NHS Resolution

19 December 2025

REF: SHA/26719

8th Floor
10 South Colonnade
Canary Wharf
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APPEAL AGAINST GREATER MANCHESTER ICB DECISION TO REFUSE AN APPLICATION BY REFINE PHARMA LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT UNIT 20, MEADOWCROFT WAY, LEIGH COMMERCE PARK, LEIGH, WN7 3XZ UNDER REGULATION 25

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:

Refine Pharma Ltd
PCSE, on behalf of Greater Manchester ICB
PCT Healthcare Ltd

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1 The Application

By application dated 30 April 2025, Refine Pharma Ltd ("the Applicant") applied to Greater Manchester ICB ("the Commissioner") for inclusion in the pharmaceutical list at Unit 20, Meadowcroft Way, Leigh Commerce Park, Leigh, WN7 3XZ under Regulation 25. In support of the application it was stated:

1.1 In response to "If you are undertaking to provide appliances, specify the appliances that you undertake to provide (or write 'none' if it is intended that the pharmacy will not provide appliances)" the Applicant left the box blank.

1.2 In response to why the application should not be refused pursuant to Regulation 31 the Applicant left the box blank.

1.3 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant left the box blank.

Pharmacy procedures

1.4 Please explain how the pharmacy procedures used within the premises will secure:

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

(b) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or someone else's behalf, and the applicant or the applicant's staff.

Please describe the procedure that will be followed where a patient attends the premises and asks for one or more of the essential services.

If you are undertaking to provide advanced services at the premises please describe how you will do so without providing any element of essential services.

You must ensure that you provide sufficient information within this application form to satisfy NHS England or the relevant delegated integrated care board on the above points. You are not required to submit your standard operating procedures for the premises but if you do they will be circulated to interested

parties unless NHS England or the relevant delegated integrated care board is satisfied that the full disclosure principle does not apply.

1.5 "To ensure uninterrupted provision of essential pharmacy services is available, the following key areas will be focussed upon; staffing management, workflow efficiency, utilisation of technology, contingency planning and most importantly patient safety and communication.

1.6 Staffing volume will be dependent upon a range of factors, such as current staffing levels at the company's other pharmacies, drug tariff recommendations and volume of dispensing received. Staff will receive appropriately tailored training depending upon their level, as a range of staff levels will be supported to work within the pharmacy.

1.7 Workflow efficiency will be optimised through using the current IT systems that support the business along with NHS specific IT systems to ensure that patient safety is prioritised. In addition, workflow SOPs will be utilised by all staff to ensure uniformity across the pharmacy services provided.

1.8 The current business continuity plan will be used and modified to ensure that service continuity can be maintained, there will be particular consideration to specific areas of the continuity plan, these include service provision, delivery and patient safety.

1.9 Patient communication will be managed across a number of suitable technology platforms. Patients will receive responses from appropriately trained members of the team via a communication service suited to the individual. An open channel of communication between the pharmacy and patient will be maintained throughout the patient's pharmacy journey."

Additional information in letter to Commissioner dated 8 July 20025

1.10 "In response to the letter dated 04/07/2025, I can confirm that the pharmacy will not have any face to face contact at the pharmacy premises with any person using the pharmacy's services.

1.11 For all services carried out from the pharmacy, patients and customers using the pharmacy will not be permitted on to the pharmacy premises – this is managed through access control on all internal and external doors to the pharmacy, there will also be no pharmacy sign on the building. Patients and customers will be able to contact the pharmacy through various communication channels such as telephone, text message, email, and a 'contact us' form all of which will be accessible through the pharmacy website, the website will also direct individuals to these forms of contact to ensure that individuals do not attend the pharmacy in person. In addition the pharmacy telephone number will be available on the medication label and a leaflet will be circulated to customers with the pharmacy contact details.

1.12 Within the distance selling application it indicates that the pharmacy will provide a New Medicines Service as part of the advanced services that pharmacies can offer. To ensure that this service is offered at a distance and not face to face, suitable patients will be contacted by telephone to discuss their new medicines. To obtain any required consent patients within the local vicinity to

the pharmacy will be asked by the local delivery driver to provide written consent, additionally local patients and those who live further afield will be able to provide their consent for any advanced services the pharmacy offers when they sign up to the pharmacy. This will be an option available on the pharmacy nomination form, which can be revoked by the patient at any time.

1.13 For all three stages of the New Medicines Service patients will be able to communicate with the pharmacist over the telephone or will be able to request a remote video consultation if required – this type of communication will best service [sic] patients who are prescribed new medicines which require counselling about administration techniques. All patients will be offered either of the two communication methods above and they will be able to select the method that they feel serves them best. The aim of providing the New Medicines Service is to provide information to patients and to create a rapport with them to ensure the successful initiation of their new medicines supplied by the pharmacy."

2 Applicant's '14 day comments' to the Commissioner

2.1 "In response to the comments made in the representations I would like to highlight the following;

2.1.1 **Clarification of the statement "staffing volume will be dependent upon a range of factors such as current staffing levels at the company's other pharmacies, drug tariff recommendations and volume of dispensing received". As requested by Community Pharmacy Greater Manchester and mentioned by PCT Healthcare.** The phrase 'current staffing levels' means the number of staff that are employed at present by the business. This part of the pharmacy business dispenses private prescriptions. The volume of prescriptions dispensed through the private pharmacy business has been used as a guide to determine the number of pharmacy staff required to dispense a similar number NHS [sic] prescriptions. Current staffing has been reviewed and a dedicated workforce of 1 full time pharmacist, 2 full time qualified dispensers and a delivery driver has been ring fenced for all essential NHS services to be carried out. I can confirm that in anticipation of the registration of the new premises the company has recruited two additional full time apprentices enrolled on the level 2 dispensing qualification, there will also be an additional pharmacist on site for busy periods.

2.1.2 In answer to Point 1 raised by PCT Healthcare "the staffing level in an individual pharmacy is not based on staffing levels within other pharmacies owned by the same legal entity", a similar business model can be used to determine staffing levels to ensure there is not understaffing or overstaffing of the pharmacy. In addition it is not for another pharmacy to decide how many staff a pharmacy decide to employ, as stated in the answer above there will be enough staff for the pharmacy to operate and provide all essential pharmacy services.

2.1.3 In response to PCT Healthcare stating that the application does not fully explain how uninterrupted provision of essential services will take place,

six points have been raised in the application. In order to fully explain this point the pharmacy business continuity plan would have to be submitted with the application and this is not requested on the portal. The business continuity plan addresses continuation of service provision, delivery issues and how to protect patient safety when essential service provision is compromised.

2.1.4 To satisfy Boots concern that “services will not be offered face to face”, it can be confirmed that the pharmacy premises is not accessible to any patients, this could’ve been determined by using an online map to look at the premises. The pharmacy is situated on an industrial estate within a warehouse style building without any signage, there are various access controls to enter the building (which can be seen on Google maps) and further facial recognition controls to gain access to the pharmacy. To offer further assurances the application for registration with the GPhC under section 4A 4.1 of the registration document states that the pharmacy is a mail order or online pharmacy. In summary the business has no intention of carrying out any face to face services and can guarantee that there is no patient access to the building.

2.1.5 As mentioned in the application “an open channel of communication will be maintained throughout the patient’s pharmacy journey”. This should answer the point raised by Boots “how patients will be signposted for support if needed”. Patients will be able to access signposting information from trained staff through the communication channels that the pharmacy offers which include telephone, email, contact form and text message. A variety of communication channels have been offered to ensure they are accessible to all individual patients. Any additional signposting for patients will be available on the pharmacy website.

2.2 To reassure the interested parties, the pharmacy will not be approaching their current patient base to entice them from their current pharmacy provision. The inclusion on the pharmaceutical list is to be able to provide essential pharmacy services to patients both within the locality and nationally and to provide an alternative pharmacy for patients who may be facing difficulties accessing community pharmacy due to the reducing number of community pharmacies nationally and the many drug shortages that are currently facing the sector.

2.3 Further to the answers above which have addressed the responses from the interested parties, additional information can be provided for further assurance.

2.3.1 Delivery of medication nationally will be by DPD with whom the pharmacy has a pharmaceutical account where further safeguards are in place including parcel tracking. Any medicines that require additional packaging e.g. cold chain lines will be delivered in cold chain verified packaging – this verification is carried out by the pharmacy at different points throughout the year. For controlled drugs, patients will be required to give the courier a PIN number to ensure safe delivery.

2.3.2 Local deliveries of medication will be carried out by a trained pharmacy delivery driver employed by the pharmacy.

2.3.3 Waste will be disposed of under the same contract that the pharmacy currently has, all staff will be trained to safely dispose of medicines correctly. Patients will be able to return medicines safely free of charge with the local delivery driver and the courier – appropriate packaging for the return of medicines will be sent to all patients wishing to return medicines to the pharmacy.

2.3.4 As currently carried out drug recalls and alerts will be actioned through the Pharmsmart portal, these will be actioned immediately and recorded for reflection at the end of the month during the patient safety report.

2.3.5 Patients will be able to access the provision of essential services nationally. The pharmacy will accept prescriptions via EPS, post, and collection from GP surgeries within the local area (with consent). In circumstances that are deemed necessary the pharmacy will be able to accept faxed or emailed prescriptions with the receipt of the original prescription in the following days.

2.4 The pharmacy is committed to the safe provision of essential services to patients. With the information included in this response the ICB should be satisfied that the pharmacy can be included on the pharmaceutical list."

3 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 22 August 2025 states:

3.1 "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.

3.2 You have a right of appeal to the Secretary of State against Greater Manchester ICB's decision. Should you choose to appeal then you should 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:

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

Decision report

3.4 "**Regulation 31 considerations**

3.5 The PSRC noted the proposed location of the distance selling premises (DSP) is Unit 20, Meadowcroft Way, Leigh Commerce Park, Leigh, WN7 3XZ.

3.6 The next nearest pharmacy to the proposed location is 1 mile away (source: the NHS Site) – Manor Pharmacy, 90-92 Manchester Road, Leigh, Wigan, Lancashire, WN7 2LD (23-minute walk).

3.7 Proposed location is shown below (source: Google Maps) [screenshot provided]

3.8 Based on all available information, the PSRC was satisfied that the application should not be refused under Regulation 31, as there is no other provider of pharmaceutical services either in the same premises or adjacent premises to the proposed location.

3.9 **Regulation 25 considerations**

3.10 **Are the premises listed in the application on the same site or in the same building as a provider of primary medical services with a patient list? (Regulation 25(2)(a))**

3.11 Based on all available information, the PSRC was satisfied that the proposed location is not on the same site or in the same building as a provider of primary medical services with a patient list.

3.12 **Will the applicant provide uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services? (Regulation 25(2)(b)(i)); and**

3.13 **Will the applicant ensure 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 the applicant or the applicant's staff? (Regulation 25(2)(b)(ii))**

3.14 The applicant has declared it will provide:

3.14.1 core/overall opening hours of 09:00 –17:00 Monday to Friday;

3.14.2 NMS

3.15 The PSRC noted that the applicant had provided information in the application with regards to Regulation 25:

3.16 [See 1.5 – 1.9 above]

3.17 And the information provided in the letter dated 8th July 2025 in response to missing information request from PCSE:

3.18 [See 1.10 – 1.13]

3.19 The PSRC noted that the information provided by the applicant neither specified sufficiently nor contained adequate assurances relating to the safe and effective provision of essential services without face-to-face contact.

3.20 There was no site-specific methodology in terms of satisfying the required regulations.

3.21 Therefore, the PSRC was not adequately assured that its procedures would enable the DSP to meet the requirements of Regulation 25(2), in addition to the ongoing requirements set out under Regulation 64 – which are:

3.21.1 that the applicant does 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;

3.21.2 that the means by which the applicant 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;

3.21.3 that the DSP 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;

3.21.4 that the applicant secures the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services,

3.21.5 that the applicant ensures 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 the applicant or applicant's staff; and

3.21.6 that nothing in the applicant's practice leaflet, publicity material in respect of the listed DSP, in material published on behalf of the applicant publicising services provided at or from the listed DSP or in any communication (written or oral) from the applicant or applicant's staff to any person seeking the provision of essential services from the applicant must represent, either expressly or impliedly, that the essential services provided at or from the premises are only available to persons in particular areas of England, or that the applicant is likely to refuse, for reasons other than those provided for in its 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 applicant is limited to other categories of patients).

3.22 The applicant is reminded that the commissioner (NHS GM) may not vary or remove any of the above conditions.

3.23 **The following interested party within a 2km radius of the proposed premises location was notified of the application:**

3.23.1 Manor Pharmacy, 90-92 Manchester Road, Leigh, Wigan, Lancashire, WN7 2LD

3.24 **The following organisations were also informed of the application**

3.24.1 Community Pharmacy Greater Manchester (CPGM)

3.24.2 Wigan Local Medical Committee

3.24.3 Wigan HWB

3.24.4 Healthwatch Wigan

3.25 **Representations received from interested parties**

3.26 **PCT Healthcare comment**

3.27 "Thank you for your letter dated 2 May 2025 regarding the above application. PCT Healthcare Ltd, trading as Peak Pharmacy in this locality, wish to comment on the above application.

3.28 We operate three pharmacies on the distribution list:

3.28.1 PEAK PHARMACY, LEIGH HEALTH PARK, DERBY STREET, LEIGH WN7 2PD

3.28.2 PEAK PHARMACY, 11 COLLEGE STREET, LEIGH WN7 2RF

3.28.3 PEAK PHARMACY,76 BRADSHAWGATE, LEIGH WN7 4NP

3.29 **We urge Greater Manchester ICB to complete fully the necessary Fitness to Practise requirements for this application.**

3.30 Regulation 64(3) sets out conditions that distance selling premises must comply with. One of those is that the pharmacy procedures for the premises must secure the uninterrupted provision of essential services during core and supplementary opening hours to persons anywhere in England who request those services, this application does not fully explain how this will take place.

3.31 Within section 7 of the application the applicant states that:

3.32 *"Staffing volume will be dependent upon a range of factors such as current staffing levels at the company's other pharmacies, drug tariff recommendations…"*

3.33 PCT Healthcare Limited shall consider these points individually.

3.34 **Point 1- the staffing level in an individual pharmacy is not based on staffing levels within other pharmacies owned by the same legal entity, we urge the ICB to carefully review this point.**

3.35 **Point 2 – the NHS Drug Tariff relevant to England no longer specifies minimum dispensing staff levels and has not required this detail for many years.**

3.36 How shall Regulation 64(3) be complied with regarding the provision of services to persons anywhere in England who request pharmaceutical services from the applicant? **Pharmaceutical services cannot be limited to a locality and must be available on a nationwide basis, once again there are no**

specifics within the application indicating how this requirement shall be met.

3.37 **This application does not fully explain how this will take place. No where within the application are the details of how patients shall receive medication ordered which are controlled drugs or fridge lines when the patient may live within Falmouth, Cornwall, for example.**

3.38 This application is required to fully meet the criteria within Regulation 25, and we wish Greater Manchester ICB to specifically consider Regulation 25(2)(b)(ii) regarding this application.

3.39 Additionally, we trust that the SOPs will satisfy Greater Manchester ICB in other key areas such as:

3.39.1 The manner in which the applicant would communicate and action drug recalls and alerts.

3.39.2 Action the applicant will take in the event of being unable to fulfil a prescription completely (i.e. how they will deal with 'owings').

3.40 Essential pharmacy services cannot be provided to patients who are present at a distance selling pharmacy premises. **This applicant needs to satisfy Greater Manchester ICB that there would be safe and effective provision of essential services without face-to-face contact with patients or carers. There is no evidence within the application that evidence this fact to meet the Regulations.**

3.41 We also ask Greater Manchester ICB to satisfy themselves that the applicant, if successful, will ensure that all communication, whether on their website, practice leaflet or via mailshots / local advertising and the like, complies with GPhC's "Guidance for Registered Pharmacies Providing Pharmacy Services at a Distance, Including on the Internet" Principle 4.1 in relation to transparency and choice.

3.42 PCT Healthcare Limited t/a Peak Pharmacy would like to be informed of the outcome of this application, and we would wish to attend the Oral Hearing, should one be deemed necessary."

3.43 **Boots Pharmacy Comment**:

3.44 "Thank you for your letter dated 2nd May 2025 informing us of the above application submitted under the NHS (Pharmaceutical Services) Regulations 2013 and inviting us to make representations. Boots UK Ltd would like to respectfully request that members of the deciding committee are satisfied that this application fully meets the criteria set out in Regulation 25 and the conditions set out in Regulation 64 when determining this application.

3.45 **There is very little information within the application to be able to satisfy the decision maker that services will not be offered face to face, or to any persons within England or how deliveries will be made and if required, a cold chain maintained.**

3.46 **There is no mention of how waste will be collected or how patients will be signposted for support if needed.**

3.47 **We have no further comments to make with regards to this application but believe that this application should be refused for the reasons as stated above.** We would be most grateful if you could notify us of the decision of the ICB in due course and would attend any oral hearing held in connection with this application."

3.48 **Wigan HWB comment:**

3.49 "We are writing to make a written representation on behalf of Wigan Health and Wellbeing Board and NHS Greater Manchester (Wigan), regarding the application for inclusion in a pharmaceutical list at Unit 20, Meadowcroft Way, Leigh Commerce Park, Leigh, WN7 3XZ in respect of distance selling premises by Refine Pharma Ltd.

3.50 The 2022 Wigan Borough Pharmaceutical Needs Assessment PNA (currently under review for publication later in 2025), did not identify any gaps in pharmaceutical provision within the geographical footprint where the proposed new pharmacy would be located.

3.51 *The opening hours described in the application do not include service provision on Saturdays and Sundays, however we acknowledge that excepted applications for distance-selling premises are not required to demonstrate that they meet a need, or secure improvements or better access, to services.*

3.52 **If the applicant has been able to demonstrate to NHS England that the pharmacy is able to provide the full range of essential services safely, effectively and timely during the pharmacy opening hours to all persons in England who present prescriptions, without seeing the patient face to face, and the pharmacy satisfies the requirements of a distance selling pharmacy, including adherence to GPhC guidance: '*Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet*', then we have no specific concerns to raise.**

3.53 Should you require any further information on this representation, please contact the Wigan Locality Medicines Optimisation Department".

3.54 **CPGM comment:**

3.55 "Thank you for your letter dated 2nd May 2025, informing us of the above application and inviting us to make representations.

3.56 Community Pharmacy Greater Manchester (CPGM) applications subgroup has reviewed this application and **would like to request the following clarity before we can officially comment.**

3.57 **The CPGM subgroup requests information on how the pharmacy will avoid face-to-face contact and ensure safe remote service provision for patients.**

3.58 **Clarification is also requested on the following pharmacy procedures information provided by the applicant within section 7 of the application form:**

3.59 **"Staffing volume will be dependent upon a range of factors, such as current staffing levels at the company's other pharmacies, drug tariff recommendations and volume of dispending received."**

3.60 **Once the subgroup receives this, we will have further comments to make.**

3.61 CPGM would like to receive any further correspondence regarding this application and wish to be kept informed of its progress".

3.62 **Representations received outside the 45 day notification period: None**

3.63 **Representations received from circulation of first representations**

3.64 Comment by the applicant: [See 2.1 – 2.4]

3.65 The PSRC reviewed the representations and was not satisfied that it meets all the requirements of Regulation 25(2)(b), in addition to the ongoing requirements set out under Regulation 64.

3.66 The PSRC determined the application does not meet the requirements of **Regulation 25(2)(b)(i) and Regulation 25(2)(b)(ii).**

3.67 The PSRC also considered the impact of decision on those with protected characteristics under the Equalities Act 2010, in accordance with NHS England/ICB's Public Sector Equality Duty and its duties on health inequality.

3.68 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.

3.69 Decision

3.70 Based on all available information, the PSRC **refused** the application, as it concluded that the application did not meet the requirements of **Regulation 25(2)(b)(i) and Regulation 25(2)(b)(ii).**

3.71 Appeal rights are awarded to the applicant."

4 The Appeal

By the online form for pharmacy application appeals dated 17 September 2025, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

4.1 “**Regulation 25(2)(b)(i): Uninterrupted provision of essential services**

4.2 The application outlined that a full understanding of business continuity measures could be achieved through review of the pharmacy's Business Continuity Plan (BCP). While this document was not requested at the time of application, the BCP is available and details robust procedures to ensure uninterrupted provision of essential pharmaceutical services in the event of any disruption. The absence of a request for this supporting document has limited the Committee's ability to fully evaluate compliance with this requirement.

4.3 **Regulation 25(2)(b)(ii): Safe and Effective Provision Without Face-to-Face Contact**

4.4 The application provided clear assurances regarding the safe and effective delivery of services without in-person interaction. Specifically, it set out:

4.4.1 The process by which prescriptions would be received and dispensed;

4.4.2 Multiple communication methods to ensure patient needs are appropriately supported;

4.4.3 Safe and efficient delivery systems to ensure medicines reach patients in a timely manner; and

4.4.4 Evidence of the pharmacy's ability to provide the New Medicine Service (NMS) remotely in a safe and effective manner to all eligible patients.

4.5 This information satisfies the regulatory requirement to demonstrate that essential and advanced services can be delivered safely and effectively without the need for face-to-face contact.

4.6 **Access to Premises**

4.7 The PSRC expressed concern that the applicant may provide pharmaceutical services to persons present at or in the vicinity of the listed premises. However, the application clearly stated that the pharmacy premises are not accessible to the public, with multiple facial recognition access controls in place to prevent entry. This ensures compliance with the requirement that no services, other than directed services, are offered to persons present at the site.

4.8 **Location in relation to primary medical services**

4.9 The regulations further state that a DSP must not be located on the same site or in the same building as a provider of primary medical services with a patient list. The application demonstrates that there are no such services within the vicinity of the pharmacy. This can be easily verified by a search of local primary medical service providers.

4.10 At the time of submission, government policy changes were introduced to prevent further DSP applications. We believe that these developments may have unduly influenced the assessment of this application, despite the fact that the evidence submitted clearly satisfies the regulatory requirements. The

evaluation of this application should be based solely on the merits of the information provided.

4.11 All relevant information necessary to support this application and demonstrate compliance with Regulations 25(2)(b)(i) and 25(2)(b)(ii) has been provided. We therefore respectfully request that the decision of the PSRC be reconsidered, and that approval be granted for this Distance Selling Pharmacy application."

5 Summary of Representations

After reviewing the paperwork provided by the Commissioner, it was noted that the comments made by the Applicant in response to the representations on the application [see 2.1 to 2.4 above] had not been circulated or seen by parties. NHS Resolution therefore applied its discretion under Schedule 3, Part 3, paragraph 7 and allowed parties the opportunity to make comments on this information.

On 23 June 2025, amendments to Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 came into force, which affect the application. The Applicant was therefore invited to make comments on this matter.

This is a summary of representations received.

5.1 The Applicant

5.1.1 "I am writing in response to the letter received from the NHS Resolution Team to provide evidence and comments to the reworded Regulation 25 that is used as a test for Distance Selling Pharmacy (DSP) applications. The comments within this letter provide clarification and further evidence demonstrating full compliance with Regulation 25(2)(b)(i) and Regulation 25(2)(b)(ii) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended. Please find attached a copy of the pharmacy's Business Continuity Plan (BCP), which is reviewed regularly and updated to reflect the continued development of the business.

5.1.2 The Business Continuity Plan outlines in detail how the pharmacy ensures the uninterrupted provision of essential pharmaceutical services during its opening hours to any person in England who requests those services, in accordance with Regulation 25(2)(b)(i). In the event of an operational disruption, the plan specifies that the pharmacy will continue to provide priority one services either from the contracted NHS pharmacy premises or from an alternative pharmacy owned by the business within a two-mile radius, subject to the approval of the Area Team. To further support service continuity, the pharmacy employs multiple audited courier services under formal contracts to deliver pharmaceutical goods, including refrigerated and controlled drugs. These arrangements ensure next-day delivery to patients, with safety mechanisms in place to verify delivery to the correct recipient.

5.1.3 The Business Continuity Plan is disseminated to all department directors, as each department plays a significant role in maintaining uninterrupted NHS service provision. The Managing Director and Pharmacy Director hold overall responsibility for activating the plan

when necessary. All staff members have access to the document and are trained to escalate concerns and alert management staff should activation be required.

5.1.4 In relation to Regulation 25(2)(b)(ii), the safe and effective provision of pharmaceutical services without face-to-face contact between patients or their representatives and pharmacy staff has been fully demonstrated within our initial application and is reaffirmed here. The pharmacy premises are not accessible to patients or their representatives, as all entry points are secured by facial recognition technology that restricts access to authorised staff only. The premises are not signposted and are not located within or in the vicinity of a medical centre, thereby ensuring that no pharmaceutical services are provided in person at the pharmacy location.

5.1.5 Patients and their representatives are able to contact the pharmacy through multiple communication channels, including telephone, SMS, email, or an online portal. For those who are vulnerable or digitally excluded, communication can be conducted by telephone, or, in exceptional circumstances, by post. The pharmacy provides a postal address for the receipt of letters and prescriptions, and all staff are trained to communicate effectively and compassionately with patients and their representatives to ensure their needs are met.

5.1.6 The Business Continuity Plan also sets out clear procedures for the receipt of prescriptions during any system outages. Prescriptions can be received through the Electronic Prescription Service, by secure email or fax (with originals posted), through secure electronic portals such as SignatureRx, or by collection from local GP practices within a set radius. The pharmacy is committed to a turnaround time of 24 to 48 hours for dispensing and delivery, which aligns with the operating practices of the business's existing private pharmacy.

5.1.7 All patient communications are recorded and stored within the PharmSmart system. These records are reviewed monthly during the pharmacy's management meetings, where any communications requiring intervention are discussed, and appropriate corrective measures are implemented to enhance patient communication and service delivery.

5.1.8 Regular delivery verification procedures are carried out every three to six months at different times of the year to ensure the continued suitability of packaging materials. A range of tamper-proof packaging solutions have been tested and verified, and the highest-performing materials are currently in use, with ongoing evaluations to identify improvements. Undelivered medicines are returned to the pharmacy and destroyed in accordance with the relevant Standard Operating Procedures (SOPs), and the pharmacy liaises with patients and their GP practices to ensure continuity of treatment. Urgent deliveries can be made by the pharmacy's own delivery driver, a member of the pharmacy team for local deliveries, or by escalating courier services to ensure delivery by 10:30a.m. where required.

5.1.9 Cold chain medicines are dispatched in validated packaging with temperature controls to ensure product integrity, while controlled drugs are delivered by a secure courier service requiring a unique PIN code upon delivery to verify the identity of the recipient.

5.1.10 The pharmacy maintains a comprehensive set of SOPs covering all operational aspects, including dispensing, delivery, controlled drugs, and complaints handling. All SOPs are accessible through the PharmSmart platform, where staff are required to read and complete comprehension checks whenever new or updated SOPs are introduced. Regular audits are undertaken to identify and implement continuous improvements, supported by a live risk register to ensure that all potential risks are actively monitored and mitigated in order to maintain the safety of both staff and patients.

5.1.11 For the delivery of advanced services such as the New Medicine Service (NMS), the pharmacy ensures that eligible patients receive the maximum benefit from their prescribed treatments. Consultations are to be conducted via secure video or telephone calls, allowing pharmacists to identify and address any questions or concerns patients may have about their new medicines, thereby ensuring safe and effective service delivery.

5.1.1 In conclusion, the evidence provided both within the original application and in this submission demonstrates that the pharmacy fully meets the requirements of Regulation 25(2)(b)(i) and Regulation 25(2)(b)(ii). The attached Business Continuity Plan and the operational frameworks described above confirm our ability to provide uninterrupted, safe, and effective pharmaceutical services nationwide without face-to-face contact. We therefore respectfully request that the Committee reconsider its decision and grant approval for the Distance Selling Pharmacy application."

5.1.2 [Pharmacy Business Continuity Plan attached]

5.2 PCT Healthcare Ltd

5.2.1 "Thank you for your letter dated 26 September 2025 regarding the above application. PCT Healthcare Ltd, trading as Peak Pharmacy in this locality, wish to make representations on the above application.

5.2.2 We urge NHS Resolution to complete fully the necessary Fitness to Practise requirements for this application.

5.2.3 We note that on the GPhC website for this registered pharmacy there is an *"Enforcement action Summary"* effective dated 08 September 2025 against this pharmacy and two others operated by the same Company.

5.2.4 Microsoft Word - 9012812-EnforcementActionSummaryConditions-Refine Pharma-20250908

5.2.5 How does this GPhC Enforcement action affect this Company's Fitness to Practise?

5.2.6 Regulation 64(3) sets out conditions that distance selling premises must comply with. One of those is that the pharmacy procedures for the premises must secure the uninterrupted provision of essential services during core and supplementary opening hours to persons anywhere in England who request those services, this application does not fully explain how this will take place.

5.2.7 PCT Healthcare Limited respectfully ask NHS Resolution consider [sic] how this application shall fully comply with Regulation 64(3).

5.2.8 Within the applicant letter dated 8 July 2025, paragraph 3, there is mention of *"local vicinity"* and the use of a *"local delivery driver".*

5.2.9 PCT Healthcare Limited wish to reiterate that in a distance selling pharmacy the services offered must be comparable to every patient throughout England irrespective of their location. The implied disparity of service for patients close to Leigh versus those outside the applicant's description of "local vicinity", implies that the applicant will offer differing essential service provision to patients based on their geography which is clearly against the Regulations for a Distance Selling Pharmacy.

5.2.10 This application is required to fully meet the criteria within Regulation 25, and we wish NHS England to specifically consider Regulation 25(2)(b)(ii) regarding this application.

5.2.11 How shall Regulation 64(3) be complied with regarding the provision of services to persons anywhere in England who request pharmaceutical services from the applicant? Pharmaceutical services cannot be limited to a locality and must be available on a nationwide basis; there are no specifics within the application indicating how this requirement shall be met.

5.2.12 This application does not fully explain how this will take place. No where [sic] within the application are the details of how patients shall receive medication ordered which are controlled drugs or fridge lines when the patient may live within Falmouth, Cornwall, for example.

5.2.13 This application is required to fully meet the criteria within Regulation 25, and we wish NHS Resolution to specifically consider Regulation 25(2)(b)(ii) regarding this application.

5.2.14 We also ask NHS Resolution to satisfy themselves that the applicant, if successful, will ensure that all communication, whether on their website, practice leaflet or via mailshots / local advertising and the like, complies with GPhC's "Guidance for Registered Pharmacies Providing Pharmacy Services at a Distance, Including on the Internet" Principle 4.1 in relation to transparency and choice.

5.2.15 PCT Healthcare Limited t/a Peak Pharmacy would like to be informed of the outcome of this application, and we would wish to attend the Oral Hearing, should one be deemed necessary."

6 Summary of Observations

This is summary of observations received.

6.1 The Applicant

6.1.1 "Please find enclosed a formal rebuttal to the representations submitted by PCT Healthcare Limited in their letters dated 9 May 2025 and 23 October 2025.

6.1.2 The correspondence from PCT Healthcare Limited is substantially similar in content and tone, with much of the information presented in the latest letter being repetitive and, in certain instances, taken out of the original context. Specifically, reference has been made to statements regarding the provision of services to patients in the "local vicinity" compared to those further afield. These statements were extracted from our letter dated 8 July 2025, which discussed the processes for obtaining patient consent for the New Medicine Service (NMS).

6.1.3 For clarity, the referenced paragraph outlined that local patients may provide written consent via a local delivery driver, while patients residing outside the immediate area would be able to provide consent electronically via the pharmacy's website. This process ensures equitable access to NHS services for all patients, regardless of their location. The same information is explicitly included within the correspondence already provided to NHS Greater Manchester.

6.1.4 Furthermore, the claim by PCT Healthcare Limited that our application does not sufficiently explain how deliveries will be carried out, including the management of controlled drugs and refrigerated medicines, is incorrect. Detailed explanations of these processes are contained within paragraphs 8 and 9 of our letter dated 7 October 2025, which clearly describe the pharmacy's delivery procedures, verification methods, and temperature-control measures designed to ensure the safe and compliant delivery of all medicines to patients nationwide.

6.1.5 In relation to the Enforcement Action issued by the General Pharmaceutical Council (GPhC), we wish to clarify that while this action is has been [sic] enforced on the premises at Unit 20 Meadowcroft Way, it has no relevance to the activities of the pharmacy subject to this application. The enforcement notice merely reiterates points drawn from the GPhC Guidance for Pharmacies Providing Services at a Distance, and applies solely to another pharmacy premises that will not be used to provide NHS-contracted services, except under the limited circumstances outlined in the Business Continuity Plan.

6.1.6 In addition, the company has provided full and transparent information to the GPhC confirming that all third-party prescribers associated with

the business are registered with appropriate UK regulatory bodies. Accordingly, the company's Fitness to Practise remains unaffected, and the enforcement action has no bearing on its ability to provide safe and compliant NHS pharmaceutical services.

6.1.7 As stated in our previous correspondence, we wish to reassure PCT Healthcare Limited and the Committee that it is not our intention to encroach upon the business operations of existing pharmacies. The inclusion of our pharmacy on the pharmaceutical list is intended to support the wider NHS system by helping to address ongoing challenges such as medicine shortages, staffing pressures, and dispensing backlogs currently affecting community pharmacies across England.

6.1.8 We therefore respectfully request that these clarifications be considered as part of the ongoing review of our application, and that the objections raised by PCT Healthcare Limited be set aside on the basis of the evidence provided."

7 Consideration

7.1 The Pharmacy Appeals Committee ("Committee") appointed by NHS Resolution, had before it the papers considered by the Commissioner.

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

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

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

Regulation 31

7.5 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") at or 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).

7.6 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 the Commissioner had stated in its decision that "*Based on all available information, the PSRC was satisfied that the application should not be refused under Regulation 31, as there is no other provider of pharmaceutical services either in the same premises or adjacent premises to the proposed location.*" The Committee noted that this had not been disputed. The Committee noted that the Applicant operates a private pharmacy from the proposed premises.

7.7 On the information available, the Committee was satisfied that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

7.8 The Committee had regard to Regulation 25 of the Regulations which reads as follows:

"(1) Section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) does not apply to an application—

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

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

in respect of pharmacy premises that are distance selling premises.

(2) NHS England must refuse an application to which paragraph (1) applies—

(a) if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and

(b) unless NHS England is satisfied that the pharmacy procedures for the pharmacy premises are likely 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 pharmaceutical services without face to face contact at the pharmacy premises between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff."

7.9 The Committee also had regard to the provisions of Schedule 2 to the Regulations shown below:

Additional information to be included with excepted applications

8. *If the applicant (A) is making an excepted application, A must include in that application details that explain—*

(a) A's belief that the application satisfies the criteria included in one of the regulations in Part 4 which need to be satisfied if section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) are not to apply in relation to that application; and

(b) if the regulation includes reasons for which the application must be refused, why the application should not be refused for those reasons.

Nature of details to be supplied

10. *Where, pursuant to this Part, a person is required to provide details, that obligation is only discharged if the information or documentation provided is sufficient to satisfy NHS England in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that NHS England may need to make of the information or documentation when carrying out its functions.*

Regulation 25(1)

7.10 In relation to Regulation 25(1), the Applicant is applying for inclusion in the relevant pharmaceutical list, as a person not already included in a pharmaceutical list, and paragraph (1)(a) therefore operates to disapply the specified provisions of section 129 of the National Health Service Act 2006, provided that paragraph (2) does not require the application to be refused.

Regulation 25(2)(a)

7.11 The Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the

Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Commissioner in its decision report stated that "*Based on all available information, the PSRC was satisfied that the proposed location is not on the same site or in the same building as a provider of primary medical services with a patient list.*" Based on the information available to it, the Committee therefore determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

7.12 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services and pharmaceutical services.

7.13 The Regulations require the Committee to be satisfied as to a number of matters, including that essential services will be provided on an uninterrupted basis, across England, and that pharmaceutical services will be provided in a safe and effective way without face to face contact.

7.14 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation is only discharged if the information or documentation provided is sufficient to satisfy the Commissioner in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the Commissioner may need to make of the information or documentation when carrying out its functions.

7.15 The Committee has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters. In this case, that evidence put forward has taken the form of the original application, the appeal, representations and observations.

7.16 The Committee noted in its application, the Applicant states:

7.16.1 "*To ensure uninterrupted provision of essential pharmacy services is available, the following key areas will be focussed upon; staffing management, workflow efficiency, utilisation of technology, contingency planning and most importantly patient safety and communication*"; and

7.16.2 "*The current business continuity plan will be used and modified to ensure that service continuity can be maintained…*"

7.17 Further, in its '14 day comments' the Applicant states:

7.17.1 "*Current staffing has been reviewed and a dedicated workforce of 1 full time pharmacist, 2 full time qualified dispensers and a delivery driver has been ring fenced for all essential NHS services to be carried out. I can confirm that in anticipation of the registration of the new premises the company has recruited two additional full time apprentices enrolled*

on the level 2 dispensing qualification, there will also be an additional pharmacist on site for busy periods."

7.18 The Committee noted that the Applicant had provided a copy of its Business Continuity Plan ("BCP"). Having regard to the BCP, the Committee noted at section j) 'Staff Shortages' it states:

7.18.1 "*There may be occasions when individual staff members may be incapacitated for a variety of reasons. Their absence will have a variable effect depending on the role they play. In some cases these roles can be covered by other staff by ensuring that knowledge and skills are shared between groups of staff. Other roles may be highly specialised and cover will need more thought and planning especially if a service depends on that person alone.*

7.18.2 There may also be a scenario when several members of staff are all incapacitated at the same time such as during a pandemic or during severe adverse weather conditions.

7.18.3 The Superintendent Pharmacist is responsible for assessing the impact on the business of the pharmacy, the minimum number of staff and staff mix required to enable the pharmacy to continue to provide services and the contingency to be employed to maintain continuity of service.

7.18.4 Options for consideration include:

7.18.4.1 If the absence of staff for a short period does not have a significant impact on the business of the pharmacy – monitor the situation only;

7.18.4.2 If the absence of staff will have direct impact on the front line services/ business of the pharmacy - divert workload to or between other staff that are capable of covering;

7.18.4.3 If the absence of staff will have a direct impact on the front line services/ business where there is no other employee who is able to cover the role(s). Seek appropriate alternative staff to cover, e.g. from other branches or pharmacies where a mutual aid arrangement is in places;

7.18.4.4 If the impact of one or a number of staff being incapacitated is such that the pharmacy is unable to continue services, the Superintendent Pharmacist will be responsible for assessing the capabilities of the pharmacy and possibly which services will be reduced or through mutual aid arrangements be diverted to other pharmacies by reference to the prioritisation section of this document. If there is any reduction in patient services the AT should be informed; and

7.18.4.5 *The withdrawal of Essential Services, with the agreement of the AT, should only be proposed where the risk to patient safety outweighs the risk in providing the services.*"

7.19 Whilst noting the information regarding the planned staff numbers and how the Applicant would deal with the absence of staff generally, the Committee was of the view that it had not been made clear how essential services would be carried out, if required, during the absence of the Responsible Pharmacist. The Committee was therefore not satisfied that the provision of essential services would be without interruption.

7.20 The Committee next considered whether the provision of essential services would be available to persons anywhere in England and noted the Applicant states the following in its representations:

7.20.1 "*Patients and their representatives are able to contact the pharmacy through multiple communication channels, including telephone, SMS, email, or an online portal. For those who are vulnerable or digitally excluded, communication can be conducted by telephone, or, in exceptional circumstances, by post. The pharmacy provides a postal address for the receipt of letters and prescriptions…*"

7.21 The Committee also noted following comments in the Applicant's '14 day comments':

7.21.1 "*Delivery of medication nationally will be by DPD with whom the pharmacy has a pharmaceutical account…*"; and

7.21.2 "*Local deliveries of medication will be carried out by a trained pharmacy delivery driver employed by the pharmacy.*"

7.22 The Committee noted PCT Healthcare Ltd' comment that "*The implied disparity of service for patients close to Leigh versus those outside the applicant's description of "local vicinity", implies that the applicant will offer differing essential service provision to patients based on their geography which is clearly against the Regulations for a Distance Selling Pharmacy.*" The Committee noted that in their letter to the Commissioner dated 8 July 2025, the Applicant had stated "*To obtain any required consent patients within the local vicinity to the pharmacy will be asked by the local delivery driver to provide written consent, additionally local patients and those who live further afield will be able to provide their consent for any advanced services the pharmacy offers when they sign up to the pharmacy.*"

7.23 The Committee was therefore satisfied that the provision of essential services would be available to persons anywhere in England.

7.24 The Committee considered how the Applicant would provide pharmaceutical services without face to face contact and noted the Applicant's statement above at paragraph 7.20.1. It also noted the Applicant had stated the following in its representations:

7.24.1 "*The pharmacy premises are not accessible to patients or their representatives, as all entry points are secured by facial recognition technology that restricts access to authorised staff only. The premises are not signposted and are not located within or in the vicinity of a medical centre, thereby ensuring that no pharmaceutical services are provided in person at the pharmacy location.*"

7.25 Further the Committee was mindful of the regulatory changes as of 1 October 2025, that distance selling pharmacies can no longer provide Directed services (Advanced, National Enhanced and Enhanced Services, with the exception of Covid-19 and Flu vaccination services) face-to-face with the patient at the pharmacy premises.

7.26 In its application, which the Committee acknowledged was completed before the amendment came into force, the Applicant had stated that it intended to provide the New Medicines Service ("NMS"). As a result of this amendment, the Committee noted that the Applicant would not be able to provide any pharmaceutical services at its premises.

7.27 The Committee noted that in its representations the Applicant had stated:

7.27.1 "*For the delivery of advanced services such as the New Medicine Service (NMS), the pharmacy ensures that eligible patients receive the maximum benefit from their prescribed treatments. Consultations are to be conducted via secure video or telephone calls, allowing pharmacists to identify and address any questions or concerns patients may have about their new medicines, thereby ensuring safe and effective service delivery.*"

7.28 The Committee was aware that when the pharmacy opens, it will be the responsibility of the Commissioner, in keeping with Regulation 64, to ensure that services are provided other than with face to face contact.

7.29 The Committee was not satisfied that the provision of essential services would be without interruption. The Committee was satisfied that the provision of essential services would be available to persons anywhere in England and pharmaceutical services would be without face to face contact. The Committee went on to consider whether the safe and effective provision of pharmaceutical services was likely to be secured.

7.30 The Committee considered pharmaceutical services including each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations ("Terms of Service") in turn.

7.31 The Committee paid particular attention to the following aspects of the essential services, which it considered were more difficult to provide safely and effectively in a distance selling context:

7.31.1 Dispensing of drugs and appliances

7.31.2 Urgent supply without a prescription

7.31.3 Preliminary matters before providing ordered drugs or appliances

7.31.4 Providing ordered drugs or appliances

7.31.5 Refusal to provide drugs or appliances ordered

7.31.6 Further activities to be carried out in connection with the provision of dispensing services

7.31.7 Disposal service in respect of unwanted drugs

7.31.8 Promotion of healthy lifestyles

7.31.9 Prescription linked intervention

7.31.10 Health campaigns

7.31.11 Signposting

7.31.12 Support for self-care

7.31.13 Discharge medicines service

7.31.14 Websites and health promotion zones

7.32 The Committee was of the opinion that the procedures adopted by the pharmacy were not likely to secure the safe and effective provision by the Applicant of the following essential services:

Preliminary matters before providing ordered drugs or appliances

7.33 The Committee considered whether the Applicant had explained how evidence will be sought and provided about the patients' entitlement to exemption or remissions from NHS Charges.

7.34 The Committee noted that no information had been provided in this regard. It was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.

7.35 The Committee considered whether the Applicant had explained how charges will be paid.

7.36 The Committee noted that no information had been provided in this regard. It was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(5)(b) of Schedule 4.

Providing ordered drugs or appliances

7.37 The Committee considered whether the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that (i) the 'cold chain' is maintained, where relevant, and (ii) that the requirements of the Misuse of Drugs Regulations 2001 and, in particular, Regulations 14 and 16, are met).

7.38 The Committee noted that in its 14 day comments the Applicant states:

7.38.1 "*Delivery of medication nationally will be by DPD with whom the pharmacy has a pharmaceutical account where further safeguards are in place including parcel tracking. Any medicines that require additional packaging e.g. cold chain lines will be delivered in cold chain verified packaging – this verification is carried out by the pharmacy at different*

points throughout the year. For controlled drugs, patients will be required to give the courier a PIN number to ensure safe delivery."

7.38.2 *Local deliveries of medication will be carried out by a trained pharmacy delivery driver employed by the pharmacy.*"

7.39 In its representations the Applicant states:

7.39.1 "*…the pharmacy employs multiple audited courier services under formal contracts to deliver pharmaceutical goods, including refrigerated and controlled drugs. These arrangements ensure next-day delivery to patients, with safety mechanisms in place to verify delivery to the correct recipient.*"

7.39.2 "*Undelivered medicines are returned to the pharmacy and destroyed in accordance with the relevant Standard Operating Procedures (SOPs), and the pharmacy liaises with patients and their GP practices to ensure continuity of treatment. Urgent deliveries can be made by the pharmacy's own delivery driver, a member of the pharmacy team for local deliveries, or by escalating courier services to ensure delivery by 10:30 a.m. where required.*"

7.39.3 "*Cold chain medicines are dispatched in validated packaging with temperature controls to ensure product integrity, while controlled drugs are delivered by a secure courier service requiring a unique PIN code upon delivery to verify the identity of the recipient.*"

7.40 The Committee noted PCT Healthcare Ltd's comment that "*No where* [sic] *within the application are the details of how patients shall receive medication ordered which are controlled drugs or fridge lines when the patient may live within Falmouth, Cornwall, for example.*"

7.41 In response, the Applicant states:

7.41.1 "*Furthermore, the claim by PCT Healthcare Limited that our application does not sufficiently explain how deliveries will be carried out, including the management of controlled drugs and refrigerated medicines, is incorrect. Detailed explanations of these processes are contained within paragraphs 8 and 9* [5.1.8 and 5.1.9] *of our letter dated 7 October 2025, which clearly describe the pharmacy's delivery procedures, verification methods, and temperature-control measures designed to ensure the safe and compliant delivery of all medicines to patients nationwide.*"

7.42 Whilst noting the information referred to, the Committee was of the view that it did not provide sufficient detail regarding the Applicant's procedures, including how the Applicant would ensure the integrity of the cold chain throughout the journey, how temperature is monitored and what would happen in the event that the cold chain is breached or an unsuccessful delivery. Further, whilst noting that Applicant's intention to use a PIN code upon delivery of controlled drugs, the Committee was of the view that no detail had been provided regarding the security of controlled drugs when with the delivery driver/courier

throughout its onward journey. The Committee saw no information to explain what would happen in the event of an unsuccessful delivery.

7.43 Based on the information before it, the Committee was not satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

Refusal to provide drugs or appliances ordered

7.44 The Committee asked itself how the Applicant will be satisfied that when dispensing a repeatable prescription other than on the first occasion, that the patient is still using the medication, is not suffering from any side effects, the medicine regimen has not changed in any way and there has been no changes to the patient's health, which may indicate the desirability of reviewing the patients treatment.

7.45 The Committee noted that no information had been provided in this regard. It was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 9(4) of Schedule 4.

Further activities to be carried out in connection with the provision of dispensing services

7.46 The Committee considered whether the Applicant had explained how appropriate advice about the benefits of repeat dispensing to be given to any patient who (i) has a long term, stable medical condition (that is, a condition that is unlikely to change in the short to medium term), and (ii) requires regular medicine in respect of that medical condition.

7.47 The Committee noted that no information had been provided in this regard. It was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Disposal service in respect of unwanted drugs

7.48 The Committee considered whether the Applicant had explained or otherwise demonstrated how it will safely and effectively accept and dispose of unwanted drugs presented to it for disposal.

7.49 The Committee noted the Applicant had stated in its 14 day comments "*Waste will be disposed of under the same contract that the pharmacy currently has, all staff will be trained to safely dispose of medicines correctly. Patients will be able to return medicines safely free of charge with the local delivery driver and the courier – appropriate packaging for the return of medicines will be sent to all patients wishing to return medicines to the pharmacy.*"

7.50 Other than indicating that it would use the same waste contractor that it currently has in place, the Committee noted the Applicant had not provided any information regarding the procedure to be followed on receipt of the drugs, for example storage of the drugs, or protective equipment to be used by staff.

7.51 The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 13 - 15 of Schedule 4.

Promotion of healthy lifestyles

7.52 The Committee considered whether the Applicant had explained how it will safely and effectively promote healthy lifestyles.

7.53 The Committee noted that the Applicant's Business Continuity Plan contains a 'List of Pharmacy Services' which states at priority 6 "*Pharmacy website healthy living blogs and online advice*". The Committee did not consider that this provided clear information as to how the Applicant would safely and effectively promote healthy lifestyles.

7.54 The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 16 - 18 of Schedule 4.

Prescription linked intervention

7.55 The Committee considered whether the Applicant had explained how it will assess whether persons require prescription linked intervention advice because they have diabetes, are at risk of coronary heart disease, smoke or are overweight.

7.56 The Committee noted the Applicant's comment that "*All patient communications are recorded and stored within the PharmSmart system. These records are reviewed monthly during the pharmacy's management meetings, where any communications requiring intervention are discussed, and appropriate corrective measures are implemented to enhance patient communication and service delivery.*" The Committee was of the view that this was not sufficient to demonstrate how the Applicant would comply with paragraph 17 in particular the retrospective element.

7.57 The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

Health campaigns

7.58 The Committee considered whether the Applicant had explained or otherwise demonstrated how it will safely and effectively participate in health campaigns, if and to the extent required by the Commissioner.

7.59 The Committee noted that no information had been provided in this regard. It was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 18 of Schedule 4.

Support for self-care

7.60 The Committee considered whether the Applicant had explained or otherwise demonstrated how it will provide advice and support for people caring for their families.

7.61 The Committee noted that no information had been provided in this regard. It was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 19 – 20 of Schedule 4.

Discharge medicines service

7.62 The Committee considered whether the Applicant had explained how it will provide advice, assistance and support to and in respect of a health service patient – (a) recently discharged from hospital who is referred to P for advice, assistance and support in respect of the patient's medication regimen by the staff of the hospital in which the patient stayed; or (b) who is otherwise referred to P for advice, assistance and support in respect of the patient's medication regiment by the staff of an NHS trust and NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.

7.63 Further, the Committee considered whether the Applicant had explained what procedures it has in place for checking referrals for the discharge medicines service.

7.64 The Committee noted that no information had been provided in this regard. It was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

7.65 In relation to all other essential services, the Committee was, on balance, satisfied that procedures adopted by the pharmacy (and general adherence to the Terms of Service) would be "likely to secure" safe and effective provision.

Summary

7.66 On the information before it, the Committee could not be satisfied that there are procedures likely to secure safe and effective provision of pharmaceutical services as required by Regulation 25(2)(b). Also, for the reasons set out at 7.19, the Committee was not satisfied that the provision of essential services would be without interruption.

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

7.67.1 confirm the Commissioner's decision;

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

7.67.3 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.

7.68 Given that limited reasoning had been provided in the Commissioner's decision report, the Committee determined that the decision of the Commissioner must be quashed.

7.69 The Committee considered 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 quash the original decision and remit the matter to the Commissioner) or whether it was preferable for the Committee to reconsider the application.

7.70 The Committee noted that representations on Regulation 25 had already been made by parties to the Commissioner, and these had been circulated and seen by all parties as part of the processing of the application by the Commissioner. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 25.

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

8 Decision

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

8.2 The Committee:

8.2.1 quashes the decision of the Commissioner; and

8.2.2 redetermines the application as follows -

8.2.2.1 the Committee was satisfied that the premises of the Applicant are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list;

8.2.2.2 the Committee was not satisfied that all essential services were likely to be secured without interruption during the opening hours;

8.2.2.3 the Committee was satisfied that all essential services were likely to be secured for persons anywhere in England;

8.2.2.4 the Committee was not satisfied that pharmaceutical services were likely to be secured in a safe and effective manner; and

8.2.2.5 the Committee was satisfied that pharmaceutical services were likely to be secured without face to face contact.

8.2.3 The application is refused.

Case Manager
Primary Care Appeals