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6 December 2024

REF: SHA/26301

APPEAL AGAINST NHS GREATER MANCHESTER ICB DECISION TO REFUSE AN APPLICATION BY MY ONLINE MEDS LIMITED FOR INCLUSION IN THE PHARMACEUTICAL LIST OFFERING IDENTIFIED IMPROVEMENTS OR BETTER ACCESS UNDER REGULATION 17 AT SYNERGIE HOUSE, 322 MANCHESTER ROAD, BOLTON, BL3 2QS

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 refused.

A copy of this decision is being sent to:

My Online Meds Limited
PCSE (on behalf of Greater Manchester ICB)

NHS Resolution

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1 The Application

By application dated 1 March 2024, My Online Meds Limited ("the Applicant") applied to Greater Manchester ICB ("the Commissioner") for inclusion in the pharmaceutical list offering identified improvements or better access under Regulation 17 at Synergie House, 322 Manchester Road, Bolton, BL3 2QS. In support of the application it was stated:

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

In making the application, the Applicant was seeking to secure the improvements or better access identified on pages 31 – 57 of the PNA.

1.1 "Minor Ailments Service: The PNA identified a gap in the provision of a minor ailments service in Bolton. This service or and [sic] alternative is not currently available but has been recognised as a potential improvement for better access to pharmaceutical services.

1.2 One-to-One Services and Early Diagnosis: Respondents in the PNA consultation expressed a need for more personalised services and early diagnosis of disabilities.

1.3 1. Implementing a Minor Ailments Service. I plan to introduce a comprehensive Minor Ailments Service at my pharmacy. This will be facilitated by:

1.4 Multi-lingual staff: Employing multi-lingual staff to cater to the diverse linguistic needs of the Bolton population, ensuring that every individual, regardless of their language, can access and understand the services provided.

1.5 Language interpretation: Incorporating language interpretation services for both in-person and remote consultations. This will ensure that information and services are accessible for all, especially the diverse communities in Bolton.

1.6 2. Enhancing One-to-One Services Early and Diagnosis to address the identified need for personalised service and early diagnosis [sic]:

1.7 Exceptional Customer Care and Service: Leveraging my extensive experience in providing exceptional customer care to offer personalised, one-to-one consultations. This will aid in the early diagnosis and management of health conditions, aligning with the needs expressed in the PNA consultation.

1.8 Adequate Stock Levels: Maintaining adequate stock levels to ensure that prescriptions, especially for minor ailments and chronic conditions are provided immediately. This will enhance the efficiency of service delivery and patient satisfaction.

1.9 3. Delivery service to multiple locations to further enhance access to pharmaceutical services:

1.10 Delivery Services: introducing a robust delivery service that caters to multiple locations in Bolton. This will ensure that medications and other pharmaceutical services are accessibly to individuals who may have mobility challenges or other barriers to accessing in-store services.

1.11 In conclusion, the integration of multi-lingual staff, language interpretation services, exceptional customer care, and a well-structed delivery service; coupled with maintaining adequate stock levels, will collectively address the identified gaps and needs in the PNA, ensuring that the Bolton community has improved and better access to essential pharmaceutical services."

2 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 9 Auguust 2024 states:

2.1 "Greater Manchester 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.

2.2 You have the right of appeal to Secretary of State against Greater Manchester ICB's decision. Should you choose to appeal then either complete the online form available on the NHS Resolution website or send a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this letter to nhsr.appeals@nhs.net or:

2.3 Primary Care Appeals, NHS Resolution, 8th Floor 10 South Colonnade, Canary Wharf, London, E14 4PU."

DECISION REPORT

2.4 "Name of applicant: My Online Meds Limited

2.5 Fitness to practise: Cleared for inclusion in the Bolton HWB and notified to Applicant 03/06/2024.

2.6 Address/best estimate of proposed premises: Synergie House, 322 Manchester Road, Bolton, BL3 2QS.

2.7 Identified improvement or better access that the applicant is offering to secure, as stated in the HWB's PNA: [Please see Application section at 1.1 above.]

2.8 Status of location: Not a controlled locality.

Regulation 31 – must the application be refused?

2.9 The proposed premises located at Synergie House, 322 Manchester Road, Bolton, BL3 2QS, which is a standalone premises. The nearest pharmacy is Asda ASDA [sic] Pharmacy, Manchester Road, Bolton, Greater Manchester, BL3 2Qs.

2.10 There is no other pharmacy in the same nor adjacent premises. Therefore, there is no reason to refuse under Regulation 31.

2.11 The PSRC determined the application should not be refused under Regulation 31.

Regulation 32 – is the application to be deferred?

32.- (1) An application, other than an excepted application, which is –

(a) for inclusion in a pharmaceutical list by a person not already included;

(b) by a person already included in a pharmaceutical list for inclusion also in respect of premises other than those already listed in relation to that person; or

(c) to provide, from the person's listed chemist premises, services that are in addition to those already listed in relation to him [sic], other than additional directed services,

may be deferred where paragraph (2) applies to the relevant premises.

(2) This paragraph applies where the relevant premises are premises or part of premises, or are located within an area, designated under –

(a) regulation 99; or

(b) regulation 4 of the 2006 Regulations (designation of priority neighbourhoods or premises),

and that designation has neither been varied so that it no longer applies to the relevant premises nor been cancelled.

(3) For the purposes of this regulation, "the relevant premises" are—

(a)the listed chemist premises or proposed listed chemist premises in the application; or

(b) as regards an application for inclusion in a pharmaceutical list by a person not already included, if no particular premises are proposed for listing in the application, premises located at the best estimate that the NHSCB is able to make as to where the proposed listed chemist premises would be, having regard to the best estimate given by the applicant under paragraph 1(7)(a)(ii) of Schedule 2.

2.12 The PSRC did [sic] wish to defer the application.

2.13 Regulation 41 – is the relevant location in a reserved location? – Not applicable.

2.14 Regulation 44 – Prejudice test – Not applicable.

The Bolton PNA

2.15 The Link to the Bolton PNA Pharmaceutical Needs Assessment – Bolton JSNA

2.16 The Bolton PNA states the following:

2.17 "1.1 Current pharmaceutical provision – necessary services Bolton Health and Wellbeing Board determines necessary services are those provided by pharmacy, location, or time and day of the week that services are provided. Necessary services, for the purposes of this PNA, are defined as follows: Essential services provided by pharmacies during standard 40 core hours in line with their terms of service as set out in the 2013 regulations, and Advanced services provided within a standard pharmacy providing 40 core hours have been considered necessary by the HWB. There are 73 such pharmacies. The 2008 White Paper, Pharmacy in England: building on strengths – delivering the future, states that it is the strength of the current system that community pharmacies are easily accessible. The HWB believe that the population of Bolton, across all 9 neighbourhoods used in the PNA and the borough as a whole, currently support this position.

2.18 There is adequate provision of essential pharmacy services across Bolton through 73 community pharmacies. In addition, there are a number of pharmacies located in neighbouring that residents can reasonably access along with a significant number of internet pharmacies. These pharmacies increase choice for Bolton residents.

2.19 1.2 Gaps in pharmaceutical provision – necessary service. This PNA has not identified any gaps in the provision of necessary pharmaceutical services in the borough. It is anticipated that the current pharmaceutical service providers will be sufficient to meet local needs over the lifetime of this PNA.

2.20 1.3 Current pharmaceutical services – other relevant services. The PNA has considered the current provision of pharmaceutical services across the borough and outside of the health and wellbeing board area which secure improvements or 6 better access to other pharmaceutical services, specifically in relation to the demography and health needs of the population. It has identified that current provision of pharmaceutical services offered by both community pharmacies and other health care providers meet the needs of the population of Bolton Borough.

2.21 1.4 Improvements and better access. A minor ailments service is not currently available in Bolton, this or an alternative, has been identified as a service to secure improvements or better access.

2.22 1.5 NHS services affecting pharmaceutical need. This PNA provides an overview of services commissioned locally and provided by other NHS services to improve population health and which have an impact on pharmaceutical need. This PNA has identified that there may be opportunities to further develop and extend the delivery of some of the existing services within pharmacies to secure health improvements or better access to services. Local commissioners will continue to explore options for improvements in service delivery and accessibility as part of their on-going service monitoring and review.

2.23 1.6 Assessment of needs. For purpose of the PNA, factors affecting the demographics and needs of the population have been considered across the Borough and an overview of pharmaceutical services, along with more detailed information on the provision of pharmaceutical services at service delivery footprint level has been provided. The PNA also includes evidence and data on the particular needs and issues, experienced by groups with a protected characteristic as defined in the Equality Act 2010".

Regulations 17 and 19 – improvements or better access: additional matters and consequences. Are listed below:

17.—(1) If the NHSCB receives a routine application and is required to determine whether granting it, or granting it in respect of some only of the services specified in it, would secure improvements, or better access—

(a) to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB; and

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

in determining whether it is satisfied as mentioned in section 129(2A) of the 2006 Act(1) (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 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 mentioned in paragraph (1) that the applicant is offering to secure;

(b) whether it is satisfied that another application offering to secure the improvements or better access 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 secure the improvements or better access 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 profile of 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 that area;

(e) whether it is satisfied that—

(i) granting the application would only secure the improvements or better access 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 those improvements or that better access would be secured;

(f) whether it is satisfied that, since the publication of the relevant pharmaceutical needs assessment, the improvements or better access mentioned in paragraph (1) have or has been secured by another person who is providing, or is due to be secured 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;

(g) whether it is satisfied that—

(i) the improvements or better access mentioned in paragraph (1) were or was in respect of services other than essential services, and

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

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

(3) For the purposes of paragraph (2)(f), the improvements are or better access is to be treated as due to be secured by another person who has undertaken to provide services if—(a)the person (P) undertaking to secure the improvements or better access is entitled to give the NHSCB a notice of commencement, as a consequence of which P will be able to commence the provision of services to secure the improvements or better access, but P has not yet given that notice; n/a

(b) P has entered into an LPS scheme with the NHSCB, as a consequence of which P will be able to commence the provision of services to secure the improvements or better access, but P has not yet commenced the provision of those services. ; n/a

Regulation 19.—

(1) If the NHSCB is satisfied as mentioned in regulation 17(2)(a), it may—

(a) defer determination of the application;

(b) invite applications from other persons to offer to secure the improvements or better access mentioned in regulation 17(1) that the applicant is offering to secure; and

(c) consider, at the same time as the applicant's application, any application it receives—

(i) as a consequence of the invitation issued in accordance with sub-paragraph (b), or

(ii) that, even if it was not received in response to that invitation, is in any event from another person offering to secure the improvements or better access mentioned in regulation 17(1) that the applicant is offering to secure, but it must not, pursuant to this paragraph, defer consideration of the application for longer than 6 months.

(2) If the NHSCB is satisfied as mentioned in regulation 18(2)(c), it may—

(a) defer determination of the application;

(b) invite applications from other persons to offer to secure the improvements or better access that the applicant is offering to secure; and

(c) consider, at the same time as the applicant's application, any application it receives—

(i) as a consequence of the invitation issued in accordance with sub-paragraph (b), or

(ii) that, even if it was not received in response to that invitation, is in any event from another person offering to secure the improvements or better access that the applicant is offering to secure, but it must not, pursuant to this paragraph, defer consideration of the application for longer than 6 months.

(3) If the NHSCB is satisfied as mentioned in regulation 17(2)(b) or 18(2)(d), it may defer consideration of the application until it can be considered at the same time as the other application.

(4) If the NHSCB is satisfied as mentioned in regulation 17(2)(c) or 18(2)(e), it may defer consideration of the application until after the appeal has reached its final outcome.

(5) If the NHSCB is satisfied as mentioned in regulation 17(2)(d) to (g) or 18(2)(a), it must refuse the application.

(6) If the NHSCB is satisfied as mentioned in regulation 18(2)(b), it may grant the application notwithstanding that the improvements or better access were or was not included in the relevant pharmaceutical needs assessment.

2.24 Outcome: The PSRC did not defer the application nor did they wish to invite other applicants to apply.

2.25 Work through Regulation 17(2) addressing each matter, adding comments, referring to Regulation 19 where necessary and arriving at an outcome on each matter.

2.26 Have there been changes to the profile of pharmaceutical services in the HWB's area since the PNA was published?

2.26.1 Yes, the changes are as follows:

2.26.2 The Closure of Lloyds, Sainsbury's instore, Trinity St, Bolton BL3 6DH 0.8 miles away There remains Asda Pharmacy Manchester Road BL3 2QS and Boots Trinity Street BL3 6DH 100 hr pharmacies in the 2km radius.

2.26.3 Since the publication of the PNA, The Minor Ailments Service (MAS) has now been commissioned been commissioned and out of the 18 pharmacies in the 2km radius of the application; 7 of those pharmacies provide the MAS service in the Bolton HWB.

2.26.4 Pharmacy First Advanced service now supersedes CPCS.

2.27 Looking at the factors below the PSRC considered the following:

2.27.1 Are there any other pharmacies or DACs in the area and what services do they provide? No

2.27.2 Has the improvement or better access been secured by another person who is providing services in the area? No

2.27.3 Is the improvement or better access due to be met by another person who has undertaken to provide services in the area? Such persons are those whose application has been granted but they have not yet submitted their notice of commencement. They may also be contractors who have entered into an LPS scheme with the AT but have not commenced service provision. No

2.28 If the application is in a controlled locality or the premises are within 1.6km of a controlled locality then gradualisation for doctors may need to be considered. Numbers of dispensing patients who may be affected should be included, along with information on what percentage of a practice's dispensing patient list this equates to.] – Not applicable, the application is not within1.6km of a controlled locality.

2.29 The applicant has highlighted the Minor Ailment Service (MAS) as being identified with the Bolton PNA and proposes to provide MAS.

2.30 They also note they have employed multi lingual staff to provide translating service and delivery service in their application along with those listed below:

2.30.1 New Medicine Service

2.30.2 Community Pharmacist Consultation Services (CPCS)

2.30.3 Smoking Cessation

2.30.4 Care Home Service

2.30.5 Disease Specific Medicines Management Service

2.30.6 Gluten Free Food Supply Service

2.30.7 Independent Prescribing Service

2.30.8 Home Delivery Service

2.30.9 Medication Review Service

2.30.10 Medicines Assessment and compliance support service

2.30.11 Patient Group Direction Service

2.30.12 Prescriber Support Service

2.30.13 Schools Service

2.30.14 Screening Service

2.30.15 Stop Smoking Service

2.30.16 Supplementary Prescribing Service

2.30.17 Emergency Supply Service

2.31 The one to one and adequate stock levels and customer service would be classed as part of the essential services.

2.32 The core hours proposed by the application are as follows:

2.32.1 Monday to Friday 09:00-12:00, 13:00-17:00, Saturday 09:00-13:00= 40 hrs

2.33 Total Proposed opening hours Monday to Friday 09:00-12:00, 12:00-13:00,13:00-17:00, Saturday 09:00:00- 13:00 = 46 Hrs

2.34 The applicant provided a floor plan, which proposes an **online consultation room.** [Emphasis added by the Commissioner.]

2.35 The proposed premises lies within the Central and Great Lever PCN (Primary Care Neighbourhood) Situated in an area of depravity >10% LSO (source Bolton PNA)

2.36 There are 18 pharmacies in the 2km area, 7 of which provide the minor ailment service.

2.37 There are also 12 GP surgeries in the area.

2.38 Considering the impact of decision on those with protected characteristics under the Equalities Act 2010 and is this in accordance with NHS England/the ICB's Public Sector Equality Duty and Consider impact of decision on NHS England/the ICB's duty on health inequality.

2.39 The PSRC Noted access to disabled access to premises and drop curb to the left of the entrance from the Manchester Road Entrance.

2.40 Additionally, it was noted that from 01/01/2021 for all face-to-face community pharmacies (and 01/04/2021 for all distance selling premises), the system of clinical governance within the Terms of Service was expanded to include the promotion of healthy living. The Healthy Living Pharmacy (HLP) framework is aimed at achieving consistent provision of a broad range of health promotion interventions through community pharmacies to meet local need, improving the health and wellbeing of the local population and helping to reduce health inequalities. NHS Greater Manchester is committed to support its community pharmacies in achieving and maintaining compliance with this framework.

2.41 Interested parties notified

2.41.1 Asda Pharmacy, Manchester Road, Bolton, BL3 2QS

2.41.2 Cohens Chemist, 171 Crescent Road, Great Lever, Bolton, BL3 2JS

2.41.3 Rupert Street Pharmacy, Great Lever Health Centre, Rupert Street, Great Lever, Bolton, BL3 6RN

2.41.4 Cohens Chemist, 281 Rishton Lane, Great Lever, BL3 2EH

2.41.5 Boots Trinity Street Retail Park ,Unit 5,Trinity Street, Bolton, BL3 6DH

2.41.6 Nash Pharmacy, 63 Castle Street, Bolton, BL2 1AD

2.41.7 Newport Pharmacy, 65 Newport Street, Bolton, BL1 1NE

2.41.8 Jhoots Pharmacy, Lever Chambers, Ashburner Street, Bolton, BL1 1SQ

2.41.9 Boots, The Shipgates Centre, Mealhouse Lane, Bolton, BL1 1DF

2.41.10 A1 Pharmacy, 491 Radcliffe Road, Darcy Lever, Bolton, BL3 1SX

2.41.11 Gately Pharmacy, 24 Tongue Old Road, Bolton, BL2 6BH

2.41.12 Derby Street Pharmacy, 317-319 Derby Street, Bolton, BL3 6LH

2.41.13 Rigbys Chemist, 14 Swan Lane, Bolton, BL3 6TL

2.41.14 Boots Unit 8B Market Place, Bolton, BL1 2AL

2.41.15 Manor Pharmacy, 28-30 Egerton Street, Farnworth, Bolton, BL4 7LE

2.41.16 S & S Dispensing Chemist, 226 Dean Road, Bolton, BL3 5DP

2.41.17 Pikes Lane Pharmacy, Pikes Lane Resource Centre, Deane Road, Bolton BL3 5HP

2.42 The following interest parties Were also informed:

2.42.1 CPGM

2.42.2 Bolton Local Medical Committee

2.42.3 Bolton HWB

2.42.4 Healthwatch Bolton

2.43 Representations received from 45 day notification period were as follows:

2.44 Boots objected to the application and made the following statement

2.44.1 “Boots UK Limited have the following comments to make.

2.44.2 This application is based on an identified improvement or better access as stated within the current Pharmaceutical Needs Assessment, Bolton PNA dated 2022. Paragraph 1.4 in the PNA states

2.44.3 1.4 Improvements and better access A minor ailments service is not currently available in Bolton, this or an alternative, has been identified as a service to secure improvements or better access.

2.44.4 However, paragraph 1.2 states

2.44.5 1.2 Gaps in pharmaceutical provision – necessary service This PNA has not identified any gaps in the provision of necessary pharmaceutical services in the borough. It is anticipated that the current pharmaceutical service providers will be sufficient to meet local needs over the lifetime of this PNA.

2.44.6 We suggest that the Health and Wellbeing board could approach existing contractors to offer any services, including Minor Ailments should a gap be identified. We do not believe that the granting a new contract on the back of a single service is within the interest of the NHS. Boots UK LTD are happy to discuss the provision of any service if it is deemed necessary or there is a gap in services.

2.44.7 For these reasons we respectfully urge the ICB to refuse these applications.

2.44.8 Please be aware that we may wish to make further representations at a later stage and attend any oral hearings that may be held in relation to the applications. We would therefore be most grateful if you could keep us informed of the progress of the applications in due course."

2.45 Cohens believe there is adequate provision and note the no gap in PNA and provided the following statement:

2.45.1 "There are no innovate/new services being offered within the application.

2.45.2 We are not aware of any complaints in the area for a lack of service provision.

2.45.3 There is no evidence of access issues for local patients.

2.45.4 There are currently no gaps in the PNA.

2.45.5 The opening hours being offered by the new application are a basic 40 core hours and only 46 hours overall.

2.45.6 There are still 13 pharmacies within a 1 mile radius of this postcode with several of them being open in the evenings/weekends with plenty of parking provision.

2.45.7 If there is a gap in the minor ailment service locally, it would make sense for the ICB to approach local contractors to provide this service."

2.46 CPGM – Seek clarity as they feel they have applied as a distance selling pharmacy and made the following statement:

2.46.1 "Community Pharmacy Greater Manchester (CPGM) applications subgroup has reviewed this application and as an LPC we are confused by this application and must request clarity before we can officially comment. The applicant seems to describe a distance selling pharmacy but has not applied under the distance selling regulations. Please could we have clarity about this. When we receive the required clarity on the type of pharmacy contract the applicant has applied for, we will have further comments to make. Community Pharmacy Greater Manchester would like to receive any further correspondence regarding this application and wish to be kept informed of its progress."

Representations received from circulation of first representations

2.47 Response from Applicant

2.48 The applicant gave the following statement in response to the IP comments provided:

2.48.1 “1. Clarification on Pharmacy Type: We apologise for any confusion regarding the nature of our application. My Online Meds Limited is applying for a community pharmacy license, specifically aimed at integrating both traditional and distance-selling services. This hybrid model will ensure that we can meet the needs of all patients, including those who prefer online services for convenience and those who require face-to-face consultations.

2.48.2 2. Innovative and High-Quality Services:

2.48.2.1a. Utilisation of Generative AI for Personalised Medication Management: One of the cornerstones of our pharmacy will be the use of advanced generative AI to provide personalised medication management plans. This technology will allow us to: Analyse patient history and current medications: Ensuring no drug interactions and optimising medication efficacy. Generate personalised reminders: AI-driven reminders for patients to take their medications, reducing the risk of missed doses. Provide virtual consultations: AI-powered chatbots and virtual assistants can handle routine queries, freeing up pharmacists to focus on more complex cases.

2.48.2.2b. Enhanced Access and Convenience: Our pharmacy will offer extended hours of operation beyond the standard 40 core hours, including evening and weekend services, to accommodate the schedules of working individuals and families. Additionally, our distance-selling model ensures that patients can access our services from the comfort of their homes, which is especially beneficial for those with mobility issues or living in remote areas.

2.48.3 3. Addressing Service Gaps and Redundancy:

2.48.3.1 a. Comprehensive Minor Ailments Service: (this has been decommissioned) While Cohens Chemist and Boots UK suggest that existing contractors can handle service gaps, we propose a dedicated Minor Ailments Service that leverages telehealth technology. This service will include: Teleconsultations: Patients can consult with pharmacists via video calls, reducing the need for in-person visits. Home delivery of medications: Ensuring timely access to necessary treatments without the need for travel.

2.48.3.2 b. Health and Wellness Programs: We will introduce innovative health and wellness programs focusing on preventive care, including: Chronic Disease Management Programs: AI-driven platforms to monitor and manage chronic conditions such as diabetes and hypertension. Wellness Workshops and Seminars: Virtual and in-person sessions on topics like nutrition, mental health, and exercise.

2.48.4 4. High-Quality Services:

2.48.4.1a. Customer Feedback and Continuous Improvement: We will implement an AI-driven feedback system to continuously gather and analyse patient feedback. This will allow us to make real-time improvements to our services, ensuring that we consistently meet and exceed patient expectations.

2.48.5 5. Core Hours. One of the objections stated from an interested party was the core hours. These core hours were suggested by the ICB.

2.48.6 Conclusion: My Online Meds Limited is committed to delivering innovative, high-quality, and accessible pharmacy services that address the needs of our community in ways that existing providers have not. By integrating advanced

technologies such as generative AI, offering comprehensive services, and maintaining competitive pricing, we aim to set a new standard for pharmacy services in the region.

2.49 The PSRC deliberated all information provided by the applicant and the interested parties and highlighted the intention to integrate a Community Pharmacy with a Distance Selling Pharmacy and therefore took into consideration Regulation 64 – which is as follows.

64.—(1) If an application in respect of distance selling premises—

(a) to which regulation 25(1) applies is granted;

(b) to which regulation 25(1) of the 2012 Regulations (distance selling premises applications) applied was granted; or

(c) to which regulation 13(1)(d) of the 2005 Regulations (exemption from the necessary or expedient test) applied was granted, paragraph (2) applies.

(2) The inclusion in the pharmaceutical list of the person (X) listed in relation to—

(a) those distance selling premises; or

(b) if there has been a relocation of the retail pharmacy business or appliance contractor business at those distance selling premises to other premises, those other premises, is subject to the conditions set out in paragraph (3).

(3) Those conditions are—

(a) X must not offer to provide pharmaceutical services, other than directed services, to persons who are present at (which includes in the vicinity of) the listed chemist premises*;* [Emphasis added by the Commissioner.]

(b) the means by which X provides pharmaceutical services, other than directed services, must be such that any person receiving those services does so otherwise than at the listed chemist premises;

(c) the listed chemist premises must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list;

(d) in the case of pharmacy premises, the pharmacy procedures for the premises must be such as to secure—

(i) the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and

(ii) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and X or X's staff; and [emphasis added by the Commissioner.]

(e) nothing in X's practice leaflet, in X's publicity material in respect of the listed chemist premises, in material published on behalf of X publicising services provided at or from the listed chemist premises or in any communication (written or oral) from X or X's staff to any person seeking the provision of essential services from X must represent, either expressly or impliedly, that—

(i) the essential services provided at or from the premises are only available to persons in particular areas of England, or

(ii) X is likely to refuse, for reasons other than those provided for in X's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (for example, because the availability of essential services from X is limited to other categories of patients).

(4) The NHSCB may not vary or remove the conditions set out in paragraph (3)

Decision

2.50 Based on all available information, the PSRC concluded that they could not be assured that granting the application would secure improvements or better access nor could they be assured that the hybrid model would not be a contravention of Regulation 64 and does not meet the requirements of Regulation 17(2)(a) for the reasons stated in this decision report.

2.51 The PSRC was satisfied that despite the recent closure, patients still have the benefit of a choice of pharmaceutical service provider, good geographical spread of pharmacy premises, services and opening hours within a mile of the proposed location. The application offers no additional benefits in terms of services and opening hours to what is already provided by existing contractors, nor any innovation in terms of service provision. The application is therefore refused.

2.52 The applicant is awarded appeal rights."

3 The Appeal

In an appeal form dated 5 September 2024 addressed to NHS Resolution the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "We respectfully submit the following points in support of our appeal and request reconsideration of the application:

1. Service Quality and Innovation

3.2 While the refusal cited that our application did not offer additional benefits of innovations in terms of services, we would like to clarify our commitment to providing a higher standard of pharmaceutical services, tailored specifically to improve patient convenience and engagement. Our application includes:

3.2.1 Development of a patient centric app: This app will allow patients to easily order and track prescriptions, receive medication reminders, and access tailored health advice, all of which contribute to better patient outcomes and adherence.

3.2.2 Telehealth and Interactive features: Our app will facilitate interactive features such as daily health advice, fitness guidance, and teleconsultation for specific health concerns, thereby extending accessibility to those who might otherwise face barriers in receiving care.

3.3 These innovative services exceed the standard pharmacy offerings, bringing unique value to the local population and addressing a broader range of health needs.

2. Addressing the "Saturation" Concern

3.4 The decision highlighted the proximity of other pharmacies as a reason for refusal. However, we aim to differentiate ourselves by focusing on superior patient care and accessibility. Our proposed services, especially the integrated use of technology, will cater to a segment of patients who seek more efficient, personalised, and non-traditional ways to access their healthcare, including remote services and ongoing health management. We would also like to state that the premises are not on the same site or in the same building as other providers with a patient list.

3. Meeting Local Needs and Addressing Service Gaps

3.5 The decision refers to adequate pharmacy provision in the area. However, we would like to draw attention to the identified gaps in services, such as the Minor Ailments Service and certain health and wellness programs, which our pharmacy aims to address comprehensively. Furthermore, our commitment to offering a wider range of services, such as smoking cessation, independent prescribing, and disease-specific management programs, reflects our dedication to fulfilling unmet healthcare needs within the community.

4. Commitment to High Standards of Care

3.6 We also emphasise our commitment to the NHS's goal of promoting healthier lifestyles and reducing health inequalities. Our multi-lingual services and home delivery options align with the NHS's goals to support diverse communities and increase access for those with mobility or geographical limitations.

5. Alternative Consideration: Distant Selling Pharmacy

3.7 If the Committee still believes the number of local pharmacies is sufficient, we respectfully propose that the application be reconsidered on a Distant Selling Pharmacy basis. All essential services would be secured without face to face contact. This model would enable us to continue offering the same high-quality services remotely without contributing to local competition or saturation, as we would then be able to offer our services to any patients anywhere in England. We are confident that through our distant selling model, we can still contribute significantly to improving patient health outcomes while adhering to regulations for non-customer-facing operations.

3.8 In conclusion, we believe our application offers innovative, patient-centred solutions that would secure improvements in pharmaceutical services within the local area and anywhere in England if granted Distant Selling Pharmacy status. We respectfully request that you reconsider the refusal in light of the clarifications and commitments outlined in this appeal.

3.9 We look forward to your positive reconsideration and remain available for any further discussions or clarifications.

3.10 Thank you for your time and consideration. "

4 Summary of Representations

Community Pharmacy Greater Manchester provided a copy of its representations as provided to the Commissioner (at 2.46 above). As no new information was provided, and the Applicant had already had sight of this (and commented upon it), NHS Resolution proceeded to consider the application.

5 Consideration

5.1 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.

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

5.3 The Committee had before it a copy of the Bolton PNA dated 1 October 2022 and prepared by Bolton Health and Wellbeing Board, which had been provided by the Commissioner.

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

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

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

Regulation 31

5.7 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).

5.8 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. The Committee noted that the Commissioner had determined that "*the application should not be refused under 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 17

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

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

"(1) If -

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

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

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

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

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

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

5.12 The Committee noted in the application form, the Applicant has focused on pages 31 - 57 of the PNA, where the improvements or better access which the Applicant seeks to address, have been supposedly identified. The Committee further noted that the pages referenced did not include a heading encompassing identified improvements or better access and so considered the PNA on a page by page basis.

5.13 Page 31 of the PNA contains a section titled "How the health needs of the population can be met by pharmaceutical services" and this contains the following statement:

5.13.1 "*The key health needs which pharmacies can help meet in Bolton are those relating to:*

5.13.1.1*Effective self management of long term conditions.*

5.13.1.2*Reduction of health inequalities, though* [sic] *health promotion activity, and provision of an accessible entry point to qualified advice on managing routine illnesses and signposting to further services as required."*

5.14 The Committee was of the opinion that the 'health needs' as referred to on page 31 did not relate to identified improvements or better access as envisaged in paragraph 4(a) of Schedule 1 to the Regulations, and instead encompassed the role of community pharmacies within any area.

5.15 On page 33, under a sub heading titled 'Sex/gender' it states:

5.15.1 *"As part of the contractor survey… pharmacies were able to say if they were aware of any gaps in access or pharmaceutical need for any groups sharing a protected characteristic. One pharmacy identified they had no male staff, which would impact on their ability to provide consultations with staff of the same gender as patients if this was required."*

5.16 The Committee was of the opinion that whilst one of the contractor's identified a potential requirement within its pharmacy, this did not translate to the wider HWB area and a gap.

5.17 The Committee noted, in the page range provided in the application, multiple references to a survey undertaken by contractors in the HWB area as part of the consultation process for the PNA. The following areas did not identify any issues that are currently being experienced:

5.17.1 Age (page 32 of the PNA);

5.17.2 Gender reassignment / gender identity (page 34 of the PNA);

5.17.3 Race (pages 34 – 36 of the PNA);

5.17.4 Religion or belief (page 36 of the PNA);

5.17.5 Disability (pages 36 – 37 of the PNA);

5.17.6 Marriage / civil partnerships (page 37 of the PNA);

5.17.7 Sexual orientation (page 38 of the PNA); and

5.17.8 Pregnancy and maternity (pages 38 – 39 of the PNA);

5.18 On page 53 of the PNA, under a heading titled "Potential services – minor ailments service or alternative", it states:

5.18.1 "*A minor ailments service is not currently commissioned in Bolton and there are no current plans to commission it. A minor ailments service is commissioned in neighbouring boroughs… This need in Bolton is met through other currently commissioned primary care services, including a scheme by which GPs are given discretion to prescribe medicines available over the counter if they feel their patient would genuinely struggle to afford them otherwise.*

…

If it was determined to commission a new service, pharmacies and commissioners should first work together to explore options as to how to best meet the needs of this patient group, as the aims of such a service may be achieved through a traditional minor ailments service or alternatively though [sic] *other schemes such as provision of vouchers to food banks which could be redeemed at pharmacies for a selection of General Sale List medicines that would typically be kept at home for the treatment of minor ailments. A minor ailment service or alternative could be delivered within existing pharmacy provision, as sufficient pharmacies indicated in the contractor survey that they would be willing to provide it. A minor ailments service or alternative has been identified as a service to secure improvements or better access."*

5.19 The Committee noted that in the Summary section of the PNA, under the heading 'Improvements and better access' (page 6), it states:

5.19.1 "*A minor ailments service is not currently available in Bolton, this or an alternative, has been identified as a service to secure improvements or better access."*

5.20 Whilst the PNA states on page 6 under a heading titled 'Gaps in Pharmaceutical Provision – necessary service' that "*this PNA has not identified any gaps in the*

provision of necessary pharmaceutical services in the borough", the Committee was of the view that the PNA has identified a pharmaceutical service, that being the Minor Ailments Service, that is currently not provided in the Bolton HWB area and, further, that if it was provided would secure better access to pharmaceutical services.

5.21 The Committee considered that the wording at 5.19.1 above falls within the requirements set out in paragraph 4(a) of Schedule 1 to the Regulations and therefore constitutes improvements or better access as envisaged in Regulation 17(1).

5.22 Having concluded that better access has been identified, as considered above, the Committee went on to consider the matters set out in Regulation 17(2) which are:

> *(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 secure the improvements or better access mentioned in paragraph (1) that the applicant is offering to secure;*
>
> *(b) whether it is satisfied that another application offering to secure the improvements or better access 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 secure the improvements or better access 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 profile of 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 that area;*
>
> *(e) whether it is satisfied that,*
>
> > *(i) granting the application would only secure the improvements or better access 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 those improvements or that better access would be secured;*
>
> *(f) whether it is satisfied that, since the publication of the relevant pharmaceutical needs assessment, the improvements or better access mentioned in paragraph (1) have or has been secured by another person who is providing, or is due to be secured by another person who has undertaken to provide, either in the area of the relevant HWB or in the area of another HWB;*
>
> *(g) whether it is satisfied that-*
>
> > *(i) the improvements or better access mentioned in paragraph (1) were or was in respect of services other than essential services, and*
> >
> > *(ii) granting the application would result in an undesirable increase in the availability of essential services in the area of the relevant HWB;*
>
> *(h) whether the application needs to be deferred or refused by virtue of any provision of Part 5 to 7."*

Regulation 17(2)(a) and (b)

5.23 The Committee determined that it was not aware of any other applications or appeals relating to applications offering to secure the improvements or better access that the Applicant was offering to secure and that there was no need to consider applications from other persons offering to secure improvements or better access.

Regulation 17(2)(c)

5.24 The Committee was not aware of any pending appeal and was therefore satisfied that no such appeal needs to be taken into consideration under the provisions of Regulation 17(2)(c).

Regulation 17(2)(d)

5.25 The Committee noted that the Commissioner had considered Regulation 17(2)(d) in its decision and that, since the publication of the PNA, there had been a change in the pharmacy profile of the area due to the closure of a Lloyds Pharmacy located 0.8 miles away from the proposed pharmacy.

5.26 The Committee considered that while this may constitute a change in the profile of pharmaceutical services in the area of the HWB, due to the distance from the proposed location (and the quoted 18 pharmacies in a 2km radius of the proposed pharmacy) it was not satisfied for the purposes of Regulation 17(2)(d) that refusing the application was essential in order to prevent significant detriment to the provision of pharmaceutical services in the area of the HWB.

Regulation 17(2)(e)

5.27 The Committee considered whether granting the application would secure the improvements or better access relating to the Bolton HWB area in full or in part.

5.28 The Committee noted that the PNA identifies that a Minor Ailments Service, or suitable alternative, would provide improvements or better access for those in the Bolton HWB area.

5.29 The Committee noted that the proposed premises were in the Bolton area, and therefore in the relevant area as envisaged by the PNA.

5.30 The Committee noted the Applicant, in its application form, states that it "*plans to introduce a comprehensive Minor Ailments Service at my pharmacy*" and summarises aspects of the running of the pharmacy which will facilitate the running of this service.

5.31 The Committee therefore considered that in relation to Regulation 17(2)(e), it was satisfied that granting the application would secure the improvements or better access mentioned in paragraph (1) in full.

Regulation 17(2)(f)

5.32 The Committee noted that the Commissioner had considered Regulation 17(2)(f) in its decision letter and confirmed that, since the publication of the PNA, the Minor Ailments Service had been commissioned in the area of the HWB.

5.33 The Committee noted the undisputed statement in the Commissioner's decision that there were a further 18 pharmacies within 2km of the Applicant's proposed pharmacy and that 7 of those pharmacies provide the Minor Ailments Service. The Committee observed the map provided by the Commissioner and noted that the closest provider that offers the Minor Ailment Service, (Rupert Street Pharmacy, Great Lever Health Centre, BL3 6RN) is located near to the Applicant's proposed pharmacy. The Commissioner's decision letter also states that there are a further six pharmacies within 2km radius of the proposed pharmacy that currently offer the Minor Ailments Service.

5.34 The Committee was therefore satisfied that since the publication of the PNA, the improvements or better access mentioned in paragraph (1) **has** been secured by multiple other contractors that have undertaken to provide the service in the Bolton HWB area.

Regulation 17(2)(g)

5.35 The Committee noted, with reference to 17(2)(g), that the Commissioner had stated in its decision letter that there were currently 18 pharmacies within 2km of the proposed pharmacy. The Committee was mindful that whilst this appears to be a large amount of pharmacies for one area, and while the Applicant had referred to the "saturation" of providers in its appeal, there had not been any information provided as to why, if the application was granted, there would be an *undesirable* increase in the availability of essential services.

5.36 The Committee noted that Regulation 17(2)(g) required both limbs to be satisfied in order for the application to be refused. As the Committee had determined that Regulation 17(2)(g)(i) was not relevant, the Committee did not, therefore, go on to consider Regulation 17(2)(g)(ii).

5.37 On the information provided with reference to 17(2)(g), the Committee was satisfied that if this application was granted then there would not be an *undesirable* increase in the availability of essential services.

Regulation 17(2)(h)

5.38 The Committee had not been provided with any information to indicate that the application should be deferred or refused by virtue of any provision of parts 5 to 7 of the Regulations.

Further matters

5.39 The Committee considered whether there were any further factors to be taken into account.

5.40 The Committee noted the comments by the Applicant that it "*respectfully propose[s] that the application be reconsidered on a Distant* [sic] *Selling Pharmacy basis*" if the criteria for an approval under Regulation 17 was not to be met. The Committee are of the view that the Regulations do not have scope for this request and, if the Appellant wished to proceed on this course, a new application would need to be submitted to the Commissioner under Regulation 25.

5.41 The Committee noted the comments by the Applicant that it was "*applying for a community pharmacy license, specifically aimed at integrating both traditional and distance-selling services*". The Committee was of the view that this is not possible under the scope of the NHS (Pharmaceutical and Local Pharmaceutical) Regulations 2013, as amended, as there is not a relevant Regulation in which to apply to open a hybrid pharmacy.

5.42 The Committee noted that the application was refused by the Commissioner under the merits of Regulation 64. As Regulation 64 provides conditions if an application under Regulation 25 (a distance selling pharmacy) is granted, the Committee did not take a view on this.

Summary

5.43 The Committee noted reference in the PNA to services which would fall within the description set out in paragraph 4(a) of Schedule 1 to the Regulations.

5.44 However the Committee concluded for the reasons above, that the identified improvements or better access as referred to in the PNA has been secured by another person in line with Regulation 17(2)(f).

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

5.45.1 confirm the Commissioner's decision;

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

5.45.3 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.

5.46 Given that the Committee had reached the decision that the application must be refused, albeit it for different reasons to the Commissioner, the Committee determined that the decision of the Commissioner must be quashed.

5.47 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.

5.48 The Committee noted that representations on Regulation 17 had already been made by parties to the Commissioner, and these had been circulated and seen by all parties who made representations on the application, as part of the processing of the application by the Commissioner. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 17.

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

6 Decision

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

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

6.3 The Committee has determined that the application should be refused for the following reasons:

6.3.1 The identified improvements or better access as referred to in the PNA has been secured by another person in line with Regulation 17(2)(f).

Case Manager
Primary Care Appeals