 6.47 The Committee was not satisfied that, having regard to the desirability of there being innovative approaches taken with regard to the deliverability of pharmaceutical services, granting the application would confer significant benefits on persons.

Regulation 18(2)(b) generally

- 6.48 The Committee noted that the Applicant is proposing to open for 40 core hours Monday to Friday. The Committee further noted that the Applicant states that the supplementary hours as documented on the application shows the intention to provide hours above the current provision. The Committee is mindful that there are currently 9 pharmacies as shown on NHS England’s map and there is no information provided to demonstrate

that the Applicant is offering any core hours above and beyond what is already provided by existing contractors. The Committee was mindful that it has already determined that access to existing pharmaceutical services is reasonable. The Committee was also mindful that where there is a need to do so, NHS England may direct changes to the opening hours of existing pharmacies and that, if successful, the Applicant would be able to apply to amend its supplementary hours in line with the Regulations.

- 6.49 The Committee noted that the application is based, predominantly, on providing Stoma Appliance Customisation services in the Anlaby area. The Committee noted that this is not an essential pharmaceutical service and, if the application were to be granted, it would still have to be commissioned.
- 6.50 The Committee was therefore not satisfied that, having regard to the desirability of there being a reasonable choice with regard to obtaining services, granting the application would confer significant benefits (in relation to opening hours) on persons.
- 6.51 The Committee has considered whether there are any other factors that would confer significant benefits including on patients who share protected characteristics. The Committee had regard to the need to eliminate discrimination and advance equality of opportunity and foster good relations between these patients and those who do not share their protected characteristics.
- 6.52 The Committee was of the view that in accordance with Regulation 18(2)(b) the granting of this application would not confer significant benefits on persons in the area of the HWB which were not foreseen when the PNA was published.

Other considerations

- 6.53 Having determined that Regulation 18(2)(b) had not been satisfied, the Committee did not need to have regard to Regulation 18(2)(c) to (e).
- 6.54 No deferral or refusal under Regulation 18(2)(f) was required in this case.
- 6.55 The Committee had regard to Regulation 18(2)(g) and found no reason that required it to refuse the application under this regulation.
- 6.56 The Committee considered whether there were any further factors to be taken into account and concluded that there were not.
- 6.57 The Committee was not satisfied that the information provided demonstrates that there is difficulty in accessing current pharmaceutical services such that a pharmacy at the proposed site would provide better access to pharmaceutical services.
- 6.58 Pursuant to paragraph 9(1)(a) of Schedule 3 to the Regulations, the Committee may:
- 6.58.1 confirm NHS England's decision;
 - 6.58.2 quash NHS England's decision and redetermine the application;
 - 6.58.3 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.
- 6.59 Although the Committee has reached the same conclusion to that of NHS England, NHS England had not referenced 18(2)(a)(i) and 18(2)(a)(iii) in its determination nor had it provided reasons under Regulation 18(2)(b). The Committee therefore considered that NHS England's decision must be quashed.

- 6.60 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.
- 6.61 The Committee noted that representations on Regulation 18 had been sought from parties by NHS England and representations had already been made by parties to NHS England in response. These had been circulated and seen by all parties 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 18.
- 6.62 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 NHS England, 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 considered whether the granting of the application would cause significant detriment to proper planning in respect of the provision of pharmaceutical services in the area covered by the HWB, or the arrangements in place for the provision of pharmaceutical services in that area and is not satisfied that it would;
- 7.4 The Committee determined that the application should be refused on the following basis:
- 7.4.1 In considering whether the granting of the application would confer significant benefits, the Committee determined that –
- 7.4.1.1 there is already a reasonable choice with regard to obtaining pharmaceutical services;
- 7.4.1.2 there is no evidence of people sharing a protected characteristic having difficulty in accessing pharmaceutical services; and
- 7.4.1.3 there is no evidence that innovative approaches would be taken with regard to the delivery of pharmaceutical services.
- 7.4.2 Having taken these matters into account, the Committee is not satisfied that granting the application would confer significant benefits as outlined above that would secure improvements or better access to pharmaceutical services.

**Case Manager
Primary Care Appeals**