NHS Resolution

12 June 2026

**REF: SHA/26882**

8th Floor
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**APPEAL AGAINST DERBY AND DERBYSHIRE ICB DECISION TO REFUSE AN APPLICATION BY THE CASTLEWARD CLINICS LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT UNIT 3, ST PETER'S MALL, DERBY, DE1 2NR 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:

The Castleward Clinics Ltd
PCSE on behalf of Derby and Derbyshire ICB
PCT Healthcare Ltd
Community Pharmacy Derbyshire

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## 1 The Application

By application dated 22 June 2025, The Castleward Clinics ("the Applicant") applied to Derby and Derbyshire ICB ("the Commissioner") for inclusion in the pharmaceutical list at Unit 3, St Peter's Mall, Derby, DE1 2NR 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 this blank.

1.2 In response to why the application should not be refused pursuant to Regulation 31 the Applicant stated:

1.2.1 "It is a distance selling pharmacy".

1.3 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant stated:

1.3.1 "No provider of a primary medical service with a patient list."

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.

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

1.6 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.

1.7 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.

1.8 “The online pharmacy will have at least one Responsible Pharmacist (RP) at the premises at all times during the contracted hours. Patients will be able to order their medication online via the NHS app or via requests to their GP and have it delivered to their doorstep the same day/next day, ensuring that they can receive the essential services they need, without any disruption. In addition, the online pharmacy will have a robust system in place to handle any potential issues or emergencies. Patients will be able to contact a qualified pharmacist directly through our online/email/video and phone service, and we will have measures in place to ensure that medication can be delivered quickly in the event of an urgent need. Urgent medications such as antibiotics or end of life will be stocked in advance and will be delivered the same day unless there is a supply issue in which case the patient will be signposted to their nearest pharmacy. We will make sure adequate staffing levels meet the demand for Essential Services during the opening hours. Staff members will be trained in providing uninterrupted essential services, including how to handle unexpected events and emergencies. All staff members will have read and signed the comprehensive list of standard operating procedures (SOP). All staff will be allocated time for training and courses from the ‘centre for pharmacy postgraduate education (CPPE).

1.9 Patients will not be provided with face to face NHS essential services inside or within the vicinity of the premises. Patients attending for advanced services will be reminded by staff that we only provide medication delivered to patients home addresses and no collection is allowed at the pharmacy. There will also be a large sign at the entrance of the premises door to remind patients of “consultation by appointment only and no public access.” Inside the pharmacy, the dispensary door will be closed to prevent patient access.”

## 2 Comments to the Commissioner

On reviewing the paperwork provided by PCSE, it was noted that the comments made by the Applicant and two of the interested parties to the representations on the application, had not been circulated or seen by parties.

In the interests of transparency and fairness, NHS Resolution sought to rely on the discretion afforded in paragraph 7 of Schedule 3 of the Regulations to vary the normal procedures and circulate these comments to parties for them to make observations on them if they so wished.

2.1 THE APPLICANT

2.1.1 “Thank you for your letter dated 22nd August 2025 regarding our distance selling pharmacy application for Unit 3 St Peters Mall, Derby DE1 2NR.

2.1.2 Response to Your Concerns

2.1.3 Regulation 25(2) and Essential Services

2.1.4 We acknowledge your reference to regulation 25(2) regarding the provision of essential services. Our application fully complies with current regulations, and we are committed to providing all required essential services within the statutory framework for distance selling pharmacies.

2.1.5 Advanced and Enhanced Services - Regulatory Compliance

2.1.6 Regarding your concerns about "safe and effective provision" of advanced and enhanced services, we wish to clarify that our pharmacy fully adheres to the updated guidance on distance selling pharmacy limitations. Specifically:

2.1.6.1 Flu vaccination services will NOT be offered via our distance selling platform, in line with current regulatory guidance

2.1.6.2 Hypertension case-finding services will NOT be administered through distance selling, as per the established restrictions

2.1.6.3 All services offered will comply with face-to-face requirements where mandated by current regulations

2.1.7 Clarification Required

2.1.8 Your third point mentions services that are "no longer commissioned or have never been commissioned." Could you please clarify what you are implying with the phrase "services that have never been commissioned"?

2.1.9 This statement requires elaboration, as it appears to suggest knowledge of specific uncommissioned services that we may be proposing. We would appreciate:

2.1.9.1 Specific identification of which services you believe fall into this category

2.1.9.2 Clarification of your concerns about service provision methodology

2.1.9.3 Details of any regulatory breaches you believe our application may contain

2.1.10 Our Commitment

2.1.11 We remain committed to operating within all regulatory frameworks and providing safe, effective pharmaceutical services to the community. We welcome the opportunity to address any specific regulatory concerns through proper channels.

2.1.12 We look forward to your detailed response regarding the uncommissioned services reference and any further clarification of your concerns."

2.2 BOOTS

2.2.1 "Thank you for your letter dated 8th July 2025 informing us of the above application submitted under the NHS (Pharmaceutical Services) Regulations 2013 and inviting us to make representations.

2.2.2 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.

2.2.3 It is of note that the proposed premises are within a busy shopping area within the city centre. With the recent change in the regulations, patients will no longer be able to be offered any services face to face and with the premises being within such a location, we ask how the applicant can reassure us that there will be no access to patients. This part of the city boasts many shops and we ask for clarification that the unit will not be made to look like a "bricks and mortar" pharmacy confusing patients.

2.2.4 We have no further comments to make, but we would be most grateful if you could notify us of the decision of the ICB in due course."

2.3 PCT HEALTHCARE LTD

2.3.1 "Thank you for your letter dated 8 July 2025 regarding the above application. PCT Healthcare Ltd, trading as Peak Pharmacy in this locality, wish to comment on the above application. We operate one pharmacy on the distribution list:

2.3.1.1 PCT Healthcare Ltd t/a Peak Pharmacy, 1 Burton Road, Derby, Derbyshire DE1 1TH (ODS Code FCF30)

2.3.2 We urge NHS England to complete fully the necessary Fitness to Practise requirements for this application.

2.3.3 Essential pharmacy services cannot be provided to patients who are present at a distance selling pharmacy premises. This applicant needs to satisfy NHS England that there would be safe and effective provision of essential services without face-to-face contact with patients or carers.

2.3.4 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.

2.3.5 As Distance Selling Pharmacy 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.

2.3.6 Regarding Section 7.1(a) there is a statement in the application:

2.3.7 *"Urgent medications such as antibiotics or end-of-life will be stocked in advance and will be delivered the same day unless there is a supply issue in which case the patient will be signposted to their nearest pharmacy."*

2.3.8 As a distance selling pharmacy the services offered must be comparable to every patient throughout England irrespective of their location. The implyed [sic] disparity of service for patients close to Derby versus those outside the applicant's description "delivered the same day" area, 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.

2.3.9 There is no detail within the application to cover the topics of mis-deliveries. There are no details as to how this is managed for a patient in Truro for example where a delivery has not been made.

2.3.10 There are no details within this application about provision of prescription items requiring special storage conditions e.g. cold storage to ensure the integrity of the product during transit from the pharmacy to patients throughout England. There are no details if a cold storage prescription item cannot be delivered e.g. insulin for a Derbyshire patient or insulin for Truro patient, to maintain integrity of the product.

2.3.11 Nor are there any details within the application regarding how controlled drugs dispensed against prescriptions shall be transported from pharmacy to patients to ensure that the misuse of drugs regulations are followed.

2.3.12 Within the application there is a coloured layout of the proposed pharmacy, it is not clear from the "red dashed line" which areas are registered with GPhC, and which areas are not, normally the pharmacy areas which are registered are those areas within the "red dashed line". From the enclosed plan in the application, it seems that neither dispensary area nor the consultation room are within the registered premises.

2.3.13 PCT Healthcare Limited would wish that NHS England evaluate which areas of the pharmacy layout are part of the proposed pharmacy.

2.3.14 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.

2.3.15 We also ask NHS England 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.

2.3.16 We 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 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 2 January 2026 states:

3.1 "Derby and Derbyshire 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 Derby and Derbyshire 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."

[Any reference to 'Committee' in this section is not to be confused with the Pharmacy Appeals Committee of NHS Resolution]

Extract from decision report

3.4 "The committee noted that the applicant has been cleared for inclusion into the pharmaceutical list for the area of Derby City HWB therefore Regulation 25(1)(a) does not apply as the applicant was not already included in the pharmaceutical list.

3.5 Regulation 25 – Distant Selling Premises Applications

3.6 Regulation 25 (1)

3.7 The application is for a distance selling premises and therefore section 129(2A) of the NHS Act 2006 doesn't apply.

3.8 Regulation (25)(2)(a)

3.9 The applicant's premises 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. There are therefore no grounds to refuse the application by virtue of this regulation.

3.10 Regulation 25(2)(b)(i) - Is the applicant seeking to restrict the provision of essential services in any way?

3.11 The applicant has provided supporting information and has confirmed within part 4 of the application form that they will provide all Essential services set out in paragraphs 3 to 22, Schedule 4 of the National Health Services (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended.

3.12 Regulation 25(2)(b)(ii) - Does any element of essential service provision involve face to face contact with the applicant or their staff?

3.13 The documentation provides assurance in relation to most aspects of how the pharmacy will safely and effectively deliver pharmaceutical services without face-to-face contact. The supporting information explains in detail how dispensing, delivery, exemption verification, repeat dispensing, disposal, health promotion, and discharge medicines services will be managed remotely, and demonstrates a clear understanding of the requirements for distance-selling pharmacies.

3.14 The only area not explicitly addressed within the documentation is how the pharmacy will identify and provide prescription-linked interventions for patients with long-term conditions or lifestyle-related risk factors, such as diabetes, coronary heart disease, smoking, or obesity. This element of the essential services framework is not covered in the supporting information, and therefore the procedures to be followed in such cases remain unclear.

3.15 Overall, while the submission clearly evidences robust arrangements for the safe and effective remote provision of nearly all essential services, it does not fully address prescription-linked interventions. As a result, the documentation substantially, but not entirely, demonstrates compliance with the expectations for safe and effective service delivery under a distance-selling model.

3.16 Regulation 31 – Refusal; same and adjacent premises

3.17 No persons on the pharmaceutical list (which may or may not be the applicant) is providing or has undertaken to provide pharmaceutical services from

3.18 The premises to which the application relates, or adjacent premises and

3.19 The Integrated Care Board 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 chemists premises should be treated as the same site)

3.20 There are therefore no grounds to refuse the application by virtue of this regulation.

3.21 Regulation 66 - conditions relating to providing directed services

3.22 The committee should note that not all services are commissioned by the ICB/NHSE.

3.23 No advanced or enhanced services are to be provided.

3.24 As such, Regulation 66(4) does not apply, and no condition under Regulation 66(5) is required in relation to the provision of advanced services.

3.25 Decision

3.26 While the applicant has confirmed its intention to provide all Essential Services remotely in line with Schedule 4, Part 2, the Committee is not satisfied that sufficient assurance has been provided to demonstrate that these services can be safely and effectively delivered without face-to-face contact, as required under Regulation 25. Accordingly, the application is not supported at this stage.

3.27 A proposed floor plan has been submitted and will be reviewed once the internal layout is finalised. However, in the absence of sufficient operational evidence to demonstrate safe and effective service delivery in line with DSP requirements, the application cannot be recommended for approval at this stage.

3.28 The applicant may provide further information to address the identified gaps and request reconsideration once full compliance with the DSP regulatory framework can be evidenced.

3.29 The committee determined the application is to be refused.

3.30 Third party rights of appeal

3.31 Appeal right will only be given to the applicant."

## 4 The Appeal

In an email dated 30 January 2026, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "I write to formally appeal against the decision to refuse the Distance Selling Pharmacy application submitted by The Castleward Clinics Ltd, application reference CAS-370508-N3S0B3.

4.2 This appeal is submitted within the statutory timeframe. In parallel, further information has been provided for reconsideration addressing the specific point identified in the refusal decision.

4.3 Grounds of Appeal

4.4 The refusal was based on the conclusion that procedures for prescription-linked interventions for patients with long-term conditions and lifestyle-related risk factors were insufficiently clear.

4.5 The Appellant submits that this conclusion is not reasonable when considered against the evidence provided, which demonstrates that:

4.5.1 all prescriptions are clinically screened by a pharmacist prior to supply

4.5.2 prescription-linked intervention triggers are identified during screening

4.5.3 interventions are delivered remotely under the distance selling model

4.5.4 appropriate escalation and referral pathways are in place

4.5.5 all actions and outcomes are documented within the PMR system (RxWeb)

4.6 The Regulations do not require face-to-face contact for the provision of Essential Services, and the distance selling model expressly permits remote delivery.

4.7 The refusal therefore relates to clarity of explanation rather than a failure to meet regulatory requirements, and places disproportionate weight on narrative detail rather than substantive compliance.

4.8 Conclusion

4.9 For these reasons, the Appellant respectfully requests that the refusal decision be overturned and the application approved."

## 5 Summary of Representations

This is a summary of representations received on the appeal.

5.1 THE COMMISSIONER

5.1.1 "Thank you for your letter dated 24 February 2026 regarding the reconsideration of the appeal for the application submitted by The Castleward Clinics Ltd for inclusion in the pharmaceutical list for a distance selling pharmacy at Unit 3, St Peter's Mall, Derby (DE1 2NR).

5.1.2 The Commissioner acknowledges the administrative error identified whereby the representations submitted by PCT Healthcare Ltd (t/a Peak Pharmacy) and Boots UK Ltd were not included as Statutory Interested Parties during the initial appeal process.

5.1.3 We note that Primary Care Appeals has exercised its discretion under Schedule 3, Paragraph 7 of the NHS (Pharmaceutical Services) Regulations 2013 to restart the relevant part of the process to allow consideration of these representations.

5.1.4 **Commissioner Position**

5.1.5 The Commissioner confirms that the original determination of the application was undertaken in accordance with the NHS (Pharmaceutical Services) Regulations 2013, with specific consideration of:

5.1.5.1 Regulation 25 – applications for distance selling premises; and

5.1.5.2 Regulation 64 – conditions relating to the provision of essential services from distance selling premises.

5.1.6 The application was assessed based on the information provided at the time of determination, including the applicant's procedures for the provision of essential services and their proposed operating model.

5.1.7 Representations Submitted by Interested Parties

5.1.8 The Commissioner has now reviewed the representations provided by:

5.1.8.1 PCT Healthcare Ltd (Peak Pharmacy), which raise concerns regarding the applicant's procedures for:

5.1.8.1.1 nationwide provision of services;

5.1.8.1.2 delivery logistics, including cold-chain and controlled drugs;

5.1.8.1.3 management of mis-deliveries; and

5.1.8.1.4 clarity regarding the registered premises layout.

5.1.8.2 Boots UK Ltd, which request assurance that the application fully meets the requirements of Regulation 25 and Regulation 64, particularly regarding the operation of a distance selling model without face-to-face access to patients.

5.1.9 These representations primarily relate to whether the applicant's procedures demonstrate that essential services can be provided safely and effectively on a national basis without face-to-face interaction, as required under the Regulations.

5.1.10 Commissioner Observations

5.1.11 The Commissioner notes that these points largely relate to:

5.1.11.1 the clarity and detail of operational procedures within the application; and

5.1.11.2 assurance that the distance selling model can operate fully in line with regulatory requirements.

5.1.12 As this matter is now subject to reconsideration through the appeals process, the Commissioner is content for the appeal panel to take these additional representations into account when determining whether the requirements of Regulation 25 and the associated conditions for distance selling pharmacies are met.

5.1.13 Conclusion

5.1.14 The Commissioner has no further additional evidence to submit at this stage but will cooperate with the appeals process and provide clarification if requested."

5.2 PCT Healthcare Ltd t/a Peak Pharmacy

5.2.1 "Thank you for your letter dated 24 February 2026 regarding the above application. PCT Healthcare Limited wish to make the following written representations on this application.

5.2.2 PCT Healthcare Limited agree with the Commissioner's decision to refuse this application.

5.2.3 We wish NHS Resolution to fully consider our representations to NHS England dated 5 August 2025 relating to this above application.

5.2.4 PCT Healthcare Limited wish to raise our concerns that a Distance Selling Pharmacy located within a City Centre, could easily be interpreted by patients and the public as available for face-to-face pharmaceutical services.

5.2.5 St Peter's Mall is an indoor retail precinct which forms one entrance to the Derbion shopping centre (formerly Intu Derby) via its link to the pedestrianised St Peter's Street. As a result, it benefits from Derbion's annual footfall of 24 million, with 2.1 million being recorded directly through St Peters Mall.

5.2.6 This is the advert for Unit 1 & Unit 3 Derby, DE1 2NR as listed on Completely retail, details are below.

5.2.7 https://completelyretail.co.uk/scheme/St-Peters-Way-Derby/property/unit-1-3-st-peters-mall-derby-137402

5.2.8 Below is a photograph of St Peters Street Unit 1 & 3 of St Peters Mall are located on the left-hand side of the main entrance to St Peters Mall. The units have a green signage above them [image provided to Committee].

5.2.9 The purpose of this photograph is to show how many shoppers / visitors to Derby are passing these units.

5.2.10 Regarding the layout plans of the pharmacy:

5.2.11 How can the applicant ensure that the pharmacy will fully comply with GDPR requirements, GPhC premises requirements and Pharmaceutical Regulations to ensure that no access is possible to the proposed premises by non-pharmacy staff?

5.2.12 From this plan it seems that neither the dispensary area on the 1st Floor nor the consultation room on the ground floor are within the registered premises [copy of plan provided to the Committee].

5.2.13 Conclusion

5.2.14 We do not believe this applicant has given sufficient evidence that the full range of essential services shall be offered to all persons in England presenting prescriptions during the proposed pharmacy opening hours.

5.2.15 We do not believe that there is sufficient evidence provided by the applicant as to how the pharmacy shall meet Regulation 25 (2)(ii) the safe and effective provision of pharmaceutical essential services without face to face contact at the pharmacy premises, between any persons receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

5.2.16 PCT Healthcare Limited urge NHS Resolution to confirm the Commissioners decision and refuse this Distance Selling Pharmacy application.

5.2.17 PCT Healthcare Limited would like to be informed of the outcome of this application, and we would wish to attend an Oral Hearing, should one be deemed necessary."

Letter dated 5 August 2025 with PCT Healthcare Ltd t/a Peak Pharmacy representations on the application

5.2.18 "As Distance Selling Pharmacy 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.

5.2.19 Regarding Section 7.1(a) there is a statement in the application:

5.2.20 *"Urgent medications such as antibiotics or end-of-life will be stocked in advance and will be delivered the same day unless there is a supply issue in which case the patient will be signposted to their nearest pharmacy."*

5.2.21 As 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 Derby versus those outside the applicant's description "delivered the same day" area, 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

5.2.22 There is no detail within the application to cover the topics of mis-deliveries. There are no details as to how this is managed for a patient in Truro for example where a delivery has not been made.

5.2.23 There are no details within this application about provision of prescription items requiring special storage conditions e.g. cold storage to ensure the integrity of the product during transit from the pharmacy to patients throughout England. There are no details if a cold storage prescription item cannot be delivered e.g. insulin for a Derbyshire patient or insulin for Truro patient, to maintain integrity of the product.

5.2.24 Nor are there any details within the application regarding how controlled drugs dispensed against prescriptions shall be transported from pharmacy to patients to ensure that the misuse of drugs regulations are followed.

5.2.25 Within the application there is a coloured layout of the proposed pharmacy, it is not clear from the “red dashed line” which areas are registered with GPhC, and which areas are not, normally the pharmacy areas which are registered are those areas within the “red dashed line”. From the enclosed plan in the application, it seems that neither dispensary area nor the consultation room are within the registered premises.

5.2.26 PCT Healthcare Limited would wish that NHS England evaluate which areas of the pharmacy layout are part of the proposed pharmacy.

5.2.27 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.

5.2.28 We also ask NHS England 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.

5.2.29 We 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.”

5.3 THE APPLICANT

5.3.1 “The Applicant provides the following representations in response to the comments submitted by Statutory Interested Parties.

5.3.2 The Applicant confirms that the proposed pharmacy will operate fully in accordance with the requirements for a Distance Selling Pharmacy and will provide Essential Services safely and effectively without face-to-face contact.

5.3.3 Response to Boots UK Ltd

5.3.4 Boots UK Ltd raise a concern regarding potential patient confusion due to the premises being located within a busy city centre shopping area. The Applicant confirms that:

5.3.4.1 no Essential Services will be provided to patients present at the premises

5.3.4.2 no walk-in service will be offered

5.3.4.3 all patient interaction will be conducted remotely (telephone, online, or delivery)

5.3.4.4 the dispensary is based on the first floor which is not accessible by patients so this will prevent any possible confusion

5.3.4.5 patients presenting at the premises will be appropriately signposted to local community pharmacies The pharmacy will operate strictly as a Distance Selling Pharmacy, and appropriate measures will be in place to ensure there is no risk of the premises being perceived as a walk-in pharmacy.

5.3.5 Response to PCT Healthcare Ltd

5.3.6 Nationwide Service Provision

5.3.7 The Applicant confirms that the pharmacy will provide Essential Services on a national basis, in line with the requirements for Distance Selling Pharmacies.

5.3.8 The same operating model, clinical processes, and service standards will apply consistently to all patients, regardless of location.

5.3.9 Delivery Model and Equity of Service

5.3.10 The Applicant confirms that services will not be provided on a locality-dependent basis.

5.3.11 Delivery timescales will be applied consistently across all patients, and no preferential service will be offered based on geographic proximity to the premises.

5.3.12 This ensures compliance with the requirement that Essential Services are provided equally to patients throughout England.

5.3.13 Failed Deliveries In the event of a failed delivery:

5.3.13.1 the patient will be contacted promptly

5.3.13.2 redelivery will be arranged at the earliest appropriate opportunity

5.3.13.3 where necessary, the patient will be supported to access medication via an alternative appropriate route

5.3.13.4 all actions will be documented within the PMR system

5.3.14 Cold Chain and Temperature-Sensitive Medicines Where medicines require specific storage conditions:

5.3.14.1 appropriate insulated packaging and validated delivery methods will be used

5.3.14.2 delivery arrangements will ensure the integrity of the medicine is maintained

5.3.14.3 medicines will not be supplied where safe delivery conditions cannot be assured

5.3.15 Controlled Drugs

5.3.16 Where controlled drugs are supplied:

5.3.16.1 all legal and regulatory requirements will be adhered to

5.3.16.2 secure delivery methods will be used

5.3.16.3 appropriate tracking, audit, and proof of delivery processes will be in place

5.3.17 Pharmacy Layout and Registered Areas

5.3.18 The Applicant confirms that all activities relating to the provision of pharmacy services, including dispensing and consultation, will take place within areas registered with the General Pharmaceutical Council. The layout of the premises will ensure compliance with regulatory requirements.

5.3.19 Provision of Separate Private Services

5.3.20 The Applicant confirms that certain private healthcare services, including ear wax removal and travel vaccinations, may be provided from the premises.

5.3.21 These services are entirely separate from NHS pharmaceutical services and will operate independently of the Distance Selling Pharmacy model.

5.3.22 The Applicant confirms that:

5.3.22.1 no NHS Essential Services will be provided to patients present at the premises

5.3.22.2 patients attending for private services will not receive NHS pharmaceutical services on site

5.3.22.3 all NHS pharmaceutical services will be provided remotely in accordance with Distance Selling Pharmacy requirements

5.3.23 This ensures full compliance with the regulatory framework.

5.3.24 Conclusion

5.3.25 The Applicant submits that the concerns raised by Statutory Interested Parties have been fully addressed.

5.3.26 The pharmacy will operate in full compliance with the requirements for Distance Selling Pharmacies and will provide Essential Services safely, effectively, and consistently on a national basis.

5.3.27 The Applicant therefore respectfully requests that the application be approved.

5.3.28 Please accept this letter as our request for reconsideration in relation to the above DSP.

5.3.29 The pharmacy will operate as a Distance Selling Pharmacy and will deliver Essential Services safely and effectively without face-to-face contact. This submission provides operational detail for the identification and delivery of prescription-linked interventions for patients with long-term conditions and lifestyle-related risk factors, including remote consultation pathways, escalation and referral processes, and documentation standards within our PMR system (RxWeb).

5.3.30 We note from the Committee's decision report that the application demonstrated a clear understanding of the Distance Selling Pharmacy requirements and the provision of Essential Services under a DSP model. This reconsideration submission is therefore focused on providing additional clarity and operational detail regarding prescription-linked interventions for patients with long-term conditions and lifestyle-related risk factors.

5.3.31 For ease of review, the reconsideration submission pack includes the following documents:

5.3.31.1 Reconsideration Statement – Prescription-Linked Interventions (Long-Term Conditions and Lifestyle Risk Factors)

5.3.31.2 Appendix 1 – Prescription-Linked Interventions

5.3.31.3 SOP - Clinical Screening & Prescription-Linked Interventions (LTC/Lifestyle) We respectfully request reconsideration and approval of the application.

5.3.32 **Appendix 1 – Prescription-Linked Interventions**

5.3.33 Prescription-linked interventions are embedded into pharmacist clinical screening for every prescription. Where a trigger is identified, the pharmacist completes a remote intervention and records the outcome in RxWeb PMR. Some examples of the pathways are shown below.

5.3.34 **Trigger: Diabetes medicines / therapy change / side effects**

5.3.34.1 *Action*: telephone counselling, safe-use advice, red-flag advice, GP referral if required

5.3.34.2 *Documentation*: RxWeb PMR intervention entry + outcome recorded

5.3.35 **Trigger: CHD/CVD medicines (statin/antiplatelet/anticoagulant) / therapy change** • *Action*: adherence and safety counselling, escalation to prescriber if required

5.3.35.1 *Documentation*: RxWeb PMR intervention entry + outcome recorded

5.3.36 **Trigger: Hypertension medicines / side effects / adherence concerns**

5.3.36.1 *Action*: counselling, referral advice if concerns persist or clinical risk identified

5.3.36.2 *Documentation*: RxWeb PMR intervention entry + outcome recorded

5.3.37 **Trigger: Respiratory medicines (inhalers) / frequent reliever ordering pattern**

5.3.37.1 *Action*: symptom check, adherence support, signposting, GP review advice where poor control suspected

5.3.37.2 *Documentation*: RxWeb PMR intervention entry + outcome recorded

5.3.38 **Trigger: Lifestyle-related risks (smoking/weight etc.) where clinically relevant**

5.3.38.1 *Action*: brief intervention and signposting to NHS support/services

5.3.38.2 *Documentation*: RxWeb PMR intervention entry + outcome recorded

5.3.39 **Trigger: Repeat ordering concerns (early/late/irregular requests)**

5.3.39.1 *Action*: adherence review, counselling, supply delay/escalation if required

5.3.39.2 *Documentation*: RxWeb PMR intervention entry + outcome recorded

5.3.40 **Trigger: Directions unclear / interaction / contraindication / allergy mismatch**

5.3.40.1 *Action*: prescriber clarification, supply delayed if required for safety

5.3.40.2 *Documentation*: RxWeb PMR intervention entry + prescriber contact recorded Outcome options recorded: Supplied / Delayed pending clarification / GP referral / NHS 111 advice / 999 advice/ The advice given

5.3.41 **SOP- Clinical Screening & Prescription-Linked Interventions (Long-Term Conditions & Lifestyle Risk Factors)**

5.3.42 *SOP created by: Alisha Mahmood (Responsible Pharmacist / Superintendent Pharmacist)*

5.3.43 *Version: 1.0*

5.3.44 *Effective Date: 1 June 2025*

5.3.45 *Review Date: 1 June 2026*

5.3.46 *Applies to: All NHS prescriptions (EPS and paper where applicable)*

5.3.47 **Purpose**

5.3.48 To ensure that all prescriptions are clinically screened appropriately and that prescription-linked interventions for long-term conditions (LTC) and lifestyle-related risk factors are delivered safely and effectively under the Distance Selling Pharmacy (DSP) model, without face-to-face contact.

5.3.49 This SOP ensures:

5.3.49.1 consistent identification of clinical triggers

5.3.49.2 remote pharmacist-led interventions where required

5.3.49.3 appropriate escalation/referral when clinically necessary

5.3.49.4 accurate documentation and audit trail in RxWeb PMR

5.3.50 **Scope**

5.3.51 This SOP applies to:

5.3.51.1 EPS prescriptions and paper prescriptions (where applicable)

5.3.51.2 acute and repeat prescriptions

5.3.51.3 patients with LTCs and/or lifestyle-related risk factors

5.3.51.4 interventions conducted by telephone and/or secure email follow-up

5.3.52 This SOP must be followed by:

5.3.52.1 Responsible Pharmacist / Superintendent Pharmacist

5.3.52.2 any pharmacist working within the DSP model

5.3.52.3 dispensing staff supporting the dispensing workflow (as directed by the pharmacist)

5.3.53 **Definitions**

5.3.54 Clinical Screening: Pharmacist clinical assessment prior to supply to confirm the prescription is appropriate, safe, and that counselling/intervention needs have been met.

5.3.55 Prescription-linked Intervention: Any pharmacist-led action arising from the prescription or PMR history, including counselling, adherence support, safety advice, escalation/referral, or supply delay pending clarification.

5.3.56 Long-Term Conditions (LTC): Includes but is not limited to diabetes, CHD/CVD, hypertension, asthma/COPD, stroke prevention, thyroid disease, CKD, epilepsy, and mental health conditions impacting medicines use.

5.3.57 Lifestyle-related Risk Factors: Includes smoking status (where clinically relevant), weight-related risk factors (where relevant), and other health behaviours where clinically relevant to prescribed therapy.

5.3.58 **Responsibilities**

5.3.59 **Pharmacist**

5.3.60 The pharmacist is responsible for:

5.3.60.1 clinical screening prior to supply

5.3.60.2 identifying intervention triggers

5.3.60.3 completing prescription-linked interventions remotely

5.3.60.4 contacting prescribers where required

5.3.60.5 deciding to supply or delay supply based on safety

5.3.60.5.1 documenting interventions and outcomes in RxWeb

5.3.61 **Dispensing Staff**

5.3.62 Dispensing staff are responsible for:

5.3.62.1 ensuring prescriptions are entered accurately

5.3.62.2 flagging queries to the pharmacist immediately

5.3.62.3 not progressing items for dispatch until pharmacist approval is recorded

5.3.63 **When Clinical Screening Must Take Place**

5.3.64 Clinical screening is completed:

5.3.64.1 for every prescription prior to supply

5.3.64.2 at first issue for new medicines

5.3.64.3 when a dose or medicine changes

5.3.64.4 when adherence patterns indicate concern

5.3.64.5 where patient contact is required for safety or counselling

5.3.65 **Clinical Screening Checks (Minimum Standard)**

5.3.66 The pharmacist completes the following checks, as appropriate:

5.3.66.1 patient identity and relevant PMR notes reviewed

5.3.66.2 allergy status reviewed

5.3.66.3 directions/dose reviewed for clarity and appropriateness

5.3.66.4 clinical appropriateness check

5.3.66.5 interactions/contraindications assessed

5.3.66.6 therapy changes assessed

5.3.66.7 adherence concerns considered through ordering patterns

5.3.66.8 triggers for prescription-linked intervention identified

5.3.66.9 **Intervention Triggers (LTC / Lifestyle)**

5.3.67 The following are examples of triggers requiring pharmacist consideration and intervention where appropriate:

5.3.67.1 first time drug dispensed for patient

5.3.67.2 diabetes medicines and therapy changes

5.3.67.3 CHD/CVD and stroke prevention medicines

5.3.67.4 hypertension medicines

5.3.67.5 respiratory medicines where patterns suggest poor control

5.3.67.6 thyroid dose changes and counselling requirements

5.3.67.7 unclear directions, interaction/contraindication risk or allergy mismatch

5.3.67.8 adherence concerns (early/late/irregular requests) • lifestyle-related risks (smoking/weight)

5.3.68 **Intervention Process (Step-by-step)**

5.3.68.1 Identify the trigger and assess urgency

5.3.68.2 Provide remote intervention (telephone; secure email follow-up where appropriate)

5.3.68.3 Provide counselling, safe-use advice, monitoring expectations, and signposting as appropriate

5.3.68.4 Contact prescriber where clarification is required

5.3.68.5 Approve supply or delay supply pending clarification where required

5.3.68.6 Document the intervention fully in RxWeb PMR

5.3.69 **Escalation and Referral**

5.3.70 Where clinical risk is identified, the pharmacist escalates appropriately:

5.3.70.1 Pharmacist conversation where advice is given

5.3.70.2 GP referral (routine/urgent as appropriate)

5.3.70.3 NHS 111 for urgent concerns

5.3.70.4 emergency escalation (999) for emergencies/red flags All escalation advice is documented in RxWeb PMR.

5.3.71 **Supply Delay**

5.3.72 Supply is delayed where patient safety cannot be assured, including:

5.3.72.1 unclear directions

5.3.72.2 unresolved interaction/contraindication risk

5.3.72.3 unclear allergy status

5.3.72.4 prescriber clarification required

5.3.72.5 safeguarding concerns requiring escalation

5.3.73 **Documentation Standards**

5.3.74 All interventions must be documented in RxWeb PMR including:

5.3.74.1 trigger/issue

5.3.74.2 contact method and outcome

5.3.74.3 advice provided

5.3.74.4supply decision

5.3.74.5any referral/escalation

5.3.74.6follow-up plan where required

5.3.75 **Quality Assurance / Audit**

5.3.76 The pharmacy maintains evidence of compliance through:

5.3.76.1spot checks of RxWeb intervention notes

5.3.76.2periodic review of intervention outcomes

5.3.76.3SOP review annually or as required

5.3.77 **Training**

5.3.78 Relevant staff are trained on:

5.3.78.1recognising triggers for pharmacist intervention

5.3.78.2confidentiality and escalation

5.3.78.3requirement for pharmacist approval prior to supply/dispatch

5.3.79 **Confidentiality and Data Protection**

5.3.80 All patient-specific advice and records are maintained within RxWeb PMR. Secure email follow-up is used appropriately with confidentiality maintained.

5.3.81 *Version: 1.0*

5.3.82 *Effective Date: 1 June 2025*

5.3.83 *Review Date: 1 June 2026*

5.3.84 *Approver: Alisha Mahmood 2210542 Superintendent Pharmacist*

5.3.85 **Reconsideration Statement – Prescription-Linked Interventions (LTC & Lifestyle Risk Factors)**

5.3.86 **Purpose**

5.3.87 This document sets out the pharmacy's operational process for identifying and providing prescription-linked interventions for patients with long-term conditions and lifestyle-related risk factors under a full Distance Selling Pharmacy model, without face-to-face contact.

5.3.88 **Identification of patients requiring prescription-linked interventions**

5.3.89 Prescription-linked interventions are embedded within the dispensing process through pharmacist clinical screening and PMR review.

5.3.90 **Pharmacist clinical screening**

5.3.91 All NHS prescriptions are clinically screened by a pharmacist prior to supply. Screening includes:

5.3.91.1 appropriateness, dose and directions

5.3.91.2 interactions, contraindications and allergy status

5.3.91.3 new medicines, dose changes and therapy changes

5.3.91.4 side effects or safety concerns

5.3.91.5 adherence concerns through ordering patterns (early requests, late requests, irregular ordering)

5.3.91.6 indicators of uncontrolled long-term conditions

5.3.91.7 **Long-term condition and lifestyle-related triggers**

5.3.91.8 Where clinically relevant, prescription-linked interventions may be triggered by medicines and patterns associated with:

5.3.91.8.1 diabetes

5.3.91.8.2 cardiovascular disease / CHD / stroke prevention

5.3.91.8.3 hypertension

5.3.91.8.4 asthma/COPD and respiratory disease control

5.3.91.8.5 thyroid disease

5.3.91.8.6 lifestyle-related risk factors such as smoking status and obesity related risk factors

5.3.91.9 **Remote delivery of prescription-linked interventions**

5.3.91.10 When a trigger is identified, the pharmacist provides a prescription-linked intervention remotely using:

5.3.91.10.1 telephone consultation as the primary method

5.3.91.10.2 secure email follow-up where appropriate (for example, written confirmation of key advice or signposting) Interventions may include:

5.3.91.10.3 adherence and safe-use counselling

5.3.91.10.4 administration advice and side effect guidance

5.3.91.10.5 monitoring expectations and red-flag advice

5.3.91.10.6 lifestyle advice and signposting consistent with Essential Services provision

5.3.91.10.7 prescriber contact where clarification is required Supply may be delayed where required pending clarification from the patient and/or prescriber.

5.3.91.11 **Escalation and referral**

5.3.91.12 Where clinical risk is identified, the pharmacist escalates appropriately, including:

5.3.91.12.1 GP referral (routine or urgent depending on the concern)

5.3.91.12.2 NHS 111 advice for urgent concerns

5.3.91.12.3 emergency escalation (999) for red-flag symptoms/emergencies All escalations are documented within RxWeb.

5.3.91.13 **Documentation and audit trail**

5.3.91.14 All prescription-linked interventions are documented within RxWeb PMR notes, including:

5.3.91.14.1 trigger identified

5.3.91.14.2 method of contact (telephone/email)

5.3.91.14.3 advice provided and actions taken

5.3.91.14.4 outcome (supplied/delayed/referred/escalated)

5.3.91.14.5 follow-up plan where required This provides an auditable record demonstrating safe and effective Essential Service delivery under a full distance selling model.

5.3.91.15 **Confirmation**

5.3.91.16 Prescription-linked interventions for long-term conditions and lifestyle-related risk factors are embedded within the clinical screening process for every prescription, delivered remotely, escalated appropriately and recorded within the PMR.

5.3.91.17 The pharmacy's process ensures that long-term condition and lifestyle-related interventions are consistently triggered through pharmacist clinical screening and PMR review, delivered through structured remote consultation, escalated where clinically necessary, and documented within RxWeb to provide

a clear audit trail. This ensures Essential Services are delivered safely and effectively under a full Distance Selling Pharmacy model."

5.4 COMMUNITY PHARMACY DERBYSHIRE

5.4.1 "Thank you for sending the appeal documents for the above distance selling pharmacy application. Community Pharmacy Derbyshire committee reviewed the appeal information and wish to make the following comments

5.4.1.1 Whilst the applicant has clarified a number of points with regards to providing a service to the whole of England and not just locally, Community Pharmacy Derbyshire would like to highlight that the proposed pharmacy location is in a retail unit in the town centre, which is not typically a location for a distance selling pharmacy.

5.4.1.2 Also, the proposed site is next door to the clinics that the applicant is already providing which are face-to-face so the applicant needs to adequately demonstrate to the ICB how they will manage this on a day to day basis including public perception so as to refrain from providing face-to-face essential and advanced services

5.4.2 Community Pharmacy Derbyshire would like the opportunity if it arises, to be able to comment further and attend any hearings, as well as be kept informed of progress. Thank you."

## 6 Summary of Observations

This is summary of observations received.

6.1 THE APPLICANT

6.1.1 "We thank the Committee for the opportunity to provide final observations in response to the representations submitted. This response is confined to clarification of the matters raised.

6.1.2 DISTANCE SELLING MODEL – OPERATIONAL ENFORCEMENT

6.1.3 The pharmacy will operate strictly as a Distance Selling Pharmacy. No NHS Essential or Advanced Services will be provided to any patient present at the premises.

6.1.4 This will be operationally enforced on a daily basis:

6.1.4.1 The dispensary is located on the first floor and is not accessible to the public

6.1.4.2 There is no NHS service signage, promotion, or invitation for walk-in access

6.1.4.3 All NHS interactions are conducted remotely (telephone, online, and delivery)

6.1.4.4 Any patient presenting at the premises will be immediately signposted to local community pharmacies, with interactions recorded

6.1.4.5 Staff are trained and required to refuse provision of NHS pharmaceutical services to patients attending in person

6.1.5 Private services provided at the premises operate entirely separately and do not interface in any way with NHS pharmaceutical service provision.

6.1.6 The operational model and physical layout prevent the provision of NHS pharmaceutical services to patients present at the premises.

6.1.7 For completeness, the premises has been selected as a suitable and secure operational base for dispensing, storage, and delivery logistics. The location does not influence how NHS pharmaceutical services are provided, as all patient interaction will be conducted remotely and the dispensary is not accessible to the public. The operational model ensures full compliance with Distance Selling Pharmacy requirements irrespective of premises location.

6.1.8 NATIONAL SERVICE CONSISTENCY – CLINICAL SERVICE IS LOCATION-INDEPENDENT

6.1.9 All patients across England will receive the same clinical service, irrespective of location.

6.1.10 This includes:

6.1.10.1 Identical clinical screening of every prescription

6.1.10.2 Identical intervention triggers

6.1.10.3 Identical pharmacist decision-making processes

6.1.10.4 Identical documentation and audit standards

6.1.11 Clinical care will be delivered prior to, and independently of, supply and delivery.

6.1.12 Medicines will be supplied using appropriate delivery methods to ensure safe and consistent service provision nationwide. Where, in exceptional circumstances, safe delivery cannot be assured, supply will not proceed and appropriate alternative arrangements will be made to ensure the patient receives timely and safe access to medication.

6.1.13 The Essential Service provided will therefore be clinically consistent nationwide and fully compliant with Regulation 64.

6.1.14 PRESCRIPTION-LINKED INTERVENTIONS – MANDATORY CLINICAL PATHWAY

6.1.15 The pharmacy will operate a structured, mandatory clinical intervention model applied to every prescription.

6.1.16 Each prescription will follow the same pathway:

6.1.16.1 Clinical screening within the PMR (RxWeb)

6.1.16.2 Identification of risk factors including:

6.1.16.2.1 Long-term conditions

6.1.16.2.2 Adherence indicators

6.1.16.2.3 High-risk medicines

6.1.16.2.4 Interactions and safety concerns

6.1.16.3 Defined intervention triggers (not discretionary)

6.1.16.4 Pharmacist-led consultation via telephone or appropriate remote method

6.1.16.5 Clinical decision to:

6.1.16.5.1 Proceed with supply

6.1.16.5.2 Modify or stage supply

6.1.16.5.3 Defer supply pending clarification

6.1.16.5.4 Refer or escalate to GP or other healthcare provider

6.1.16.6 Mandatory documentation of all interventions and outcomes within the PMR

6.1.17 This model ensures that clinical intervention will be systematic, consistent, and not dependent on patient presentation or individual discretion.

6.1.18 Illustrative examples:

6.1.18.1 Repeated short-acting bronchodilator prescribing will trigger a control and adherence review, pharmacist contact, and referral where appropriate

6.1.18.2 High-risk medicines (e.g. anticoagulants) will trigger safety checks and follow-up prior to supply

6.1.18.3 Patterns of non-adherence will trigger proactive patient engagement and support

6.1.19 This demonstrates an active, intervention-led clinical service rather than a supply-only model.

6.1.20 DELIVERY, COLD CHAIN AND CONTROLLED DRUGS – SAFETY-LED DECISION MAKING

6.1.21 Operational procedures will ensure that patient safety governs all supply decisions:

6.1.21.1 Failed deliveries will trigger immediate patient contact, redelivery or escalation, and PMR documentation

6.1.21.2 Temperature-sensitive medicines will be supplied using validated packaging and controlled delivery methods to maintain product integrity

6.1.21.3 Controlled drugs will be supplied with secure transport, tracking, and proof of delivery in full compliance with legal requirements

6.1.22 Where delivery conditions cannot guarantee safety, supply will not proceed and appropriate alternative arrangements will be made to ensure the patient receives timely and safe access to medication.

6.1.23 PREMISES GOVERNANCE AND SECURITY

6.1.24 All dispensing and consultation activities will take place within GPhC-registered areas.

6.1.24.1 Access to pharmacy areas will be restricted to authorised staff only

6.1.24.2 Physical separation and controlled access will prevent unauthorised entry

6.1.24.3 GDPR, GPhC and regulatory requirements will be fully met

6.1.25 The layout and operational controls will ensure that medicines and patient data remain secure at all times.

6.1.26 CLINICAL GOVERNANCE AND AUDIT

6.1.27 The Applicant confirms that compliance with the clinical intervention model will be subject to ongoing governance and audit:

6.1.27.1 Regular audit of prescription screening and intervention records within the PMR

6.1.27.2 Review of intervention rates and outcomes to ensure consistency of clinical practice

6.1.27.3 Documentation checks to confirm that intervention triggers are applied appropriately

6.1.27.4 Ongoing pharmacist training and governance oversight

6.1.28 This ensures that the clinical model will be consistently applied in practice and not limited to policy.

6.1.29 RESPONSE TO REPRESENTATIONS – CLARITY AND PROPORTIONALITY

6.1.30 The representations received raise concerns regarding perception and operational clarity.

6.1.31 The Applicant has provided clear, specific and operationally defined processes demonstrating:

6.1.31.1 A fully remote, enforced DSP model

6.1.31.2 Clinically consistent national service provision

6.1.31.3 A structured and mandatory clinical intervention framework

6.1.31.4 Robust governance and delivery procedures

6.1.32 The concerns raised relate to perceived risk rather than evidence of inability to comply with Regulation 25 or Regulation 64.

6.1.33 CONCLUSION

6.1.34 The Applicant respectfully submits that:

6.1.34.1 The pharmacy will operate strictly as a Distance Selling Pharmacy in practice, with no public access to NHS pharmaceutical services

6.1.34.2 Essential Services will be delivered remotely, safely and effectively

6.1.34.3 Every prescription will be subject to structured clinical assessment and intervention

6.1.34.4 Patients will receive consistent, clinically managed care nationwide

6.1.35 The Applicant recognises the importance of maintaining the integrity of the Distance Selling Pharmacy model and confirms that systems are in place to ensure ongoing compliance with all regulatory requirements.

6.1.36 The additional clarification demonstrates a compliant, safe and clinically proactive model.

6.1.37 The Applicant therefore respectfully requests that the appeal be allowed and the application approved.

6.1.38 The Applicant would be happy to attend an oral hearing should the Committee consider that this would assist in clarifying any aspect of the application."

## 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, in Part 5 of the application form (pertaining to Regulation 31), the Applicant stated: "*it is a distance selling pharmacy*." Additionally, the Committee noted that the Commissioner's decision letter stated: "*There are therefore no grounds to refuse the application by virtue of this regulation*." This information was not challenged during the appeal process. Consequently, the Committee concluded that there were no grounds to refuse the application under Regulation 31.

***Regulation 25***

7.7 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."*

7.8 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)***

7.9 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)***

7.10 As far as Regulation 25(2)(a) is concerned, the Committee had regard to the application form in which the Applicant states "*No provider of a primary medical service with a patient list*." The Committee noted that this had not been disputed and that it had not been provided with any information to persuade it otherwise. The Committee was therefore satisfied 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)***

7.11 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.

7.12 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.

7.13 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.

7.14 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 and the Applicant's appeal and observations.

7.15 The Committee considered whether the Applicant had explained the arrangements which ensure that, for appliances which require fitting /

measuring, a registered pharmacist measures / fits them. The Committee noted that on the application form the Applicant had not indicated that it wished to supply any appliances. Therefore, in the event that the application is granted, the Applicant would not be able to supply appliances which require measuring and fitting.

7.16 The Committee considered the arrangements proposed by the Applicant to ensure the uninterrupted provision of essential services.

7.17 The Committee noted the Applicant's statement in the application that "*The online pharmacy will have at least one Responsible Pharmacist (RP) at the premises at all times during the contracted hours*."

7.18 The Committee noted that, although the Applicant had stated that a pharmacist would be present throughout the pharmacy's opening hours, no procedure had been provided to address circumstances in which the Responsible Pharmacist might be absent, nor was any reference made to the availability of a second pharmacist. The Applicant had also not explained how it would ensure continuity of service during core hours if the pharmacist were called away or failed to attend as expected. Accordingly, the Committee considered that it had not been sufficiently demonstrated how essential services would be delivered, if required, in the absence of the Responsible Pharmacist. On the basis of the information before it, the Committee was therefore not satisfied that adequate arrangements were in place to secure the uninterrupted provision of essential services.

7.19 In considering whether services would be available to persons anywhere in England, the Committee noted the comments submitted by PCT Healthcare Ltd regarding the Applicant's reference to the "*same day*" delivery of urgent medications. PCT Healthcare Ltd submitted that this suggested that services might not be provided equally to patients across different geographical areas. The Committee also considered the Applicant's response that "*services will not be provided on a locality-dependent basis. Delivery timescales will be applied consistently across all patients, and no preferential service will be offered based on geographic proximity to the premises. This ensures compliance with the requirement that Essential Services are provided equally to patients throughout England*." In addition, the Applicant stated in its observations that "*Medicines will be supplied using appropriate delivery methods to ensure safe and consistent service provision nationwide*," and that "*all patient interaction will be conducted remotely (telephone, online, or delivery)*." However, while the Applicant maintained that the same services would be available to persons anywhere in England, the Committee considered that insufficient evidence had been provided to demonstrate *how* nationwide delivery would be achieved, particularly as no details were given regarding courier arrangements for either local or national deliveries.

7.20 On the basis of the information before it, the Committee was not satisfied that the provision of essential services would be available to persons anywhere in England.

7.21 The Committee also considered how the Applicant intended to provide pharmaceutical services without face to face contact. In doing so, it noted the

Community Pharmacy Derbyshire's observation that "*the proposed site is next door to the clinics that the applicant is already providing which are face-to-face so the applicant needs to adequately demonstrate to the ICB how they will manage this on a day to day basis including public perception so as to refrain from providing face-to-face essential and advanced services*." The Committee had regard to the Applicant's response that:

*7.21.1* "*The pharmacy will operate strictly as a Distance Selling Pharmacy. No NHS Essential or Advanced Services will be provided to any patient present at the premises.*

*The Applicant stated that this would be enforced operationally on a daily basis as follows:*

*The dispensary is located on the first floor and is not accessible to the public.*

*There is no NHS service signage, promotion, or invitation for walk-in access.*

*All NHS interactions are conducted remotely, by telephone, online, or through delivery.*

*Any patient presenting at the premises will be immediately signposted to local community pharmacies, and the interaction will be recorded.*

*Staff are trained and required to refuse the provision of NHS pharmaceutical services to patients attending in person.*

*Private services provided at the premises operate entirely separately and do not interface in any way with NHS pharmaceutical service provision*."

7.22 The Committee also had regard to the comments from Boots and PCT Healthcare Ltd regarding the nature of the proposed premises, described as being "*within a busy shopping area within the city centre*", which could "*easily be interpreted by patients and the public as available for face-to-face pharmaceutical services*." The Committee noted that the Applicant intended to provide some face to face private services from the proposed premises, "*including ear wax removal and travel vaccinations*." It also noted the Applicant's assurance that "*patients attending for private services will not receive NHS pharmaceutical services on site, all NHS pharmaceutical services will be provided remotely in accordance with Distance Selling Pharmacy requirements.*" The Applicant further stated that "*There is no NHS service signage, promotion, or invitation for walk-in access*" and that the "*physical layout prevents the provision of NHS pharmaceutical services to patients present at the premises*."

7.23 The Committee considered that, because the premises were proposed to be located in a retail unit within a city-centre shopping area, there was an increased risk that face to face NHS pharmaceutical services might be provided, given that the unit would be open to the public. The Committee also

had regard to the likelihood that a member of the public encountering the pharmacy in such a setting might reasonably assume that face to face services were available from the premises.

7.24 It was not clear to the Committee how the pharmacy would distinguish between NHS patients and private patients attending the premises for face to face services. Given the heightened level of risk arising from the proposed location, the Committee considered it reasonable to expect a greater degree of detail than might be required in other settings in order to be satisfied that services would be provided without face to face contact. The absence of detailed information as to how the pharmacy would operate in this particular setting in compliance with the Regulations led the Committee to conclude that it was not satisfied that services would be provided without face to face contact. On that basis, the Committee was not satisfied that pharmaceutical services would be provided without face to face contact.

7.25 The Committee also had regard to the regulatory changes that came into effect on 1 October 2025 and 31 March 2026, under which distance selling pharmacies may 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 patients at the pharmacy premises.

7.26 In its application, which the Committee acknowledged had been completed before the amendment came into force, the Applicant stated that there would be "*patients attending for advanced services*" and that a sign above the entrance would indicate that "*consultation [is] by appointment only*." In light of the amendment, the Committee noted that the Applicant would no longer be permitted to provide any pharmaceutical services at the premises. The Committee also noted the Applicant's statement, submitted on appeal, that "*all NHS pharmaceutical services will be provided remotely in accordance with Distance Selling Pharmacy requirements*."

7.27 The Committee was not satisfied that the provision of essential services would be without interruption and would be available to persons anywhere in England and that pharmaceutical services would be provided 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.

7.28 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.

7.29 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:

7.29.1 Dispensing of drugs and appliances.

7.29.2 Urgent supply without a prescription

7.29.3 Preliminary matters before providing ordered drugs or appliances

7.29.4 Providing ordered drugs or appliances

7.29.5 Refusal to provide drugs or appliances ordered

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

7.29.7 Disposal service in respect of unwanted drugs

7.29.8 Promotion of healthy lifestyles

7.29.9 Prescription linked intervention

7.29.10 Health campaigns

7.29.11 Signposting

7.29.12 Support for self-care

7.29.13 Discharge medicines service

7.29.14 Websites and health promotion zones

Dispensing of drugs and appliances

7.30 The Committee considered whether the Applicant had explained how non-electronic prescriptions will be presented by the patient and how products will be provided.

7.31 The Committee noted that no information had been provided in this regard to receiving non-electronic prescriptions. It was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 5(2) and 5(3) of Schedule 4.

Urgent supply without a prescription

7.32 The Committee considered whether the Applicant had explained how it proposes to safely and effectively receive requests from prescribers for urgent supplies of drugs and appliances.

7.33 The Committee noted that in its application the Applicant states:

7.33.1 "*urgent medications such as antibiotics or end of life will be stocked in advance and will be delivered the same day unless there is a supply issue in which case the patient will be signposted to their nearest pharmacy*."

7.34 The Committee noted that no further information had been provided in this regard. The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

Preliminary matters before providing ordered drugs or appliances

7.35 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.

7.36 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(3) of Schedule 4.

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

7.38 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

7.39 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).

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

*7.40.1* "*Cold Chain and Temperature-Sensitive Medicines*

*Where medicines require specific storage conditions:*

*appropriate insulated packaging and validated delivery methods will be used*

*delivery arrangements will ensure the integrity of the medicine is maintained*

*medicines will not be supplied where safe delivery conditions cannot be assured*

*Controlled Drugs*

*Where controlled drugs are supplied:*

*all legal and regulatory requirements will be adhered to*

*secure delivery methods will be used*

*appropriate tracking, audit, and proof of delivery processes will be in place*."

7.41 And further in their observations, the Applicant states:

*7.41.1* "*DELIVERY, COLD CHAIN AND CONTROLLED DRUGS – SAFETY-LED DECISION MAKING*

*Operational procedures will ensure that patient safety governs all supply decisions:*

*Failed deliveries will trigger immediate patient contact, redelivery or escalation, and PMR documentation*

*Temperature-sensitive medicines will be supplied using validated packaging and controlled delivery methods to maintain product integrity*

*Controlled drugs will be supplied with secure transport, tracking, and proof of delivery in full compliance with legal requirements*

*Where delivery conditions cannot guarantee safety, supply will not proceed and appropriate alternative arrangements will be made to ensure the patient receives timely and safe access to medication*."

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. Whilst noting the Applicant's intention to use "*secure transport, tracking, and proof of delivery"* for the 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. 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.

7.44 The Committee considered whether the Applicant had explained what containers will be "suitable" for posted/delivered items.

7.45 The Committee noted the Applicants comments that cold chain items would be packaged in "*insulated packaging*" however no further information was provided as to what outer packaging it would be using for items other than cold chain items and how this would be suitable for posted/delivered items to ensure that the integrity of the medication would be maintained.

7.46 Based on the information before it, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(15) of Schedule 4.

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

7.47 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.

7.48 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

7.49 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.

7.50 The Committee noted that no information had been provided in this regard. 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

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

7.52 The Committee did not consider there to be any clear information provided as to how the Applicant would safely and effectively promote healthy lifestyles.

7.53 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.

Health campaigns

7.54 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.

7.55 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.

Signposting

7.56 The Committee considered whether the Applicant had explained how it will provide information to users of the pharmacy about other health and social care providers and support organisations.

7.57 The Committee noted that no information had been provided in this regard. The Committee 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.

Support for self-care

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

7.59 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 paragraphs 19 – 20 of Schedule 4.

Discharge medicines service

7.60 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.

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

7.62 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.

Websites and health promotion zones

7.63 The Committee considered whether the Applicant had explained how it will ensure that it has a website for use by the public for the purpose of accessing pharmaceutical services from those premises, on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues.

7.64 The Committee noted that no information had been provided in this regard. The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 28C 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 the safe and effective provision of pharmaceutical services as required by Regulation 25(2)(b).

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 Although the Committee reached the same conclusion as the Commissioner, it did so for different reasons therefore 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 not 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 not 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**